

**SUMMARY MONTHLY SAFETY REPORT 5**  
**for**  
**ACTIVE SUBSTANCE: PF-07302048 (BNT162b2)**

**ATC CODE: J07BX03<sup>1</sup>**

**AUTHORISATION PROCEDURE in the EU: Centralised**

**INTERNATIONAL BIRTH DATE (IBD):<sup>2</sup> 19 December 2020**

**EUROPEAN UNION REFERENCE DATE (EURD):<sup>3</sup> 19 December 2020**

**INTERVAL COVERED BY THIS REPORT:**

**01 APRIL 2021 through 29<sup>4</sup> APRIL 2021**

**DATE OF THIS REPORT: 13 MAY 2021**

**Report Prepared by: Worldwide Medical & Safety**

**Pfizer - BioNTech**

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<sup>1</sup> Temporary ATC code.

<sup>2</sup> It corresponds to the earliest conditional approval date.

<sup>3</sup> Re-aligned with IBD as per EMA/630645/2012 Rev.101 Procedure Management Department.

<sup>4</sup> Please consider that for the April month reporting period, cut-off date is 29 April 2021 due to MedDRA 24.0 up-versioning activities that prevented to use 30 April 2021 as cut-off date.

## EXECUTIVE SUMMARY

This is the 5<sup>th</sup> Summary Monthly Safety Report (SMSR) for PF-07302048 [Coronavirus disease 2019 (COVID-19) mRNA Vaccine, hereafter referred to as BNT162b2)], covering the reporting interval 01 April 2021 through 29 April 2021.

BNT162b2 is a white to off-white frozen dispersion (pH: 6.9 - 7.9), provided as concentrate for dispersion for injection (sterile concentrate) as multidose vial to be diluted before use. The multidose vial contains 6 doses of 0.3 mL after dilution; low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose contains 30 micrograms of BNT162b2 embedded in lipid nanoparticles (LNPs). The vaccine also contains (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose and water for injections as excipients.

BNT162b2 is highly purified single-stranded, 5'-capped mRNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.<sup>5</sup> No dosage adjustment is required in elderly individuals  $\geq 65$  years of age. It is administered intramuscularly in the deltoid muscle after dilution as a series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.

It is estimated that approximately 415,922,715 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 29 April 2021 and that approximately 172,777,410 doses of BNT162b2 were shipped worldwide during the current reporting interval from 01 April 2021 through 29 April 2021. Estimated worldwide shipped doses may serve as a reasonable indicator of subject exposure, considering that approximately 80% of the shipped doses were

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<sup>5</sup> Please note that after the data-lock point of this report, respectively on 05 May 2021 and on 10 May 2021, BNT162b2 was authorized for use in individuals 12 years of age and older in Canada and in the US. Variation 0030 (EMA/H/C/005735/II/0030) has been also submitted to EMA on 30 April 2021 to seek expansion of the indication to subjects 12 to 15 years of age. The relevant procedure is currently ongoing.



administered; this estimation is based on the proportion of doses administered out of those shipped upon review of data currently available for the EU<sup>6</sup> countries and the US.<sup>7</sup>

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped in the EU from the receipt of the first conditional marketing approval authorisation on 21 December 2020 through 29 April 2021 and that approximately (b) (4) doses of BNT162b2 were shipped in the EU during the current reporting interval from 01 April 2021 through 29 April 2021.

BNT162b2 has received temporary authorisation for emergency supply in 32 countries and conditional marketing authorisation approval in 42 countries globally.

There were no authorisation withdrawals for safety reasons during the reporting interval.

During the reporting period, no actions have been taken with respect to BNT162b2 for safety reasons, either by a Health Authority or by the MAH.

The Reference Safety Information (RSI) for this SMSR is the BNT162b2 Core Data Sheet (CDS) Version 3.0, dated 20 April 2021, in effect at the end of the reporting period. The previous CDS Version 2.0, dated 02 March 2021, was also in effect during the reporting period, and was updated on 20 April 2021 due to planned data analysis from the ongoing multi-country clinical trial, C4591001, on adolescent study participants 12 through 15 years of age. As a result, a summary of the safety profile in the adolescents 12 through 15 years of age was added in Section 4.8 Undesirable effects.

During the reporting period, the following signals were addressed:

1. Asthenia, lethargy, decreased appetite, hyperhidrosis, night sweats were evaluated to be risks (not important for the purpose of inclusion in the Risk Management Plan or Pharmacovigilance Plans) and will be added to the RSI and subsequently to the local product labels;
2. Herpes Zoster including Ophthalmic Herpes Zoster was evaluated and determined not to be a risk;
3. Seizure was evaluated and determined not to be a risk;
4. Myocarditis and Pericarditis were evaluated and determined not to be risks.

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<sup>6</sup> This proportion has been calculated considering, out of total number of vaccine doses distributed in the EU-EEA countries, the total number of vaccine doses administered as per report on <https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#distribution-tab>, as of 01 May 2021.

<sup>7</sup> This proportion has been calculated considering, out of total number of vaccine doses distributed in the US, the total number of vaccine doses administered as per report on <https://covid.cdc.gov/covid-data-tracker/#vaccinations>, as of 30 April 2021.

During the reporting period, the following safety topics were addressed and determined not to be validated signals:

1. Cranial nerve palsy;
2. Hemolytic anemia;
3. Hepatic events;
4. Nephrotic syndrome;
5. Optic neuritis;
6. Trigeminal neuralgia.

Based on the new safety and efficacy/effectiveness data from the reporting interval for BNT162b2, the benefit-risk profile of BNT162b2 remains favorable.

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## LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
ADR	adverse drug reaction
AESI	adverse event of special interest
AERP	adverse event reporting proportion
BC	Brighton Collaboration
BLA	biologics license application
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CDS	core data sheet
CI	confidence interval
COPD	chronic obstructive pulmonary disease
COVAX	COVID-19 Vaccines Global Access
COVID-19	coronavirus disease 2019
DLP	data lock point
DME	designed medically event
DNA	deoxyribonucleic acid
DSPC	Distearoyl-sn-glycero-3-phosphocholine
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EUA	emergency use authorisation
EURD	European Union Reference Date
HA	health authority
HC	Health Canada
HBV	hepatitis B virus
HCP	healthcare professional
HCV	Hepatitis C virus
HIV	human immunodeficiency virus
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
IBD	international birth date
ICH	International Conference on Harmonisation
LNP	lipid nanoparticle
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
mRNA	messenger ribonucleic acid
NAAT	nucleic acid amplification tests
NSAID	non-steroidal anti-inflammatory drug
PM	post-marketing
PRAC	Pharmacovigilance Risk Assessment Committee
PT	(MedDRA) Preferred Term



<b>Acronym</b>	<b>Term</b>
PVP	pharmacovigilance plan
RMP	risk management plan
RNA	ribonucleic acid
ROW	rest of world
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SmPC	Summary of Product Characteristics
SMQ	standardised MedDRA query
SMSR	summary monthly safety report
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

## 1. INTRODUCTION

This is the 5<sup>th</sup> SMSR for PF-07302048 (COVID-19 mRNA Vaccine, hereafter referred to as BNT162b2), covering the reporting interval 01 April 2021 through 29 April 2021. The format and content of this SMSR is in accordance with the EMA coreRMP19 Guidance (EMA/544966/2020) and, as applicable, with ICH Guideline E2C (R2) Periodic Benefit-Risk Evaluation Report [Step 5, January 2013] considering the information for the evidence from post-EUA/conditional marketing authorisation approval data sources.

BNT162b2 is a white to off-white frozen dispersion (pH: 6.9 – 7.9), provided as concentrate for dispersion for injection (sterile concentrate) as multidose vial to be diluted before use. The multidose vial contains 6 doses of 0.3 mL after dilution; low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose contains 30 micrograms of BNT162b2 (embedded in LNPs). The vaccine also contains ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose and water for injections as excipients.

BNT162b2 is highly purified single-stranded, 5'-capped mRNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2. The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

BNT162b2 is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.<sup>5</sup> No dosage adjustment is required in elderly individuals  $\geq 65$  years of age. It is administered intramuscularly in the deltoid muscle after dilution as a series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.

Pfizer is responsible for the preparation of the SMSR on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

A complete list of the finalized SMSRs is provided in Table 1 below.

**Table 1. List of SMSRs**

SMSR Number	Reporting Period
1	01 December 2020 through 31 December 2020
2	01 January 2021 through 31 January 2021
3	01 February 2021 through 28 February 2021
4	01 March 2021 through 31 March 2021

## 2. WORLDWIDE APPROVAL OR AUTHORISATION STATUS

BNT162b2 received first temporary authorisation for emergency supply under regulation 174 in the UK<sup>8</sup> on 01 December 2020 and is currently authorised for emergency use in 32 countries.

BNT162b2 received first regulatory conditional marketing authorisation approval in Switzerland on 19 December 2020 and is currently conditionally approved in 42 countries (including EEA).

Details of the current authorisation/approval status are presented in [Appendix 4](#).

## 3. ACTIONS TAKEN IN THE REPORTING INTERVAL FOR SAFETY REASONS

During the reporting period, no actions have been taken with respect to BNT162b2 for safety reasons, either by a HA or by the MAH.

There were no authorisation withdrawals for safety reasons during the reporting interval.

## 4. CHANGES TO REFERENCE SAFETY INFORMATION

The RSI for this SMSR is the BNT162b2 CDS Version 3.0, dated 20 April 2021, in effect at the end of the reporting period which is located in [Appendix 1](#).

The previous CDS Version 2.0, dated 02 March 2021, was also in effect during the reporting period, and it was updated on 20 April 2021 due to planned data analysis from the ongoing multi-country clinical trial, C4591001, on adolescent study participants 12 through 15 years of age. As a result, a summary of the safety profile in the adolescents 12 through 15 years of age was added in Section 4.8 Undesirable effects. The summary of the safety-related changes made is presented in [Appendix 1.1](#).

## 5. ESTIMATED EXPOSURE AND USE PATTERNS

### 5.1. Cumulative and Interval Exposure Data Worldwide

It is not possible to determine with certainty the number of individuals who received BNT162b2 during the period of this review. Estimated worldwide shipped doses may serve as a reasonable indicator of subject exposure, considering that approximately 80% of the shipped doses were administered; this estimation is based on the proportion of doses administered out of those shipped upon review of data currently available for the EU<sup>6</sup> countries and the US.<sup>7</sup>

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<sup>8</sup> Upon that on 22 April 2021 conditional marketing authorisation approval was also granted in the UK, both the authorisation for emergency supply under regulation 174 and the conditional marketing authorization approval are currently active.

With these caveats in mind, it is estimated that:

- approximately 415,922,715 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 29 April 2021, corresponding to 332,738,172 estimated administered doses;
- approximately 172,777,410 doses of BNT162b2 were shipped worldwide during the current reporting interval from 01 April 2021 through 29 April 2021, corresponding to 138,221,928 estimated administered doses.

The estimated cumulative number of shipped and administered doses of BNT162b2 by region<sup>9</sup> based on data provided in the shipment tracker (b) (4),<sup>10</sup> from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 29 April 2021, are summarized in Table 2.

**Table 2. Cumulative Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
<b>Europe</b>	<b>(b) (4)</b>	<b>(4)</b>	<b>123400992</b>
European Union <sup>a</sup> (27)			96285540
European Economic Area Countries <sup>a</sup> (3)			1218828
Switzerland <sup>a</sup>			1418040
UK <sup>b</sup>			19610916
Other Countries <sup>c</sup>			4731012
<b>Commonwealth of Independent States<sup>d</sup></b>			<b>136656</b>
<b>North America<sup>e</sup></b>			<b>138967140</b>
US			131232660
Canada			7734480
<b>Central and South America<sup>f</sup></b>	<b>17064216</b>		
<b>Asia</b>	<b>50902176</b>		
Japan <sup>a</sup>	27281592		
Other Countries <sup>g</sup>	23620584		
<b>Oceania</b>	<b>1901952</b>		
Australia/New Zealand <sup>a</sup>	1901952		
Other Countries	0		
<b>Africa<sup>h</sup></b>	<b>501696</b>		
<b>Total</b>	<b>100.0%</b>	<b>415922715</b>	<b>332738172</b>

<sup>9</sup> Currently there are no available data that allow to estimate exposure by gender; for age group data available for some EU-EEA countries see below data in Table 5.

<sup>10</sup> The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) (b) (4).

**Table 2. Cumulative Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
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- a. In this Region BNT162b2 was conditionally approved;
- b. In the UK, both the authorisation for emergency supply under regulation 174 and the conditional marketing authorisation approval are currently active for BNT162b2;
- c. Includes Albania where BNT162b2 was conditionally approved, Serbia where it received authorization for emergency supply, Bosnia where it was shipped for COVAX, North Macedonia where it was shipped for a non-COVAX agreement and Turkey where it was shipped according to a pharmacovigilance agreement in place by the MAH and the Turkish government;
- d. Includes Georgia, Moldova and Ukraine; in these countries BNT162b2 was shipped for COVAX;
- e. In this Region BNT162b2 received authorization for emergency supply;
- f. Includes Chile, Colombia, Costa Rica, Ecuador, Mexico, Panama, Peru and Uruguay where BNT162b2 received authorisation for emergency supply (some doses in Colombia and Peru were also shipped for COVAX), Brazil where BNT162b2 was conditionally approved, and Bolivia and El Salvador where BNT162b2 was shipped for COVAX;
- g. Includes Bahrain, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Singapore, United Arab Emirates where BNT162b2 received authorization for emergency supply, Malaysia and South Korea where BNT162b2 was conditionally approved (some doses in South Korea were also shipped for COVAX), and West Bank & Gaza, Maldives and Mongolia where BNT162b2 was shipped for COVAX;
- h. Includes Cape Verde, Rwanda and Tunisia where BNT162b2 was shipped for COVAX and South Africa where BNT162b2 received authorization for emergency supply.

The estimated interval number of shipped and administered doses of BNT162b2 by region<sup>11</sup> based on data provided in the shipment tracker (b) (4)<sup>12</sup> from 01 April 2021 through 29 April 2021, are summarized in Table 3.

**Table 3. Interval Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
<b>Europe</b>	<b>(b) (4)</b>	<b>(4)</b>	<b>49060440</b>
European Union <sup>a</sup> (27)			43429464
European Economic Area Countries <sup>a</sup> (3)			550368
Switzerland <sup>a</sup>			608400
UK <sup>b</sup>			3597048
Other Countries <sup>c</sup>			781560
<b>Commonwealth of Independent States<sup>d</sup></b>			<b>93600</b>
<b>North America<sup>e</sup></b>	<b>50839776</b>		

<sup>11</sup> Currently there were no available data that allow to estimate exposure by gender; for age group data available for some EU-EEA countries see below data in Table 6.

<sup>12</sup> The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) (b) (4).

**Table 3. Interval Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
US	<b>(b) (4)</b>	<b>(4)</b>	47530080
Canada			3309696
<b>Central and South America<sup>f</sup></b>			<b>9293544</b>
<b>Asia</b>			<b>27947088</b>
Japan <sup>a</sup>			21008520
Other Countries <sup>g</sup>			6938568
<b>Oceania</b>			<b>741312</b>
Australia/New Zealand <sup>a</sup>			741312
Other Countries			0
<b>Africa<sup>h</sup></b>			<b>339768</b>
<b>Total</b>			<b>100.0%</b>

- a. In this Region BNT162b2 was conditionally approved;
- b. In the UK, both the authorisation for emergency supply under regulation 174 and the conditional marketing authorisation approval are currently active for BNT162b2;
- c. Includes Albania where BNT162b2 was conditionally approved, Serbia where it received authorization for emergency supply, Bosnia where it was shipped for COVAX, North Macedonia where it was shipped for a non-COVAX agreement, and Turkey where it was shipped according to a manufacturing and supply agreement in place by the MAH and the Turkish government;
- d. Includes Georgia, Moldova and Ukraine; in these countries BNT162b2 was shipped for COVAX;
- e. In this Region BNT162b2 received authorization for emergency supply;
- f. Includes Chile, Colombia, Costa Rica, Ecuador, Mexico, Panama, Peru and Uruguay where BNT162b2 received authorisation for emergency supply (some doses in Colombia and Peru were also shipped for COVAX), Brazil where BNT162b2 was conditionally approved, and Bolivia and El Salvador where BNT162b2 was shipped for COVAX;
- g. Includes Bahrain, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Singapore, United Arab Emirates where BNT162b2 received authorization for emergency supply, Malaysia and South Korea where BNT162b2 was conditionally approved (some doses in South Korea were also shipped for COVAX), and West Bank & Gaza, Maldives and Mongolia where BNT162b2 was shipped for COVAX;
- h. Includes Cape Verde, Rwanda and Tunisia where BNT162b2 was shipped for COVAX and South Africa where BNT162b2 received authorization for emergency supply.

**5.2. Cumulative and Interval Exposure Data in the EU**

Estimated shipped doses in the EU-EEA countries may serve as a reasonable indicator of subject exposure in these countries, considering that approximately **(b) (4)** % of the shipped doses were administered; this estimation is based on the proportion of doses administered out of those shipped upon review of data currently available for the EU<sup>6</sup> countries.

With these caveats in mind, it is estimated that:

- approximately **(b) (4)** doses of BNT162b2 were shipped in the EU-EEA countries from the receipt of the first conditional marketing authorisation approval on 21 December 2020 through 29 April 2021, corresponding to 97,504,368 estimated administered doses;

- approximately (b) (4) doses of BNT162b2 were shipped in the EU-EEA countries during the current reporting interval from 01 April 2021 through 29 April 2021, corresponding to 43,979,832 estimated administered doses.

Table 4 provides the estimated interval/cumulative number of shipped doses of BNT162b2 from the receipt of the first conditional marketing authorisation approval through 29 April 2021 for the 27 EU Countries and for the 3 EEA Countries.

**Table 4. Interval/Cumulative Estimated Shipped/Administered Doses of BNT162b2 by EU-EEA Countries (30)**

EU Country	Total Number of Interval Shipped Doses	Total Number of Interval Administered Doses	Total Number of Cumulative Shipped Doses	Total Number of Cumulative Administered Doses
<b>EU (27)</b>	<b>(b) (4)</b>	<b>43429464</b>	<b>(b) (4)</b>	<b>96285540</b>
Austria		710424		1693692
Belgium		961272		2219100
Bulgaria		259272		477672
Croatia		199368		440856
Cyprus		107640		210912
Czech Republic		1010880		2181816
Denmark		710424		1504776
Estonia		100152		242268
Finland		529776		1220076
France		6480864		14399424
Germany		9520992		21511308
Greece		995904		2175576
Hungary		879840		2040012
Ireland		481104		1070784
Italy		5587920		12588264
Latvia		54288		85020
Lithuania		263952		568620
Luxembourg		59904		128700
Malta		77688		201396
Netherlands		1715688		3905304
Poland		4106232		8104200
Portugal		951912		2083536
Romania		1807416		4051944
Slovakia		282672		902304
Slovenia		150696		369876
Spain		4388904		9613344
Sweden	1034280	2294760		
<b>EEA (3)</b>	<b>550368</b>	<b>1218828</b>		
Iceland	32760	75660		
Liechtenstein	0	0		
Norway	517608	1143168		
<b>Total</b>	<b>43979832</b>	<b>97504368</b>		

[Table 5](#) and [Table 6](#) provide, respectively cumulatively and in the interval period, the estimated number of persons who received 1 dose or 2 doses of BNT162b2, in total, and by age group where available, in the EU-EEA countries.



**Table 5. Cumulative Administered 1&2 doses of BNT162b2 by Age Group in EU-EEA Countries<sup>a</sup>**

Countries	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		≥80 years		Age Unknown		All	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Austria	32601	18144	239207	130993	219059	90021	318379	75014	326639	140700	335807	293603	4546	2246	1476238	750721
Belgium	52593	35800	293119	213871	244493	116179	509734	90760	521985	95815	379603	200561	2596	2161	2004123	755147
Bulgaria	6159	2994	91073	53735	62270	40928	68639	39715	45433	21092	13544	6110	230	114	287348	164688
Croatia	4569	1560	66321	29122	57981	20840	104365	27281	95611	32417	54000	28683	82	34	382929	139937
Cyprus	67	132	24777	1459	17825	1449	7243	5255	112	877	19812	7812	58343	47244	128179	64228
Czech Rep	24298	14744	300516	182307	186681	102898	411983	75205	462712	285166	233366	213979	1024	415	1620580	874714
Denmark	12172	11349	100433	95272	70155	64869	215219	79996	489102	148799	234027	216113	807	0	1121915	616398
Estonia	3900	1995	35929	15436	29141	9623	39210	10497	51796	18286	38854	24687	96	25	198926	80549
Finland	20009	5211	164266	52763	163750	27400	211291	16390	432259	13109	249309	50709	0	0	1240884	165582
France													10678144	5870393	10678144	5870393
Germany													16302110	6165751	16302110	6165751
Greece	8657	5508	178846	131191	123573	76311	174906	40155	478077	215987	463446	402532	3193	77	1430698	871761
Hungary	68071	19492	532097	164815	234138	84751	323113	159588	287650	208967	197264	170584	4142	928	1646475	809125
Iceland	1510	515	12660	4461	8658	1911	12582	4204	8571	8268	12357	12290	131	63	56469	31712
Ireland	14443	9893	121182	83267	73386	35093	48177	20871	297164	119213	163486	151163	2070	610	719908	420110
Italy	152389	107855	1179042	1023120	914562	659910	1258996	558357	1603504	535098	3295757	2773399	515532	2289	8919782	5660028
Latvia	1701	831	12069	2349	7009	1394	8473	1285	3894	1714	1595	776	15986	13069	50727	21418
Liechtenstein													4617	2152	4617	2152
Lithuania	17322	6725	86710	42364	72027	36875	109972	60902	89537	66043	52024	37840	752	292	428344	251041
Luxembourg	999	647	8506	5009	23442	2410	28819	1773	12309	11142	18133	17509	5221	4796	97429	43286
Malta	3715	2544	34966	18553	16833	9036	17636	10225	35820	32940	21394	19093	500	1	130864	92392
Netherlands													2867626	1059516	2867626	1059516
Norway													666707	77265	666707	77265
Poland	85825	60529	987763	418915	926701	235199	1332294	267273	1748066	896698	899037	738724	5781	3406	5985467	2620744
Portugal	19908	10838	248888	132357	143630	61761	248335	49080	400468	76875	557181	498668	365	232	1618775	829811
Romania													2626409	1655770	2626409	1655770
Slovakia													610591	451720	610591	451720
Slovenia	1710	1419	21019	18350	16002	11063	69804	30038	85139	70616	61059	56730	227	132	254960	188348
Spain	74690	66594	780878	720572	437097	401459	411832	270351	3037645	697953	2640774	2434770	1744	1209	7384660	4592908
Sweden	22699	12657	154168	96111	158728	61720	498361	63157	526616	125817	418347	323265	0	8	1778919	682735
<b>Total</b>	<b>630007</b>	<b>397976</b>	<b>5674435</b>	<b>3636392</b>	<b>4207141</b>	<b>2153100</b>	<b>6429363</b>	<b>1957372</b>	<b>11040109</b>	<b>3823592</b>	<b>10360176</b>	<b>8679600</b>	<b>34379572</b>	<b>15361918</b>	<b>72720803</b>	<b>36009950</b>

a. Source is <https://covid19-vaccine-report.ecdc.europa.eu/> (point 6, cumulative period as of week 17, 02 May 2021).

**Table 6. Interval Administered 1&2 doses of BNT162b2 by Age Group in EU-EEA Countries<sup>a</sup>**

Countries	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		≥80 years		Age Unknown		All	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Austria	13844	6650	104052	37682	125729	26490	243565	39803	180654	92426	29698	64708	2205	1625	699747	269384
Belgium	13985	4921	64055	26569	120363	14892	405904	24058	382181	52332	55139	77529	210	216	1041837	200517
Bulgaria	3627	1694	43244	25489	24905	15415	35472	16905	30934	12503	9376	3715	113	61	147671	75782
Croatia	2592	446	30465	5624	30515	5103	60198	12895	40025	20335	11492	11656	41	19	175328	56078
Cyprus	67	132	24777	1459	17825	1449	7243	5255	112	877	34	199	20336	8273	70394	17644
Czech Rep	9563	5466	119742	56584	84614	35007	337260	25951	182834	191209	14296	23575	601	135	748910	337927
Denmark	1875	3629	11417	22189	8803	16515	137069	21044	372596	82626	23651	76174	0	0	555411	222177
Estonia	1767	189	18817	1664	18130	1223	26055	2091	28940	6763	11813	3989	59	3	105581	15922
Finland	13018	2414	98748	16941	126196	10385	172935	7222	107636	8368	6395	30472	0	0	524928	75802
France													4545983	2898738	4545983	2898738
Germany													9448390	1853332	9448390	1853332
Greece	4026	1871	58430	28582	58872	22008	142969	16680	333911	148435	70323	47933	2666	3	671197	265512
Hungary	45465	4733	303047	59543	110972	24990	98645	110127	42974	148357	16763	52745	3071	231	620937	400726
Iceland	1045	274	8665	1973	7001	938	10225	2399	468	4141	19	237	60	18	27483	9980
Ireland	4425	295	36766	1839	37734	991	26801	1974	171657	100678	3725	52454	1341	273	282449	158504
Italy	62418	24573	422001	181452	439164	161579	871724	230884	1248664	427351	869075	1346120	5505	1819	3918551	2373778
Latvia	839	63	9699	302	5600	230	7152	363	2116	730	790	314	2763	530	28959	2532
Liechtenstein													2442	766	2442	766
Lithuania	13579	3758	49604	10769	39620	9967	65414	35390	33623	35616	10670	8767	558	122	213068	104389
Luxembourg	348	122	3461	445	21020	305	27033	652	1068	10126	320	8540	381	184	53631	20374
Malta	856	794	15143	4620	8301	2280	9331	3665	9207	24038	618	2607	0	0	43456	38004
Netherlands													1424983	344328	1424983	344328
Norway													596265	67099	596265	67099
Poland	22542	3143	540745	32264	667950	22406	907411	98054	648444	436026	110719	125489	1713	333	2899524	717715
Portugal	8044	250	109033	2094	78408	2935	197000	11363	320382	45784	41994	224660	108	19	754969	287105
Romania													1063035	534479	1063035	534479
Slovakia													143112	208287	143112	208287
Slovenia	258	116	2180	845	4869	1064	58278	25119	19701	45335	2709	4408	108	71	88103	76958
Spain	7629	5202	52074	30795	33858	18615	147614	25791	2872166	588306	568278	1180735	646	380	3682265	1849824
Sweden	8696	1217	49958	8016	92447	5386	426839	9439	290176	47991	19369	98446	0	0	887485	170495
<b>Total</b>	<b>240508</b>	<b>71952</b>	<b>2176123</b>	<b>557740</b>	<b>2162896</b>	<b>400173</b>	<b>4422137</b>	<b>727124</b>	<b>7320469</b>	<b>2530353</b>	<b>1877266</b>	<b>3445472</b>	<b>17266695</b>	<b>5921344</b>	<b>35466094</b>	<b>13654158</b>

a. Source is <https://covid19-vaccine-report.ecdc.europa.eu/> (point 6, interval period weeks 14, 15, 16 and 17, as of 02 May 2021).

## 6. DATA IN SUMMARY TABULATIONS

### 6.1. Reference Information

The MedDRA version 23.1 was used to code adverse events/reactions in summary tabulations.

### 6.2. Cumulative and Interval Summary Tabulations from Post-Marketing Data Sources<sup>13</sup>

- [Appendix 2](#) and [Appendix 2.1](#) respectively provide interval and cumulative numbers of case reports (serious and non-serious, medically confirmed and non-medically confirmed) received from post-marketing authorisation data sources,<sup>13</sup> overall, by sex, country, age groups and in special populations, and summary tabulations of events by PT and SOC respectively for the interval and cumulative periods.

The cumulative data include all data up to 29 April 2021 while the interval data are for the period from 01 April 2021 to 29 April 2021.

- [Appendix 2.2](#) provides an interval summary tabulation of case reports with DMEs from post-marketing data sources.<sup>13</sup>
- [Appendices 2.3](#) and [2.4](#) provide data stratified by country. In these appendices, spontaneous cases (including regulatory authority and literature cases) are presented separately from non-interventional cases:
  - [Appendix 2.3](#) provides a cumulative and interval summary tabulation of cases by medically confirmed and non-medically confirmed status (fatal, serious and non-serious).
  - [Appendix 2.4](#) provides a cumulative and interval summary tabulation of fatal cases.
- [Appendix 2.5](#) and [Appendix 2.6](#) provide a cumulative and interval summary tabulation of adverse reactions from post-marketing authorisation data sources<sup>13</sup> respectively by PT and by HLT organized according to SOC. Please refer to [Appendix 2.5.1](#)<sup>14</sup> and [Appendix 2.6.1](#)<sup>14</sup> for data per country.

Adverse events totals presented in [Appendix 2](#), [Appendix 2.1](#) and for safety topic evaluations in [Section 9.5](#) may differ from those presented in [Appendix 2.5](#) and [Appendix 2.6](#), due to the

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<sup>13</sup> This refers to post-EUA/conditional marketing authorisation approval data sources. Only cases having a complete workflow cycle in the safety database (meaning that they went to Distribution or Closed workflow status at least once) have been included. This approach will prevent the inclusion of cases initially received and not fully processed since cases in early steps of the workflow process may still undergo changes and not accurately reflect final data. Each month, Pfizer applies a Late condition process that retrieves cases received in the reporting period but not included due to lack of completeness; this ensures no cases will be missed for inclusion in monthly reports.

<sup>14</sup> Due to a technical formatting issue, blank pages may be present in this Appendix; the total data are however correctly displayed.

fact that [Appendix 2.5](#) and [Appendix 2.6](#) only display the number of serious and non-serious reactions from spontaneous sources, serious reactions from non-interventional studies and from solicited sources as described above, whereas [Appendix 2](#), [Appendix 2.1](#) and the safety topic evaluations includes all reported events.

[Appendix 2.5.2](#),<sup>14</sup> [Appendix 2.5.3](#)<sup>14</sup> and [Appendix 2.5.4](#)<sup>14</sup> were added to include a cumulative and interval summary tabulation of adverse events from post-authorisation data sources<sup>13</sup> by PT per country, stratified respectively for age, gender and relevant co-morbidities.

Available relevant information with regard to the differences in vaccination prioritization in EU countries,<sup>15</sup> US<sup>16</sup>, UK and ROW<sup>17</sup> was taken into account in the evaluation of adverse events trends, clusters or signals.

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<sup>15</sup> Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA. ECDC, February 2021.

<sup>16</sup> <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html>.

<sup>17</sup> WHO Roadmap for Prioritizing Population Groups for Vaccines against COVID-19; ACIP COVID-19 Vaccines Working Group, Phased Allocation of COVID-19 Vaccines (Dec 01, 2020); JCVI updated interim advice on priority groups for COVID-19 vaccination (Sept 25, 2020)

## 7. MEDICATION ERRORS

Cases potentially indicative of medication errors<sup>18</sup> that occurred in the reporting period are summarized below.

- Number of cases: 1258 (4.1% of 30,752 cases, the total PM<sup>13</sup> dataset) of which 563 (44.8%) are medically confirmed, compared to 771 (2.6%) in the fourth monthly report of which 61.9% were medically confirmed. The increase in medication errors reported during this reporting period in comparison to the previous monthly report is mainly due to an approximate 5-fold increase in reported medication errors related to administration or scheduling of the second vaccine dose more than 21 days from the first vaccine dose as recommended in the RSI. In the majority of these medication errors, the reasons for administration or scheduling of the second vaccine dose more than 21 days from the first vaccine dose were not provided.
- Of the 1258 cases, 27 cases were determined to be non-contributory and are not included in the discussion for the following reasons:
  - No indication that a patient experienced an event with the vaccine in 11 cases;
  - Reporting information was not consistent for paediatric patients (e.g., height, weight, clinical details, etc. indicative of an adult patient) and did not meet the medication error criteria for product administered to patient of inappropriate age in 4 cases;
  - Off-label use rather than medication error was reported in 4 cases;
  - An unspecified number of individuals were described in 3 cases;
  - Unknown if any consumer received the vaccine in 2 cases;
  - Medication error-related events were related to concomitant medication and not the vaccine in 2 cases;
  - A medication error-related event was mistakenly coded in 1 case (i.e., case details on a US Federal Emergency Management Agency event for vaccine distribution was erroneously coded to the PT Product dispensing issue) and has been flagged for correction after the DLP;

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<sup>18</sup> MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

- Number of relevant medication error cases: 1231  
Number of relevant events: 1437.
- Number of medication errors by country:
  - There were 202 cases describing medication errors that occurred in the EU/EEA countries [Germany (47), Belgium (37), Italy (19), Ireland (17), France (16), Spain (14), Netherlands, Romania (8 each), Sweden (6), Czech Republic, Hungary, Portugal (4 each), Norway, Poland (3 each), Austria, Denmark, Finland (2 each), Croatia, Cyprus, Greece, Liechtenstein, and Slovakia (1 each)].
  - There were 1029 cases with medication errors from non-EU/EEA countries [US (537), UK (431), Mexico (19), Japan (11), Canada (8), Switzerland (5), Israel (4), Chile, Turkey (3 each), Colombia (2), Australia, India, Puerto Rico, Serbia, Singapore, and United Arab Emirates (1 each)].

In some instances, clusters of medication errors were reported, generally by HCPs, suggesting that rather than a systematic issue worldwide, these errors were repeated mistakes at certain vaccination centres:

- In the EU/EEA region there were 3 clusters, the largest reported cluster was received from Belgium (112 cases);
  - In non-EU/EEA countries there were 13 clusters, the largest reported clusters were received from the US [(16 cases, 12 cases, and 11 cases (3 clusters)].
- Medication error PTs in the EU/EEA and non-EU/EEA countries:<sup>19</sup>
    - In the EU/EEA countries, a total of 272 PTs indicative of medication errors were reported; those events reported at least thrice included: Incorrect route of product administration (91), Wrong technique in product usage process (50), Inappropriate schedule of product administration (48), Poor quality product administered (25), Product preparation error (10), Incorrect dose administered (9), Product temperature excursion issue (7), Product preparation issue (5), Product administered at inappropriate site and Product storage error (4 each), and Underdose (3 each).<sup>20</sup>

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<sup>19</sup> As per EMA assessment received on the first SMSR, the MAH was requested to keep medication errors under close scrutiny especially within the EU context and discuss whether the current product information is sufficiently clear or whether there is room for improvement. The Rapporteurs should be notified immediately in case of unexpected findings or trends.

<sup>20</sup> The PTs reported less than 3 times included: Accidental overdose (2), Accidental exposure to product, Circumstance or information capable of leading to medication error, Expired product administered, Exposure via skin contact, Inadequate aseptic technique in use of product, Incomplete course of vaccination, Incorrect product formulation administered, Medication error, Product administration error, Product dose omission issue, Product label confusion, Recalled product administered, Vaccination error, and Wrong product administered (1 each).

- In non-EU/EEA countries, a total of 1165 medication errors were reported; those events reported at least thrice included: Inappropriate schedule of product administration (559), Product preparation issue (103), Poor quality product administered (84), Circumstance or information capable of leading to medication error (58), Product temperature excursion issue (55), Incorrect route of product administration (39), Underdose (37), Product administered at inappropriate site, Product dose omission issue (34 each), Product preparation error (23), Expired product administered (21), Wrong technique in product usage process (19), Incorrect dose administered, Wrong product administered (18 each), Product storage error (17), Product administered to patient of inappropriate age (12), Accidental exposure to product, Incomplete course of vaccination (5 each), Counterfeit product administered<sup>21</sup>, Exposure via skin contact (4 each), Accidental overdose, and Product administration error (3 each).
- Medication errors by seriousness:
  - Serious (32 events of medication error):
    - Of these serious events of medication error, 5 serious medication errors<sup>22</sup> accompanied by clinical AEs were reported in EU/EEA countries [France (2), Belgium, Italy, and Slovakia (1 each)];
      - Seriousness criteria were medically significant events (4 events), hospitalization required, and disability (1 event each);
      - Of note, more than 1 serious criteria applied to 1 event;
      - All but 1 event were medically confirmed.
  - Non-serious (1405 events of medication error).

Please see the *Medication errors associated with harm* and *Medication errors without Harm* sections below for further details on co-reported AEs in cases involving serious medication error.

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<sup>21</sup> In 2 of the 4 events, investigation by the MAH confirmed that the administered vaccine was falsified on the basis that the product deliberately or fraudulently misrepresents the identity, composition, or source. Follow up attempts for investigation of the remaining 2 events is not possible, and no further information is expected.

<sup>22</sup> PTs Inappropriate schedule of product administration (2), Incorrect route of product administration, Product administered at inappropriate site, and Product administration error (1 each).

## Medication Errors Harm Analysis

Among the medication error cases, the following scenarios, categorized according to the EMA guidance “Good practice guide on recording, coding, reporting and assessment of medication errors” (EMA/762563/2014) were described:

- Medication errors associated with harm [i.e., resulting in adverse reaction(s)] were reported in 34 cases (2.8% of relevant medication error cases) compared to 19 cases (2.6%) in the fourth SMSR;
- Medication errors without harm [i.e. not resulting in adverse reaction(s)]<sup>23</sup> were reported in 1157 cases (94.0% of relevant medication error cases), of which 652 cases involved co-reported AEs, compared to 696 cases (94.3%), of which 345 included co-reported AEs, in the fourth SMSR;
- Potential medication errors were reported in 46 cases (3.7% of relevant medication error cases) compared to 23 cases (3.1%) in the fourth SMSR.
- Similar to the fourth SMSR, intercepted medication errors were not reported during the reporting interval.

Of note, some cases involved more than one medication error.

### *Medication errors associated with harm (34 medication errors in 34 cases)*

There were 9 cases from the EU/EEA area [Germany (3), Belgium, Czech Republic, Italy, Ireland, Portugal, and Slovakia (1 each)] and 25 from non-EU/EEA countries [US (15), Japan (5), UK (4), and Mexico (1)].

### Serious medication errors

In 6 cases (involving 6 medication error events), serious medication errors potentially contributed to the occurrence of SAEs.

- Vaccination site hypoaesthesia [arm (unspecified)] and Hypoaesthesia [hand (unspecified)] (both serious) were reported in a 50-year-old man after receiving the vaccine that was described as being administered with improper injection technique leading to numbness (PT Wrong technique in product usage process). Numbness of the arm occurred on the day of vaccination, and numbness of the hand occurred about 5 days after vaccination. Additional SAEs in the same subject coded to the PTs Chills, Back pain, Vaccination site pain, Muscular weakness, and Myalgia were also reported and are considered related to the vaccine. Concomitant medications were not reported. At the time of the report, all SAEs were not resolved and the patient plans to seek further medical care.

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<sup>23</sup> AEs may be co-reported in a case, but they are not considered to be a result of the medication error.



- Cervicobrachial syndrome and Brachial plexus injury (both serious) were reported in a 33-year-old woman approximately 2 days after receiving the vaccine that was possibly injected near a nerve in her arm (PT Product administration error). No remarkable findings were found on a magnetic resonance imaging scan of the affected arm. Treatment consisted of NSAIDs (unspecified), “tramadol-containing” pain medication and pregabalin along with supplements (benfotiamine and cyanocobalamin). Additional events of Peripheral swelling, Headache, Body temperature increased, Fatigue, and Face oedema (all non-serious) were also reported for this subject. Clinical outcomes for all events were unknown at the time of the report.
- Hypersensitivity, Palpitations, Chest discomfort, and Hypertension (all serious) occurred in a 50-year-old man a few minutes after receiving his second dose of vaccine that was reported as being expired (details not provided; PT Expired product administered). He was monitored and “everything went back to normal” a few minutes later. This description of events seems consistent with a vaccination stress reaction more so than a reaction due to an expired product. Medical history included suspected COVID-19 about 2 months prior to vaccination and tuberculosis diagnosed 6 years ago. All events were resolved.
- A 42-year-old woman reported experiencing Vaccination site lymphadenopathy (serious) described as “large swelling on her left armpit” after receiving “expired vaccine” (PT Expired product administered; details not provided). At the time of the report, the serious event was resolving. Of note, this case is not medically confirmed. The report AE in this case does not appear to be due to the administration of an expired product.
- A 44-year-old woman reported experiencing Vaccination site reaction, Vaccination site pain, Axillary pain, Breast pain, Myalgia, Fatigue, and Chills (all serious) after the vaccine was injected into her left bicep muscle (as reported) (PT Product administered at inappropriate site). All SAEs resolved 1 day after onset. Of note, this case is not medically confirmed.

#### Non-serious medication errors

In 29 cases (involving 29 medication error events), non-serious medication errors potentially contributed to the occurrence of non-serious AEs.

#### *Errors in the route of administration (9 events, 9 cases)*

- This error occurred in 3 cases from the EU/EEA area [Germany, Portugal, and Italy (1 each)] and in 6 cases from non-EU/EEA countries [Japan (4) and US (2)]. The vaccine was administered subcutaneously and intravenously (4 events each) and intradermally (1 event). Local vaccination site reactions mainly included erythema, pain and swelling. Additionally, in 2 of the 4 cases involving intravenous administration, non-serious events coded to the PTs Blood pressure increased and Oropharyngeal discomfort (1 event each) were reported. Outcomes for both events were unknown at the time of the report.

*Errors of vaccination at the wrong anatomical site (6 events, 6 cases)*

- This error occurred in 6 cases from the US. The vaccination was not administered in the deltoid muscle (PT Product administered at inappropriate site). When provided, the vaccination site was described as being the bicep muscle and the shoulder (not in the muscle) (2 cases each). Local vaccination site reactions included pain, mass, swelling, decreased mobility, and vaccination site haemorrhage.

*Incorrect interval between doses (4 events, 4 cases)*

- This error occurred in 1 case from the EU/EEA area (Germany) and in 3 cases from a non-EU/EEA country (US). In all 4 cases, the second vaccine dose was administered less than 21 days from the first vaccine dose and the dosing interval ranged from 10 to 17 days. Events of fatigue, chills, pain, myalgia, malaise, influenza-like illness, headache, and nausea were reported.

*Use in unauthorized individuals (2 events, 2 cases)*

- This error occurred in 2 cases from a non-EU/EEA country (UK). The vaccine was inadvertently administered to paediatric individuals below 16 years of age (see [Section 9.5.4 Use in Paediatric Individuals <16 Years of Age](#)) (2 events) with ages ranging from 1 to 2 months. Events of vaccination site erythema/pain, malaise, miliaria, and pain in extremity were reported.

*Error in vaccine dosage (2 events, 2 cases)*

- This error occurred in 2 cases from the EU/EEA area (Germany and Ireland), in which accidental overdose (unspecified) and 2 doses in 1 day were reported. Events of pallor, dizziness, chills, nausea, headache, and asthenia were reported.

*Errors in administration technique (2 events, 2 cases)*

- This error occurred in 2 cases from a non-EU/EEA country (US) and involved administration technique errors described as an artery injury from injection per the vaccinee (not medically confirmed) and administration of an additional dose due to leakage of the initial dose from an improperly secured needle. Reported events included arthralgia, pyrexia, and vaccination site haemorrhage.

*Incorrect dilution (2 events, 2 cases)*

- This error occurred in 1 case from the EU/EEA area (Czech Republic) and in 1 case from a non-EU/EEA country (US), in which a single vaccine dose was administered without performing the dilution in 1 case and dilution was performed with a smaller volume of normal saline in another case. Events of pyrexia, fatigue, asthenia, myalgia, pain, and vaccination site reaction were reported.

*Other vaccine administration errors (2 events, 2 cases)*

- This error occurred in 2 cases from non-EU/EEA countries (US and Mexico), in which expired vaccines were administered.<sup>24</sup> Reported events included pyrexia, headache, pain, sensitive skin, nausea, myalgia, muscle spasms, and feeling abnormal.

***Medication errors without harm (1357 medication errors in 1157 cases)***

These medication error PTs describe errors occurring during 1 or more steps of the vaccination process: preparation, administration, or scheduling of second dose.

Overall, there were

- 192 cases from the EU/EEA area: Germany (44), Belgium (36), Italy (17), France, Ireland (16 each), Spain (14), Netherlands, Romania (8 each), Sweden (6), Hungary, Czech Republic, Norway, Poland, Portugal (3 each), Austria, Denmark, Finland (2 each), Croatia, Cyprus, Greece, Liechtenstein, and Slovenia (1 each);
- 965 cases from non-EU/EEA countries: (those with more than 1 medication error) US (488), UK (427), Mexico (14), Canada (8), Japan (6), Switzerland (5), Israel (4), Chile, Turkey (3 each), and Australia (1).

*Vaccine preparation errors (246 events, all non-serious)*: Events mainly described errors during dilution (before use) or in storage conditions.

- *Incorrect dilution (137 events, all non-serious)*: Dilution was performed with a smaller volume of normal saline than instructed (85 events), a single vaccine dose was administered without dilution (17 events), dilution was performed with a larger volume of normal saline than instructed (16 events), vaccine was diluted with expired diluent (12 events), dilution was performed with sterile water for injection rather than normal saline (6 events), and a full vial of vaccine was administered without dilution (1 event).
- *Temperature excursion (83 events, all non-serious)*: In the majority of the events, the vaccine vials were either left in the refrigerator, in the freezer at a temperature range of -25°C to -15°C, or at room temperature for a longer time period than recommended in the RSI; no adverse events were reported upon vaccine administration.
- *Other preparation errors (26 events, all non-serious)*: In majority of the events, errors included vaccine doses prepared as prefilled syringes (5 events), only normal saline solution or expired vaccine<sup>25</sup> were pulled into the syringe for injection (5 events and 3

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<sup>24</sup> In 1 case, vaccine that expired approximately 1 month prior to the administration date was injected into a patient. The second case did not provide details and was reported by the consumer as “maybe they gave me an expired dose” (note: this case is not medically confirmed).

<sup>25</sup> Vaccine was administered more than 6 hours after dilution in 2 events, and a vaccine vial was kept at temperatures up to 30°C for more than the recommended 2 hours in 1 event.

events, respectively), and improper dilution and aseptic technique were reported (3 events each).

*Vaccine administration errors (968 events, 27 of which were serious<sup>26</sup>):* Events mainly described errors in administering the second dose outside the recommended 21 days after the first dose per the RSI, errors in route of administration, errors in administration of vaccine dose not adequately prepared (see Preparation subset), errors in administration technique, errors in the volume or dosage of the vaccine administered, and errors of vaccination at the wrong anatomical site.

- *Incorrect interval between doses (502 events, 18 of which were serious<sup>27</sup>):* Errors included second dose administration more than 21 days after the first dose (426 events), second dose administration less than 21 days after the first dose [73 events; interval between the first and the second dose ranged between 1 day (1 event) to 18 days with the majority of the second doses administered between the 14<sup>th</sup> and the 17<sup>th</sup> day after the first dose (39 events)], and unspecified errors with the administration date of the second dose (3 events).
- *Errors in the route of administration (119 events, 3 of which were serious<sup>28</sup>):* The route of administration for the vaccine was subcutaneous (95 events), intravenous (9 events), intradermal/cutaneous, unspecified routes other than intramuscular (5 events each), parenteral without any further detail (3 events), intra-articular, and trans-mammary (not medically confirmed) (1 event each).
- *Administration after inadequate preparation (98 events, all non-serious):* These events referred to vaccine administered after inadequate preparation: unspecified temperature excursion (34 events), vaccine stored in the refrigerated temperatures for a longer time than specified in the RSI, temperature excursion of thawed vials (18 events each), dilution with expired diluent (12 events), dilution with sterile water for injection rather than normal saline (6 events), doses prepared as pre-filled syringes (3 events), presence

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<sup>26</sup> Upon review, these 27 medication errors did not lead to harm (i.e., clinical AEs) in patients.

<sup>27</sup> Upon review, these 18 medication errors did not lead to harm in patients. Co-reported AEs unrelated to medication errors in these cases were coded to the PTs Fatigue (7), Arthralgia (4), Headache, Myalgia, Nausea, Pain in extremity (3 each), Chills, Contusion, Cough, Disease recurrence, Lymphadenopathy (2 each), Angioedema, Asthma, Asymptomatic COVID-19, Axillary pain, Bedridden, Bursitis, Cardiac failure congestive, Chest discomfort, Diarrhoea, Dizziness, Eye disorder, Eye swelling, Face oedema, Feeling abnormal, Feeling of body temperature change, Gastroesophageal reflux disease, Habit cough, Lip swelling, Lower respiratory tract infection, Malaise, Mouth ulceration, Movement disorder, Muscle fatigue, Muscle tightness, Nasal discomfort, Neck mass, Oedema, Oral herpes, Pain, Peripheral swelling, Pruritus, Psoriasis, Rash, Sudden hearing loss, Syncope, Tendonitis, Tension headache, Throat irritation, Urticaria, Vaccination site mass, Vaccination site pain, and White blood cell count decreased (1 each).

<sup>28</sup> Upon review, these 3 medication errors did not lead to harm in patients. Co-reported AEs unrelated to medication errors in these cases were coded to the PTs Blood pressure increased, Cardiac disorder, Heart valve incompetence, Hypertension, Malaise, Shoulder injury related to vaccine administration, and Troponin increased.

of particulates [white particulate and piece of latex (1 event each)], vaccine discolouration [brownish-orange and brown (1 event each)], unspecified administration of inadequately prepared vaccine (2 events each), and vaccine dose from a cracked vial (1 event).

- *Errors in administration technique (48 events, 1 of which was serious<sup>29</sup>):* These errors involved the use of an incorrect needle or syringe (38 events), improper aseptic technique during administration, unspecified administration technique errors (4 events each), vaccine administered too quickly per vaccinee, and additional dose administered due to leakage of the initial injection (1 event each).
- *Errors in vaccine dosage (41 events, 1 of which was serious<sup>30</sup>):* These errors involved administration of vaccine doses with a lower concentration (17 events), 2 vaccine doses administered on the same day (11 events), unspecified improper dilution, unspecified errors in vaccine dosage (3 events each), administration of vaccine doses with a higher concentration (5 events), administration of an entire vial as 1 injection, and administration of a third dose (1 event each).
- *Errors in the volume administered (37 events, all non-serious):* Errors included administration of partial doses due to leakage (16 events), larger volumes of the correct dosage of vaccine (8 events), partial doses due to syringe or needle malfunction (7 events), smaller volumes of the correct dosage of vaccine (6 events).
- *Vaccination site other than deltoid muscle (32 events, 2 of which were serious<sup>31</sup>):* The vaccine was administered in the vaccinee's arm but not in the deltoid muscle (10 events), an unspecified location other than the deltoid muscle (7 events), leg, shoulder, tricep (4 events each), forearm, gluteus muscle, and hand (1 event each).
- *Wrong vaccine other than recommended in the RSI administered (16 events, 1 of which was serious<sup>32</sup>):* Vaccinees received 1 dose of the AstraZeneca vaccine and 1 dose of the BioNTech-Pfizer vaccine, 1 dose of the Moderna vaccine and 1 dose of the BioNTech-Pfizer vaccine (6 events each), 1 dose of the Sinovac vaccine and 1 dose of the BioNTech-Pfizer vaccine, and 1 dose of an unknown vaccine and 1 dose of the BioNTech-Pfizer vaccine (2 events each).

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<sup>29</sup> Upon review, this medication error did not lead to harm in the patient. A co-reported AE unrelated to the medication error in this case was coded to the PT Pain in extremity.

<sup>30</sup> Upon review, this medication error did not lead to harm in the patient. Co-reported AEs unrelated to the medication error in this case were coded to the PTs Dizziness, Headache, Illness, and Pain.

<sup>31</sup> Upon review, these 2 medication errors did not lead to harm in patients. Co-reported AEs unrelated to medication errors in these cases were coded to the PTs Vaccination site pain (2), Arthralgia, Cerebrovascular accident, Balance disorder, Gait disturbance, Limb discomfort, Hypoaesthesia, Hypokinesia, Multiple sclerosis, Muscular weakness, Myocardial infarction, and Thrombosis (1 each).

<sup>32</sup> Upon review, this medication error did not lead to harm in the patient. A co-reported AE unrelated to the medication error in this case was coded to the PT Atonic seizures.

- *Use in unauthorized individuals (11 events, all non-serious):* The vaccine was inadvertently administered to paediatric individuals below 16 years of age (see [Section 9.5.4 Use in Paediatric Individuals <16 Years of Age](#)) (10 events), and an individual with active infection (sinus) (1 event each).
- *Accidental exposure to vaccine (12 events, all non-serious):* These errors involved exposure to the skin (10 events) and eye (2 events).
- *Dose of vaccine not administered (4 events, all non-serious):* Errors included administration of only normal saline solution (2 events), injection with an empty syringe, and injection of the needle without dose administration (1 event each).
- *Other vaccine administration errors (48 events, 1 of which was serious<sup>33</sup>):* Errors mainly included administration of expired vaccine<sup>34</sup> (23 events), the use of concomitant drugs<sup>35</sup> (7 events), underdose (i.e., from poor administration technique, over-diluted vaccine, syringe/needle malfunction, incorrect route of administration, and leakage) (5 events), administration of a poor quality vaccine (i.e., recalled lot and “manufacturing defect”) (2 events).

*Vaccine scheduling errors (131 events, all non-serious):* Events mainly described errors involving scheduled second dose vaccinations outside the recommended 21 days after the first dose.

- *Incorrect interval between doses (38 events, all non-serious):* The second dose was scheduled more than 21 days after the first dose (26 events) and the second dose of the vaccine was scheduled less than 21 days after the first dose (12 events).
- *Other scheduling errors (93 events, all non-serious):* The vaccinee cancelled or missed their appointment (48 events), no scheduled appointment for the second dose (32 events), the second dose was not available due to a supply issue (9 events), appointment cancelled by the vaccination site (2 events), the vaccination date conflicted with another

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<sup>33</sup> Upon review, this medication error did not lead to harm in the patient. Co-reported AEs unrelated to the medication error in this case were coded to the PTs Allergic reaction to excipient, Erythema, and Rash pruritic.

<sup>34</sup> Vaccine was administered more than 6 hours after dilution in 6 events, a vial was left in the refrigerator for more than 5 days in 1 event, a consumer reported that the administered vaccine was expired based on information on her vaccination card in 1 event, and expiry details were not provided in the remaining 15 events.

<sup>35</sup> No co-suspect drugs were reported.

appointment/procedure, and the second dose was not administered for an unknown reason (1 event each).

*Other medication errors (12 events, all non-serious):* Events mainly described vaccination appointment unavailability (3 events), patient resistance for a second dose, error on the vaccination card (2 events each).

***Potential medication errors (46 medication errors in 46 cases)***

There were 2 cases from the EU/EEA area (France and Italy) and 44 cases from non-EU/EEA countries [US (38), Mexico (4), Australia, and Colombia (1 each)].

- *Potential dosing interval errors (8 events, all non-serious):* Events mainly described potential errors posed from patients not notified their second dose vaccination appointment is by the vaccination site (3 events), scheduling of the second dose vaccination outside of the 21-day interval, and patients potentially missing their scheduled vaccination appointment (2 events each).
- *Other potential errors (38 events, all non-serious):* Events mainly described patient questions around potential drug-drug interactions, scheduling, vaccine dosing, counterfeit vaccines, concurrent treatment/procedures, and potential AEs.

Some medication errors are expected to occur despite written instructions and educational activities for HCPs administering the vaccine. The number and seriousness of the reported medication errors do not indicate a need for additional mitigation activity.

**8. GENERAL OVERVIEW**

A total of 30,752 case reports (15,233 medically confirmed and 15,519 non-medically confirmed) containing 112,836 events fulfilled criteria for inclusion in this SMSR. Refer to [Appendix 2](#) for the summary tabulations of all cases received during the current reporting period.

**PRESENTATION OF CASE CHARACTERISTICS**

**Table 7. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval**

	Characteristics	Relevant cases (N=30752)
Gender:	Female	21429
	Male	7571
	No Data	1752
Age range (years): 0.08 -106 years Mean = 53.4 years Median = 52 years n = 25851	≤ 17	157 <sup>a</sup>
	18-30	3450
	31-50	8828
	51-64	5794
	65-74	2805
	≥ 75	4929
	Unknown	4778 <sup>b</sup>
Case outcome:	Resolved/Resolving	13648

**Table 7. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval**

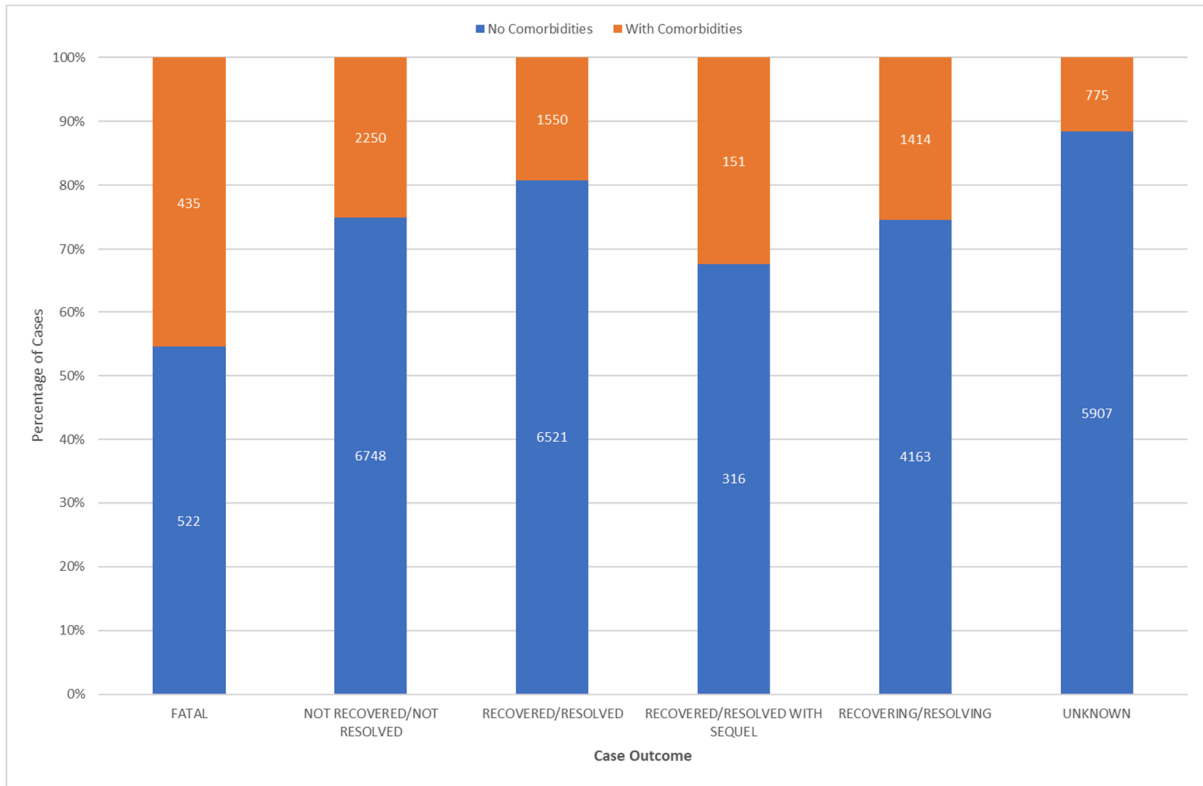
	Characteristics	Relevant cases (N=30752)
	Resolved with sequelae	467
	Not resolved at the time of report	8998
	Fatal	957
	Unknown	6682
Presence of comorbidities	Yes	6575 <sup>c</sup>
	No	24177

- a. Including 12 cases for which a paediatric age was initially reported but that they re-evaluated as not consistent with this age upon review (see [Table 14](#), *Use in Paediatric Individuals <16 Years of Age*) and 31 breastfed babies for which paediatric age was reported;
- b. Including 31 breastfed babies for which age was not reported;
- c. Cases retrieved applying the criteria in place to identify the reports involving the special populations of Immunocompromised patients, Patients with autoimmune or inflammatory disorders, Frail patients with comorbidities (e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders, active tuberculosis) described as Missing Information in [Table 14](#).

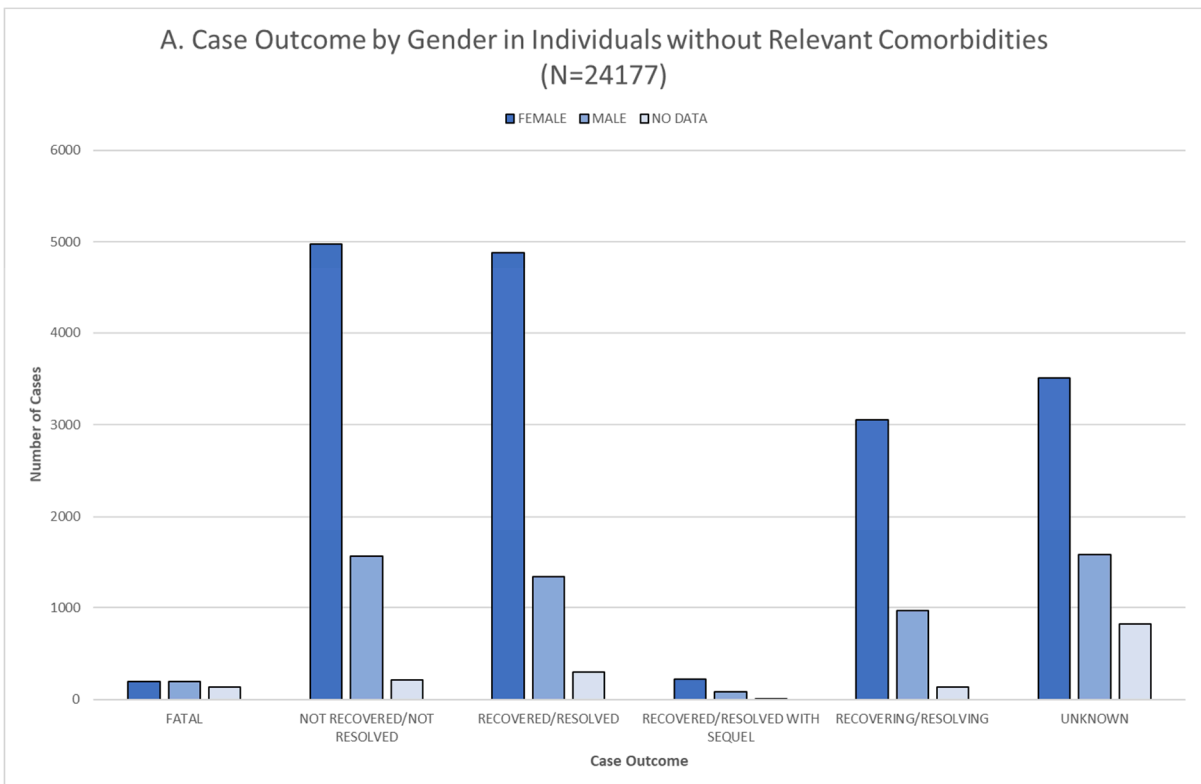
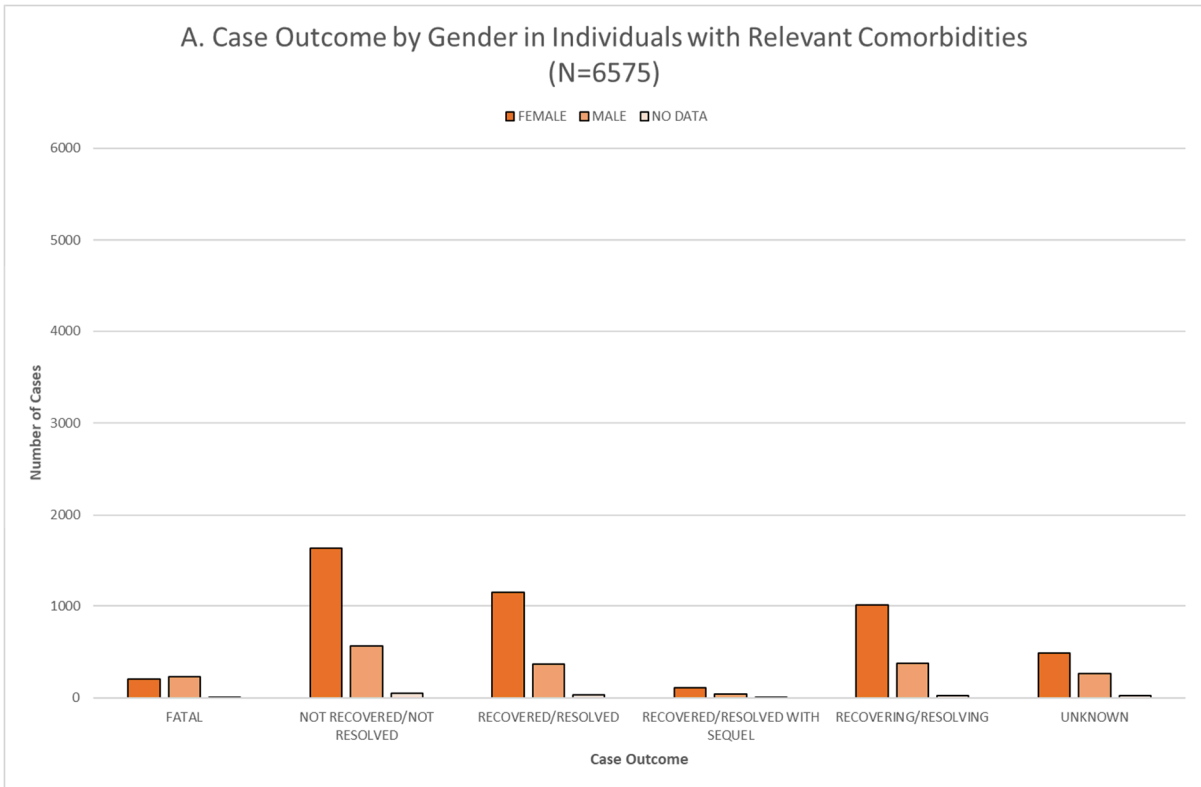
Case outcome by age group, gender and presence of relevant comorbidities is presented in [Figure 1](#), [Figure 2](#) and [Figure 3](#). Across all age groups, there were more females than males reporting adverse events. Overall, the proportion of cases with fatal outcome is higher when relevant comorbidities are reported ([Figure 1](#)). Among the cases with a fatal outcome, there is a similar pattern for gender both in presence or in absence of relevant comorbidities ([Figure 2-A](#)). Keeping in consideration the age group ([Figure 2-B](#)), when the age was known, there are no differences in the proportion of cases with a fatal outcome, with the highest number of cases in individuals aged 75 years and older, either in presence or absence of relevant comorbidities. (please also see *Death* in [Table 13](#) and *Frail patients with co-morbidities e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders, active tuberculosis*, described as Missing Information in [Table 14](#)).

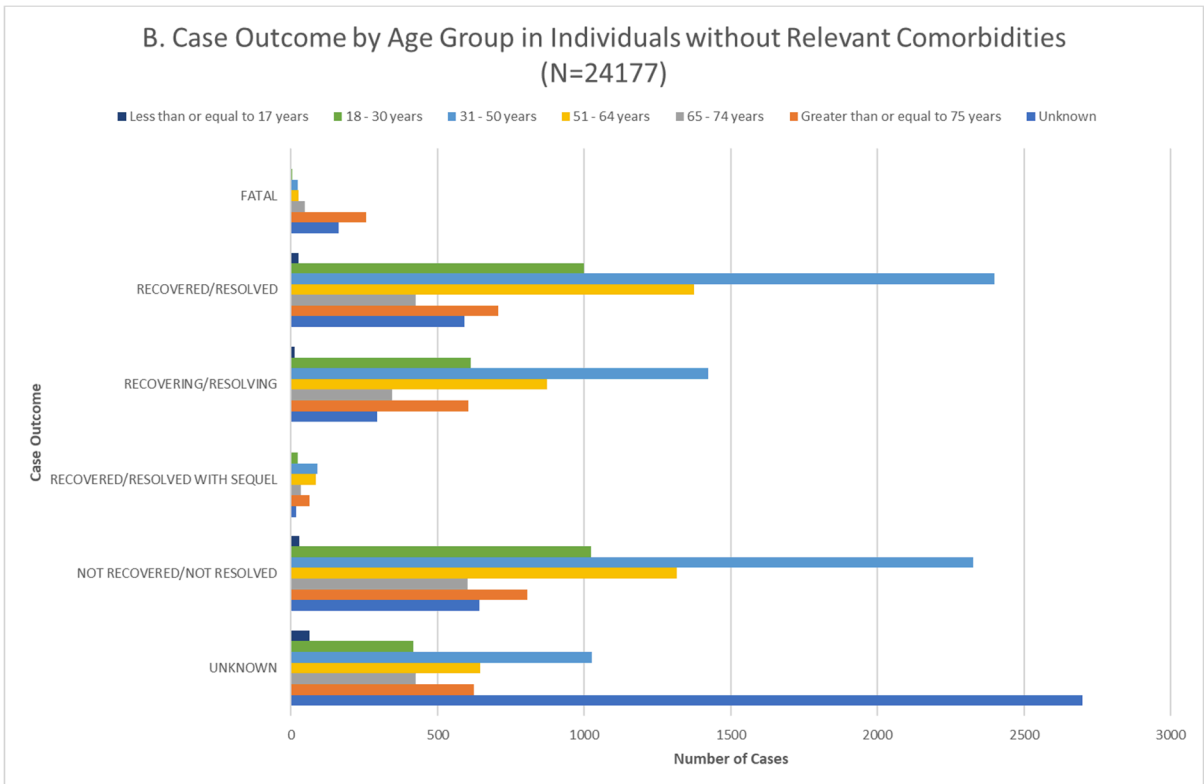
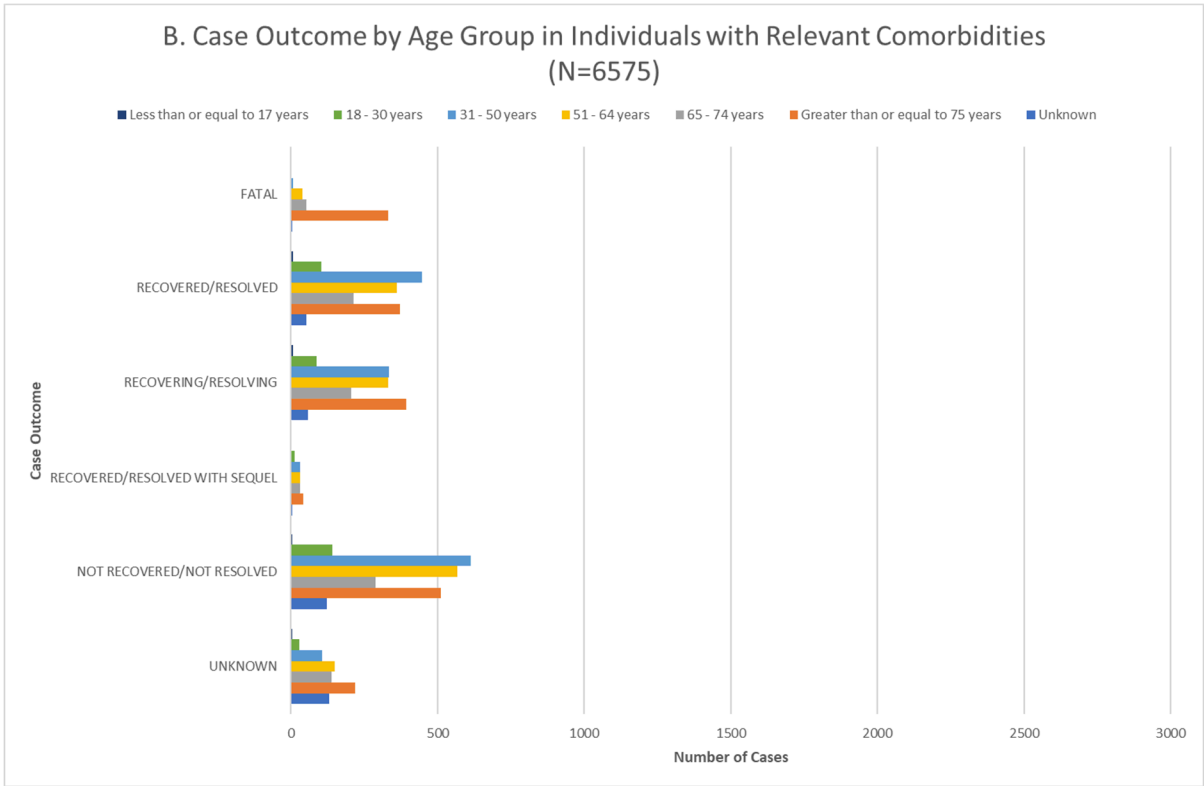


**Figure 1. Case Outcome by Presence of Relevant Comorbidities**

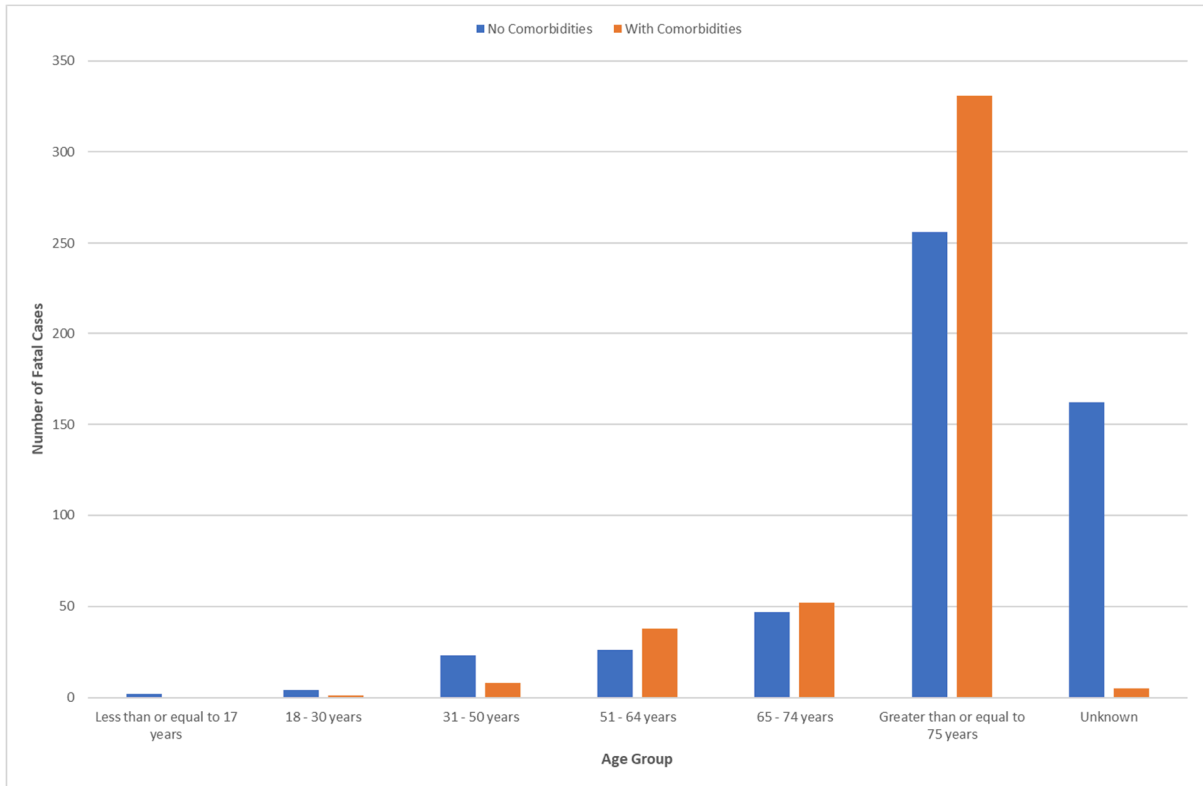


**Figure 2. Case Outcome by Presence of Relevant Comorbidities, Gender and Age Group**





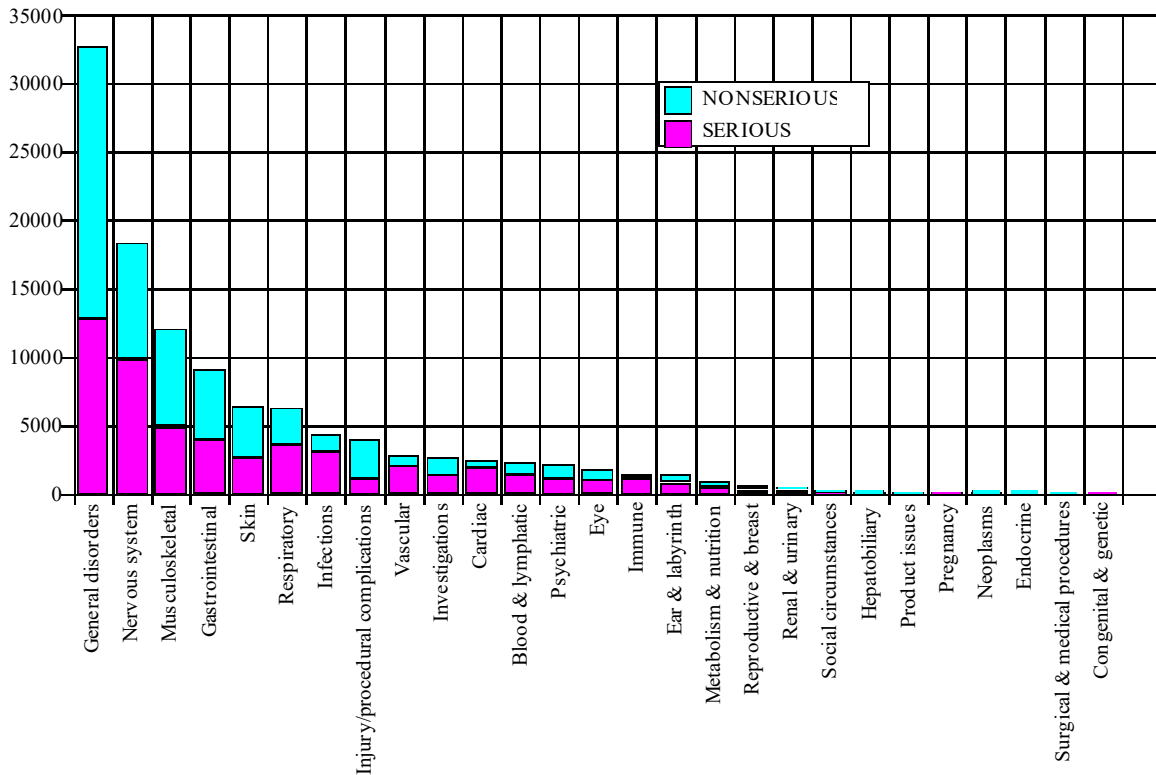
**Figure 3. Fatal Case Outcome by Presence of Relevant Comorbidities and Age Group**



**ADVERSE EVENT DATA**

As shown in Figure 4, the MedDRA SOC containing the greatest number of events ( $\geq 2\%$ ) were General disorders and administration site conditions (32,762), Nervous system disorders (18,369), Musculoskeletal and connective tissue disorders (11,981), Gastrointestinal disorders (9,020), Skin and subcutaneous tissue disorders (6373), Respiratory, thoracic and mediastinal disorders (6345), Infections and infestations (4297), Injury, poisoning and procedural complications (3926), Vascular disorders (2864), Investigations (2750), Cardiac disorders (2479) and Blood and lymphatic system disorders (2311). Of note, multiple adverse events may be reported in a single case.

**Figure 4. General Overview: Total Number of Events by MedDRA SOC and Event Seriousness**



The overall safety evaluation includes a review of the most frequently reported events by SOC and by the PT for events reported in ( $\geq 2\%$ ) of all cases during the reporting interval as compared to the cumulative period since the first temporary authorisation for emergency supply on 01 December 2020.

**Table 8. Events Reported in  $\geq 2\%$ \* Cases**

	<b>01 April 2021 Through 29 April 2021</b>	<b>Cumulatively Through 29 April 2021</b>
<b>MedDRA SOC</b> MedDRA PT	<b>AEs (AERP%)</b> <b>N = 30752</b>	<b>AEs (AERP%)</b> <b>N = 109692</b>
<b>Blood and lymphatic system disorders</b>		
Lymphadenopathy <sup>a</sup>	1556 (5.06%)	5643 (5.14%)
<b>Gastrointestinal disorders</b>		
Nausea <sup>a</sup>	3184 (10.35%)	12843 (11.71%)
Diarrhoea <sup>a</sup>	1161 (3.78%)	4669 (4.26%)
Vomiting <sup>a</sup>	1148 (3.73%)	4307 (3.93%)
<b>General disorders and administration site conditions</b>		
Fatigue <sup>a</sup>	4763 (15.49%)	18540 (16.90%)
Pyrexia <sup>a</sup>	4313 (14.03%)	19385 (17.67%)
Chills <sup>a</sup>	3007 (9.78%)	13285 (12.11%)
Vaccination site pain <sup>a</sup>	2701 (8.78%)	11928 (10.87%)
Pain <sup>a</sup>	2263 (7.36%)	8656 (7.89%)
Malaise <sup>a</sup>	2133 (6.94%)	8001 (7.29%)
Asthenia <sup>a</sup>	1496 (4.86%)	6600 (6.02%)
Drug ineffective <sup>b</sup>	972 (3.16%)	3566 (3.25%)
Feeling abnormal	701 (2.28%)	2199 (2.00%)
Influenza like illness	665 (2.16%)	2518 (2.30%)
<b>Immune system disorders</b>		
Anaphylactic reaction <sup>a</sup>	758 (2.46%)	1965 (1.79%)
<b>Infections and infestations</b>		
COVID-19 <sup>b</sup>	1816 (5.91%)	5125 (4.67%)
<b>Injury, poisoning and procedural complications</b>		
Off label use <sup>b</sup>	625 (2.03%)	1930 (1.76%)
<b>Musculoskeletal and connective tissue disorders</b>		
Myalgia <sup>a</sup>	3100 (10.08%)	13094 (11.94%)
Pain in extremity <sup>a</sup>	2797 (9.10%)	10348 (9.43%)
Arthralgia <sup>a</sup>	2422 (7.88%)	9740 (8.88%)
<b>Nervous system disorders</b>		
Headache <sup>a</sup>	6234 (20.27%)	25526 (23.27%)
Dizziness	2251 (7.32%)	8704 (7.93%)
Paraesthesia	862 (2.80%)	3710 (3.38%)
Hypoesthesia	715 (2.33%)	2475 (2.26%)
<b>Respiratory, thoracic and mediastinal disorders</b>		
Dyspnoea <sup>c</sup>	1437 (4.67%)	5185 (4.73%)
Cough <sup>c</sup>	808 (2.63%)	2853 (2.60%)
<b>Skin and subcutaneous tissue disorders</b>		
Rash <sup>a</sup>	1090 (3.54%)	3668 (3.34%)
Pruritus <sup>a</sup>	1074 (3.49%)	3845 (3.51%)
Erythema <sup>a</sup>	777 (2.53%)	2806 (2.56%)
<b>Total number of events</b>	<b>56829</b>	<b>223114</b>

a. Listed or consistent with listed AEs in current RSI;

b. Listed per case processing conventions, except for fatal cases; for discussion of relevant cases of Drug ineffective/COVID-19 see Table 13, *Lack of Efficacy* subsection;

c. Consistent with anaphylactic reactions listed in the current RSI;

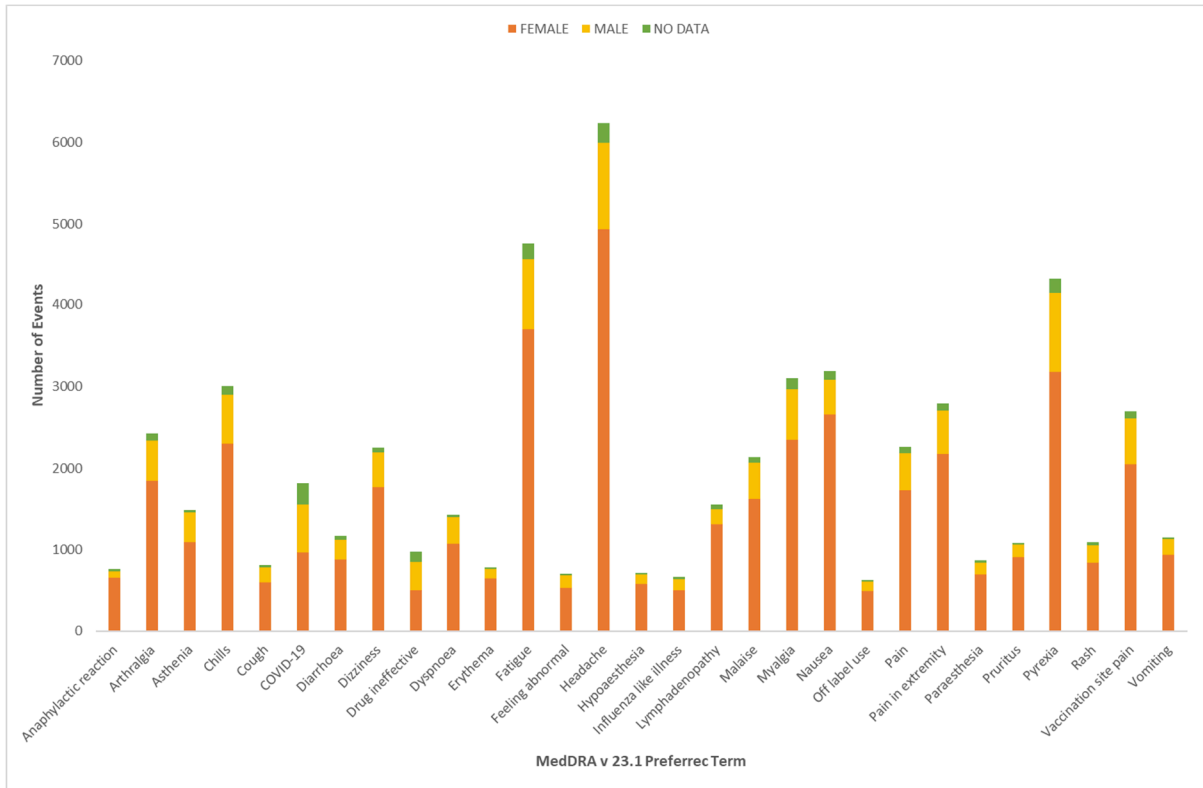
\* Reporting proportion (% of total cases) in the current reporting period.

Most of the frequently reported events are listed or consistent with listed events as per the current RSI. Of note, the frequently reported events Dizziness and Paraesthesia, not listed as per the current RSI, are being added to the RSI.

During the reporting interval, the distribution of the AEs reported in more than 2% of the cases by gender is presented in [Figure 5](#). The observed imbalance in the female gender distribution reflects the imbalance in the gender distribution of the cases received in the reporting period.

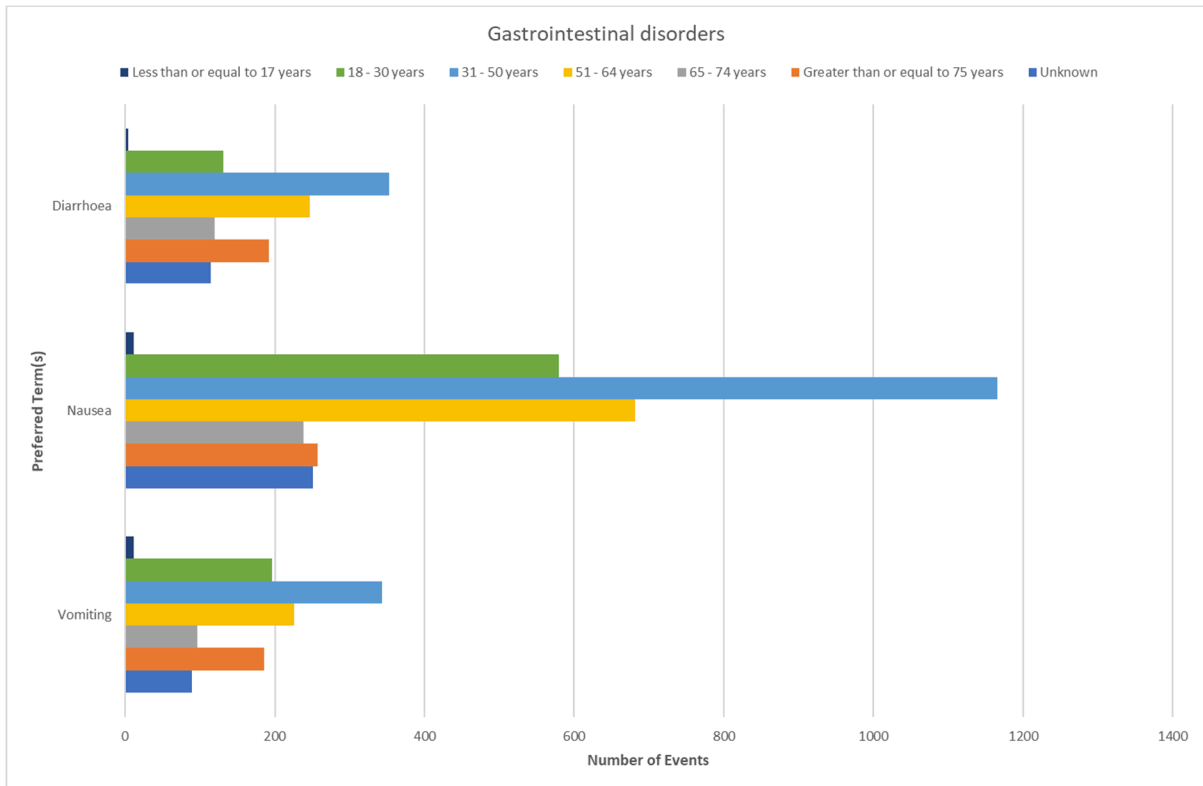
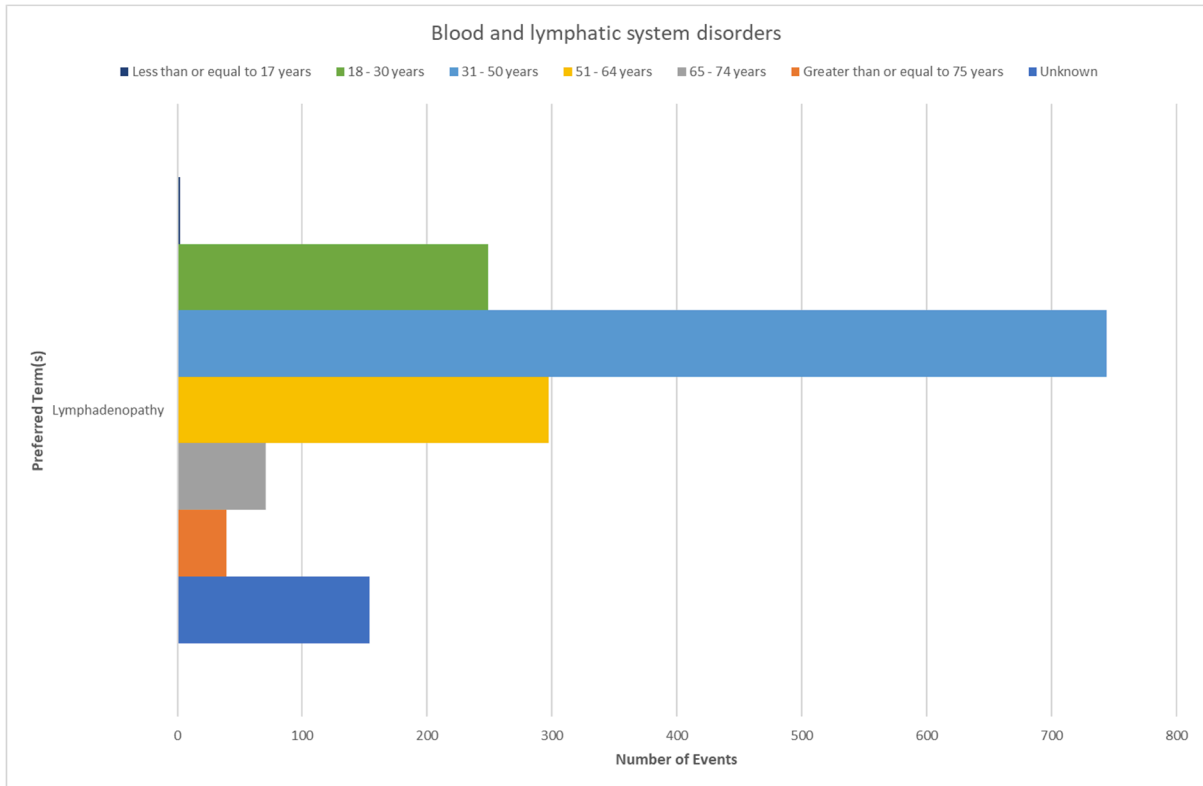
The distribution of the AEs reported in more than 2% of the cases by age group and by SOC is shown in [Figure 6](#) and [Figure 7](#). Across the SOCs, the largest number of events is reported overall in the 31-50 years age group, followed by the 51-64 years age group with the exception of COVID-19. When the age was reported, the largest number of COVID-19 occurrences is reported in the 75 years and older group followed by the 31-50 years age group, and by the 51-64 years age group, respectively.

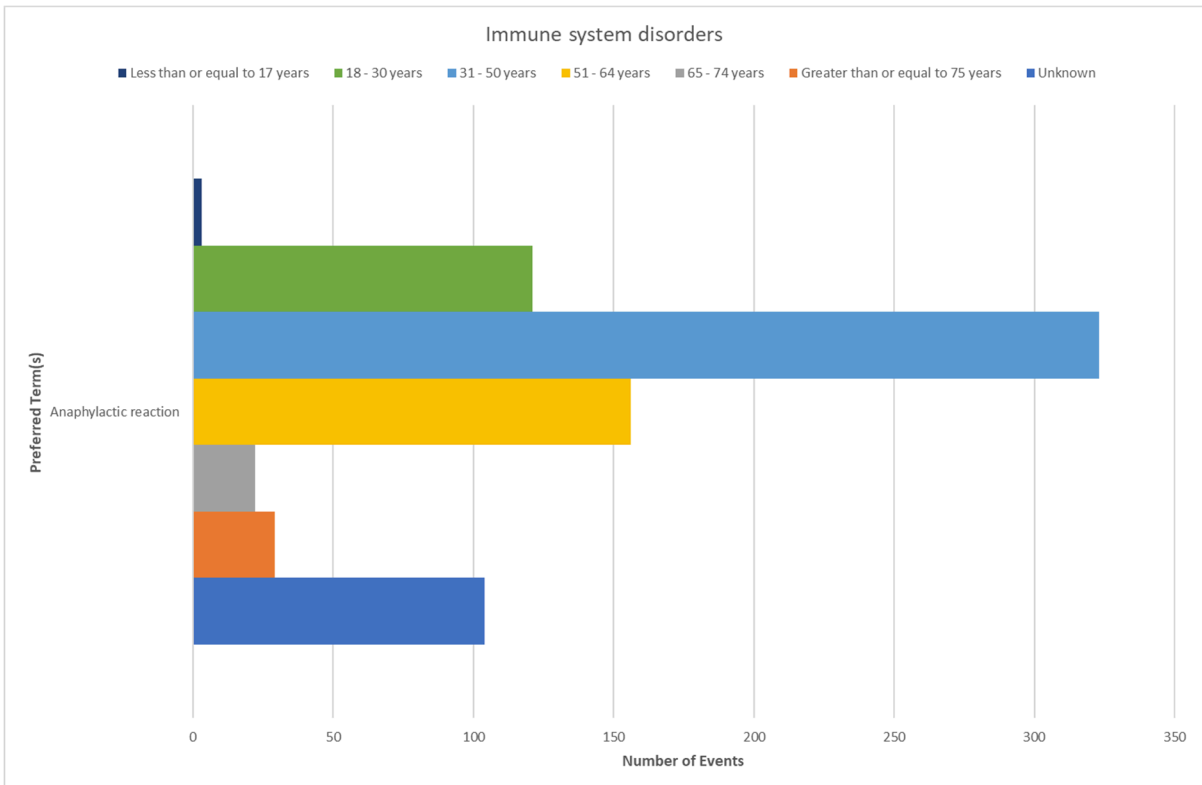
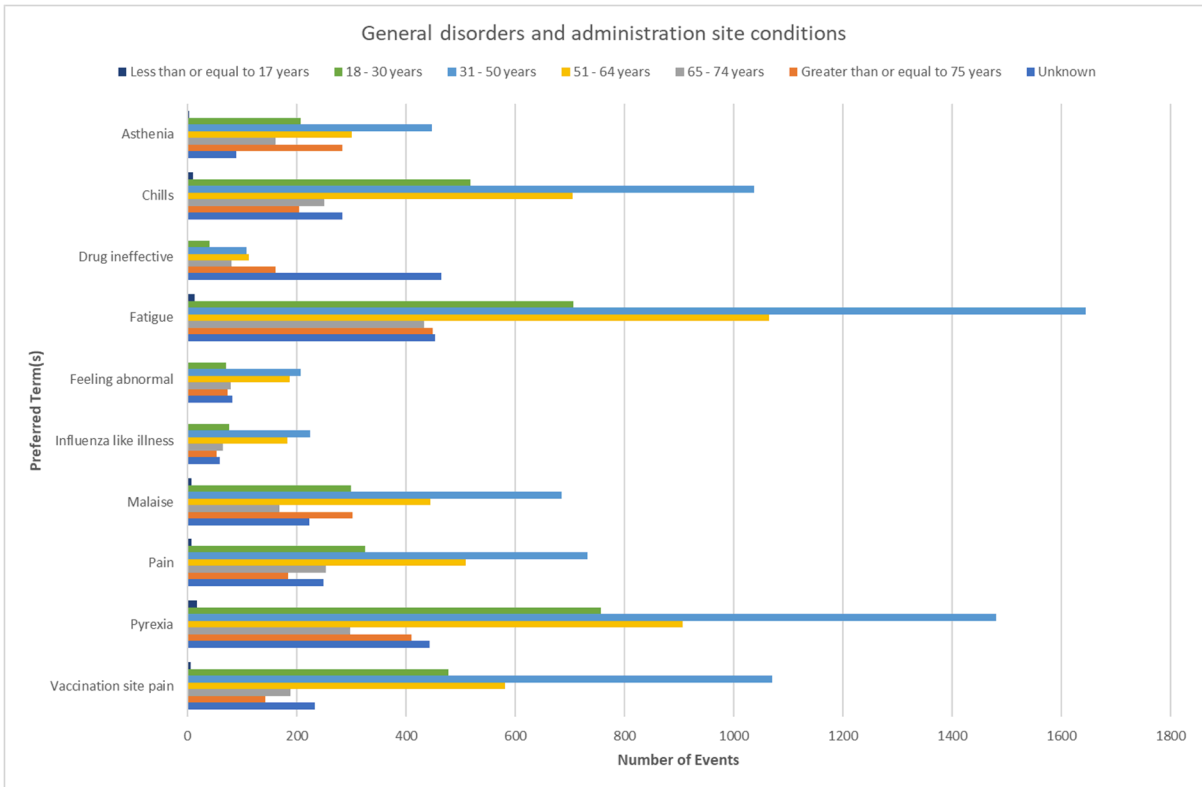
**Figure 5. Events Reported in  $\geq 2\%$  Cases in the Interval Period by Gender**

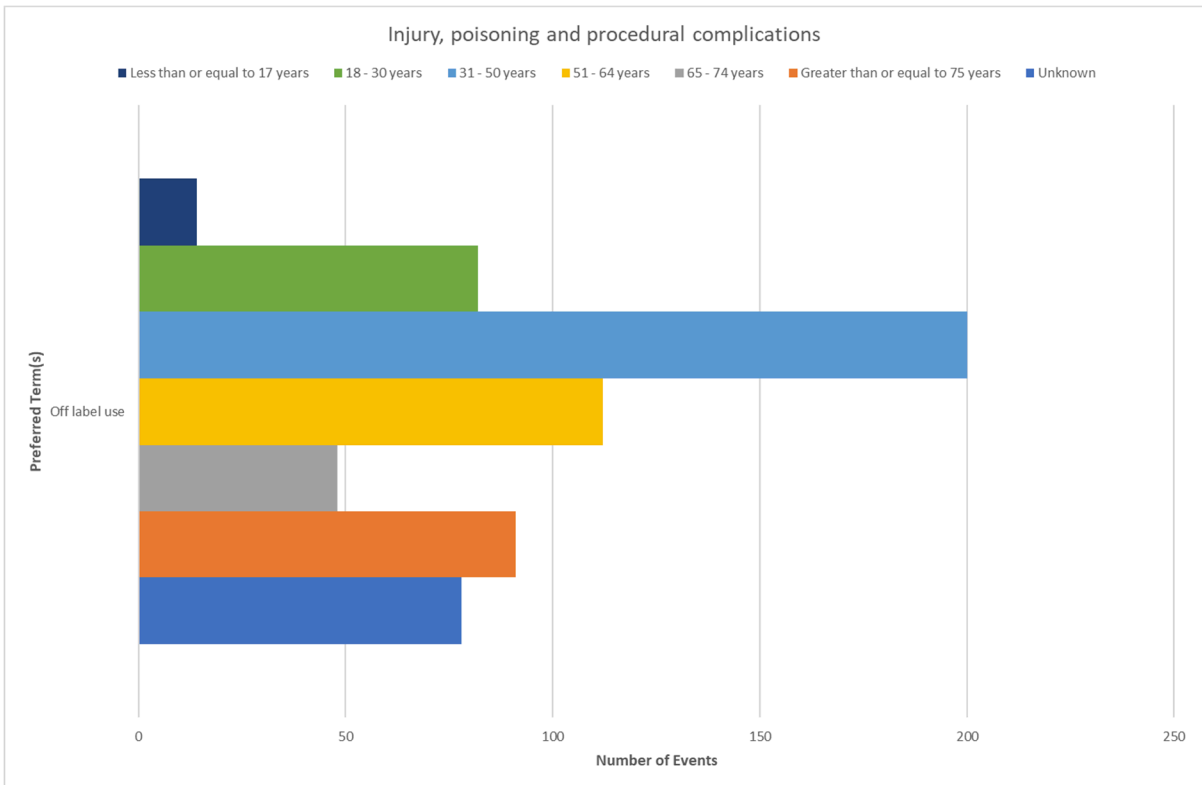
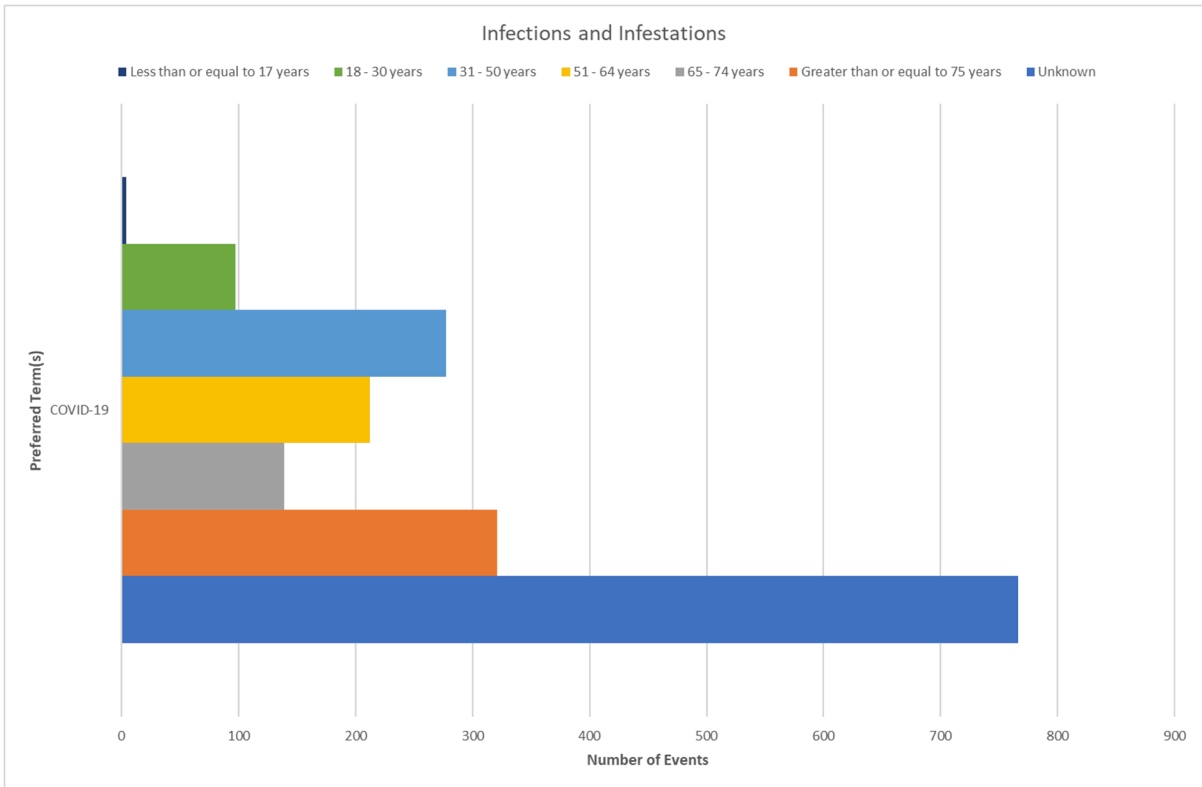


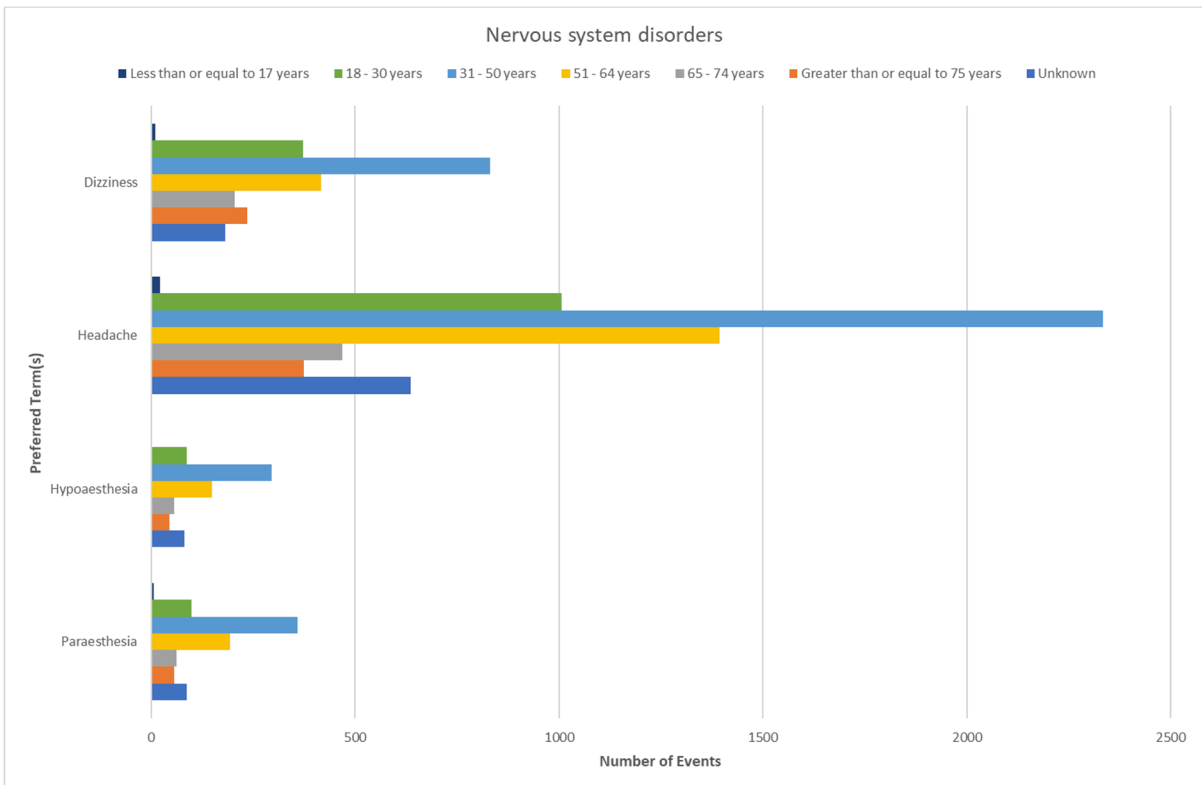
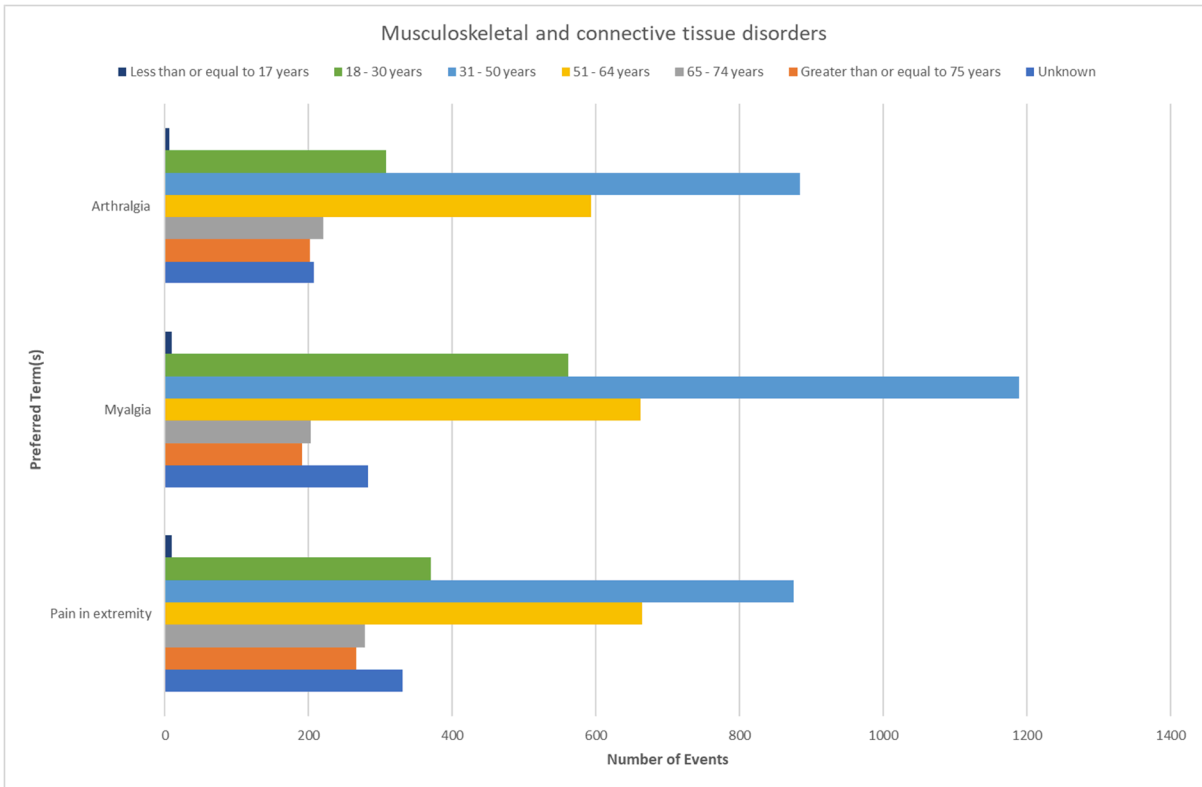


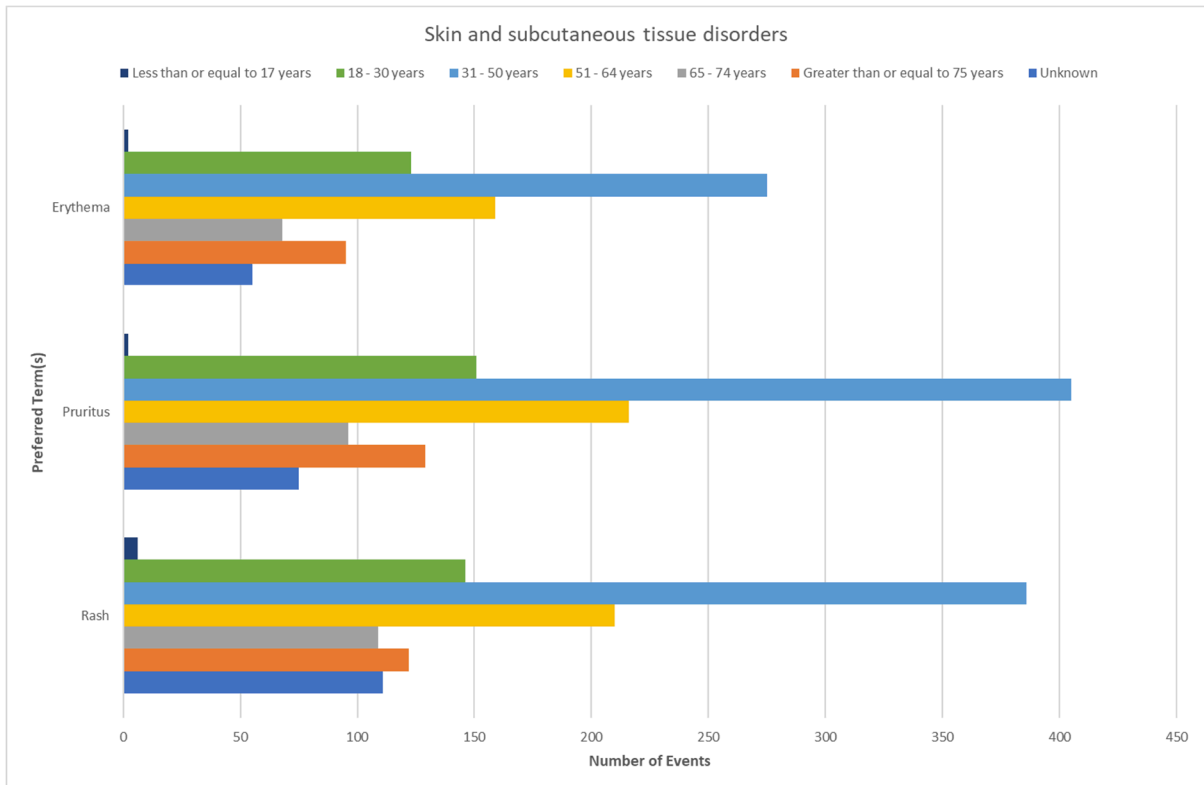
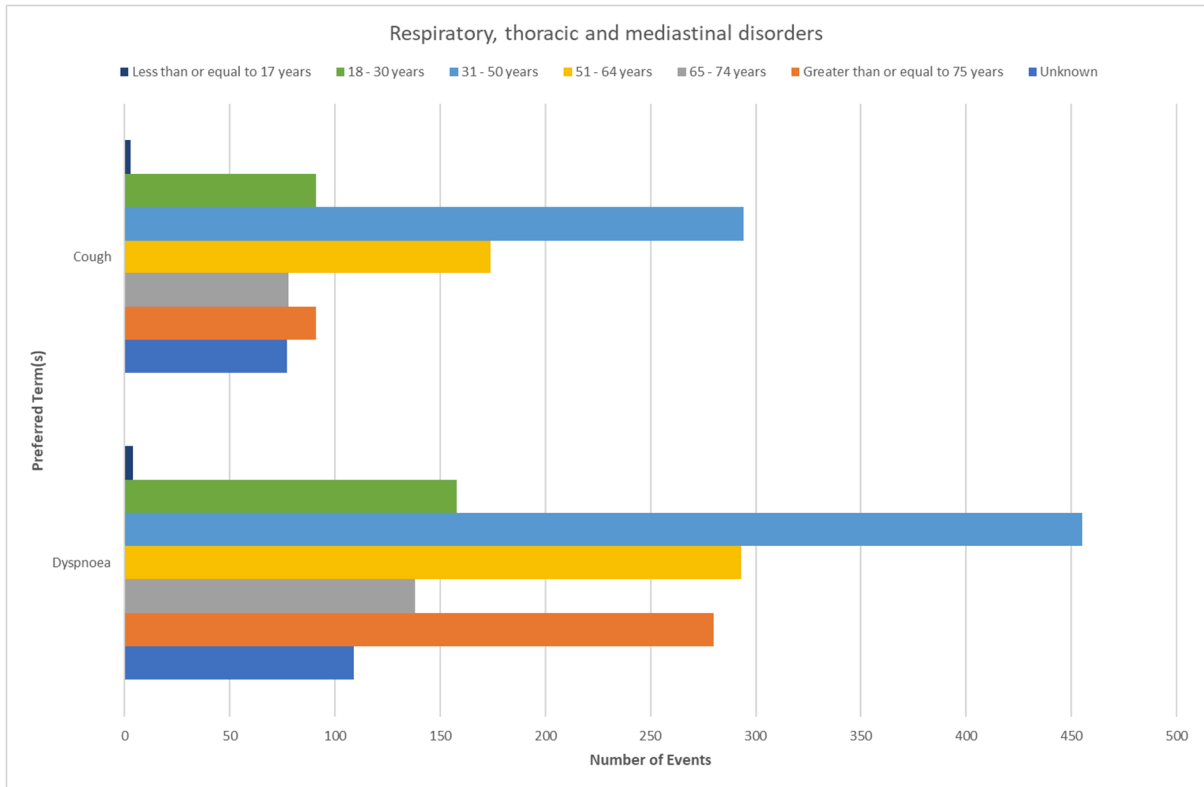
**Figure 6. PT Reported in  $\geq 2\%$  in the Interval Period - by SOC and Age Group**



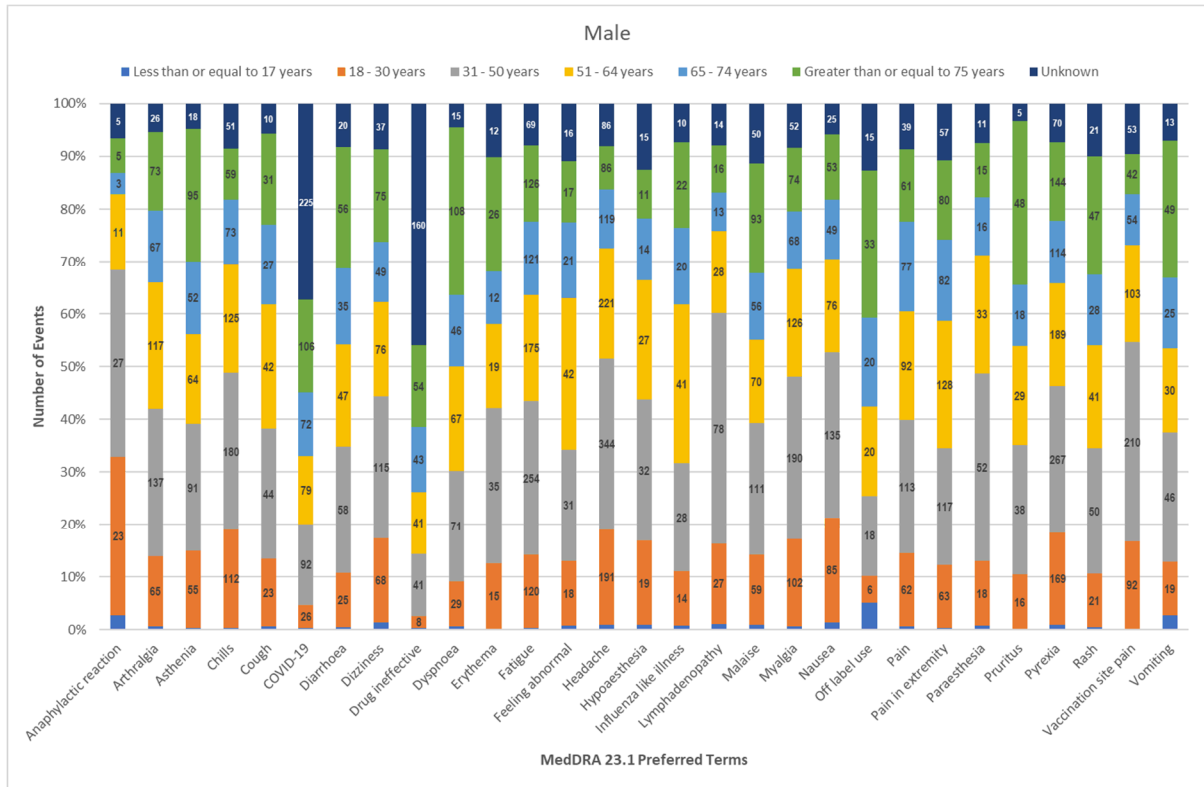
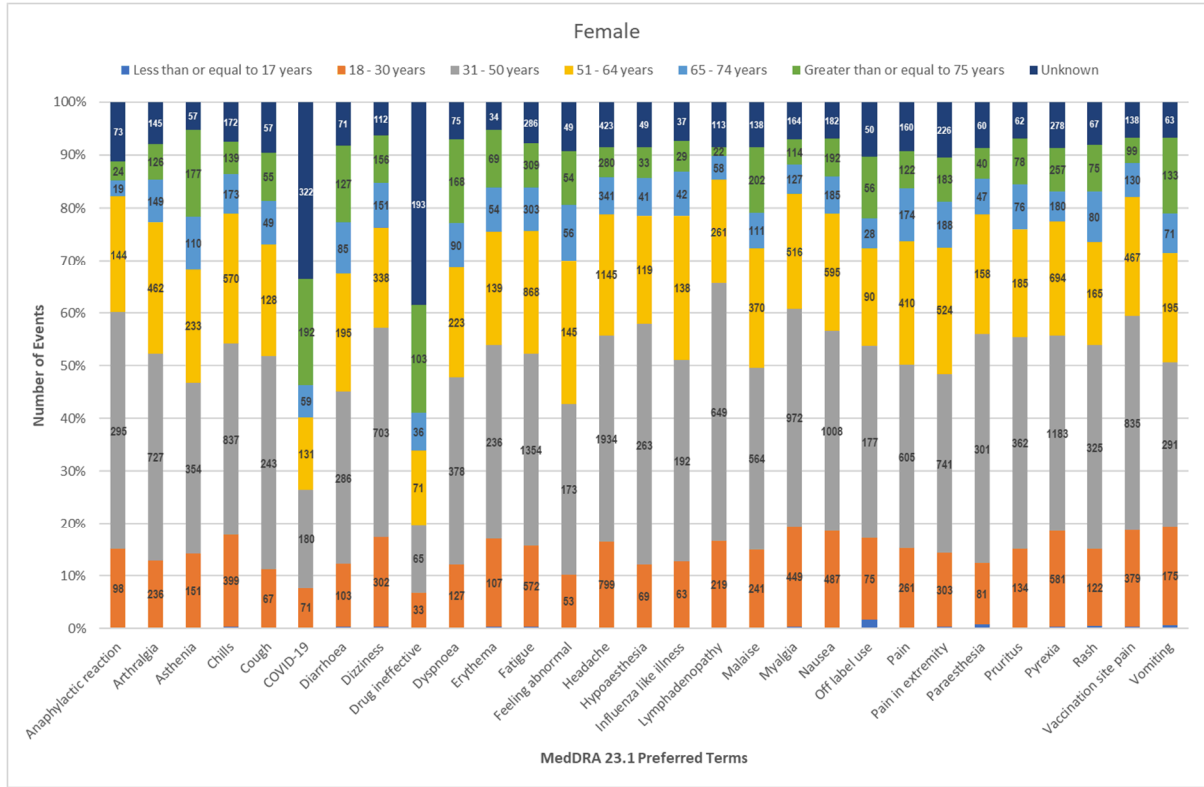








**Figure 7. Events Reported in  $\geq 2\%$  in the Interval Period by Age Group within Gender**



## 9. SIGNAL AND RISK EVALUATION

### 9.1. Literature Review

Please refer to [Appendix 6](#) for a summary description of the interval literature review that is performed for the purpose of signal detection.

There was 1 literature article, a case report, that described the occurrence of minimal change disease (MCD) with nephrotic syndrome (NS) and acute kidney injury (AKI) in a patient who had received the first dose of BNT162b2. As per the article: “A 50-year-old previously healthy male was admitted to the hospital following the appearance of peripheral edema. Ten days earlier, he had received the first injection of the vaccine. Four days after injection, he developed lower leg edema, which rapidly progressed to anasarca. On admission, serum creatinine was 2.31 mg/dL and 24-hr urinary protein excretion was 6.9 grams. As kidney function continued to decline over the next days, empiric treatment was initiated with prednisone 80 mg/day. A kidney biopsy was performed and the findings were consistent with MCD. Ten days later, kidney function began to improve, gradually returning to normal. The clinical trial of MCD, NS and AKI has been previously described under a variety of circumstances, but not following the Pfizer COVID-19 vaccine. The association between the vaccination and MCD is at this time temporal and by exclusion, and by no means firmly established. We await further reports of similar cases to evaluate the true incidence of this possible vaccine side-effect.” The safety topic of nephrotic syndrome was evaluated by the MAH and determined not to be validated signal (see [Appendix 3](#) and [Appendix 3.1](#)).

In addition, as per the *EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.3) received on the fourth SMSR*, the MAH reviewed the article by Krammer et al., entitled “Robust spike antibody responses and increased reactogenicity in seropositive individuals after a single dose of SARS-CoV-2 mRNA vaccine”. The MAH maintains that the most informative data comparing reactogenicity of vaccine doses 1 and 2 in individuals who have previous exposure to SARS-CoV-2 is from the clinical study C4591001. The most recent safety data cut-off for the clinical study data is 13 Mar 2021 and a clinical study report is in progress. The MAH did an analysis for individuals positive at baseline compared to those negative at baseline. It was shown that that the first dose gave higher reactogenicity rates in individuals positive at baseline than observed in those negative at baseline. This is consistent with the publication. However, with administration of the second dose, those positive at baseline had much lower rates of reactogenicity compared to those negative at baseline. If you look at any reactogenicity for Dose 1 and Dose 2, the rates were basically the same (although numerically lower in those positive at baseline). Hence the conclusion that, for a 2-dose series, baseline serostatus does not impact the overall safety profile of a population of people where serostatus is not known. In the recent analysis for the BLA the MAH found the same thing. The flaw in the analysis in the paper is that they only gave 1 dose and assumed that the second dose would be worse, when in reality, it was not. Additionally, the MAH could also say that while 1 dose of vaccine gives increased antibody responses we do not know whether those responses are sufficient given all the variants of concern circulating. The in vitro data shows potent neutralization responses after two doses – not one. The laboratory data and the measured efficacy from the MAH trial supports 2 doses of vaccine especially in the setting of emerging variants. Only a randomized controlled

clinical trial can address whether a vaccine could be as successful with 1 dose as opposed to measured neutralization responses and efficacy of 2 doses.

## 9.2. Overview of Safety Topics and Signals During the Reporting Interval

Safety topics and Signals addressed during the reporting interval are presented below in Table 9.

**Table 9. Overview of Safety Topics and Signals**

Signal/Safety Topic	Status	Category
Asthenia, lethargy, decreased appetite, hyperhidrosis, night sweats	Signal Closed	Identified Risks (Not Important)
Herpes Zoster including Ophthalmic herpes zoster	Signal Closed	No Risk
Seizure	Signal Closed	No Risk
Myocarditis and Pericarditis	Signal Closed	No Risk
Cranial nerve palsy	Safety Topic Closed	No Validated Signal
Hemolytic anemia	Safety Topic Closed	No Validated Signal
Hepatic events	Safety Topic Closed	No Validated Signal
Nephrotic syndrome	Safety Topic Closed	No Validated Signal
Optic neuritis	Safety Topic Closed	No Validated Signal
Trigeminal neuralgia	Safety Topic Closed	No Validated Signal

[Appendix 3](#) provides a summary of the safety topics and signals addressed during the reporting interval and [Appendix 3.1](#) an evaluation of these safety topics and signals.

*As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.3) received on the fourth SMSR, the following cumulative overviews were performed for:*

Polyneuropathy and Neuropathy peripheral ([Appendix 3.2](#));

Herpes Zoster ([Appendix 3.3](#)).

*As per request received from Saudi Arabia HA, the following cumulative overview was performed for:*

Seizure ([Appendix 3.4](#)).



*As per request received from Singapore HA, the following cumulative overview was performed for:*

Optic neuritis ([Appendix 3.5](#)) and Cranial nerve palsy ([Appendix 3.6](#)).

*As per request received from different HAs, the following cumulative overview was performed for:*

Myocarditis and Pericarditis ([Appendix 3.7](#)).

### 9.3. Summary of Safety Concerns

Table 10 summarises the comprehensive list of important risks and missing information reflected in risk management and pharmacovigilance plans globally for BNT162b2 at the beginning of the reporting period. The pharmacovigilance and risk management activities implemented for the safety concerns by Pfizer on behalf of BioNTech are global.

**Table 10. Safety Concerns**

Important Identified Risk	Anaphylaxis <sup>a</sup>
Important Potential Risk	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-Associated Enhanced Respiratory Disease (VAERD) <sup>a</sup>
Missing Information	Use in Pregnancy and While Breast Feeding <sup>a</sup>
	Use in Immunocompromised Patients <sup>b</sup>
	Use in Frail Patients With Co-Morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular disorders, Active tuberculosis) <sup>b,d</sup>
	Use in Patients With Autoimmune or Inflammatory Disorders <sup>b</sup>
	Interaction With Other Vaccines <sup>b</sup>
	Long-Term Safety Data <sup>b</sup>
	Use in Paediatric Individuals <16 Years of Age <sup>c</sup>
	Vaccine Effectiveness <sup>c,e</sup>

a. As per both the EU RMP Version 1.0, dated 21 December 2020 and the US PVP Version 0.3, dated 20 January 2021;

b. As per the EU RMP Version 1.0, dated 21 December 2020;

c. As per the US PVP Version 0.3, dated 20 January 2021; this Missing Information has been reworded to “Use in paediatric individuals <12 years of age” in the US PVP, Version 0.4, submitted on 09 April 2021;

d. As per the South Africa RMP, Version 1.0, dated 24 March 2021, active tuberculosis is included as an additional co-morbidity;

e. As per the South Africa RMP, Version 1.0, dated 24 March 2021, this safety concern is stated as “Vaccine effectiveness against novel variant(s) in South Africa”. For vaccine effectiveness against novel variant(s) in South Africa, in the Lack of Efficacy Section (Section 9.5.3) it will be reviewed whether any reports and/or virological analysis of variant type on any breakthrough infection is reported among the relevant cases.

### 9.4. Summary of Adverse Events of Special Interest (AESIs)

Please refer to [Appendix 5](#) for the list of the company’s AESIs for BNT162b2. Please refer to [Appendix 5.1](#) for the observed versus expected analysis for AESIs.

The company’s AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS

protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list includes MedDRA PTs, HLTs, HLGTS or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

## 9.5. Evaluation of Safety Concerns

Evaluation of new information collected from post-marketing data sources<sup>13</sup> for BNT162b2 during the interval reporting period for important identified and important potential risks, AESIs, special situations and missing information is provided below in Section 9.5.1, Section 9.5.2, Section 9.5.3 and Section 9.5.4.

### 9.5.1. Evaluation of Important Identified and Important Potential Risks

Table 11 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources<sup>13</sup> for the important identified and important potential risks of BNT162b2.

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
<b>Important Identified Risk</b>	
<p>Anaphylaxis<sup>b</sup></p> <p><i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i></p>	<p>Number of cases from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm based on all terms in the SMQ: 1444<sup>36</sup> (4.7% compared to 4.4% of the total PM dataset of the previous SMSR), of which 1079 were medically confirmed and 365 were non-medically confirmed.</p> <ul style="list-style-type: none"> <li>• Number of events: 3017;</li> <li>• Country of incidence (&gt;2%): Japan (554), US (249), UK (174), Mexico (68), Germany (47), Australia (44), Italy (37) and France (31);</li> <li>• Subjects' gender: female (1195), male (204) and unknown (45);</li> <li>• Subjects' age (n = 1277): ranged from 1 year (1 subject) to 104 years (mean = 48.1 years, median = 46 years);</li> <li>• Most frequently reported individual PTs (≥2%): Anaphylactic reaction (758), Dyspnoea (323), Pruritus (187), Rash (162), Cough (155), Erythema (141), Urticaria (87), Swelling face (77), Chest discomfort (73), Throat tightness (71), Anaphylactic shock and Swollen tongue (61 each), Hypotension (56), Circulatory collapse (54), Lip swelling (48), Pharyngeal swelling and Swelling (46 each), Respiratory distress (43), Flushing and Wheezing (41 each), Blood pressure decreased (33) and Oedema (32).</li> </ul>

<sup>36</sup> One (1) additional case was made invalid after the DLP due to lack of minimum valid criteria to process the case.

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)														
	<ul style="list-style-type: none"> <li>• Relevant event seriousness:<sup>d</sup> serious (2169), non-serious (849);</li> <li>• Relevant event outcome:<sup>e</sup> fatal (61), resolved/resolving (1909), resolved with sequelae (50), not resolved (336), unknown (675).</li> </ul> <p>Cases (1444) were individually reviewed and assessed according to Brighton Collaboration (BC) case definition and level of diagnostic certainty as shown in the Table below.</p> <table border="1" data-bbox="662 573 1412 793"> <thead> <tr> <th>Brighton Collaboration Level</th> <th>Number of cases</th> </tr> </thead> <tbody> <tr> <td>BC 1</td> <td>120</td> </tr> <tr> <td>BC 2</td> <td>218</td> </tr> <tr> <td>BC 3</td> <td>8</td> </tr> <tr> <td>BC 4</td> <td>511</td> </tr> <tr> <td>BC 5</td> <td>587</td> </tr> <tr> <td><i>Total</i></td> <td><i>1444</i></td> </tr> </tbody> </table> <p>Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis, with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.</p> <p><b>BC Level 1 and 2 cases:</b>  <u>Number of cases:</u> 338 (1178 events of interest).  <u>Medical history (n=237):</u> the most frequently (<math>\geq 2\%</math>) reported medical conditions included Asthma (58), Food allergy (41), Drug hypersensitivity (37), Hypersensitivity (28), Seasonal allergy (27), Hypertension (25), Suppressed lactation (12), Anaphylactic reaction and Diabetes mellitus (11 each), Contrast media allergy (9), Suspected COVID-19, Rhinitis allergic and Rubber sensitivity (8 each), COVID-19 and Urticaria (7 each), Allergy to animal, Dermatitis contact and Epilepsy (6 each), Allergy to arthropod sting, Dermatitis atopic and Hysterectomy (5 each).  <u>Number of vaccine doses administered at the time of the event onset:</u> 1 dose in 222 cases, 2 doses in 88 cases and number of doses was not specified in 28 cases.  <u>Time to event onset:</u></p> <ul style="list-style-type: none"> <li>• Within 15 minutes: 119 cases</li> <li>• 20 to 30 minutes: 49 cases</li> <li>• 30 minutes to 2 hours: 43 cases</li> <li>• 3 to 12 hours: 31 cases</li> <li>• Same day (timing unspecified): 91 cases</li> <li>• Not specified (5 cases)</li> </ul> <p><u>Relevant PTs (&gt;2%):</u> Dyspnoea (154), Anaphylactic reaction (103), Erythema (99), Rash (90), Cough (83), Pruritus (81), Urticaria (53), Throat tightness (42), Swollen tongue (38), Wheezing (36), Swelling face (34), Respiratory distress (31), Pharyngeal swelling (24), Chest discomfort (22), Lip swelling (21), Hypotension and Blood pressure decreased (18 each), Oedema (17), Flushing (16), Angioedema (15), Swelling (14), Eye swelling, Anaphylactic shock and Bronchospasm (11 each), Laryngeal oedema and Tongue oedema (10 each), Asthma, Face oedema and Sensation of foreign body (9 each), Eye pruritus, Lip</p>	Brighton Collaboration Level	Number of cases	BC 1	120	BC 2	218	BC 3	8	BC 4	511	BC 5	587	<i>Total</i>	<i>1444</i>
Brighton Collaboration Level	Number of cases														
BC 1	120														
BC 2	218														
BC 3	8														
BC 4	511														
BC 5	587														
<i>Total</i>	<i>1444</i>														

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**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>oedema, Mouth swelling, Ocular hyperaemia, Rash erythematous (7 each).</p> <p><u>Relevant event outcome:</u> ° fatal (10), resolved/resolving (833), resolved with sequelae (18), not resolved (116), unknown (207).</p> <p><u>Fatal cases: 6</u></p> <ol style="list-style-type: none"> <li>1. <u>Country:</u> Netherlands.                      The case involved an elderly male patient (77 years). Medical history included: Cataract, Diabetes mellitus, Diabetic neuropathy, Diabetic retinopathy, Gout, Hypercholesterolaemia, Hypertension, Large intestine polyp, Liver function test abnormal, Myelodysplastic syndrome, Osteoarthritis and Renal failure. Twenty (20) minutes after the first dose administration (Lot Number: EW9127) the following events were reported: Depressed level of consciousness, Malaise, Anaphylactic reaction, Stridor, Blood pressure decreased, Pharyngeal swelling, Cold sweat, Myocardial infarction. He was transferred to the ER and died on the same day, despite treatment with epinephrine. All the reported events had a fatal outcome. An autopsy was performed, and the results were not available at the time of the report.</li> <li>2. <u>Country:</u> Italy.                      The case involved an elderly male patient (86 years) with Burkitt's lymphoma who experienced Loss of consciousness, Tremor and Dyspnoea a few hours after receiving the 2<sup>nd</sup> vaccine dose (Lot number: ET3620). He was admitted to the medical ward and Hypotension and Oxygen saturation were also noted. The patient died at the hospital the following day. The outcome for all the reported events was reported as 'fatal'. There was no information on the treatments received. It was unknown if an autopsy was performed. The quality investigations on the impacted lot did not reveal any deviations.</li> <li>3. <u>Country:</u> Germany.                      The case involved an elderly male patient (91 years) with Prostate cancer stage I, Conjunctivitis, Diabetes mellitus and Hypertension. On the same day of the 2<sup>nd</sup> vaccination, he complained of Blood pressure decreased, Dizziness and Asthenia. Twenty (20) days later he was diagnosed with leukaemia and 6 days later Laryngeal oedema and Malignant pleural effusion were co-reported. The patient died 10 days later due to Laryngeal oedema, Malignant pleural effusion, and Leukaemia. The case also described a medication error due to iv administration of the vaccine (see <a href="#">Section 7 Medication Errors</a>).</li> <li>4. <u>Country:</u> US.                      The case involved an elderly female patient (69 years) with a medical history of Asthma, Obesity, Lip swelling and Antidepressant therapy. Nine (9) hours after the 2<sup>nd</sup> vaccine dose (Lot number: ER8733), the patient experienced several</li> </ol>

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>symptoms including Pharyngeal swelling, Swollen tongue, Oropharyngeal pain, Lip swelling, Swelling face and Vomiting. The patient took diphenhydramine but there were no improvements and she was transferred to the ER. On the way to the hospital 2 rounds of CPR were performed and they were repeated at the hospital. The patient started to experience seizures and was treated with lorazepam. The following day she was intubated. Four days later she died. The outcome of the event Vomiting was reported as ‘fatal’ and ‘unknown’ for the remaining events.</p> <p>5. <u>Country: Japan</u>                      The case involved an elderly female patient (90 years). Medical history was not provided at the time of the report. The patient received the first dose of the vaccine (Lot Number: ET9096) and 1 hour and 30 minutes later she experienced Anaphylactic reaction, Wheezing, Oxygen saturation decreased, Dyspnoea, Blood pressure decreased. Despite treatment with oxygen and epinephrine, she died 4 days later. The cause of death was reported as ‘Anaphylactic reaction’.</p> <p>6. <u>Country: Mexico</u>                      The case involved a male patient of an unknown age. He received the vaccine (dose number was not specified) and experienced Paraesthesia on the same day and in the subsequent 2 days the following events were reported: Hyperhidrosis, Night sweats, Rash, Toxicity to various agents, Blister, Mouth swelling. On an unspecified date he reported, Drug hypersensitivity, Toxic epidermal necrolysis, Burn oral cavity and Thermal burn. The patient died more than one month later. All the events reported a fatal outcome.</p> <p><b><u>Discussion</u></b>                      Anaphylaxis is an adverse reaction in Section 4.8 of the EU SmPC, in the CDS and local labels/fact sheets. It is also included as an Important identified risk in the EU RMP and in the US PVP. Based upon review of the available information, no additional change to the RSI is warranted at this time.</p> <p>Based on the assessment report for the post-authorisation measure LEG-022.1 for the ‘cumulative review anaphylaxis’ (EMA/PRAC/181346/2021), no amendment of the current labeling is warranted.</p> <p>Conclusion: Evaluation of BC cases Level 1 and 2 as well as 3 and 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</p> <p><b><u>Proposal for Updated Search Strategy Starting from the Next SMSR</u></b></p>

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p><i>Anaphylaxis is an identified risk for the BNT162 vaccine and is described in the product labeling. The MAH proposes to update the search criteria in subsequent reports to more specifically focus on anaphylaxis to ensure that the analysis provides useful information about this topic and recommendations pertaining to it (e.g. observation time post vaccination). Thus, the search will be based on the following PTs: Anaphylactic reaction, Anaphylactic shock, Anaphylactoid reaction, Anaphylactoid shock and same criteria will be applied also to calculate the O/E analysis. Identified cases with a fatal outcome will be scrutinized to understand the clinical details and evolution of the event/s. Note that all retrieved cases will be considered in the analysis of this safety topic (the Brighton Collaboration criteria gauging the reliability of the diagnosis will only be applied to a case if warranted for individual discussion of that case).</i></p>
<p><b>Important Potential Risk</b>                      Vaccine-Associated Enhanced Disease (VAED) Including Vaccine-Associated Enhanced Respiratory Disease (VAERD)<sup>b,c</sup></p>	<p>VAED is a modified and/or severe presentation of an infectious disease affecting individuals exposed to the wild-type pathogen after having received vaccine designed to prevent infection.<sup>37</sup></p> <p>As noted by the Brighton Collaboration, there is currently no uniformly accepted definition of VAED (or VAERD) and the BC working group considers that a definitive case of VAED (Level 1 diagnostic certainty) cannot be ascertained with current knowledge of the mechanisms of pathogenesis of the condition; they have provided guidance on levels of diagnostic certainty of VAED cases based on various laboratory and clinical findings.</p> <p>No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.</p> <p>The search criteria utilised to identify potential cases of VAED for this SMSR includes PTs indicating a lack of effect of the vaccine and medical disorders chosen because they are PTs potentially indicative of severe or atypical COVID-19.</p> <p><b>Overview</b></p> <ul style="list-style-type: none"> <li>Number of cases based on search strategy: 114<sup>f</sup> (0.4% of the total PM dataset, compared to 0.3% in the previous reporting period), all serious (of which 81 are medically confirmed).</li> </ul>

<sup>37</sup> Flor M Munoz, et al. Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data. Brighton Collaboration. September 2020, Vaccine Journal Draft Manuscript.

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Country of incidence: US (28), France (24), Italy (19), UK (16), Germany, Spain (4 each), Czech Republic, Estonia (3 each), Austria, Hungary, Poland, Portugal (2 each); the remaining 5 cases originated from 5 different countries.</li> <li>• Gender: female (57), male (54), unknown (3).</li> <li>• Age: 22 to 103 years (n = 109), mean = 74.1 years, median = 80.0 years.</li> <li>• Respiratory system PTs: COVID-19 pneumonia (35), Dyspnoea (31), Respiratory failure (10), Pulmonary embolism (7), Acute respiratory distress syndrome (4), Hypoxia (3), and Tachypnoea (1).</li> <li>• Gastrointestinal system PTs: Diarrhoea (27), Vomiting (7), and Abdominal pain (3).</li> <li>• Cardiac system PTs: Cardiac failure (5) and Arrhythmia (2).</li> <li>• Renal system PTs: Renal failure (4) and Acute kidney injury (3).</li> <li>• Nervous system PTs: Cerebrovascular accident (3), Altered state of consciousness, and Seizure (1 each).</li> <li>• Other systems, relevant PTs: Multiple organ dysfunction syndrome (3), Deep vein thrombosis, and Shock (1 each).</li> <li>• Case outcome: resolved/resolving (33), resolved with sequelae (1), not resolved (34), unknown (19), and fatal (27).</li> </ul> <p><b><i>COVID-19 positivity and severity of events</i></b></p> <ul style="list-style-type: none"> <li>• Suspected COVID-19 infection: 8 (no information on confirmatory tests performed or test negative or test inconclusive).</li> <li>• Confirmed COVID-19 infection: 106 (test positive or implied COVID infection).</li> <li>• Seriousness criteria for the total 114 cases:                         <ul style="list-style-type: none"> <li>○ Medically significant: 39 (of which 1 serious also for disability)</li> <li>○ Hospitalisation required (non-fatal/non-life threatening): 45</li> <li>○ Life threatening: 3</li> <li>○ Death: 27</li> </ul> </li> </ul> <p><b><i>Seriousness criteria: medically significant (39)</i></b></p> <ul style="list-style-type: none"> <li>• In 33 out of 39 cases where the seriousness criterion was “medically significant”, the subjects had a confirmed COVID-19 infection after vaccination, while 6 subjects had unconfirmed suspected COVID-19 infection. These 39 subjects did not require hospitalisation.</li> <li>• In the 33 confirmed COVID-19 cases, subjects’ age ranged from 32 to 103 years (n = 31), Mean = 63.2 years, Median = 50.0 years.</li> <li>• Among the 33 confirmed COVID-19 cases, latency of COVID occurrence was reported for 29 cases:                         <ul style="list-style-type: none"> <li>○ day 14 to 56 days after dose 1 (6).</li> <li>○ 1 to 91 days after dose 2 (23).</li> </ul> </li> </ul>



**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>The commonly (&gt;3 occurrences) reported events (PTs) in these 33 cases were: COVID-19 (25), Vaccination failure (21), Diarrhoea (17), Dyspnoea (13), Drug ineffective (12), Fatigue (8), Cough, Pyrexia (6 each), Headache, Pain (5 each), Asthenia, Myalgia, SARS-CoV-2 test positive (4 each).</p> <p>The outcome of COVID-19 infection related events (33) reported in these 33 cases were: resolved/resolving (12), not resolved (4), and unknown (17).</p> <p><b>Seriousness criteria: hospitalization (non-fatal, non-life threatening) (45)</b></p> <ul style="list-style-type: none"> <li>• Hospitalisation occurred in 45 subjects, for 2 of them COVID-19 was not confirmed.</li> <li>• In the 43 confirmed COVID-19 cases, subjects' age ranged from 36 to 95 years (n = 41), Mean = 80.0 years, Median = 84.0 years</li> <li>• Among the 43 confirmed COVID-19 cases, latency of COVID occurrence was reported for 37 cases:                         <ul style="list-style-type: none"> <li>○ Day 14 to 53 days after dose 1 (12).</li> <li>○ 1 to 48 days after dose 2 (24).</li> <li>○ 37 days after vaccination [dose number not reported] (1)</li> </ul> </li> </ul> <p>The commonly (&gt;3 occurrences) reported events (PTs) in these 43 cases were: COVID-19 (29), Drug ineffective (25), COVID-19 pneumonia (19), Vaccination failure (18), Dyspnoea (12), Pyrexia (7), Pulmonary embolism (6), Decreased appetite, Fatigue (5 each), Chills, Cough, Diarrhoea, Pneumonia, and SARS-CoV-2 test positive (4 each).</p> <p>The outcome of COVID-19 infection related events (52) reported in these 43 cases were: resolved/resolving (18), resolved with sequelae (1), not resolved (13), and unknown (20).</p> <p><b>Seriousness criteria: life threatening (3)</b></p> <ul style="list-style-type: none"> <li>• Hospitalisation occurred in all the 3 cases characterised as life-threatening; COVID-19 was confirmed in all the 3 subjects.</li> <li>• Subject's age: 77 years (1) and 80 years (2)</li> <li>• Latency of COVID-19 occurrence was reported in 2 of the 3 cases:                         <ul style="list-style-type: none"> <li>○ 11 and 16 days after dose 2 (2)</li> </ul> </li> </ul> <p>The PTs reported in these 3 cases were: COVID-19 pneumonia, Vaccination failure (2 each), Abdominal distension, Acute respiratory distress syndrome, Bacterial sepsis, COVID-19, Drug ineffective, Dyspnoea, Escherichia urinary tract infection, Flatulence, Haemoptysis, Inflammation, and Respiratory failure (1 each).</p>



**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>The outcome of COVID-19 infection related events (3) reported in these 3 cases were: not resolved (2), and unknown (1).</p> <p><b>Seriousness criteria: death (27)</b></p> <ul style="list-style-type: none"> <li>• Twenty-seven (27) subjects died; COVID-19 was confirmed in all the 27 subjects.                             <ul style="list-style-type: none"> <li>○ Age: 50 to 99 years (n = 26), Mean = 81.0 years, Median = 85.0 years.</li> <li>○ Country of incidence: France (9), Italy (4), UK (3), Hungary, Poland (2 each), Austria, Estonia, Germany, Greece, Netherlands, Spain, and US (1 each).</li> <li>○ Gender: female (7), male (20).</li> <li>○ Medical history (n = 20) of clinical significance included PTs in the following SOCs:                                     <ul style="list-style-type: none"> <li>▪ Vascular disorders: 13 (48.1%) [Hypertension (10), Deep vein thrombosis (3), Aortic aneurysm, Arteritis, Peripheral arterial occlusive disease, and Peripheral venous disease (1 each)]</li> <li>▪ Cardiac disorders: 12 (44.4%) [Atrial fibrillation (9), Myocardial ischaemia (5), Cardiac failure (3), Myocardial infarction (2), Cardiac disorder, Cardiomyopathy, Hypertensive heart disease, and Ischaemic cardiomyopathy (1 each)]</li> <li>▪ Respiratory, thoracic and mediastinal disorders: 9 (33.3%) [Chronic obstructive pulmonary disease, Pulmonary embolism (3 each), Bronchopulmonary disease, Dependence on respirator, Pulmonary mass, and Wheezing (1 each)]</li> <li>▪ Metabolism and nutrition disorders: 8 (29.6%) [Obesity, Type 2 diabetes mellitus (3 each), Diabetes mellitus (2), and Malnutrition (1)]</li> <li>▪ Neoplasms benign, malignant and unspecified (incl cysts and polyps): 6 (22.2%) [B-cell lymphoma (2), Anal cancer, Haematological malignancy, Lung cancer metastatic, Malignant melanoma, Metastases to bone, Metastases to the mediastinum, Myelodysplastic syndrome, Prostatic adenoma, Renal cancer, and Renal cancer metastatic (1 each)]</li> <li>▪ Renal and urinary disorders: 6 (22.2%) [Chronic kidney disease (3), Renal failure (2), and End stage renal disease (1)]</li> <li>▪ Nervous system disorders: 3 (11.1%) [Cognitive disorder (2), and Encephalopathy (1)]</li> <li>▪ Infections and infestations: 2 (7.4%) [Cellulitis, Herpes zoster, and <i>Pneumocystis jirovecii</i> pneumonia (1 each)]</li> <li>▪ Congenital, familial and genetic disorders: 1 (3.7%) [Factor V Leiden carrier (1)]</li> <li>▪ Investigations: 1 (3.7%) [Antiphospholipid antibodies positive (1)]</li> <li>▪ Psychiatric disorders: 1 (3.7%) [Alcoholism (1)]</li> </ul> </li> </ul> </li> </ul>

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Latency of COVID-19 occurrence was reported in 22 of the 27 cases:                             <ul style="list-style-type: none"> <li>○ 16 to 31 days after dose 1 (4).</li> <li>○ 3 to 58 days after dose 2 (15).</li> <li>○ 5 to 36 days after vaccination [dose number not reported] (3).</li> </ul> </li> <li>• Cause of death (n = 27) reported more than twice were: COVID-19 (11), COVID-19 pneumonia (10), Drug ineffective (9), Vaccination failure (8), and Respiratory failure (5)</li> </ul> <p>In 11 fatal cases, vaccination failure was reported (cross ref. with <a href="#">Section 9.5.3– Lack of efficacy</a>):</p> <ul style="list-style-type: none"> <li>• 10 of these cases involved subjects with underlying medical history of clinical significance; 9 of which involved elderly subjects (aged 70 to 93 years).</li> <li>• 11<sup>th</sup> case involved a 50-year-old male subject, with epilepsy, haemangioma, and schwannoma, who had a positive SARS-CoV-2 test 25 days after dose 2. It was reported that the subject died due to COVID-19 pneumonia. No further information was available.</li> </ul> <p>VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 106 subjects with confirmed COVID-19 following one or both doses of the vaccine; 73 of the 106 cases were severe, resulting in hospitalisation, life-threatening consequences or death. None of the 106 cases could be definitively considered as having VAED/VAERD.</p> <p>Conclusion: In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.</p>

- a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- b. As per both the EU RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.3, dated 20 January 2021;
- c. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children;
- d. Multiple episodes of the same PT event were reported with a different seriousness within some cases hence the sum of the events seriousness exceeds the total number of PT events.
- e. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;

**Table 11. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing <sup>a</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
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f. Note that 3 additional cases, retrieved with this search strategy, were excluded from the discussion because, upon review, they were determined not to report lack of efficacy as the patients did not develop COVID-19 infection.

**9.5.2. Evaluation of AESIs**

Table 12 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources<sup>13</sup> with regard to the AESIs for BNT162b2. Where applicable, observed versus expected analysis is provided in [Appendix 5.1](#).

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
<b>Anaphylactic Reactions</b> <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i>	Please refer to the Risk ‘Anaphylaxis’ in <a href="#">Table 11</a> .
<b>Cardiovascular AESIs</b> <i>Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia</i>	<ul style="list-style-type: none"> <li>• Number of cases: 874 (2.8 % of the total PM dataset, compared to 3.4% in the previous reporting period), of which 597 are medically confirmed and 277 are non-medically confirmed;</li> <li>• Country of incidence: UK (125); France (119); Mexico (117); US (94); Italy (59); Germany (49); Japan (38); Netherlands (34); Spain (32); Greece (18); Czech Republic and Switzerland (16 each); Sweden (14); Portugal (13); Australia and Belgium (12 each); Austria (11); Croatia (10); Israel (9); Finland and Poland (8 each); Romania and Canada (7 each); Denmark and Singapore (6 each); Norway, Slovakia and Slovenia (4 each); the remaining 22 cases were distributed among 14 other countries;</li> <li>• Subjects’ gender: female (582), male (262) and unknown (30);</li> <li>• Subjects’ age (n = 818): ranged from 17 to 103 years (mean = 57.8 years, median = 56 years);</li> <li>• Subjects’ age group (n = 824): Adult<sup>39</sup> (493), Elderly<sup>40</sup> (330) and Adolescent<sup>41</sup> (1);</li> <li>• Number of relevant events: 902, of which 670 serious, 232 non-serious; when provided (n = 618) in the cases reporting</li> </ul>

<sup>38</sup> For the complete list of the AESIs, please refer to [Appendix 5](#).

<sup>39</sup> Subjects with age ranged between 18 and 64 years.

<sup>40</sup> Subjects with age equal to or above 65 years.

<sup>41</sup> Subjects with age between 12 and 17 years.

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>relevant serious events, subject’s age ranges from 17 to 103 years (mean = 62.3 years, median = 65 years);</p> <ul style="list-style-type: none"> <li>• Reported relevant PTs: Tachycardia (471), Arrhythmia* (130), Myocardial infarction* (120), Cardiac failure* (99), Acute myocardial infarction* (48), Cardiac failure acute* (11), Cardiogenic shock* and Coronary artery disease* (7 each); Postural orthostatic tachycardia syndrome* (5), Stress cardiomyopathy (4);</li> <li>• Relevant event onset latency (n = 691): Range from &lt;24 hours to 109 days, median 1 day;</li> <li>• Relevant event outcome: fatal (93), resolved/resolving (450), resolved with sequelae (19), not resolved (108) and unknown (232);</li> <li>• In 99 out of 874 cases, 20 of which had fatal outcome, the subject’s medical history was significant for the specific events of Cardiac failure (32), Myocardial infarction (28), Arrhythmia (21), Coronary artery disease (12), Acute myocardial infarction and Tachycardia (6 each), Postural orthostatic tachycardia syndrome (3), Cardiac failure acute and Cardiogenic shock (1 each). More than 1 relevant medical history event was reported in 10 cases. These cases involved 49 females, 46 males and 4 subjects of unknown gender. When provided (n = 96), ages ranged from 24 to 98 years, mean was 72.7 years and median was 77.5 years.</li> <li>• Additionally, in 106 out of 874 cases, the subject’s medical history was significant for other cardiac disorders, with the following conditions reported most frequently (≥3 cases): Atrial fibrillation (39); Myocardial ischaemia (18); Cardiac disorder (14); Mitral valve incompetence (5); Angina pectoris and Mitral valve prolapse (4 each); Atrioventricular block, Bundle branch block left, Ventricular extrasystoles, Supraventricular tachycardia, Congestive cardiomyopathy, Hypertensive heart disease, Cardiomyopathy (3 each);</li> <li>• In 55 out of 874 cases, the subjects’ medical history was significant for COVID-19 or suspected COVID-19.</li> </ul> <p>* Observed/Expected analysis was performed for Arrhythmia, Acute myocardial infarction/Myocardial infarction, Cardiac failure/Cardiac failure acute, Cardiogenic shock, Coronary Artery disease, Postural orthostatic tachycardia syndrome, Stress cardiomyopathy (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No cardiovascular signals have emerged from the review of post-authorisation data. The review of cases and O/E analysis do not raise new concerns. Safety surveillance will continue.</p>
<p><b>COVID-19 AESIs</b>  <i>Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 2372 (7.7% of the total PM dataset, compared to 6.3% in the previous reporting period), of which 1103 are medically confirmed and 1269 are non-medically confirmed;</li> <li>• Country of incidence: US (1077); UK (293); France (209); Romania (124); Germany (119); Italy (105); Spain (40); Portugal (36); Poland (34); Israel (31); Mexico (29); Belgium (28); Czech Republic (26); Estonia (25); Austria (21); Hungary (18); Croatia</li> </ul>

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>(14); Canada and Netherlands (12 each); Sweden and Switzerland (10 each); Greece and Japan (9 each); Lebanon (7); the remaining 74 cases were distributed among 28 other different countries;</p> <ul style="list-style-type: none"> <li>• Subjects' gender: female (1317), male (773) and unknown (282);</li> <li>• Subjects' age group (n=1487): Adult<sup>39</sup> (856), Elderly<sup>40</sup> (625), Adolescent<sup>41</sup> (6);</li> <li>• Number of relevant events: 2533, of which 1718 serious, 815 non-serious;</li> <li>• Most frequently reported relevant PTs (&gt;1 occurrence): COVID-19 (1816); Suspected COVID-19 (132); Ageusia* (126); SARS-CoV-2 test positive (111); Asymptomatic COVID-19 (102); Anosmia* (94); COVID-19 pneumonia (48); Exposure to SARS-CoV-2 (44); SARS-CoV-2 antibody test negative (25); SARS-CoV-2 antibody test positive (11); Coronavirus infection (10); SARS-CoV-2 test negative (4); COVID-19 immunisation, SARS-CoV-2 antibody test and SARS-CoV-2 test false positive (3 each);</li> <li>• Relevant event onset latency (n=1504): Range from &lt;24 hours to 112 days, median 11 days;</li> <li>• Relevant event outcome:<sup>42</sup> resolved/resolving (505), not resolved (317), fatal (173), resolved with sequelae (12) and unknown (1529).</li> </ul> <p>* Observed/Expected analysis was performed for Ageusia and Anosmia (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No safety signals have emerged based on the review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p><b>Dermatological AESIs</b>  <i>Search criteria: PT Chillblains;                  Erythema multiforme</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 47 cases (0.2% of the total PM dataset, compared to 0.1% in the previous reporting period), of which 23 are medically confirmed and 24 are non-medically confirmed;</li> <li>• Country of incidence: UK (29), US (5), Italy (4), Netherlands (3), Japan (2); the remaining 4 cases originated from 4 different countries;</li> <li>• Subjects' gender: female (30), male (16) and unknown (1);</li> <li>• Subjects' age group (n=41): Adult<sup>39</sup> (28), Elderly<sup>40</sup> (13);</li> <li>• Number of relevant events: 47 events, 17 serious, 30 non-serious;</li> <li>• Reported relevant PTs: Erythema multiforme* (12) and Chillblains* (35);</li> <li>• Relevant event onset latency (n=30): Range from &lt;24 hours to 36 days, median 4 days;</li> <li>• Relevant event outcome: not resolved (22), resolved/resolving (14) and unknown (11).</li> </ul> <p>* Observed/Expected analysis was performed for Chillblains and Erythema multiforme (see <a href="#">Appendix 5.1</a>).</p>

<sup>42</sup> Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events.

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>Conclusion: No safety signals have emerged based on the review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p><b>Facial Paralysis</b>  <i>Search criteria: PTs Facial paralysis, Facial paresis, Oculofacial paralysis</i></p>	<p>Number of cases: 434<sup>43</sup> (1.4% of the total PM dataset, compared to 1.6% of previous reporting period), of which 234 medically confirmed and 200 non-medically confirmed;                      Country of incidence: US (115), UK (96), France (45), Italy and Germany (17 each), Israel (14), Japan (13), Spain (12), Greece (11), Australia (10), Mexico and Netherlands (9 each), Austria (8), Canada, Romania and Sweden (5 each), Belgium and Czech Republic (4 each), Croatia, Denmark, Hong Kong, Norway, Poland, Singapore and Switzerland (3 each), Finland, Ireland, Malta and Portugal (2 each); the remaining 6 cases originated from 6 different countries;                      Subjects' gender: female (261), male (153), unknown (20);                      Subjects' age group (n=381): Adolescent<sup>41</sup> (2), Adult<sup>39</sup> (257), Elderly<sup>40</sup> (122);                      Number of relevant events:<sup>44</sup> 434, of which 413 serious, 21 non-serious;                      Reported relevant PTs: Facial paralysis* (374), Facial paresis* (58), Oculofacial paralysis (2);                      Relevant event onset latency (n = 328): Range from &lt;24 hours to 83 days, median 5 days;                      Relevant event outcome: resolved/resolving (158), resolved with sequelae (3), not resolved at the time of the report (162) and unknown (111);                      Duration of events till resolution was reported in 33 out of 67 occurrences with outcome of resolved; it ranged from 2 minutes to 82 days, with a median value of 2 days.</p> <p>* Please see <a href="#">Appendix 5.1</a> for Observed versus Expected analysis of Facial paralysis/Facial paresis/Oculofacial paralysis (Bell's palsy).</p> <p>Interval conclusion: No new significant safety information was identified based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p> <p>Overall Conclusion: The MAH has performed previous reviews on facial paralysis and concluded that the data did not support a causal relationship to BNT162b2. An updated review was conducted following availability of further unblinded clinical study safety data from Study C4591001 (data lock date 13 Mar 2021).</p>

<sup>43</sup> Forty-two additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy (BC Category 5) because they reported also other disorders (cerebrovascular accident, cerebral thrombosis or transient ischaemic attack).

<sup>44</sup> If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important.



**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>The clinical study adverse event safety data were reviewed for the blinded placebo-controlled follow-up period and for the open-label observational follow-up period. The blinded placebo-controlled follow-up period analyses were done for the following periods:</p> <ul style="list-style-type: none"> <li>• From vaccine dose 1 to 1 month after dose 2;</li> <li>• From vaccine dose 1 to the unblinding date for each participant;</li> <li>• Blinded placebo-controlled and open-label follow-up periods from dose 1 to 6 months after dose 2 for the original BNT162b2 participants.</li> </ul> <p>The open-label observational follow-up period analyses consisted of:</p> <ul style="list-style-type: none"> <li>• Open-label follow-up period for the original BNT162b2 participants;</li> <li>• Open-label follow-up period for the original placebo participants who then received BNT162b2.</li> </ul> <p>During the blinded placebo-controlled follow-up period in participants <math>\geq 16</math> years of age, there were 6 participants who developed one-sided facial paralysis (Bell’s palsy, including facial paresis):</p> <ul style="list-style-type: none"> <li>• 4 were randomized to BNT162b2 (all male) and</li> <li>• 2 were randomized to placebo (1 male; 1 female).</li> </ul> <p>Of the 4 vaccinated participants, ages ranged from 40 to 70 and the events began from 3 to 48 days after their last dose; they were mild to moderate in severity and duration ranged from 3 to 68 days. The investigator causality assessments of 2 were related and 2 were unrelated. Of the placebo participants, ages were 71 and 73 and severity was moderate; duration was 15 days in one placebo participant and ongoing in the other and the investigator assessments of causality were not related for both.</p> <p>During the open-label observational follow-up period in participants <math>\geq 16</math> years of age, 3 participants who were originally randomized to placebo experienced facial paralysis after being dosed with BNT162b2. All were female and their ages ranged from 19 to 34 years. Events began 3 to 8 days after Dose 3 (first dose of BNT) and were mild to severe in severity. One case had a duration of 12 days while the other 2 were ongoing as of the data cutoff date. All these events of facial paralysis were considered by the investigator as related to study intervention. During the open-label follow-up period for participants originally randomized to BNT162b2, a 51-year-old male developed Bell’s palsy 154 days after receiving Dose 2.</p> <p>Post-authorisation cumulative reports of Facial paralysis and Facial paresis to 23 April 2021 (N=1447), were reviewed. Of the 1447 cases, 571 are not medically confirmed; 923 reports are in women, 461 in men and 63 do not report sex. Not including 2 reports (Health authority reports for a 1 year old and 2 year old that are suspected to be inaccurately reporting age), ages range from 16 to 100 years (mean 54.9, median 53) with the bulk of cases (33%) being between the ages of 31 and 50. Many of the 1447 cases are reported to be Bell’s palsy</p>

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>without provision of information (e.g. neurological exam, HCP assessment) to confirm the diagnosis. Many describe only sensory symptoms and not motor function loss. Further, many (&gt;1 report in 20) reports describe the occurrence of potential TIAs or strokes. Other commonly co-reported conditions include potential viral infections (&gt; 1 in 100, with the majority being herpetic), migraine (&lt;1 in 100) and sensory symptoms suggestive of stress reactions. Of the cases without other events reported, 1 in 10 occur the same day as vaccination, the timing of which make an immunologic cause unlikely.</p> <p>In regard to other signal detection activities, the post-authorization spontaneous data observed vs expected analyses have been &lt; 1, and the actual O/E may be lower because all cases of facial paralysis and facial paresis reported are included regardless of the strength of the certainty of diagnosis. In addition, routine disproportionality analysis has not been elevated.</p> <p>Considering the totality of data on this topic, including the epidemiology of facial paralysis, the data is not conclusive of a causal association between the event and Pfizer/BNT COVID-19 Vaccine. The MAH is hopeful that large epidemiologic surveillance studies that are ongoing will contribute to the assessment of facial paralysis in a meaningful way. Of note, cases of Bell’s palsy are being collected in epidemiology studies that are both primary data collection studies (e.g. C4591008, C4591010) and secondary data collection studies (e.g. C4591009, C4591012, C4591021).</p>
<p><b>Haematological AESIs</b>  <i>Search criteria: Leukopenias NEC (HLT) OR Neutropenias (HLT) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 1431 (4.6% of the total PM dataset, compared to 3.2 % in the previous reporting period), of which 703 medically confirmed and 728 non-medically confirmed;</li> <li>• Country of incidence: UK (472); US (292); France (111); Netherlands (80); Mexico (56); Italy (54); Japan and Spain (50 each); Sweden (48); Germany (37); Czech Republic (21); Austria (19); Norway (15); Israel and Portugal (13 each); Australia (11); Denmark and Greece (10 each); Canada (9); Finland (8); Belgium (7); Poland and Switzerland (6 each); Hungary (5); Croatia (4); Bulgaria, Chile, Costa Rica, Ireland and Romania (3 each); the remaining 9 cases were distributed among 7 other countries;</li> <li>• Subjects’ gender: female (990), male (408) and unknown (33);</li> <li>• Subjects’ age group (n = 1304): Adult<sup>39</sup> (792), Elderly<sup>40</sup> (508), Adolescent<sup>41</sup> (3), Infant<sup>45</sup> (1);</li> <li>• Number of relevant events: 1746, of which 1267 serious, 479 non-serious;</li> <li>• Most frequently reported relevant PTs (≥15 occurrences) include: Contusion (185), Epistaxis (181), Thrombocytopenia* (126), Haemorrhage* (99), Cerebral haemorrhage* (69), Vaccination site bruising (68), Menorrhagia (64), Petechiae (58), Haematoma (48), Immune thrombocytopenia* (43), Haematochezia (41), Eye</li> </ul>

<sup>45</sup> Subjects with age ranged between 1 (28 days) and 23 months.



**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>haemorrhage (39), Vaccination site haematoma and Vaginal haemorrhage (38 each), Haemoptysis (31), Conjunctival haemorrhage (29), Rectal haemorrhage and Vaccination site haemorrhage (27 each), Purpura (22), Blood urine present (21), Haematuria and Internal haemorrhage (20 each), Subarachnoid haemorrhage* (19), Haematemesis (18), Gingival bleeding (17), Gastrointestinal haemorrhage and Haemorrhagic stroke* (16 each), Leukopenia (15);</p> <ul style="list-style-type: none"> <li>• Relevant event onset latency (n = 1225): Range from &lt;24 hours to 91 days, median = 2 days;</li> <li>• Relevant event outcome:<sup>46</sup> fatal (117), resolved/resolving (730), resolved with sequelae (20), not resolved (343) and unknown (547).</li> </ul> <p>* Observed/Expected analysis was performed for Cerebral haemorrhage, Haemorrhage, Haemorrhagic stroke, Immune thrombocytopenia, Thrombocytopenia and Subarachnoid haemorrhage (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No signals for the hematological AESIs have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p><b>Hepatic AESIs</b>  <i>Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 88 cases (0.3% of the total PM dataset, compared to 0.2% of the previous reporting period), of which 58 medically confirmed and 30 non-medically confirmed;</li> <li>• Country of incidence: US (20), UK (18), France (13), Japan (8), Italy and Netherlands (4 each), Canada and Germany (3 each), Australia, Mexico, Singapore and Spain (2 each); the remaining 7 cases originated from 7 different countries;</li> <li>• Subjects' gender: female (47), male (35) and unknown (6);</li> <li>• Subjects' age group (n=78): Adult<sup>39</sup> (48), Elderly<sup>40</sup> (30);</li> <li>• Number of relevant events: 120, of which 67 serious, 53 non-serious;</li> <li>• Most frequently reported relevant PTs (≥2 occurrences): Hepatic enzyme increased (22), Alanine aminotransferase increased (15), Gamma-glutamyltransferase increased and Hepatic function abnormal (11 each), Aspartate aminotransferase increased (9), Liver function test increased (7), Blood alkaline phosphatase increased (6), Blood bilirubin increased, Liver function test abnormal, Liver injury* and Transaminases increased (5 each), Hepatic pain and Hyperbilirubinaemia (4 each), Hepatic enzyme abnormal and Hepatomegaly (3 each) and Blood bilirubin abnormal (2);</li> <li>• Relevant event onset latency (n = 78): Range from &lt;24 hours to 57 days, median 7 days;</li> </ul>

<sup>46</sup> Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events.

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>Relevant event outcome: fatal (2), resolved/resolving (29), resolved with sequelae (2), not resolved (24) and unknown (63).</li> </ul> <p>* Observed/Expected analysis was performed for Liver injury (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: Hepatic events were a safety topic determined not to be a validated signal (see <a href="#">Appendix 3</a> and <a href="#">Appendix 3.1</a>). No other safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p><b>Immune-Mediated/Autoimmune AESIs</b>  <i>Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity</i></p>	<ul style="list-style-type: none"> <li>Number of cases: 1035 (3.4% of the total PM dataset, compared to 2.9% of the previous reporting period), of which 562 medically confirmed and 473 non-medically confirmed;</li> <li>Country of incidence: UK (244), US (212), Israel (95), France (79), Japan (55), Germany (48), Italy (46), Czech Republic (25), Spain (23), Romania (22), Netherlands (19), Mexico (18), Switzerland (16), Belgium (14), Greece (13), Canada and Denmark (12 each), Sweden (11), Austria, Finland and Norway (8 each), Hungary and Singapore (6 each), Australia, Chile, Ireland and New Zealand (5 each), Malta (4), Colombia, Hong Kong and Portugal (2 each); the remaining 5 cases originated from 5 different countries;</li> <li>Subjects' gender: female (683), male (321) and unknown (31).</li> <li>Subjects' age group (n=920): Adult<sup>39</sup> (633), Elderly<sup>40</sup> (273) and Adolescent<sup>41</sup> (14);</li> <li>Number of relevant events: 1072, of which 795 serious, 277 non-serious;</li> <li>Most frequently reported relevant PTs (≥10 occurrences): Hypersensitivity (382), Myocarditis* (83), Pericarditis* (62), Dermatitis (27), Diabetes mellitus (23), Psoriasis (22), Colitis (21), Autoimmune disorder (20), Polymyalgia rheumatica* (19), Colitis ulcerative (18), Raynaud's phenomenon (17), Erythema nodosum and Systemic lupus erythematosus (14 each), Encephalitis* and Psoriatic arthropathy (12 each), Hyperthyroidism (11) and Dermatitis bullous, Hepatitis, Hypothyroidism and VI<sup>th</sup> nerve paralysis (10 each);</li> <li>Relevant event onset latency (n = 660): Range from &lt;24 hours to 81 days, median 2 days;</li> <li>Relevant event outcome:<sup>42</sup> fatal (11), resolved/resolving (428), resolved with sequelae (12), not resolved (230) and unknown (395).</li> </ul> <p>* Please see <a href="#">Appendix 5.1</a> for Observed/Expected analysis performed for Autoimmune thyroiditis, Encephalitis, Myasthenia gravis, Myelitis, Myocarditis, Pericarditis, Polymyalgia rheumatica, Type 1 diabetes mellitus.</p> <p>Conclusion: Myocarditis and Pericarditis were signals evaluated and determined not to be risks (see <a href="#">Appendix 3</a>, <a href="#">Appendix 3.1</a> and <a href="#">Appendix 3.7</a>). No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
<p><b>Musculoskeletal AESIs</b>  <i>Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial;<sup>47</sup> Chronic fatigue syndrome; Polyarthritits; Post viral fatigue syndrome; Rheumatoid arthritis</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 2543 (8.3% of the total PM dataset, compared to 9.9% of the previous reporting period), of which 1067 medically confirmed and 1476 non-medically confirmed;</li> <li>• Country of incidence: UK (1120), US (414), Mexico (163), Netherlands (162), Italy (122), Japan (61), Belgium (59), France (52), Czech Republic (51), Portugal and Spain (49 each), Germany (46), Australia and Slovakia (15 each), Romania (14), Finland and Ireland (12 each), Austria and Norway (11 each), Greece (10), Canada (9), Denmark (8), Bulgaria, Poland, Sweden and Switzerland (7 each), Estonia (6), Hungary, Israel and Luxembourg (5 each), Lithuania (4), Chile, Colombia, Cyprus and Singapore (3 each), Croatia, Hong Kong and Malta (2 each); the remaining 7 cases originated from 7 different countries;</li> <li>• Subjects' gender: female (1936), male (513) and unknown (94);</li> <li>• Subjects' age group (n=2333): Adult<sup>39</sup> (1863), Elderly<sup>40</sup> (466), Adolescent<sup>41</sup> (3) and Child<sup>48</sup> (1);</li> <li>• Number of relevant events: 2594, of which 1142 serious, 1453 non-serious;<sup>49</sup></li> <li>• Reported relevant PTs: Arthralgia (2422), Rheumatoid arthritis* (64), Arthritis (60), Chronic fatigue syndrome* (20), Post viral fatigue syndrome* (17) and Polyarthritits* (11);</li> <li>• Relevant event onset latency (n = 1975): Range from &lt;24 hours to 81 days, median 1 day;</li> <li>• Relevant event outcome:<sup>42</sup> fatal (4), resolved/resolving (1278), resolved with sequelae (30), not resolved (720) and unknown (593).</li> </ul> <p>* Observed/Expected analysis was performed for Rheumatoid arthritis, Polyarthritits, Chronic fatigue syndrome, and Post viral fatigue syndrome (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p><b>Neurological AESIs (including demyelination)</b>  <i>Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 657 (2.1% of the total PM dataset, as in the previous reporting period), of which 370 medically confirmed and 287 non-medically confirmed;</li> <li>• Country of incidence: UK (163), US (147), France (52), Japan (50), Mexico (38), Netherlands (35), Italy and Spain (21 each), Germany (17), Australia and Israel (13 each), Sweden (10), Singapore (9), Austria (8), Canada and Czech Republic (7 each), Greece and Hong Kong (6 each), Portugal (5), Belgium, Finland</li> </ul>

<sup>47</sup> This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria.

<sup>48</sup> Subjects with age between 2 and 11 years.

<sup>49</sup> Multiple episodes of the same PT event were reported with a different seriousness within 1 case hence the sum of the events seriousness exceeds the total number of PT events.

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
<p><i>pressure increased; Meningitis; Meningitis aseptic; Narcolepsy; Neuropathy peripheral; Polyneuropathy</i></p>	<p>and Poland (4 each), Denmark and Romania (3 each) and Luxembourg and Switzerland (2 each); the remaining 7 cases originated from 7 different countries;</p> <ul style="list-style-type: none"> <li>• Subjects' gender: female (429), male (207) and unknown (21);</li> <li>• Subjects' age group (n=603): Adult<sup>39</sup> (419), Adolescent<sup>41</sup> (3), Elderly<sup>40</sup> (180) and Infant<sup>45</sup> (1);</li> <li>• Number of relevant events: 716, of which 672 serious, 44 non-serious;</li> <li>• Most frequently reported relevant PTs (≥5 occurrences) included: Seizure* (228), Neuropathy peripheral* (87), Epilepsy (81), Guillain-Barre syndrome* (51), Generalised tonic-clonic seizure* (29), Febrile convulsion* (21), Status epilepticus (18), Ataxia (16), Fibromyalgia* and Multiple sclerosis relapse* (15 each), Trigeminal neuralgia (14), Multiple sclerosis* (13), Optic neuritis* (11), Petit mal epilepsy (10), Meningitis*, Myelitis transverse* and Polyneuropathy* (9 each), Aura, Demyelination, Intracranial pressure increased and Narcolepsy* (6 each) and Foaming at mouth and Partial seizures (5 each);</li> <li>• Relevant event onset latency (n=509): Range from &lt;24 hours to 71 days, median 1 day;</li> <li>• Relevant events outcome:<sup>42</sup> fatal (16), resolved/resolving (322), resolved with sequelae (27), not resolved (148) and unknown (206);</li> <li>• A relevant medical history was reported in 154 out of 657 cases with the most frequently reported relevant medical history (≥ 2 occurrences) terms coded to: Epilepsy (67), Seizure (23), Multiple sclerosis (19), Fibromyalgia (14), Neuropathy peripheral (13), Generalised tonic-clonic seizure (5), Petit mal epilepsy and Trigeminal neuralgia (4 each), Polyneuropathy and Relapsing-remitting multiple sclerosis (3 each) and Partial seizures, Optic neuritis and Narcolepsy (2 each).</li> </ul> <p>* Observed/Expected analysis was performed for Encephalopathy, Guillain-Barre syndrome, Fibromyalgia, Meningitis, Multiple sclerosis, Myelitis transverse, Narcolepsy, Optic neuritis, Polyneuropathy and Seizure/Seizure disorders (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: Seizure was a signal evaluated and determined not to be a risk (see <a href="#">Appendix 3</a>, <a href="#">Appendix 3.1</a> and <a href="#">Appendix 3.4</a>). Optic neuritis and Polyneuropathy/Neuropathy peripheral were reviewed as safety topics and determined not to be validated signals (see respectively <a href="#">Appendix 3.5</a> and <a href="#">Appendix 3.2</a>). No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p><b>Other AESIs</b>  <i>Search criteria: Herpes viral infections (HLT) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue;</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 4805 (15.6% of the total PM dataset, compared to 20.8% of the previous reporting period), of which 2489 were medically confirmed and 2316 non-medically confirmed;</li> <li>• Country of incidence: UK (1489); US (897); Italy (319); Japan (264); Spain (229); Netherlands (211); Mexico (180); France (172); Belgium (155); Germany (104); Portugal (83); Czech Republic (77); Sweden (49); Romania (48); Australia and Greece</li> </ul>

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
<p><i>Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive</i></p>	<p>(41); Israel (39); Switzerland (37); Poland (35); Austria (33); Norway and Slovakia (24 each); Canada (23); Chile, Denmark and Finland (22 each); Hungary and Ireland (21 each); the remaining 123 cases were distributed among 27 other countries;</p> <ul style="list-style-type: none"> <li>• Subjects' gender: female (3540), male (1086), unknown (179);</li> <li>• Subjects' age group (n = 4383): Adult<sup>39</sup> (3451), Elderly<sup>40</sup> (914), Adolescent<sup>41</sup> (13), Infant<sup>45</sup> (4), Child<sup>48</sup> (1);</li> <li>• Number of relevant events: 4893, of which 1870 serious, 3027 non-serious;<sup>46</sup></li> <li>• Most frequently reported relevant PTs (≥5 occurrences) included: Pyrexia (4313), Herpes zoster* (263), Inflammation (144), Oral herpes (57), Ophthalmic herpes zoster* (18), Product supply issue (12), Herpes simplex, Herpes virus infection and Multiple organ dysfunction syndrome* (10 each), Genital herpes (8), Herpes ophthalmic and Herpes zoster oticus* (7 each), Varicella (5);</li> <li>• Relevant event onset latency (n = 3842): Range from &lt;24 hours to 369 days, median 1 day;</li> <li>• Relevant events outcome:<sup>42</sup> resolved/resolving (2991), not resolved (764), resolved with sequelae (55), fatal (49), and unknown (1072).</li> </ul> <p>* Among multiple different events grouped under this Other AESIs category, Observed/Expected analysis was performed on specific PTs relevant for Herpes zoster disorders and Multiple organ dysfunction syndrome (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: Herpes Zoster, including Ophthalmic herpes zoster, was a signal evaluated and determined not to be a risk (see <a href="#">Appendix 3</a>, <a href="#">Appendix 3.1</a> and <a href="#">Appendix 3.3</a>). No other safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p>
<p><b>Pregnancy Related AESIs</b>  <i>Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia</i></p>	<p>For relevant cases, please refer to the subsection <i>Use in Pregnancy and While Breast Feeding</i> in <a href="#">Table 14</a>.</p>
<p><b>Renal AESIs</b>  <i>Search criteria: PTs Acute kidney injury; Renal failure.</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 68 cases (0.2% of the total PM dataset, as in the previous reporting period), of which 53 medically confirmed and 15 non-medically confirmed;</li> <li>• Country of incidence: France (14), UK (13), US (6), Spain (4), Germany, Italy, Norway and Sweden (3 each), Denmark, Netherlands, Poland, Portugal and Switzerland (2 each); the remaining 9 cases originated from 9 different countries;</li> <li>• Subjects' gender: female and male (33 each) and unknown (2);</li> <li>• Subjects' age group (n=61): Adult<sup>39</sup> (13), Elderly<sup>40</sup> (48);</li> </ul>



**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Number of relevant events: 69, all serious;</li> <li>• Reported relevant PTs: Acute kidney injury* (38) and Renal failure* (31);</li> <li>• Relevant event onset latency (n=36): Range from &lt;24 hours to 51 days, median 8 days;</li> <li>• Relevant event outcome: fatal (17), resolved/resolving (19), resolved with sequelae (1), not resolved (6) and unknown (26).</li> </ul> <p>* Observed/Expected analysis performed for Acute kidney injury and Renal failure (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Surveillance will continue.</p>
<p><b>Respiratory AESIs</b>  <i>Search criteria: Lower respiratory tract infections NEC (HLT) OR Respiratory failures (excl neonatal) (HLT) OR Viral lower respiratory tract infections (HLT) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 375 cases (1.2% of the total PM dataset compared to 1.3% of the previous reporting period), of which 232 medically confirmed.</li> <li>• Country of incidence: US (64), UK (50), France (38), Italy (29), Belgium, Netherlands (24 each), Japan (20), Spain (13), Mexico (12), Denmark, Germany (11 each), Australia (8), Norway (7), Hungary, Sweden (6 each), Austria, Czech Republic, Poland (5 each); the remaining 37 cases originated from 18 different countries.</li> <li>• Subjects' gender (n=367): male (161).</li> <li>• Subjects' age group (n=342): Elderly<sup>40</sup> (212), Adult<sup>39</sup> (130).</li> <li>• Number of relevant events: 376 serious events, 23 non-serious events.</li> <li>• Reported relevant PTs: Pneumonia (144), Respiratory disorder (59), Respiratory failure (47), Cardio-respiratory arrest (33), Lower respiratory tract infection (32), Hypoxia (31), Bronchitis (18), Acute respiratory distress syndrome (13), Cardiopulmonary failure (6), Pneumonia viral (5), Pulmonary haemorrhage (4), Severe acute respiratory syndrome (3), Atypical pneumonia, Cardio-respiratory distress, Parainfluenzae viral laryngotracheobronchitis, and Pulmonary sepsis (1 each).</li> <li>• Relevant event onset latency (n=269): range from &lt; 24 hours to 87 days, median 3 days.</li> <li>• Relevant events outcome: fatal (95), resolved/resolving (114), not resolved (64), resolved with sequelae (5) and unknown (121).</li> <li>• Out of these 375 cases, 20 cases (8 fatal, 1 life-threatening, and 11 hospitalisation) in which the PTs Respiratory failure (10), Pneumonia (5), Acute respiratory distress syndrome (4), Hypoxia (3), Respiratory disorder (2), Bronchitis, Cardiopulmonary failure, Cardio-respiratory distress, and Pneumonia viral (1 each) were reported in a context of vaccine lack of efficacy (PTs Drug ineffective or Vaccination failure), were also reviewed among the potential relevant cases for the Risk 'VAED Including VAERD' in <a href="#">Table 11</a>.</li> </ul> <p>* Observed/Expected analysis performed for Acute respiratory distress syndrome (see <a href="#">Appendix 5.1</a>).</p>

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Surveillance will continue.</p>
<p><b>Thromboembolic Events</b>  <i>Search criteria: Embolism and thrombosis (HLGT), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 1152 (3.7% of the total PM dataset, compared to 1.3% of the previous reporting period), which 738 medically confirmed and 414 non-medically confirmed;</li> <li>• Country of incidence: US (228), UK (227), France (145), Germany (88), Netherlands (71), Sweden (65), Italy and Spain (58 each), Denmark (37), Austria (21), Finland and Norway (17 each), Portugal (12), Australia (10), Greece (9), Belgium (8), Czech Republic and Switzerland (7 each), Canada and Israel (6 each), Hungary, Ireland and Japan (5 each), Cyprus, Mexico and Poland (4 each), Estonia, Luxembourg, Romania and Slovenia (3 each); the remaining 16 cases originated from 10 different countries;</li> <li>• Subjects' gender: female (654), male (468) and unknown (30);</li> <li>• Subjects' age group (n=1074): Adult<sup>39</sup> (430), Adolescent<sup>41</sup> (2), Elderly<sup>40</sup> (642);</li> <li>• Number of relevant events: 1362, of which 1310 serious, 52 non-serious;</li> <li>• Most frequently reported relevant PTs (≥5 occurrences) included: Pulmonary embolism* (441), Deep vein thrombosis* (280), Thrombosis (277), Thrombophlebitis (50), Thrombophlebitis superficial (49), Embolism (43), Pulmonary thrombosis (35), Venous thrombosis limb (23), Retinal vein occlusion (19), Venous thrombosis (15), Retinal artery occlusion (14), Portal vein thrombosis (9), Peripheral embolism and Retinal vein thrombosis (8 each), Mesenteric vein thrombosis (7), Disseminated intravascular coagulation, Ophthalmic vein thrombosis and Peripheral artery thrombosis (6 each) and Arterial thrombosis, Blue toe syndrome, Coronary artery thrombosis and Retinal vascular thrombosis (5 each);</li> <li>• Relevant event onset latency (n = 1027): Range from &lt;24 hours to 96 days, median 8 days;</li> <li>• Relevant event outcome:<sup>42</sup> fatal (69), resolved/resolving (576), resolved with sequelae (46), not resolved (368) and unknown (309).</li> </ul> <p>* Observed/Expected analysis performed for Deep vein thrombosis and Pulmonary embolism (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No other safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis performed. Surveillance will continue. The topic of thromboembolism, specifically in association with thrombocytopenia, has emerged as a concern for some COVID-19 vaccines and is being carefully monitored for the Pfizer/BTN COVID-19 vaccine. This current SMSR includes a review of cases that are of potential interest (see <a href="#">Appendix 3.8</a>) and the MAH will continue to present these cases in the SMSR for the time being. The increase in reported thromboembolic events compared to last SMSR may be due to stimulated reporting of events in light of recent</p>

**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
<p><b>Stroke</b>  <i>Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents (Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)</i></p>	<p>widely publicized cases of thromboembolism in conjunction with thrombocytopenia for some COVID-19 vaccines.</p> <ul style="list-style-type: none"> <li>• Number of cases: 674 (2.2% of the total PM dataset, compared to 1.3% of the previous reporting period), of which 401 medically confirmed and 273 non-medically confirmed;</li> <li>• Country of incidence: UK (138), US (95), France (92), Netherlands (52), Italy (46), Germany (41), Spain (29), Sweden (28), Japan (17), Norway (16), Austria (14), Denmark (13), Portugal (12), Czech Republic (11), Finland (9), Belgium and Israel (6 each), Australia, Canada and Mexico (5 each), Croatia and Greece (4 each), Costa Rica, Poland and Romania (3 each) and Ireland, Slovenia and Switzerland (2 each); the remaining 11 cases originated from 11 different countries;</li> <li>• Subjects' gender: female (370), male (292) and unknown (12);</li> <li>• Subjects' age group (n=636): Adolescent<sup>41</sup> (3), Adult<sup>39</sup> (163), Elderly<sup>40</sup> (470);</li> <li>• Number of relevant events: 783, all serious;</li> <li>• Most frequently reported relevant PTs (≥5 occurrences) included:                         <ul style="list-style-type: none"> <li>○ PTs indicative of Ischaemic stroke: Cerebrovascular accident* (308), Ischaemic stroke* (90), Cerebral infarction* (68), Cerebral thrombosis* (31), Cerebral venous sinus thrombosis* (27), Cerebral ischaemia (20), Ischaemic cerebral infarction (19), Embolic stroke (11), Cerebral venous thrombosis (9), Carotid artery occlusion and Cerebral artery thrombosis (7 each), Cerebral artery occlusion (6) and Lacunar stroke (5);</li> <li>○ PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage* (69), Subarachnoid haemorrhage* (19), Haemorrhagic stroke* (16) and Cerebral haematoma* (5);</li> </ul> </li> <li>• Relevant event onset latency (n=604): Range from &lt;24 hours to 87 days, median 5 days;</li> <li>• Relevant event outcome:<sup>42</sup> fatal (118), resolved/resolving (248), resolved with sequelae (63), not resolved (183) and unknown (173).</li> </ul> <p>* Observed/Expected analysis was performed for Ischemic strokes and Hemorrhagic strokes (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Safety surveillance will continue.</p>
<p><b>Vasculitic Events</b>  <i>Search criteria: Vasculitides HLT</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 83 cases (0.3% of the total PM dataset, compared to 0.1% of the previous reporting period), of which 61 medically confirmed and 22 non-medically confirmed;</li> <li>• Country of incidence: UK (21), France and Italy (14 each), Netherlands (6), Germany, Spain and US (5 each), Greece and Japan (2 each); the remaining 9 cases originated from 9 different countries;</li> <li>• Subjects' gender: female (62), male (20) and unknown (1);</li> <li>• Subjects' age group (n=74): Adult<sup>39</sup> (31), Elderly<sup>40</sup> (43);</li> </ul>



**Table 12. AESIs Evaluation for BNT162b2**

AESIs <sup>38</sup> Category	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Number of relevant events: 88, of which 64 serious and 24 non-serious;</li> <li>• Most frequently reported relevant PTs (&gt;1 occurrence) included: Vasculitis* (34), Hypersensitivity vasculitis and Peripheral ischaemia* (14 each), Giant cell arteritis* (11), Vasculitic rash* (3), Behcet's syndrome*, Cutaneous vasculitis* and Henoch-Schonlein purpura (2 each);</li> <li>• Relevant event onset latency (n=64): Range from &lt;24 hours to 48 days, median 5 days;</li> <li>• Relevant event outcome: fatal (2), resolved/resolving (41), resolved with sequelae (1), not resolved (24) and unknown (20).</li> </ul> <p>* Observed/Expected analysis was performed for Vasculitis and Cutaneous vasculitis disorders (see <a href="#">Appendix 5.1</a>).</p> <p>No new significant safety information was identified based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>

**9.5.3. Evaluation of Special Situations**

Table 13 below presents the evaluation of new information received during the current reporting period from post-marketing data sources for BNT162b2 in relation to special situations (Death, Lack of Efficacy and Vaccine Interactions).

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)
Death	<p><b>Overview</b></p> <ul style="list-style-type: none"> <li>• Number of fatal cases: 954<sup>50</sup> (3.1% of the total PM dataset, compared to 3.3% of the total PM cases received in the previous reporting period) of which 709 were medically confirmed and 245 non-medically confirmed;</li> <li>• Country of incidence: the majority were from France (134), Germany (100), Romania (96), US (85), Netherlands (74), UK (60), Italy (58), Sweden (49), Australia (39), Spain (33), Poland (26), and Denmark (22); the remaining 178 cases occurred in 27 other countries;</li> <li>• Subjects' Gender: females (394), males (426), unknown (134);</li> </ul>

<sup>50</sup> During the current reporting interval, there were 3 additional cases reporting subjects' death that were excluded from further analysis in this subsection as the death was mentioned as an incidental information only with none of the reported events presenting a fatal outcome. Another 9 cases were excluded as these cases reported foetal death and are reviewed in [Table 14](#) under *Use in Pregnancy and While Breast Feeding*.

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Subjects' Age: 2<sup>51</sup> to 104 years (n = 777), mean = 80, median = 83;</li> <li>• Paediatric<sup>51</sup> (2), Adults (99), Elderly (686), subjects with unknown age (167);</li> <li>• Causes of death most frequently reported (&gt;2% of total fatal cases): Death (203), COVID-19 (151), Cardiac arrest (66), Sudden death (51), Dyspnoea (44), Cerebral haemorrhage, Drug ineffective (37 each), Pulmonary embolism (36), Cerebrovascular accident (35), Malaise (34), Pyrexia (32), Cardiac failure, Myocardial infarction, Pneumonia (30 each), Cardio-respiratory arrest (25), Vomiting (22), General physical health deterioration, Asthenia, Fatigue, and Respiratory failure (21 each).</li> <li>• PTs most frequently reported (&gt;2% events): Death (209), COVID-19 (173), Dyspnoea (81), Cardiac arrest (73), Malaise (69), Pyrexia (66), and Drug ineffective (61).</li> <li>• Concomitant medications were reported in 350 out of 954 cases and the most frequently present (&gt;2% of total fatal cases) are listed below:                      furosemide (83), acetylsalicylic acid (58), paracetamol (56), pantoprazole (36), apixaban (32), atorvastatin (31), allopurinol, colecalciferol, omeprazole, simvastatin (30 each), bisoprolol fumarate, levothyroxine sodium (29 each), amlodipine, and metformin (24 each).</li> <li>• Lot/Batch Number (#) information by Country was available in 500 cases with no related quality issues identified during investigations of the impacted lot/batch numbers. The list of Lot/Batch #s most frequently reported (&gt;2% of total fatal cases) is presented hereinafter:                         <ul style="list-style-type: none"> <li>○ Lot # ER7812 in 37 cases from Germany (17), Netherlands (9), Ireland, Sweden (4 each), Poland (2), and Spain (1).</li> <li>○ Lot # ET3620 in 35 cases from France (16), Italy (9), Spain (3), Slovenia (2), Austria, Czech Republic, Malta, Portugal, and Sweden (1 each).</li> <li>○ Lot # EJ6789 in 25 cases from France (18), Netherlands (4), Denmark (2), and Germany (1).</li> <li>○ Lot/Batch # EP2166 in 25 cases from Sweden (10), France (6), Italy, Portugal (2 each), Belgium, Greece, Netherlands, Norway, and Spain (1 each).</li> <li>○ Lot # ET7205 in 23 cases from Italy (14), France (4), Austria, Croatia, Czech Republic, Hungary, and Spain (1 each)</li> <li>○ Lot # EP9605 in 22 cases from France (6), Denmark (4), Japan, Netherlands (3 each), Ireland, Switzerland (2), Belgium, and Norway(1 each).</li> <li>○ Lot # EP9598 in 21 cases from France (6), Denmark (4), Germany (3), Italy, Netherlands (2 each), Norway, Poland, Portugal, and Slovenia (1 each).</li> <li>○ Lot # ER2659 in 21 cases from Denmark (5), Germany, Ireland, Poland (3 each), France, Japan, Norway (2 each), and Estonia (1).</li> </ul> </li> </ul>

<sup>51</sup> The 2 cases reporting paediatric deaths were reported to have occurred in children during a COVID vaccine trial, however, were incorrectly attributed as no death was reported from clinical trials enrolling pediatric subjects up to date. These cases will be re-evaluated accordingly. These 2 cases are also included in [Table 14](#) under *Use in Paediatric Individuals <16 Years of Age*.

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>○ Lot # ET1831 in 20 cases from Italy (7), Spain (5), Austria (4), Hungary (3), and France (1).</li> <li>○ Lot # ET3674 in 20 cases from Netherlands (9), Poland (5), Denmark (3), Belgium, Japan, and Norway (1 each).</li> <li>○ Lot # ER9470 in 20 cases from France (9), Italy (7), Portugal (3), and Sweden (1).</li> </ul> <ul style="list-style-type: none"> <li>● Time to onset of fatal events was reported for 651 subjects and ranged from the day of vaccination to 109 days after vaccination:                         <ul style="list-style-type: none"> <li>○ Same day to 3 days after vaccination: 293 cases</li> <li>○ 4-7 days after vaccination: 122 cases</li> <li>○ 8-14 days after vaccination: 95 cases</li> <li>○ 15-30 days after vaccination: 98 cases</li> <li>○ 30+ days after vaccination: 43 cases</li> </ul> </li> <li>● Number of vaccine doses administered at the time of the subjects' death:                         <ul style="list-style-type: none"> <li>○ In 412 cases the death occurred after the administration of the first dose</li> <li>○ In 306 cases the fatal outcome was observed after the administration of the second dose. Of the 306 cases:                                 <ul style="list-style-type: none"> <li>▪ 94 cases (30.7%) reported a latency of same day to 3 days after vaccination.</li> <li>▪ There were 634 fatal events. Of the 634 fatal events, there were 18 fatal anaphylaxis events<sup>52</sup> and 90 cardiovascular/stroke/thrombotic events<sup>53</sup>. The most frequently reported (&gt;2% of total fatal cases) fatal events were coded to PTs Death (67), COVID-19 (45), Drug ineffective, Vaccination failure (26 each), and Cardiac Arrest (24).</li> </ul> </li> <li>○ In the remaining cases (236), it was not specified if the subjects received the first or the second vaccine dose at the time of the fatal events.</li> </ul> </li> <li>● Test for COVID-19 was reported for 175 subjects as follows: in 82 cases subjects tested positive (29 after 1st vaccine dose, 45 after 2nd vaccine dose and in 8 cases there was no information available about the dose they received), 81 cases were negative, 1 case reported prior history of positive COVID-19 test, and in 11 cases test results were unknown.</li> </ul> <p><b>Analysis</b></p> <p>Most of the cases reporting a fatal outcome (61.5%) were in subjects over 75 years of age. This reflects one of the priority groups targeted for vaccination by many regions and countries, including Europe and the US, that is, elderly (with various lower age cut-offs across countries), because of their higher risk of severe disease and mortality if infected with SARS-CoV-2.<sup>15,16</sup></p> <p>Among the total of 954 cases with a fatal outcome, when the medical history was provided (in 687 cases), the majority had multiple concomitant comorbidities. The most frequently reported medical conditions included cardiac and vascular disorders (eg atrial</p>

<sup>52</sup> Search aligned to the important identified risk of anaphylaxis

<sup>53</sup> Search aligned to the cardiovascular, stroke, and thromboembolic events AESIs

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)						
	<p>fibrillation, cardiac failure, cerebrovascular accident, coronary artery disease, dyslipidaemia, hypercholesterolaemia, hypertension, myocardial infarction, and myocardial ischaemia). Other frequently reported significant medical histories included chronic kidney disease, chronic obstructive pulmonary disease, cognitive disorder, dementia/dementia Alzheimer’s type, diabetes mellitus/type 2 diabetes mellitus, obesity, and renal failure. No specific pattern regarding underlying conditions or cause of death have been identified. Further reports will continue to be closely monitored.</p> <p>Please see <a href="#">Appendix 5.1</a> for Observed versus Expected analysis of Death.</p> <p>Conclusion: No new risks were identified following review of the signal of death, particularly in the comorbid elderly population.</p>						
Lack of Efficacy	<p><b>Company conventions for coding cases indicative of lack of efficacy:</b></p> <ul style="list-style-type: none"> <li>• The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine was revised on 12 February 2021, as shown below: PT “Vaccination failure” is coded when ALL of the following criteria are met:                         <ul style="list-style-type: none"> <li>○ The subject has received the appropriate series of two doses based on the labeling.</li> <li>○ At least 7 days have elapsed since the second dose of vaccine has been administered.</li> <li>○ The subject experiences SARS-CoV-2 infection (confirmed laboratory tests).</li> </ul> </li> <li>• PT “Drug ineffective” is coded when either of the following applies:                         <ul style="list-style-type: none"> <li>○ The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., “the vaccine did not work”, “I got COVID-19”.</li> <li>○ It is unknown:                                 <ul style="list-style-type: none"> <li>▪ Whether the subject has received the appropriate series of two doses in correct timing based on the labeling instructions;</li> <li>▪ How many days have passed since the first dose (including unspecified number of days like “a few days”, “some days”, etc.);</li> <li>▪ If 7 days have passed since the second dose of the vaccine administration</li> </ul> </li> <li>○ The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose.</li> </ul> </li> </ul> <p>Note: after the immune system has had sufficient time (14 days) to respond to the vaccine, this is considered a potential lack of efficacy even if the vaccination course is not complete.</p> <p>This is the summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:</p> <table border="1" data-bbox="509 1724 1414 1864"> <thead> <tr> <th data-bbox="509 1724 808 1780">1<sup>st</sup> dose (day 1-13)</th> <th data-bbox="808 1724 1110 1780">From day 14 post 1<sup>st</sup> dose to day 6 post 2<sup>nd</sup> dose</th> <th data-bbox="1110 1724 1414 1780">Day 7 post 2<sup>nd</sup> dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="509 1780 808 1864">Code only the events describing the SARS-CoV-2 infection</td> <td data-bbox="808 1780 1110 1864">Code “Drug ineffective”</td> <td data-bbox="1110 1780 1414 1864">Code “Vaccination failure”</td> </tr> </tbody> </table>	1 <sup>st</sup> dose (day 1-13)	From day 14 post 1 <sup>st</sup> dose to day 6 post 2 <sup>nd</sup> dose	Day 7 post 2 <sup>nd</sup> dose	Code only the events describing the SARS-CoV-2 infection	Code “Drug ineffective”	Code “Vaccination failure”
1 <sup>st</sup> dose (day 1-13)	From day 14 post 1 <sup>st</sup> dose to day 6 post 2 <sup>nd</sup> dose	Day 7 post 2 <sup>nd</sup> dose					
Code only the events describing the SARS-CoV-2 infection	Code “Drug ineffective”	Code “Vaccination failure”					

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)		
	Scenario Not considered LOE	Scenario considered LOE as “Drug ineffective”	Scenario considered LOE as “Vaccination failure”
	<p><b>Lack of efficacy cases</b></p> <ul style="list-style-type: none"> <li>• Number of cases<sup>54</sup>: 1354 (4.4% of the total PM dataset, compared to 3.1% in the previous reporting period) of which 698 were medically confirmed and 656 non-medically confirmed.</li> <li>• Number of lack of efficacy events:<sup>55</sup> 1354 (Drug ineffective [950] and Vaccination failure [404]).</li> <li>• Country of incidence: US (609), France (176), UK (112), Italy (74), Germany (48), Romania (39), Portugal (30), Israel (28), Estonia, Poland (24 each), Austria, Czech Republic, Spain (18 each), Belgium (17), Hungary (15), Croatia (14); the remaining 90 cases originated from 28 different countries.</li> <li>• COVID-19 infection was confirmed in 1307 cases and suspected in 47 cases.</li> <li>• Outcome was reported as resolved/resolving (221), resolved with sequelae (4), not resolved (149), or unknown (904) at the time of the reporting; there were 76 cases where a fatal outcome was reported (see also <i>Death</i> section above in this table).</li> </ul> <p><b>Drug ineffective cases (950)</b></p> <ul style="list-style-type: none"> <li>• Drug ineffective seriousness: all serious (950)<sup>56</sup></li> <li>• Lack of efficacy term was reported:                             <ul style="list-style-type: none"> <li>○ after the first dose in 550 cases</li> <li>○ after the second dose in 274 cases</li> <li>○ in 126 cases it was unknown after which dose the lack of efficacy occurred</li> </ul> </li> <li>• Latency of lack of efficacy term reported after the first dose was known for 237 cases:                             <ul style="list-style-type: none"> <li>○ day 14 to ≤ 30 days: 207 subjects</li> <li>○ ≥ 31 days to ≤ 60 days: 24 subjects</li> <li>○ 71 to 88 days: 3 subjects</li> <li>○ 91 to 112 days: 3 subjects</li> </ul> </li> <li>• Latency of lack of efficacy term reported after the second dose was known for 132 cases:                             <ul style="list-style-type: none"> <li>○ before day 7: 55 subjects</li> </ul> </li> </ul>		

<sup>54</sup> Thirty-three (33) additional cases retrieved in this dataset were excluded from the analysis; upon review, 9 cases cannot be considered true lack of efficacy cases because the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; 16 cases were identified as not to report lack of efficacy, these patients did not develop COVID-19 infection; in 5 cases, the lack of efficacy PT did not refer to BNT162b2 vaccine; 3 cases were invalidated in the safety database after DLP.

<sup>55</sup> LOE PTs recorded in these 1354 cases were Drug ineffective (944), Vaccination failure (411), and Virologic failure (1). Upon review after DLP, the following changes were made: PT recoded from Vaccination failure to Drug ineffective (8), PT recoded from Drug ineffective to Vaccination failure (1), PT Drug ineffective removed in case reporting both Drug ineffective and Vaccination failure (1), and PT Virologic failure removed in case reporting both Drug ineffective and Virologic failure (1).

<sup>56</sup> Includes 1 case where event seriousness captured as non-serious was upgraded to serious after DLP.

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>○ day 7 to ≤ 30 days: 40 subjects</li> <li>○ ≥ 31 days to ≤ 60 days: 31 subjects</li> <li>○ ≥ 61 days to ≤ 91 days: 6 subjects</li> <li>• Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known for 55 cases:                             <ul style="list-style-type: none"> <li>○ before day 7: 6 subjects</li> <li>○ day 7 to ≤ 30 days: 31 subjects</li> <li>○ ≥ 31 days to ≤ 60 days: 16 subjects</li> <li>○ 89 and 94 days: 2 subjects</li> </ul> </li> </ul> <p>According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 950 cases where lack of efficacy was reported after the first dose or the second dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.</p> <p><b><i>Vaccination failure cases (404)</i></b></p> <ul style="list-style-type: none"> <li>• Vaccination failure seriousness: all serious<sup>57</sup></li> <li>• Lack of efficacy term was reported in all cases after the second dose</li> <li>• Latency of lack of efficacy term was known for 357 cases; in the remaining 47 cases, it was implied that lack of efficacy term was reported on or after day 7 post second dose, but specific information of latency was not provided.                             <ul style="list-style-type: none"> <li>○ day 7 to ≤ 30 days: 169 subjects</li> <li>○ ≥ 31 days to ≤ 60 days: 157 subjects</li> <li>○ ≥ 61 days and ≤ 90 days: 29 subjects</li> <li>○ 91 and 96 days: 2 subjects</li> </ul> </li> <li>• COVID-19 (309),<sup>58</sup> Asymptomatic COVID-19 (55), SARS-CoV-2 test positive (29), COVID-19 pneumonia (16), Coronavirus infection (2), and Coronavirus test positive (1) were the reported vaccine preventable infections in these cases.</li> </ul> <p><b><i>South African variant (34 cases)</i></b></p> <ul style="list-style-type: none"> <li>• In 13 of the 1354 cases, COVID-19 infection with South African variant was reported. In another 21 cases, COVID-19 variant was identified as South African or Brazilian variant. Country of incidence: France (33) and Finland (1); Of note, 18 of these were cluster cases reported from 3 reporters (8 cases, 5 cases, and 5 cases from 3 different reporters, respectively)</li> <li>• LOE term: Vaccination failure (30) and Drug ineffective (4)</li> <li>• COVID-19 infection outcome: resolved/resolving (13), not resolved (8), unknown (11), and fatal (2).</li> </ul> <p>Conclusion: No new safety signals have emerged based on a review of these cases.</p>
Vaccine Interactions	<ul style="list-style-type: none"> <li>• Number of cases: 28 (0.09% of the total PM dataset, compared to 0.06% of the previous reporting period) of which, 13 cases were medically confirmed and 15 cases were non-medically confirmed.</li> </ul>

<sup>57</sup> Includes 1 case where event seriousness captured as non-serious was upgraded to serious after DLP.

<sup>58</sup> Includes 1 case where event coding was revised from PT Suspected COVID-19 to COVID-19 after DLP.

**Table 13. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Country of incidence: US (9), UK (5), Norway (3), Canada, France, Germany, Hungary (2 each), Czech Republic, Italy, and Portugal (1 each).</li> <li>• Subject Gender: Female (15) and Male (13);</li> <li>• Subjects' Age: 30 to 91 years; (n=22); mean=62.9; median 64.5;</li> <li>• Relevant reported interaction PTs: Drug interaction (24) and Potentiating drug interaction (4);</li> <li>• Relevant event seriousness: Serious (16) and Non-serious (12);</li> <li>• Relevant event outcome: Resolved/Resolving (8), Not resolved (3), and Unknown (17);</li> <li>• Co-reported events coded to the PTs (&gt;1 event): Fatigue (5), Dizziness, Headache, Malaise (3 each), Blood glucose increased, Condition aggravated, Drug level increased, Epilepsy, Feeling hot, Incorrect route of product administration, Nausea, Pain, SARS-CoV-2 antibody test negative, and Seizure (2 each).</li> <li>• Reported Interacting Agents: clozapine (3), apixaban, sertraline (2 each), acetylsalicylate lysine, atorvastatin, cannabis sativa, chlortalidone, clopidogrel, dulaglutide, fluindione, glatiramer, golimumab, heparin, ketoprofen, mesalamine, metformin, metoprolol succinate, metronidazole, mycophenolate sodium, panax ginseng, pantoprazole, phenoxymethylpenicillin potassium, and prednisone (1 each). In addition, there were potential interactions with medications which were not specified (such as blood thinners (1), oral or injectable steroids (1), and in 2 cases, unknown medication) and 1 case reported potential cross-reactivity with a hepatitis B surface antigen test which resulted in a false positive reading.</li> </ul> <p>Conclusion: There is no indication of a safety signal of interference of immune response of vaccines noted based on a review of these cases.</p>

a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources.

**9.5.4. Evaluation of Missing Information**

Table 14 below summarises the evaluation of new information received during the current reporting period from post-marketing data sources<sup>13</sup> in relation to the Missing information associated with the use of BNT162b2.

**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
Use in Pregnancy and While Breast Feeding <sup>59</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 274<sup>60</sup> (0.9% of the total PM dataset, as in the previous reporting period) of which 122 were medically confirmed and 152 were non-medically confirmed;</li> </ul>

<sup>59</sup> Missing information as per both the EU-RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.3, dated 20 January 2021.

<sup>60</sup> Eight cases were excluded from the analysis because pregnancy was not confirmed, or the case did not involve breast feeding.



**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Country of incidence: UK (110), US (61), Italy (13), Netherlands (11), France (8), Canada, Mexico, Portugal (6 each), Ireland, Israel (5), Greece, Spain (4 each), Germany, Hungary (3 each), Belgium, Chile, Estonia, Iceland, Japan, Peru, Poland Romania (2 each), Australia, Austria, Colombia, Croatia, Denmark, Finland, Hong Kong, Latvia, Malaysia, Qatar, Slovenia, Switzerland, and Turkey (1 each).</li> </ul> <p><u>Pregnancy cases:</u> 198 cases including:</p> <ul style="list-style-type: none"> <li>• 186 mother cases and 12 foetus/baby cases representing 188 unique pregnancies (2 cases [a mother case and a foetus/baby case or 2 mother cases for each dose] were created for 10 pregnancies);</li> <li>• Pregnancy outcomes for the 188 pregnancies were reported as spontaneous abortion<sup>61</sup> (52), spontaneous abortion with intrauterine death (8), spontaneous abortion with neonatal death (6), premature birth (3), intrauterine death (2), spontaneous abortion with congenital anomaly, elective termination, therapeutic abortion, full-term normal birth, premature live birth with neonatal/intrauterine death, premature birth of normal neonate, intrauterine death with still birth, neonatal death (1 each), and no outcome was provided for 115 pregnancies;</li> <li>• 57 cases (all non-serious<sup>62</sup>) reported exposure to vaccine in utero without the occurrence of any clinical event. The exposure PTs coded to the PTs<sup>63</sup> Maternal exposure during pregnancy (37), Exposure during pregnancy (18), Maternal exposure before pregnancy, Maternal exposure timing unspecified, Foetal exposure during pregnancy (1 each). Trimester of exposure was reported in 12 of these cases: 1st trimester (9 cases), 2nd trimester (2 cases), 3rd trimester (1 case);</li> <li>• 129 mother cases, 18 non-serious and 111 serious, reported additional clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (59), Abortion missed (6), Foetal death (5), Abortion (3), Pregnancy with contraceptive device, Premature labour, Stillbirth (2 each), Anembryonic gestation, Foetal hypokinesia, Gestational diabetes, Haemorrhage in pregnancy, Pre-eclampsia, and Pregnancy (1 each). Other clinical events which occurred in 4 or more cases coded to the PTs Headache (13), Fatigue (11), Chills, Pain, Pain in extremity, Vaccination site pain (9 each), Pyrexia (7), Nausea, Vaginal haemorrhage (6 each), Arthralgia, Myalgia (5 each), and Paraesthesia (4). Trimester of exposure was reported in 45 of these cases: 1st trimester (35 cases), 2nd trimester (8 cases), 3rd trimester (2 cases);</li> <li>• 12 serious foetus/baby cases reported the PTs Maternal exposure during pregnancy (7), Premature baby (5), Exposure during pregnancy (3), Abortion spontaneous, Anembryonic gestation, Anencephaly, Congenital multiplex</li> </ul>

<sup>61</sup> Birth type of spontaneous abortion was added to 27 cases after the data-lock point.

<sup>62</sup> Two cases reporting exposure to vaccine in utero without the occurrence of any clinical event were downgraded to non-serious after the data-lock point.

<sup>63</sup> One case reported 2 exposure PTs.



**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>arthrogryposis, Foetal exposure during pregnancy, Foetal growth restriction, Foetal heart rate decreased, Foetal hypokinesia, Foetal malformation, Maternal exposure before pregnancy, Respiratory disorder neonatal, and Small for dates baby (1 each). Trimester of exposure was reported for 4 cases: 1st trimester (3 cases), 3rd trimester (1 case).</p> <p><u>Breast feeding baby cases: 62, of which:</u></p> <ul style="list-style-type: none"> <li>• 40 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical events;</li> <li>• 22 cases, 17 serious and 5 non-serious, reported clinical events that occurred in the infant/child exposed to vaccine via breastfeeding (PTs Exposure via breast milk, Maternal exposure during breast feeding); the events that were reported more than once coded to the PTs Pyrexia, Rash (3 each), Agitation, Asthenia, Crying, Fever neonatal, Infant irritability, Insomnia, and Wheezing (2 each).</li> </ul> <p><u>Breast feeding mother cases: 14, of which</u></p> <ul style="list-style-type: none"> <li>• 10 were serious and 4 were non-serious;</li> <li>• Of the 14 cases that reported clinical events in mothers who were breast feeding, 2 cases reported lactation issues that coded to the PTs Lactation disorder (2) and Suppressed lactation (1);</li> <li>• The other events reported in more than 1 case coded to the PTs Maternal exposure during breast feeding, Off label use (7 each), Product use issue (6), Exposure via breast milk, Nausea, Pain in extremity (4 each), Fatigue, Headache, Pyrexia, Chills, Insomnia, Pain, and Vaccination site pain (2 each).</li> </ul> <p>Conclusion: Whether the frequency of pregnancy outcomes, pregnancy related events, and newborn events is consistent with expectation cannot be evaluated based on the spontaneous reports. The number of pregnant women who have received the COVID-19 vaccine is unknown. Additionally, the COVID-19 vaccine is currently not indicated for use in pregnancy, therefore most pregnant women exposed to the vaccine are assumed to have been exposed early in pregnancy prior to knowledge of the pregnancy. Most such pregnancies will not yet have completed as vaccine has only been available since December 2020. The MAH is conducting study C4591015 to study the safety of vaccine in pregnancy as well as within Post-Authorization Safety studies. There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.</p>
Use in Immunocompromised Patients <sup>64</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 1342 (4.4% of the total PM dataset, as in the previous reporting period) of which 595 were medically confirmed and 747 non-medically confirmed;</li> <li>• Case Seriousness: Serious (1006), Non-Serious (336);</li> <li>• Country of incidence: UK (504), US (325), France (180), Italy (45), Japan (33), Czech Republic (28), Sweden (26), Netherlands (23), Germany (22), Israel (19), Denmark and Spain (18 each), Portugal (11), Canada (10), Austria and Belgium (9 each), Romania and Switzerland (8 each), Greece, Mexico and</li> </ul>

<sup>64</sup> Missing information as per the EU-RMP Version 1.0, dated 21 December 2020.

**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>Norway (5 each), Croatia (4), Hungary, Ireland and Turkey (3 each), Malta, Poland and Slovakia (2 each); the remaining 12 cases originated from 12 different countries;</p> <ul style="list-style-type: none"> <li>• Gender: females (911), males (403) and unknown (28);</li> <li>• Age (n = 1223) ranged from 16 to 102 years, mean = 61.3 years, median = 61 years;</li> <li>• Relevant subjects’ medical histories most frequently reported (≥20 cases) coded to the PTs: Immunodeficiency (241), Breast cancer (176), Neoplasm malignant (98), Chemotherapy (78), Hysterectomy (63), Renal transplant (59), Radiotherapy (56), Prostate cancer (52), Thyroidectomy (51), Neoplasm (49), Breast cancer female (33), Mastectomy and Lung neoplasm malignant (29 each), Chronic lymphocytic leukaemia (28), Lymphoma (26), Splenectomy and Colon cancer (22 each), Breast conserving cancer and Leukaemia (21 each) and Malignant melanoma (20);</li> <li>• Of the 5809 events overall reported, the most frequent (&gt;50 occurrences) coded to the PTs: Headache (258), Fatigue (236), Pyrexia (172), Nausea (136), Pain in extremity (128), Chills (125), Malaise (110), Myalgia (108), Pain (105), Dizziness (95), Dyspnoea (94), Arthralgia (93), Vaccination site pain (85), Lymphadenopathy (82), Asthenia (67), Vomiting (65), Diarrhoea and Pruritus (57 each), COVID-19 and Rash (52 each) and Pulmonary embolism (51);</li> <li>• Case outcome: fatal (61, see <a href="#">Table 13</a>, <i>Death</i>), resolved/resolving (596), resolved with sequelae (31), not resolved (485) and unknown (169).</li> </ul> <p>Conclusion: The most frequently reported events observed in immunocompromised subjects were consistent with those observed in the overall population, except for pulmonary embolism which is consistent with what would be expected given the disease states of this population (e.g. cancers). The reporting proportion of cases with fatal outcome (4.5%), unresolved cases (36.1%) and cases resolved with sequelae (2.3%) in immunocompromised subjects is slightly higher compared to the reporting proportion observed in the overall population (3.1% for fatal outcome, 29.3% for outcome of not resolved, 1.5% for outcome of resolved with sequelae), but this is expected considering that underlying comorbidities are likely to be contributory to delayed events recovery or to subjects’ death.</p> <p>No safety signals have emerged that would be considered specific to this population.</p>
Use in Patients With Autoimmune or Inflammatory Disorders <sup>64</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 1987 (6.5% of the total PM dataset, compared to 6.8% of the previous reporting period) of which 801 were medically confirmed and 1186 non-medically confirmed;</li> <li>• Case Seriousness: Serious (1290), Non-Serious (697);</li> <li>• Country of incidence: UK (782), US (564), France (120), Italy (70), Germany (53), Japan (46), Israel (32), Spain (29), Canada (28), Czech Republic and Denmark (21 each), Netherlands (18), Belgium (17), Austria and Ireland (16 each), Sweden (15), Finland and Romania (14 each), Portugal (13), Greece and Hungary (10 each), Croatia (9), Norway and Poland (8 each), Singapore and Switzerland (7 each), Mexico (6), Chile, Estonia, Luxembourg and Slovakia (4 each), Puerto Rico and Turkey (3 each) and Colombia and United Arab Emirates (2 each); the remaining 7 cases originated from 7 different countries;</li> <li>• Gender: Females (1587), Males (348) and Unknown (52);</li> </ul>

**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Age (n=1855) ranged from 5 months to 99 years, mean = 54.5 years, median=54 years;</li> <li>• Relevant subjects’ medical histories most frequently reported (≥40 cases) coded to the PTs: Hypothyroidism (417), Rheumatoid arthritis (275), Arthritis (174), Autoimmune thyroiditis (124), Colitis ulcerative (101), Crohn’s disease (88), Multiple sclerosis (84), Type 1 diabetes mellitus and Inflammatory bowel disease (79 each), Psoriasis (76), Thyroid disorder (73), Coeliac disease (56), Autoimmune disorder (51), Systemic lupus erythematosus (48), Diabetes mellitus (42) and Hyperthyroidism (40);</li> <li>• Of the 8629 events overall reported, the most frequent (&gt;80 occurrences) coded to the PTs: Headache (441), Fatigue (390), Pain in extremity (244), Pyrexia (243), Nausea (238), Arthralgia (207), Chills (195), Myalgia (180), Pain (176), Dizziness (165), Vaccination site pain (157), Malaise (141), Dyspnoea (116), Lymphadenopathy (109), Asthenia (91), Diarrhoea (89), Paraesthesia (86), Rash (84) and Vomiting (83);</li> <li>• Case outcome: fatal (27, see <a href="#">Table 13</a>, <i>Death</i>), resolved/resolving (894), resolved with sequelae (59), not resolved (774) and unknown (233).</li> </ul> <p>Conclusion: The most frequently reported clinical events observed in subjects with autoimmune or inflammatory disorders were consistent with those observed in the overall population. The reporting proportion of unresolved cases (39%) and cases resolved with sequelae (3.0%) is slightly higher compared to the reporting proportion observed in the overall population (29.3% for outcome of not resolved and 1.5% for outcome of resolved with sequelae). Of note, the reporting proportion of cases with fatal outcome in subjects with autoimmune or inflammatory conditions (1.4%) is below the reporting proportion of cases with fatal outcome in the overall population (3.1%).</p> <p>No safety signals have emerged that would be considered specific to this population.</p>
Use in Frail Patients With Co-morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular Disorders, Active tuberculosis) <sup>65</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 3246 (10.6% of the total PM dataset, compared to 11.0% of the previous reporting period) of which 1869 were medically confirmed and 1377 non-medically confirmed;</li> <li>• Case Seriousness: Serious (2430), Non-Serious (816);</li> <li>• Country of incidence: UK (784), US (709), France (425), Japan (237), Spain (145), Italy (103), Sweden (101), Germany (96), Netherlands (88), Czech Republic (54), Denmark (53), Israel (41), Austria (38), Portugal (32), Finland (31), Canada (29), Belgium, Greece and Switzerland (27 each), Norway (26), Mexico (24), Ireland (22), Singapore (19), Hungary (16), Romania (14), Poland (13), Costa Rica and Estonia (9 each), Croatia (8), Bulgaria, Luxembourg, Slovakia and Slovenia (5 each), Chile, Malta and Puerto Rico (3 each) and Peru (2); the remaining 8 cases originated from 8 different countries;</li> <li>• Gender: Females (2092), Males (1097) and Unknown (57);</li> <li>• Age (n=3108) ranged from 4 to 104 years, mean = 65.1 years, median = 70 years;</li> <li>• Relevant subjects’ medical histories most frequently reported (&gt;150 cases) coded to the PTs: Asthma (2312), Hypertension (965), Diabetes mellitus (633),</li> </ul>

<sup>65</sup> Missing information as per the EU-RMP Version 1.0, dated 21 December 2020; as per the South Africa RMP, Version 1.0, dated 24 March 2021, active tuberculosis is included as an additional co-morbidity.

**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<p>COPD (592), Type 2 diabetes mellitus and Cardiac failure (390 each), Chronic kidney disease (384), Dementia (246), Atrial fibrillation (245), Renal failure (188), Drug hypersensitivity (187), Dementia Alzheimer’s type (184), Pulmonary embolism (176), Cognitive disorder (162), and Parkinson’s disease (154);</p> <ul style="list-style-type: none"> <li>• Of the 13420 events overall reported, the most frequent (≥120 occurrences) coded to the PTs: Headache (471), Fatigue (459), Pyrexia (413), Dyspnoea (288), Pain in extremity (274), Nausea (266), Chills (254), Malaise (224), Dizziness (222), Asthenia (210), Myalgia (205), Arthralgia (184), Vaccination site pain (179), COVID-19 and Pain (176 each), Vomiting (153), Diarrhoea (150), Cough (138), Anaphylactic reaction (136), Pruritus (123) and Pulmonary embolism (120); all these events were consistent with the most frequent events observed in the overall population, except for pulmonary embolism which is consistent with what may be expected in this population given the underlying risk factors for pulmonary embolism;</li> <li>• Case outcome: fatal (347, see <a href="#">Table 13, Death</a>), resolved/resolving (1474), resolved with sequelae (61), not resolved (991) and unknown (373).</li> </ul> <p>Conclusion: The reporting proportion of not resolved cases (30.5%) and cases resolved with sequelae (1.9%) in frail subjects is similar to the reporting proportion observed in the overall population (29.3% for outcome of not resolved, 1.5% for outcome of resolved with sequelae).</p> <p>The reporting proportion of cases reporting fatal outcome (10.7%) in frail subjects is higher than the reporting proportion of cases reporting fatal outcome in the overall population (3.1%). This is expected, considering that most of the cases reporting a fatal outcome (81%) among the frail subjects involved subjects over 75 years of age who, due to their advanced age and underlying comorbidities, are more likely to die than younger individuals. Underlying comorbidities are likely to be contributory to their deaths.</p> <p>No safety signals have emerged that would be considered specific to this population.</p>
Interaction With Other Vaccines <sup>64</sup>	There were no cases reporting an interaction with other vaccines during the reporting interval (please refer to <a href="#">Table 13, Vaccine Interactions</a> ).
Long-Term Safety Data <sup>64</sup>	Not applicable
Use in Paediatric Individuals <16 Years of Age <sup>66</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 22<sup>67</sup> (0.07% of the total PM dataset, compared to 0.06% of the previous reporting period), of which 13 were medically confirmed and 9 were non-medically confirmed, and indicative of administration in paediatric subjects &lt;16 years of age;</li> <li>• Country of incidence: US (11), UK (9), Albania, Austria (1 each);</li> <li>• Cases Seriousness: Serious (3), Non-Serious (19);</li> <li>• Gender: Females (11), Males (9), Unknown (2);</li> </ul>

<sup>66</sup> Missing information as per the US PVP, Version 0.3, dated 20 January 2021.

<sup>67</sup> Upon review, 12 cases were excluded from analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects; other paediatric cases, including a case involving a 1-month-old subject, might be reported with a miscoded pediatric age however, since they reported limited details and no follow-up is possible for clarification, they were conservatively discussed in this section.

**Table 14. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing <sup>13</sup> Cases Evaluation Total Number of Cases in the Reporting Period (N=30752)
	<ul style="list-style-type: none"> <li>• Age (n=20) ranged from 1 month to 15 years, mean = 8.5, median = 9;</li> <li>• Case outcome: resolved/resolving (4), not resolved (5), fatal (2), and unknown (11).</li> <li>• The 2 fatal cases were consumer reports claiming that a 2-year-old and a child of unknown age died following vaccination during a trial with Comirnaty. These cases were incorrectly attributed as no death was reported from clinical trials enrolling paediatric subjects up to date, hence these cases will be accordingly re-evaluated (see <a href="#">Table 13, Death</a>).</li> <li>• In the remaining 20 cases, of the 57 reported events,                         <ul style="list-style-type: none"> <li>○ The most frequent (&gt;1 case) were coded to the PTs Product administered to patient of inappropriate age (10, see <a href="#">Section 7 Medication Errors</a>), Off label use (9), Product use issue (7), Malaise (3) and Myalgia, Pain in extremity and Pruritus (2 each);</li> <li>○ There were 9 unlisted events reported in 4 cases. These events coded to the PTs Increased appetite, Infection, Influenza like illness, Joint swelling, Miliaria, Nasopharyngitis, Oropharyngeal pain, Sneezing, Swelling, (1 each).</li> </ul> </li> </ul> <p>No new significant safety information was identified based on a review of these cases.</p>
Vaccine effectiveness <sup>68</sup>	Relevant cases for vaccine effectiveness during the reporting interval are reviewed in <a href="#">Table 13, Lack of Efficacy</a> .

<sup>68</sup> As per the US PVP Version 0.3, dated 20 January 2021; as per the South Africa RMP, Version 1.0, dated 24 March 2021, this safety concern is stated as “Vaccine effectiveness against novel variant(s) in South Africa”.

## 10. OVERALL BENEFIT-RISK EVALUATION

### 10.1. Benefits

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.

#### Efficacy in participants 16 years of age and older

In the Phase 2/3 portion, approximately 44,000 participants were randomised equally and were to receive 2 doses of COVID-19 mRNA Vaccine or placebo (normal saline) separated by 21 days. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. Participants are planned to be followed for up to 24 months after Dose 2, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. In addition, 134 participants were between the ages of 16 to 17 years of age (66 in the COVID-19 mRNA Vaccine group and 68 in the placebo group) and 1616 participants 75 years of age and older (804 in the COVID-19 mRNA Vaccine group and 812 in the placebo group).

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for in total 2,214 person-years for the COVID-19 mRNA Vaccine and in total 2,222 person-years in the placebo group. There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI)  $\geq$  30 kg/m<sup>2</sup>, chronic pulmonary disease, diabetes mellitus, hypertension).

The vaccine efficacy information is presented in Table 15.

**Table 15. Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population**

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	COVID-19 mRNA Vaccine N <sup>a</sup> = 18,198 Cases n1 <sup>b</sup> Surveillance time <sup>c</sup> (n2 <sup>d</sup> )	Placebo N <sup>a</sup> = 18,325 Cases n1 <sup>b</sup> Surveillance time <sup>c</sup> (n2 <sup>d</sup> )	Vaccine efficacy % (95% CI) <sup>f</sup>
All subjects <sup>e</sup>	8 2,214 (17,411)	162 2,222 (17,511)	95.0 (90.0, 97.9)
16 to 64 years	7 1,706 (13,549)	143 1,710 (13,618)	95.1 (89.6, 98.1)
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)

**Table 15. Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*</b>			
<b>Subgroup</b>	<b>COVID-19 mRNA Vaccine N<sup>a</sup> = 18,198 Cases n1<sup>b</sup> Surveillance time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup> = 18,325 Cases n1<sup>b</sup> Surveillance time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine efficacy % (95% CI)<sup>f</sup></b>
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8)
75 years and older	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 [\*Case definition: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhoea or vomiting.]

\* Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by nucleic acid amplification tests (NAAT) [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- a. N = number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of subjects at risk for the endpoint.
- e. No confirmed cases were identified in participants 12 to 15 years of age.
- f. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time. CI not adjusted for multiplicity.

In the second primary analysis, compared to placebo, efficacy of COVID-19 mRNA Vaccine in participants from first COVID-19 occurrence from 7 days after Dose 2 compared to participants with or without evidence of prior infection with SARS-CoV-2 was 94.6% (95% credible interval of 89.9% to 97.3%) in participants 16 years of age and older.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

Secondary efficacy analyses suggested benefit of the COVID-19 mRNA Vaccine in preventing severe COVID-19. Efficacy against severe COVID-19 (as defined by the study protocol\*) occurring after the first dose was 88.9% (95% CI: 20.1, 99.7) (1 case in COVID-19 mRNA Vaccine group and 9 cases in placebo group), with an estimated vaccine efficacy of 75.0% (95% CI: -152.6, 99.5) (1 case in COVID-19 mRNA Vaccine group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2.



## Efficacy and immunogenicity in adolescents 12 to 15 years of age

Study 2 is a multicenter, placebo-controlled efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the  $\geq 56$ -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with HIV, HCV, or HBV).

In Study 2 an analysis of SARS-CoV-2 neutralizing titers in a randomly selected subset of participants was performed to demonstrate non-inferior immune responses (within 1.5-fold) comparing adolescents 12 to 15 years of age to participants 16 to 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection. The immune response to BNT162b2 in adolescents 12 to 15 years of age (n=190) was non-inferior to the immune response in participants 16 to 25 years of age (n=170), based on results for SARS-CoV-2 neutralizing titers at 1 month after Dose 2. The GMT ratio of the adolescents 12 to 15 years of age group to the participants 16 to 25 years of age group was 1.76, with a 2-sided 95% CI of 1.47 to 2.10, meeting the 1.5-fold non-inferiority criterion (the lower bound of the 2-sided 95% CI for the GMR  $>0.67$ ) which indicates a statistically greater response in the adolescents 12 to 15 years of age than that of participants 16 to 25 years of age.

### **10.2. Risks**

Based on pharmacovigilance monitoring activities, since first authorisation, anaphylaxis has been recognised as an important identified risk. Hypersensitivity reactions (other than Anaphylaxis), Diarrhoea, Pain in extremity (arm) and Vomiting were also assessed as identified risks (not important for the purpose of inclusion in the RMPs and PVP) and added as adverse reactions to the labeling. Vaccine stress-related responses (including Dizziness, Paraesthesia and Tachycardia among other) and Asthenia, Lethargy, Decreased appetite, Hyperhidrosis, Night sweats were evaluated to be identified risks (not important for the purpose of inclusion in the in the RMPs and PVP) and they will be added to the RSI.

Based on all available safety and efficacy data for BNT162b2 the benefit-risk profile of the vaccine remains favourable.

### **10.3. Overall Benefit-Risk**

The identified risks associated with the use of BNT162b2 are mitigated through provision of relevant product information in the RSI to support safe use of the product. Risks have been evaluated in the context of the enumerated benefits of the product. Based on the available safety and efficacy data for BNT162b2, the overall benefit-risk profile of BNT162b2 remains favourable.



## **11. CONCLUSION AND ACTIONS**

Based on all available safety and efficacy data for BNT162b2 the benefit-risk profile of the vaccine remains favourable.

The MAH will continue to review the safety of BNT162b2, including reports of adverse experiences and will revise the product documents if an evaluation of the safety data yields significant new information.

**PREPARED BY PFIZER INC**

**CDS EFFECTIVE DATE: 20-APR-2021**

**Date of Superseded CDS: 02-Mar-2021**

**COVID-19 mRNA Vaccine**

**CORE DATA SHEET**

**VERSION 3**

PFIZER CONFIDENTIAL

1

## 1. NAME OF THE MEDICINAL PRODUCT

COVID-19 mRNA Vaccine (nucleoside modified) and COMIRNATY are called TRADENAME.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1,2</sup>

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see Section 6.6.

One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

For the full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM<sup>2,3</sup>

Concentrate for solution for injection.

The vaccine is a white to off-white frozen solution.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

The following is a representative indication. Locally approved indications may differ.

Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus, in individuals 12 years of age and older.<sup>4,49</sup>

### 4.2. Posology and method of administration

#### Posology

##### *Individuals 12 years of age and older*

TRADENAME is administered intramuscularly after dilution as a series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.<sup>5,49</sup>

There are no data available on the interchangeability of TRADENAME with other COVID-19 vaccines to complete the vaccination series. Individuals who have received 1 dose of

TRADENAME should receive a second dose of TRADENAME to complete the vaccination series.

Individuals may not be protected until at least 7 days after their second dose of the vaccine.<sup>6</sup>

For further information on efficacy, see Section 5.1.

#### *Pediatric population*

The safety and efficacy of TRADENAME in individuals under 12 years of age have not yet been established.

#### *Geriatric population*

Clinical studies of TRADENAME include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.<sup>7</sup> Of the total number of TRADENAME recipients in Study 2 (N=20,033), 17.1% (n=3434) were 65 through 74 years of age and 4.3% (n=860) were 75 years of age and older (see Section 5.1).<sup>8</sup>

#### Method of administration

Administer TRADENAME intramuscularly in the deltoid muscle after dilution.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

After dilution, vials of TRADENAME contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

For instructions on the handling, dilution, and dose preparation of the vaccine before administration, see Section 6.6.

### **4.3. Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

### **4.4. Special warnings and precautions for use**

#### Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

### General recommendations

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of a rare anaphylactic event following the administration of the vaccine.<sup>9</sup>

The administration of TRADENAME should be postponed in individuals suffering from acute severe febrile illness.<sup>9</sup>

Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.<sup>9</sup>

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

As with any vaccine, vaccination with TRADENAME may not protect all vaccine recipients.

#### **4.5. Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

Do not mix TRADENAME with other vaccines/products in the same syringe.

#### **4.6. Fertility, pregnancy and lactation**

##### Pregnancy

There are limited amount of data from the use of TRADENAME in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development (see Section 5.3).<sup>10,11</sup> Administration of TRADENAME in pregnancy should be considered when the potential benefits outweigh any potential risks for the mother and fetus.

##### Lactation

It is unknown whether TRADENAME is excreted in human milk.

##### Fertility

It is unknown whether TRADENAME has an impact on fertility. Animal studies do not indicate direct or indirect harmful effects with respect to female fertility or reproductive toxicity (see Section 5.3).<sup>10,11</sup>

#### 4.7. Effects on ability to drive and use machines

TRADENAME has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under Section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines.

#### 4.8. Undesirable effects

##### Summary of safety profile

The safety of TRADENAME was evaluated in participants 12 years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.<sup>12,49</sup> Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) enrolled approximately 46,000 participants,<sup>41</sup> 12 years of age or older.<sup>12</sup>

##### *Participants 16 years of age and older*

In Study 2, a total of 21,720 participants 16 years of age or older received at least 1 dose of TRADENAME and a total of 21,728 participants 16 years of age or older received placebo.<sup>13</sup>

The most frequent adverse reactions in participants 16 years of age and older (in order from highest to lowest frequencies) were injection site pain (>80%),<sup>14</sup> fatigue (>60%),<sup>13</sup> headache (>50%),<sup>13</sup> myalgia and chills (>30%),<sup>13</sup> arthralgia (>20%),<sup>13</sup> pyrexia<sup>13</sup> and injection site swelling<sup>14</sup> (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A lower frequency of reactogenicity events was associated with greater age.<sup>15</sup>

The safety profile in 545 participants receiving TRADENAME, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.<sup>17,28,31</sup>

##### *Adolescents 12 through 15 years of age*

In an analysis of Study 2, based on data up to the cutoff date of 13 March 2021, 2260 adolescents (1131 TRADENAME; 1129 placebo) were 12 to 15 years of age. Of these, 1308 adolescents (660 TRADENAME and 648 placebo) have been followed for at least 2 months after the second dose of TRADENAME.<sup>41,42</sup> The safety evaluation in Study 2 is ongoing.

The most frequent adverse reactions in adolescents 12 through 15 years of age were injection site pain (>90%), fatigue and headache (>70%), myalgia and chills (>40%), arthralgia and fever (>20%).<sup>43,44,45</sup>

**Table 1. Adverse Drug Reactions<sup>13,14,16</sup>**

System Organ Class	Adverse Drug Reactions
Blood and lymphatic system disorders	Lymphadenopathy
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)

**Table 1. Adverse Drug Reactions<sup>13,14,16</sup>**

<b>System Organ Class</b>	<b>Adverse Drug Reactions</b>
Nervous system disorders	Headache
Gastrointestinal disorders	Nausea
Musculoskeletal and connective tissue disorders	Arthralgia Myalgia
General disorders and administration site conditions	Pyrexia Chills Malaise Fatigue Injection site pain Injection site swelling Injection site redness

Adverse reactions from TRADENAME post-authorization experience

The following events have been identified as adverse reactions during the post-authorization use of TRADENAME.

**Table 2. Adverse Drug Reactions<sup>38</sup>**

<b>System Organ Class</b>	<b>Adverse Drug Reactions</b>
Gastrointestinal disorders	Diarrhea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

#### 4.9. Overdose

Participants who received 58 micrograms of TRADENAME in clinical trials did not report an increase in reactogenicity or adverse events.<sup>18</sup>

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

Pharmacological class, therapeutic class

Vaccines

Refer to the current ATC code index for the appropriate code assignment for the pharmacologic and/or therapeutic class.

### Mechanism of action

The nucleoside-modified messenger RNA in TRADENAME is formulated in lipid nanoparticles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.<sup>19,20</sup>

### Efficacy

Study 2 is a multicenter, placebo-controlled efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the  $\geq 56$ -year stratum.<sup>12</sup> The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19.<sup>12</sup> Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment,<sup>21</sup> were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).<sup>12</sup>

#### *Efficacy in participants 16 years of age and older*

In the Phase 2/3 portion of Study 2, based on data accrued through 14 November 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of COVID-19 mRNA Vaccine or placebo separated by 21 days. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.<sup>12,27</sup>

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.<sup>22</sup> Table 3 presents the specific demographic characteristics in the studied population.

**Table 3. Demographics (Population for the Primary Efficacy Endpoint)<sup>a,22</sup>**

	<b>TRADENAME (N=18,242) n (%)</b>	<b>Placebo (N=18,379) n (%)</b>
<b>Sex</b>		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
<b>Age (years)</b>		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)



**Table 3. Demographics (Population for the Primary Efficacy Endpoint)<sup>a,22</sup>**

	<b>TRADENAME (N=18,242) n (%)</b>	<b>Placebo (N=18,379) n (%)</b>
<b>Age group</b>		
12 to 15 years	46 (0.3)	42 (0.2)
16 to 17 years	66 (0.4)	68 (0.4)
16 to 64 years	14,216 (77.9)	14,299 (77.8)
65 to 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
<b>Race</b>		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other <sup>b</sup>	534 (2.9)	516 (2.8)
<b>Ethnicity</b>		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
<b>Comorbidities<sup>c</sup></b>		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

- a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
- b. Includes multiracial and not reported.
- c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19.
  - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
  - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
  - Obesity (body mass index  $\geq 30$  kg/m<sup>2</sup>)
  - Diabetes (Type 1, Type 2, or gestational)
  - Liver disease
  - Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for at least 2214 person-years for the COVID-19 mRNA Vaccine and at least 2222 person-years in the placebo group.<sup>32</sup>

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 [e.g., asthma, body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>, chronic pulmonary disease, diabetes mellitus, hypertension].<sup>23,24</sup>

The vaccine efficacy information is presented in Table 4.

**Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection<sup>*,34</sup></b>			
<b>Subgroup</b>	<b>TRADENAME N<sup>a</sup>=18,198 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=18,325 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
All participants <sup>e</sup>	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6) <sup>f</sup>
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1) <sup>g</sup>
≥65 years	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9) <sup>g</sup>
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8) <sup>g</sup>
≥75 years	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0) <sup>g</sup>
<b>First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection<sup>28</sup></b>			
<b>Subgroup</b>	<b>TRADENAME N<sup>a</sup>=19,965 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=20,172 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
All participants <sup>e</sup>	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3) <sup>f</sup>
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7) <sup>g</sup>
≥65 years	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9) <sup>g</sup>
65 to 74 years	1 0.424 (3239)	14 0.423 (3255)	92.9 (53.2, 99.8) <sup>g</sup>
≥75 years	0 0.106 (805)	5 0.109 (812)	100.0 (-12.1, 100.0) <sup>g</sup>

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

Abbreviations: NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

**Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection<sup>*,34</sup></b>			
<b>Subgroup</b>	<b>TRADENAME N<sup>a</sup>=18,198 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=18,325 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- a. N = number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.
- e. No confirmed cases were identified in adolescents 12 to 15 years of age.
- f. Credible interval for VE was calculated using a beta-binomial model with a beta (0.700102, 1) prior for  $\theta=r(1-VE)/(1+r(1-VE))$ , where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
- g. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

The subgroup analyses of vaccine efficacy including important demographic characteristics is presented in Table 5.

**Table 5. Subgroup Analyses of Vaccine Efficacy - Participants Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population<sup>33</sup>**

<b>Subgroup</b>	<b>TRADENAME N<sup>a</sup>=18,198 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=18,325 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
<b>Sex</b>			
Female	5 1.090 (8536)	81 1.114 (8749)	93.7 (84.7, 98.0)
Male	3 1.124 (8875)	81 1.108 (8762)	96.4 (88.9, 99.3)
<b>Ethnicity</b>			
Hispanic or Latino	3 0.605 (4764)	53 0.600 (4746)	94.4 (82.7, 98.9)
Not Hispanic or Latino	5 1.596 (12,548)	109 1.608 (12,661)	95.4 (88.9, 98.5)

**Table 5. Subgroup Analyses of Vaccine Efficacy - Participants Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population<sup>33</sup>**

Subgroup	TRADENAME N <sup>a</sup> =18,198	Placebo N <sup>a</sup> =18,325	Vaccine Efficacy % (95% CI)
	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	
Race			
Black or African American	0 0.165 (1502)	7 0.164 (1486)	100.0 (31.2, 100.0)
White	7 1.889 (14,504)	146 1.903 (14,670)	95.2 (89.8, 98.1)
All others <sup>f</sup>	1 0.160 (1405)	9 0.155 (1355)	89.3 (22.6, 99.8)

- a. N = number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.
- e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
- f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

The subgroup analyses of vaccine efficacy by risk status in participants is presented in Table 6.

**Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population<sup>23</sup>**

Efficacy Endpoint Subgroup	TRADENAME N <sup>a</sup> =18,198	Placebo N <sup>a</sup> =18,325	Vaccine Efficacy % (95% CI <sup>e</sup> )
	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	
First COVID-19 occurrence from 7 days after Dose 2			
At risk <sup>f</sup>			
Yes	4 1.025 (8030)	86 1.025 (8029)	95.3 (87.7, 98.8)
No	4 1.189 (9381)	76 1.197 (9482)	94.7 (85.9, 98.6)

**Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population<sup>23</sup>**

Efficacy Endpoint Subgroup	TRADENAME N <sup>a</sup> =18,198	Placebo N <sup>a</sup> =18,325	Vaccine Efficacy % (95% CI <sup>e</sup> )
	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	
Age group (years) and at risk			
16 to 64 and not at risk	4 0.962 (7671)	69 0.964 (7701)	94.2 (84.4, 98.5)
16 to 64 and at risk	3 0.744 (5878)	74 0.746 (5917)	95.9 (87.6, 99.2)
≥65 and not at risk	0 0.227 (1701)	7 0.233 (1771)	100.0 (29.0, 100.0)
≥65 and at risk	1 0.281 (2147)	12 0.279 (2109)	91.7 (44.2, 99.8)
Obese <sup>g</sup>			
Yes	3 0.763 (6000)	67 0.782 (6103)	95.4 (86.0, 99.1)
No	5 1.451 (11,406)	95 1.439 (11,404)	94.8 (87.4, 98.3)
Age group (years) and obese			
16 to 64 and not obese	4 1.107 (8811)	83 1.101 (8825)	95.2 (87.3, 98.7)
16 to 64 and obese	3 0.598 (4734)	60 0.609 (4789)	94.9 (84.4, 99.0)
≥65 and not obese	1 0.343 (2582)	12 0.338 (2567)	91.8 (44.5, 99.8)
≥65 and obese	0 0.165 (1265)	7 0.173 (1313)	100.0 (27.1, 100.0)

Abbreviations: BMI = body mass index; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.

**Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population<sup>23</sup>**

Efficacy Endpoint Subgroup	TRADENAME N <sup>a</sup> =18,198	Placebo N <sup>a</sup> =18,325	Vaccine Efficacy % (95% CI <sup>e</sup> )
	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	Cases n1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	

e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

f. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI  $\geq$ 30 kg/m<sup>2</sup>).

g. Obese is defined as BMI  $\geq$ 30 kg/m<sup>2</sup>.

*Efficacy against severe COVID-19*

Secondary efficacy analyses suggested benefit of the COVID-19 mRNA Vaccine in preventing severe COVID-19.

Efficacy against severe COVID-19 (as defined by the study protocol\*) occurring after the first dose was 88.9% (95% CI: 20.1, 99.7) (1 case in COVID-19 mRNA Vaccine group and 9 cases in placebo group), with an estimated vaccine efficacy of 75.0% (95% CI: -152.6, 99.5) (1 case in COVID-19 mRNA Vaccine group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2.<sup>36</sup>

*\*Severe illness from COVID-19 is defined by the study protocol as confirmed COVID-19 and presence of at least 1 of the following:*

- *Clinical signs at rest indicative of severe systemic illness (respiratory rate  $\geq$ 30 breaths per minute, heart rate  $\geq$ 125 beats per minute, saturation of oxygen  $\leq$ 93% on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen  $<$ 300 mm Hg);*
- *Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];*
- *Evidence of shock (systolic blood pressure  $<$ 90 mm Hg, diastolic blood pressure  $<$ 60 mm Hg, or requiring vasopressors);*
- *Significant acute renal, hepatic, or neurologic dysfunction;*
- *Admission to an Intensive Care Unit;*
- *Death.*

Efficacy against severe COVID-19 which is defined (by the Centers for Disease Control and Prevention) as hospitalization, admission to the Intensive Care Unit, intubation or mechanical ventilation, or death occurring after the first dose was 92.9% (95% CI: 53.2, 99.8) (1 case in COVID-19 mRNA Vaccine group and 14 cases in placebo group).<sup>37</sup>

*Efficacy and immunogenicity in adolescents 12 to 15 years of age*

An analysis of Study 2 has been performed in adolescents 12 to 15 years of age up to a data cutoff date of 13 March 2021.

The vaccine efficacy information in adolescents 12 to 15 years of age is presented in Table 7.

**Table 7. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 to 15 Years of Age Evaluable Efficacy (7 Days) Population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age without evidence of prior SARS-CoV-2 infection<sup>*,46</sup></b>			
	<b>TRADENAME N<sup>a</sup>=1005 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=978 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI<sup>e</sup>)</b>
Adolescents 12 to 15 Years of Age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)
<b>First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age with or without evidence of prior SARS-CoV-2 infection<sup>47</sup></b>			
	<b>TRADENAME N<sup>a</sup>=1119 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=1110 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI<sup>e</sup>)</b>
Adolescents 12 to 15 Years of Age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = Number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

In Study 2 an analysis of SARS-CoV-2 neutralizing titers in a randomly selected subset of participants was performed to demonstrate non-inferior immune responses (within 1.5-fold) comparing adolescents 12 to 15 years of age to participants 16 to 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection. The immune response to TRADENAME in adolescents 12 to 15 years of age (n=190) was non-inferior to the immune

response in participants 16 to 25 years of age (n=170), based on results for SARS-CoV-2 neutralizing titers at 1 month after Dose 2. The geometric mean titers (GMT) ratio of the adolescents 12 to 15 years of age group to the participants 16 to 25 years of age group was 1.76, with a 2-sided 95% CI of 1.47 to 2.10, meeting the 1.5-fold non-inferiority criterion (the lower bound of the 2-sided 95% CI for the geometric mean ratio [GMR] >0.67) which indicates a statistically greater response in the adolescents 12 to 15 years of age than that of participants 16 to 25 years of age.<sup>48</sup>

## 5.2. Pharmacokinetic properties

Not applicable.

## 5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproduction and developmental toxicity.<sup>10,11</sup>

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients<sup>2,3</sup>

(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC0159)

1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)

Cholesterol

Potassium chloride

Potassium dihydrogen phosphate

Sodium chloride

Disodium hydrogen phosphate dihydrate

Sucrose

Water for injections

### 6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Sections 6.3 and 6.6.

### 6.3. Shelf life

#### Unopened vial

6 months at -90 °C to -60 °C.

Alternatively, unopened vials may be stored and transported at -25 °C to -15 °C for a total of 2 weeks and can be returned to -90 °C to -60 °C.<sup>39</sup>



Once removed from the freezer, the unopened vial can be stored for up to 5 days at 2 °C to 8 °C. Within the 5 days shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.<sup>29</sup> Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C.

**Once thawed, the vaccine should not be re-frozen.**

*Transfers of frozen vials stored at ultra-low temperature (<-60 °C)*

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (<-60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (<-60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

*Transfers of frozen vials stored at -25 °C to -15 °C<sup>40</sup>*

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

Diluted medicinal product

Chemical and physical in-use stability, including during transportation,<sup>30</sup> has been demonstrated for 6 hours at 2 °C to 30 °C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

**6.4. Special precautions for storage<sup>2,25</sup>**

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vials can be handled in room light conditions.

For storage conditions after thawing and dilution of the medicinal product, see Section 6.3.

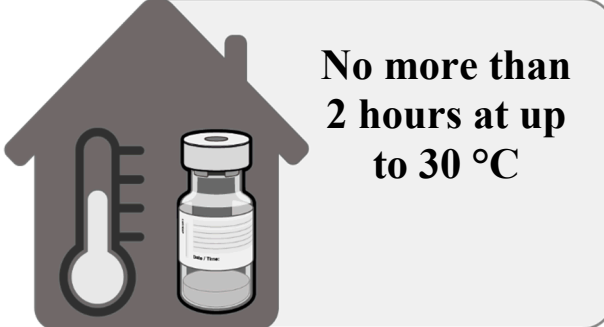
**6.5. Nature and contents of container**

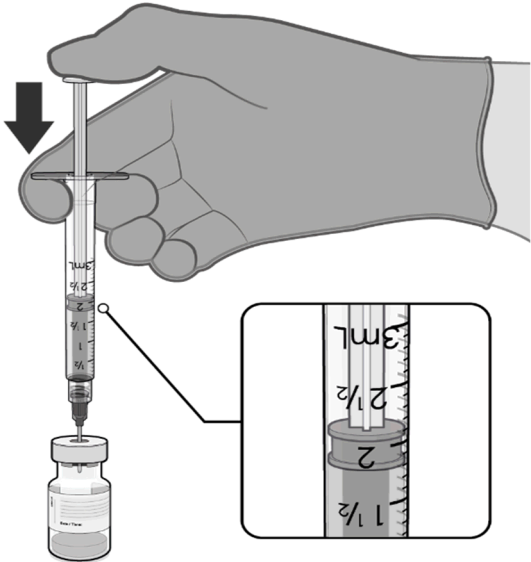
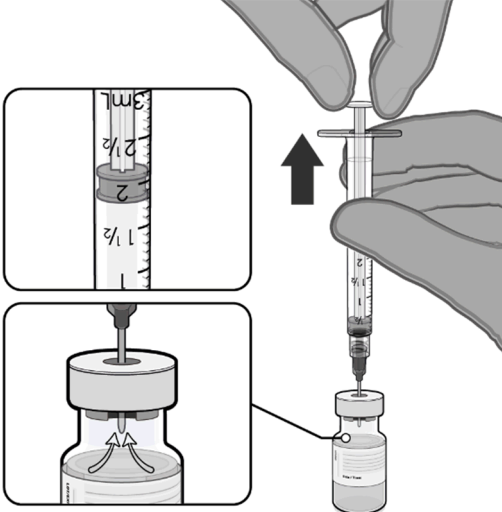
*Information to be provided by local subsidiary.*

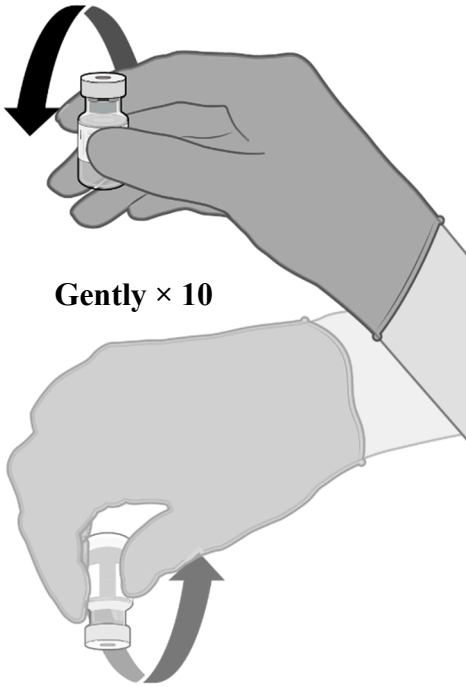

## 6.6. Special precautions for disposal and other handling<sup>2,3,26,29,30,35</sup>

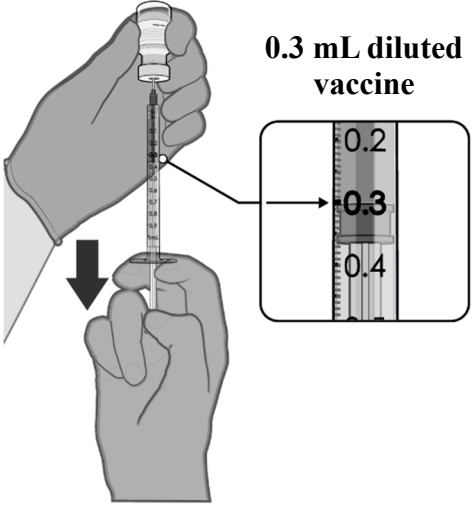
### Handling instructions

TRADENAME should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

THAWING PRIOR TO DILUTION	
 <p><b>No more than 2 hours at up to 30 °C</b></p>	<ul style="list-style-type: none"><li>• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.</li><li>• The unopened vial can be stored for up to 5 days at 2 °C to 8 °C. Within the 5 days shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.</li><li>• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.</li><li>• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</li></ul>

<b>DILUTION</b>	
 <p><b>1.8 mL of 0.9% sodium chloride injection</b></p>	<ul style="list-style-type: none"><li>• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</li></ul>
 <p><b>Pull back plunger to 1.8 mL to remove air from vial.</b></p>	<ul style="list-style-type: none"><li>• Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.</li></ul>

 <p><b>Gently × 10</b></p>	<ul style="list-style-type: none"><li>• Gently invert the diluted dispersion 10 times. Do not shake.</li><li>• The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.</li></ul>
 <p><b>Record appropriate date and time. Use within 6 hours after dilution.</b></p>	<ul style="list-style-type: none"><li>• The diluted vials should be marked with the appropriate date and time.</li><li>• After dilution, store at 2 °C to 30 °C and use within 6 hours, including any transportation time.</li><li>• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</li></ul>

<b>PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY</b>	
 <p><b>0.3 mL diluted vaccine</b></p>	<ul style="list-style-type: none"><li>• After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.</li><li>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.</li><li>• Withdraw 0.3 mL of TRADENAME.</li></ul> <p>Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters.</p> <p>If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</p> <ul style="list-style-type: none"><li>• Each dose must contain 0.3 mL of vaccine.</li><li>• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.</li><li>• Discard any unused vaccine within 6 hours after dilution.</li></ul>

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. REFERENCES

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3. BB-IND19736 Section 3.2.P.1
4. Global Emergency Use Authorization Application, Section 1.3 Intended Use
5. Global Emergency Use Authorization Application, Section 1.2 Description of Product
6. Vaccine Efficacy – First COVID-19 Occurrence  $\geq 7$  Days After Dose 2 – Subjects Without Evidence of Infection Before Vaccination, by Subgroup – Evaluable Efficacy (7 Days) Population
7. Global Emergency Use Authorization Application, Section 7.3.1 Geriatric use
8. Module 5.3.5.1 Table 5: Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
9. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
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11. Module 4.2.3.5 Study 20256434 (RN9391R58) Summary for BNT162b2 DART
12. Global Emergency Use Authorization Application, Section 6.2.1.2
13. Module 5.3.5.1 Study 20256434 (RN9391R58), Table Title: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population
14. Module 5.3.5.1 Study 20256434 (RN9391R58), Table Title: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population
15. Module 2.7.4 Summary of Clinical Safety, Section 2.7.4.5 Overall Conclusions
16. Module 2.5 Clinical Overview, COVID-19 Vaccine, 2021, CO for CDS (anaphylaxis & hypersensitivity)
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18. Module 2.7.4 Summary of Clinical Safety, Section 2.7.4.4.5
19. Global Emergency Use Authorization Application, Section 1.2.2 RNA-Lipid Nanoparticle Formulation
20. Global Emergency Use Authorization, Section 6.2.2.1.1.3 Study BNT162-01 Immunogenicity Conclusions in Phase 1
21. Global Emergency Use Authorization, Section 6.2.1.1 Phase 1 First-in-Human BNT162-01

22. Module 5.3.5.1 Study C4591001, Table Title: Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 Evaluable Efficacy (7 Days) Population
23. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
24. Baseline Charlson Comorbidities – ~38,000 Subjects for Phase 2/3 Analysis – Safety Population
25. BB-IND19736, Section 3.2.P.8
26. BB-IND19736, Section 3.2.P.5.2
27. Global Emergency Use Authorization, Table 5: Demographic Characteristics – Phase 2 – Dose 2 Evaluable Immunogenicity Population
28. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
29. BB-IND19736, Section 3.2.P.3.5
30. BB-IND19736, Section 3.2.P.2.6
31. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status -- ~38000 Subjects for Phase 2/3 Analysis – Safety Population
32. Global Emergency Use Application, Table 35 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
34. Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup - Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy
35. Module 3.2.P Dosage and Administration Instructions for BNT162 (PF-07302048) Vaccine, 0.5 mg/mL
36. Module 5.3.5.1 C4591001 Clinical Study Report, Section 11.1.2.3.2.1.3 Table 40
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39. Module 3.2.P.8.1 Stability Summary and Conclusion
40. IND Section 3.2.P.2.3 Storage Shipping and Distribution

41. Module 2.7.4 Summary of Clinical Safety, MAA Type II Variation (12-15 Years) Table 6: Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population
42. Table: Follow-up Time After Dose 2 – Subjects 12 Through 15 Years of Age – Safety Population
43. Table: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
44. Table: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
45. Table: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
46. Table: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
47. Table: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
48. Table: Summary of Geometric Mean Ratio – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population
49. Module 2.7.4 Summary of Clinical Safety, COVID-19 Vaccine – MAA Type II Variation (12-15 Years) April 2021





**GLOBAL LABELING MANAGEMENT  
CDS Safety Log**

**PRODUCT NAME:** COVID-19 mRNA Vaccine

**CDS Version History:**

CDS version number	GDMS version number & GDMS <a href="#">link</a>	Effective date	Sections changed
3	CDS_COVID 19 mRNA Vaccine <i>Version:</i> 6.0;CURRENT <i>Status:</i> Effective	20-Apr-2021	4.8 Undesirable effects

**1. NAME OF THE MEDICINAL PRODUCT**

No safety changes during the reporting period

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

No safety changes during the reporting period

**3. PHARMACEUTICAL FORM**

No safety changes during the reporting period

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

No safety changes during the reporting period

**4.2 Posology and method of administration**

No safety changes during the reporting period

**4.3 Contraindications**

No safety changes during the reporting period

**4.4 Special warnings and precautions for use**

No safety changes during the reporting period

**4.5 Interaction with other medicinal products and other forms of interaction**

No safety changes during the reporting period

**4.6 Fertility, pregnancy and lactation**

No safety changes during the reporting period

**4.7 Effects on ability to drive and use machines**

No safety changes during the reporting period



**GLOBAL LABELING MANAGEMENT  
CDS Safety Log**

**PRODUCT NAME:** COVID-19 mRNA Vaccine

**4.8 Undesirable effects**

Version 3	Effective Date: 20-Apr-2021	PfLEET: 2021-0068016 2021-0068996		
<p><b><u>Safety/Non-safety:</u></b> Safety</p> <p><b><u>Content change:</u></b></p> <p><u>Summary of safety profile</u></p> <p>The safety of TRADENAME was evaluated in participants <del>16</del><u>12</u> years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.<sup>12,49</sup> Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) enrolled approximately <del>44,000</del><u>46,000</u> participants,<sup>41</sup> 12 years of age or older.<sup>12</sup></p> <p><u>Participants 16 years of age and older</u></p> <p>In Study 2, a total of 21,720 participants 16 years of age or older received at least 1 dose of TRADENAME and a total of 21,728 participants 16 years of age or older received placebo.<sup>13</sup></p> <p>The most frequent adverse reactions in participants 16 years of age and older (in order from highest to lowest frequencies) were <u>injection site pain at the injection site</u> (&gt;80%),<sup>14</sup> fatigue (&gt;60%),<sup>13</sup> headache (&gt;50%),<sup>13</sup> myalgia and chills (&gt;30%),<sup>13</sup> arthralgia (&gt;20%),<sup>13</sup> pyrexia<sup>13</sup> and injection site swelling<sup>14</sup> (&gt;10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A lower frequency of reactogenicity events was associated with greater age.<sup>15</sup></p> <p><u>The safety profile in 545 participants receiving TRADENAME, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.</u><sup>17,28,31</sup></p> <p><u>Adolescents 12 through 15 years of age</u></p> <p><u>In an analysis of Study 2, based on data up to the cutoff date of 13 March 2021, 2260 adolescents (1131 TRADENAME; 1129 placebo) were 12 to 15 years of age. Of these, 1308 adolescents (660 TRADENAME and 648 placebo) have been followed for at least 2 months after the second dose of TRADENAME.</u><sup>41,42</sup> The safety evaluation in Study 2 is ongoing.</p> <p><u>The most frequent adverse reactions in adolescents 12 through 15 years of age were injection site pain (&gt;90%), fatigue and headache (&gt;70%), myalgia and chills (&gt;40%), arthralgia and fever (&gt;20%).</u><sup>43,44,45</sup></p> <p><b>Table 1. Adverse Drug Reactions</b><sup>13,14,16</sup></p> <table border="1" data-bbox="185 1724 1409 1759"> <tr> <td data-bbox="185 1724 656 1759">[...]</td> <td data-bbox="656 1724 1409 1759">[...]</td> </tr> </table> <p><u>The safety profile in 545 participants receiving TRADENAME, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.</u><sup>17,28,31</sup></p> <p><u>Adverse reactions from TRADENAME post-authorization experience</u></p>			[...]	[...]
[...]	[...]			



## GLOBAL LABELING MANAGEMENT CDS Safety Log

PRODUCT NAME: COVID-19 mRNA Vaccine

[...]

### 4.9 Overdose

No safety changes during the reporting period

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

No safety changes during the reporting period

### 5.2 Pharmacokinetic properties

No safety changes during the reporting period

### 5.3 Preclinical safety data

No safety changes during the reporting period

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

No safety changes during the reporting period

### 6.2 Incompatibilities

No safety changes during the reporting period

### 6.3 Shelf life

No safety changes during the reporting period

### 6.4 Special precautions for storage

No safety changes during the reporting period

### 6.5 Nature and contents of container

No safety changes during the reporting period

### 6.6 Special precautions for disposal and other handling

No safety changes during the reporting period

## 7. REFERENCES

All new references can be found in the References section of the affected CDS.



**GLOBAL LABELING MANAGEMENT  
CDS Safety Log**

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**PRODUCT NAME:** COVID-19 mRNA Vaccine

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**Appendix A. Adverse Drug Reactions (ADRs) and Numeric Frequencies Listed in Order of Decreasing Frequency Within Each System Organ Class (SOC)**

No safety changes during the reporting period

Not applicable



**GLOBAL LABELING MANAGEMENT  
CDS Safety Log**

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**PRODUCT NAME:** COVID-19 mRNA Vaccine

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**Appendix B. Adverse Drug Reactions (ADRs) and Council for International Organizations of Medical Sciences (CIOMS) Frequency Categories Listed in Order of Decreasing Medical Seriousness or Clinical Importance Within Each Frequency Category and SOC**

No safety changes during the reporting period

Not applicable

**APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

BNT162B2 - ALL

Reporting Period: 01-APR-2021 Through 29-APR-2021  
Total Number of Cases: 30752 (100%) (ALL) / 30752 (OVERALL)  
Total Number of Adverse Events (PT): 112836 (ALL)

**NON CT**

Total Number of Cases: 30752  
Total Number of Adverse Events (PT): 112836

		Number of Cases	Percentage (%)
<b>Sex</b>			
	FEMALE	21429	69.7 %
	MALE	7571	24.6 %
	NO DATA	1752	5.7 %
<b>Age Range</b>			
Min = 0.0 Years	0 to 27 days	5	0.0 %
Max = 895.0 Years*	28 days to 23 months	31	0.1 %
	2 to 11 years	20	0.1 %
Mean = 53.4	12 to 17 years	102	0.3 %
Median = 52.0	18 - 30 years	3450	11.2 %
Standard Deviation = 20.54	31 - 50 years	8827	28.7 %
n = 25855	51 - 64 years	5794	18.8 %
	65 - 74 years	2805	9.1 %
	Greater than or equal to 75 years	4929	16.0 %
	Unknown	4778	15.5 %
	N/A - age range only applies to post-birth patients	11	0.0 %
<b>Country Where Event Occurred</b>			
	UNITED KINGDOM	9794	31.8 %
	UNITED STATES	7178	23.3 %
	JAPAN	1735	5.6 %
	FRANCE	1634	5.3 %
	ITALY	1340	4.4 %
	NETHERLANDS	1124	3.7 %
	GERMANY	1050	3.4 %
	SPAIN	859	2.8 %
	MEXICO	708	2.3 %
	PORTUGAL	582	1.9 %
	BELGIUM	507	1.6 %
	ROMANIA	373	1.2 %
	SWEDEN	335	1.1 %
	ISRAEL	303	1.0 %
	CZECH REPUBLIC	299	1.0 %
	AUSTRALIA	294	1.0 %
	GREECE	228	0.7 %
	DENMARK	219	0.7 %

\* Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP

		Number of Cases	Percentage (%)
<b>Country Where Event Occured</b>			
	AUSTRIA	212	0.7 %
	CANADA	190	0.6 %
	NORWAY	150	0.5 %
	SWITZERLAND	149	0.5 %
	IRELAND	147	0.5 %
	POLAND	131	0.4 %
	FINLAND	121	0.4 %
	HUNGARY	105	0.3 %
	SLOVAKIA	101	0.3 %
	HONG KONG	96	0.3 %
	SINGAPORE	82	0.3 %
	CROATIA	77	0.3 %
	COSTA RICA	69	0.2 %
	BULGARIA	62	0.2 %
	CHILE	61	0.2 %
	LUXEMBOURG	53	0.2 %
	ESTONIA	49	0.2 %
	SLOVENIA	33	0.1 %
	LEBANON	30	0.1 %
	COLOMBIA	26	0.1 %
	MALTA	24	0.1 %
	LITHUANIA	22	0.1 %
	TURKEY	21	0.1 %
	CYPRUS	20	0.1 %
	SERBIA	19	0.1 %
	UNITED ARAB EMIRATES	16	0.1 %
	ECUADOR	14	0.0 %
	PERU	12	0.0 %
	ICELAND	11	0.0 %
	PANAMA	9	0.0 %
	SAUDI ARABIA	9	0.0 %
	LATVIA	8	0.0 %
	PUERTO RICO	8	0.0 %
	NEW ZEALAND	7	0.0 %
	QATAR	7	0.0 %
	TUNISIA	6	0.0 %
	BERMUDA	4	0.0 %
	MALAYSIA	4	0.0 %
	MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	3	0.0 %
	GEORGIA	2	0.0 %
	INDIA	2	0.0 %
	IRAQ	2	0.0 %
	KUWAIT	2	0.0 %

\* Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP

		Number of Cases	Percentage (%)
<b>Country Where Event Occured</b>			
	ALBANIA	1	0.0 %
	ARGENTINA	1	0.0 %
	BAHRAIN	1	0.0 %
	BOSNIA AND HERZEGOVINA	1	0.0 %
	BRAZIL	1	0.0 %
	EGYPT	1	0.0 %
	FRENCH SOUTHERN TERRITORIES	1	0.0 %
	GUINEA	1	0.0 %
	JORDAN	1	0.0 %
	KOREA, REPUBLIC OF (SOUTH KOREA)	1	0.0 %
	LIECHTENSTEIN	1	0.0 %
	TURKS AND CAICOS ISLANDS	1	0.0 %
	UKRAINE	1	0.0 %
	URUGUAY	1	0.0 %
<b>Source</b>			
	Clinical Study	104	0.3 %
	Literature - Non Study	83	0.3 %
	Literature - Study	10	0.0 %
	Solicited	15	0.0 %
	Spontaneous	30540	99.3 %
<b>Case Seriousness</b>			
	SERIOUS	17480	56.8 %
	NONSERIOUS	13272	43.2 %
<b>HP/Medically Confirmed</b>			
	Yes	15233	49.5 %
	No	15519	50.5 %
<b>Special Populations</b>	<b>Pregnant/Breastfeeding Women</b>		
	Yes	282	0.9 %
	<b>Pediatric Non EIU</b>		
	Yes	126	0.4 %
	<b>Elderly</b>		
	Yes	7734	25.1 %

\* Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP



	Number of Cases	Percentage (%)
<b>Race/Ethnicity</b>		
ASIAN - HISPANIC OR LATINO	2	0.0 %
ASIAN - NO DATA	519	1.7 %
ASIAN - NOT HISPANIC OR LATINO	105	0.3 %
BLACK - HISPANIC OR LATINO	10	0.0 %
BLACK - NO DATA	153	0.5 %
BLACK - NOT HISPANIC OR LATINO	82	0.3 %
BLACK - OTHER	4	0.0 %
CAUCASIAN - HISPANIC OR LATINO	128	0.4 %
CAUCASIAN - NO DATA	1528	5.0 %
CAUCASIAN - NOT HISPANIC OR LATINO	1591	5.2 %
CAUCASIAN - OTHER	19	0.1 %
NATIVE AMERICAN - HISPANIC OR LATINO	5	0.0 %
NATIVE AMERICAN - NO DATA	26	0.1 %
NATIVE AMERICAN - NOT HISPANIC OR LATINO	9	0.0 %
NATIVE AMERICAN - OTHER	1	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO	1	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA	3	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	2	0.0 %
NO DATA - HISPANIC OR LATINO	136	0.4 %
NO DATA - NO DATA	26297	85.5 %
NO DATA - NOT HISPANIC OR LATINO	59	0.2 %
NO DATA - OTHER	72	0.2 %

\* Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP

**APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

BNT162B2 - ALL

Reporting Period: 01-APR-2021 Through 29-APR-2021  
Total Number of Cases: 30752 (100%) (ALL) / 30752 (OVERALL)  
Total Number of Adverse Events (PT): 112836 (ALL)

**NON CT**

Total Number of Cases: 30752  
Total Number of Adverse Events (PT): 112836

Preferred Term	System Organ Class (SOC)	Number of Cases
Headache	Nervous system disorders	6234 (20.27%)
Fatigue	General disorders and administration site conditions	4763 (15.49%)
Pyrexia	General disorders and administration site conditions	4313 (14.03%)
Nausea	Gastrointestinal disorders	3184 (10.35%)
Myalgia	Musculoskeletal and connective tissue disorders	3100 (10.08%)
Chills	General disorders and administration site conditions	3007 (9.78%)
Pain in extremity	Musculoskeletal and connective tissue disorders	2797 (9.10%)
Vaccination site pain	General disorders and administration site conditions	2701 (8.78%)
Arthralgia	Musculoskeletal and connective tissue disorders	2422 (7.88%)
Pain	General disorders and administration site conditions	2263 (7.36%)
Dizziness	Nervous system disorders	2251 (7.32%)
Malaise	General disorders and administration site conditions	2133 (6.94%)
COVID-19	Infections and infestations	1816 (5.91%)
Lymphadenopathy	Blood and lymphatic system disorders	1556 (5.06%)
Asthenia	General disorders and administration site conditions	1496 (4.86%)
Dyspnoea	Respiratory, thoracic and mediastinal disorders	1437 (4.67%)
Diarrhoea	Gastrointestinal disorders	1161 (3.78%)
Vomiting	Gastrointestinal disorders	1148 (3.73%)
Rash	Skin and subcutaneous tissue disorders	1090 (3.54%)
Pruritus	Skin and subcutaneous tissue disorders	1074 (3.49%)
Drug ineffective	General disorders and administration site conditions	972 (3.16%)
Paraesthesia	Nervous system disorders	862 (2.80%)
Cough	Respiratory, thoracic and mediastinal disorders	808 (2.63%)
Erythema	Skin and subcutaneous tissue disorders	777 (2.53%)
Anaphylactic reaction	Immune system disorders	758 (2.46%)
Hypoaesthesia	Nervous system disorders	715 (2.33%)
Feeling abnormal	General disorders and administration site conditions	701 (2.28%)
Influenza like illness	General disorders and administration site conditions	665 (2.16%)
Off label use	Injury, poisoning and procedural complications	625 (2.03%)
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	612 (1.99%)
Urticaria	Skin and subcutaneous tissue disorders	607 (1.97%)
Peripheral swelling	General disorders and administration site conditions	591 (1.92%)
Chest pain	General disorders and administration site conditions	582 (1.89%)
Hypertension	Vascular disorders	564 (1.83%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vaccination site erythema	General disorders and administration site conditions	564 (1.83%)
Vaccination site swelling	General disorders and administration site conditions	557 (1.81%)
Back pain	Musculoskeletal and connective tissue disorders	551 (1.79%)
Syncope	Nervous system disorders	544 (1.77%)
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	537 (1.75%)
Palpitations	Cardiac disorders	535 (1.74%)
Hyperhidrosis	Skin and subcutaneous tissue disorders	519 (1.69%)
Swelling	General disorders and administration site conditions	475 (1.54%)
Tachycardia	Cardiac disorders	472 (1.53%)
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	441 (1.43%)
Neck pain	Musculoskeletal and connective tissue disorders	439 (1.43%)
Decreased appetite	Metabolism and nutrition disorders	421 (1.37%)
Vaccination failure	Injury, poisoning and procedural complications	411 (1.34%)
Facial paralysis	Nervous system disorders	410 (1.33%)
Illness	General disorders and administration site conditions	410 (1.33%)
Tremor	Nervous system disorders	405 (1.32%)
Feeling hot	General disorders and administration site conditions	401 (1.30%)
Abdominal pain	Gastrointestinal disorders	396 (1.29%)
Migraine	Nervous system disorders	395 (1.28%)
Axillary pain	General disorders and administration site conditions	394 (1.28%)
Insomnia	Psychiatric disorders	385 (1.25%)
Tinnitus	Ear and labyrinth disorders	385 (1.25%)
Loss of consciousness	Nervous system disorders	384 (1.25%)
Hypersensitivity	Immune system disorders	382 (1.24%)
Vertigo	Ear and labyrinth disorders	376 (1.22%)
Chest discomfort	General disorders and administration site conditions	369 (1.20%)
Lethargy	Nervous system disorders	360 (1.17%)
Abdominal pain upper	Gastrointestinal disorders	346 (1.13%)
Blood pressure increased	Investigations	346 (1.13%)
Somnolence	Nervous system disorders	330 (1.07%)
Muscular weakness	Musculoskeletal and connective tissue disorders	320 (1.04%)
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	316 (1.03%)
Heart rate increased	Investigations	312 (1.01%)
Cerebrovascular accident	Nervous system disorders	308 (1.00%)
Feeling cold	General disorders and administration site conditions	296 (0.96%)
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	285 (0.93%)
Deep vein thrombosis	Vascular disorders	280 (0.91%)
Condition aggravated	General disorders and administration site conditions	277 (0.90%)
Thrombosis	Vascular disorders	277 (0.90%)
Limb discomfort	Musculoskeletal and connective tissue disorders	276 (0.90%)
Lymph node pain	Blood and lymphatic system disorders	271 (0.88%)
Herpes zoster	Infections and infestations	263 (0.86%)
Vaccination site warmth	General disorders and administration site conditions	262 (0.85%)
Fall	Injury, poisoning and procedural complications	258 (0.84%)
Confusional state	Psychiatric disorders	256 (0.83%)
Body temperature increased	Investigations	253 (0.82%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Swelling face	General disorders and administration site conditions	246 (0.80%)
Paraesthesia oral	Gastrointestinal disorders	245 (0.80%)
Influenza	Infections and infestations	244 (0.79%)
Sensitive skin	Skin and subcutaneous tissue disorders	241 (0.78%)
Vaccination site pruritus	General disorders and administration site conditions	241 (0.78%)
Gait disturbance	General disorders and administration site conditions	239 (0.78%)
Nasopharyngitis	Infections and infestations	231 (0.75%)
Vision blurred	Eye disorders	231 (0.75%)
Seizure	Nervous system disorders	228 (0.74%)
Presyncope	Nervous system disorders	227 (0.74%)
Dysgeusia	Nervous system disorders	226 (0.73%)
Muscle spasms	Musculoskeletal and connective tissue disorders	217 (0.71%)
Hot flush	Vascular disorders	210 (0.68%)
Hypotension	Vascular disorders	210 (0.68%)
Death	General disorders and administration site conditions	209 (0.68%)
Anxiety	Psychiatric disorders	193 (0.63%)
Burning sensation	Nervous system disorders	192 (0.62%)
Vaccination site reaction	General disorders and administration site conditions	189 (0.61%)
Contusion	Injury, poisoning and procedural complications	185 (0.60%)
Rash pruritic	Skin and subcutaneous tissue disorders	182 (0.59%)
Atrial fibrillation	Cardiac disorders	181 (0.59%)
Epistaxis	Respiratory, thoracic and mediastinal disorders	181 (0.59%)
Rash erythematous	Skin and subcutaneous tissue disorders	181 (0.59%)
Eye pain	Eye disorders	175 (0.57%)
Abdominal discomfort	Gastrointestinal disorders	171 (0.56%)
Discomfort	General disorders and administration site conditions	168 (0.55%)
Disease recurrence	General disorders and administration site conditions	167 (0.54%)
Respiratory distress	Respiratory, thoracic and mediastinal disorders	165 (0.54%)
Dysphagia	Gastrointestinal disorders	164 (0.53%)
Flushing	Vascular disorders	164 (0.53%)
Ear pain	Ear and labyrinth disorders	161 (0.52%)
Balance disorder	Nervous system disorders	160 (0.52%)
Transient ischaemic attack	Nervous system disorders	157 (0.51%)
Cold sweat	Skin and subcutaneous tissue disorders	155 (0.50%)
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	154 (0.50%)
Visual impairment	Eye disorders	153 (0.50%)
Vaccination site inflammation	General disorders and administration site conditions	150 (0.49%)
Lip swelling	Gastrointestinal disorders	146 (0.47%)
Overdose	Injury, poisoning and procedural complications	145 (0.47%)
Inflammation	General disorders and administration site conditions	144 (0.47%)
Pneumonia	Infections and infestations	144 (0.47%)
Throat tightness	Respiratory, thoracic and mediastinal disorders	144 (0.47%)
Bone pain	Musculoskeletal and connective tissue disorders	140 (0.46%)
Throat irritation	Respiratory, thoracic and mediastinal disorders	139 (0.45%)
Nasal congestion	Respiratory, thoracic and mediastinal disorders	137 (0.45%)
Suspected COVID-19	Infections and infestations	132 (0.43%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Swollen tongue	Gastrointestinal disorders	132 (0.43%)
Joint swelling	Musculoskeletal and connective tissue disorders	131 (0.43%)
Arrhythmia	Cardiac disorders	130 (0.42%)
Incorrect route of product administration	Injury, poisoning and procedural complications	130 (0.42%)
Extensive swelling of vaccinated limb	General disorders and administration site conditions	129 (0.42%)
Head discomfort	Nervous system disorders	128 (0.42%)
Hypoaesthesia oral	Gastrointestinal disorders	128 (0.42%)
Oxygen saturation decreased	Investigations	128 (0.42%)
Wheezing	Respiratory, thoracic and mediastinal disorders	127 (0.41%)
Ageusia	Nervous system disorders	126 (0.41%)
Thrombocytopenia	Blood and lymphatic system disorders	126 (0.41%)
Sleep disorder	Psychiatric disorders	123 (0.40%)
Myocardial infarction	Cardiac disorders	120 (0.39%)
Angioedema	Skin and subcutaneous tissue disorders	119 (0.39%)
Disturbance in attention	Nervous system disorders	118 (0.38%)
Peripheral coldness	Vascular disorders	115 (0.37%)
Dry mouth	Gastrointestinal disorders	112 (0.36%)
Poor quality product administered	Injury, poisoning and procedural complications	112 (0.36%)
SARS-CoV-2 test positive	Investigations	111 (0.36%)
Blood pressure decreased	Investigations	110 (0.36%)
General physical health deterioration	General disorders and administration site conditions	109 (0.35%)
Loss of personal independence in daily activities	Social circumstances	109 (0.35%)
Mobility decreased	Musculoskeletal and connective tissue disorders	109 (0.35%)
Dysphonia	Respiratory, thoracic and mediastinal disorders	108 (0.35%)
Product preparation issue	Injury, poisoning and procedural complications	108 (0.35%)
Asthma	Respiratory, thoracic and mediastinal disorders	106 (0.34%)
Neuralgia	Nervous system disorders	106 (0.34%)
Rash macular	Skin and subcutaneous tissue disorders	103 (0.33%)
Asymptomatic COVID-19	Infections and infestations	102 (0.33%)
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	102 (0.33%)
Product use issue	Injury, poisoning and procedural complications	102 (0.33%)
Diplopia	Eye disorders	100 (0.33%)
Vaccination site mass	General disorders and administration site conditions	100 (0.33%)
Cardiac failure	Cardiac disorders	99 (0.32%)
Haemorrhage	Vascular disorders	99 (0.32%)
Tenderness	General disorders and administration site conditions	99 (0.32%)
Cardiac arrest	Cardiac disorders	98 (0.32%)
Disorientation	Psychiatric disorders	98 (0.32%)
Eye swelling	Eye disorders	98 (0.32%)
Hypertensive crisis	Vascular disorders	96 (0.31%)
Speech disorder	Nervous system disorders	95 (0.31%)
Anosmia	Nervous system disorders	94 (0.31%)
Dizziness postural	Nervous system disorders	93 (0.30%)
Night sweats	Skin and subcutaneous tissue disorders	92 (0.30%)
Oedema peripheral	General disorders and administration site conditions	92 (0.30%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Breast pain	Reproductive system and breast disorders	91 (0.30%)
Vaccination site rash	General disorders and administration site conditions	91 (0.30%)
Aphasia	Nervous system disorders	90 (0.29%)
Ischaemic stroke	Nervous system disorders	90 (0.29%)
Deafness	Ear and labyrinth disorders	88 (0.29%)
Feeling of body temperature change	General disorders and administration site conditions	88 (0.29%)
Injection site pain	General disorders and administration site conditions	88 (0.29%)
Neuropathy peripheral	Nervous system disorders	87 (0.28%)
Vaccination site induration	General disorders and administration site conditions	87 (0.28%)
Dehydration	Metabolism and nutrition disorders	86 (0.28%)
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	86 (0.28%)
Pallor	Vascular disorders	85 (0.28%)
Myocarditis	Cardiac disorders	83 (0.27%)
Nodule	General disorders and administration site conditions	83 (0.27%)
Dysarthria	Nervous system disorders	82 (0.27%)
Oedema	General disorders and administration site conditions	82 (0.27%)
Epilepsy	Nervous system disorders	81 (0.26%)
Cellulitis	Infections and infestations	80 (0.26%)
Vaccination site oedema	General disorders and administration site conditions	80 (0.26%)
C-reactive protein increased	Investigations	79 (0.26%)
Dyspepsia	Gastrointestinal disorders	77 (0.25%)
Hypersomnia	Nervous system disorders	77 (0.25%)
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	77 (0.25%)
Movement disorder	Nervous system disorders	77 (0.25%)
Taste disorder	Nervous system disorders	74 (0.24%)
Urinary tract infection	Infections and infestations	74 (0.24%)
Blister	Skin and subcutaneous tissue disorders	73 (0.24%)
Hyperpyrexia	General disorders and administration site conditions	73 (0.24%)
Ocular hyperaemia	Eye disorders	73 (0.24%)
Pain in jaw	Musculoskeletal and connective tissue disorders	73 (0.24%)
Facial paresis	Nervous system disorders	72 (0.23%)
Nervousness	Psychiatric disorders	70 (0.23%)
Vaccination site movement impairment	General disorders and administration site conditions	70 (0.23%)
Abdominal distension	Gastrointestinal disorders	69 (0.22%)
Cerebral haemorrhage	Nervous system disorders	69 (0.22%)
Thirst	General disorders and administration site conditions	69 (0.22%)
Wrong technique in product usage process	Injury, poisoning and procedural complications	69 (0.22%)
Cerebral infarction	Nervous system disorders	68 (0.22%)
Hemiparesis	Nervous system disorders	68 (0.22%)
Vaccination site bruising	General disorders and administration site conditions	68 (0.22%)
Irritability	Psychiatric disorders	67 (0.22%)
Pain of skin	Skin and subcutaneous tissue disorders	67 (0.22%)
Dysstasia	Nervous system disorders	66 (0.21%)
Gait inability	General disorders and administration site conditions	66 (0.21%)
Infection	Infections and infestations	66 (0.21%)
Lymphadenitis	Blood and lymphatic system disorders	66 (0.21%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Memory impairment	Nervous system disorders	66 (0.21%)
Sneezing	Respiratory, thoracic and mediastinal disorders	66 (0.21%)
Tension headache	Nervous system disorders	66 (0.21%)
Angina pectoris	Cardiac disorders	65 (0.21%)
Exposure via breast milk	Injury, poisoning and procedural complications	65 (0.21%)
Induration	General disorders and administration site conditions	65 (0.21%)
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	64 (0.21%)
Menorrhagia	Reproductive system and breast disorders	64 (0.21%)
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	64 (0.21%)
Hypoacusis	Ear and labyrinth disorders	63 (0.20%)
Platelet count decreased	Investigations	63 (0.20%)
Product temperature excursion issue	Product issues	63 (0.20%)
Anaphylactic shock	Immune system disorders	62 (0.20%)
Constipation	Gastrointestinal disorders	62 (0.20%)
Pericarditis	Cardiac disorders	62 (0.20%)
Photophobia	Eye disorders	62 (0.20%)
Weight decreased	Investigations	62 (0.20%)
Delirium	Psychiatric disorders	61 (0.20%)
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	60 (0.20%)
Arthritis	Musculoskeletal and connective tissue disorders	60 (0.20%)
Facial pain	General disorders and administration site conditions	59 (0.19%)
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	59 (0.19%)
Skin discolouration	Skin and subcutaneous tissue disorders	59 (0.19%)
Therapeutic response unexpected	General disorders and administration site conditions	59 (0.19%)
Ear discomfort	Ear and labyrinth disorders	58 (0.19%)
Muscle fatigue	Musculoskeletal and connective tissue disorders	58 (0.19%)
Petechiae	Skin and subcutaneous tissue disorders	58 (0.19%)
Eye pruritus	Eye disorders	57 (0.19%)
Oral herpes	Infections and infestations	57 (0.19%)
Rash papular	Skin and subcutaneous tissue disorders	57 (0.19%)
Restlessness	Psychiatric disorders	57 (0.19%)
Amnesia	Nervous system disorders	56 (0.18%)
Productive cough	Respiratory, thoracic and mediastinal disorders	55 (0.18%)
Circulatory collapse	Vascular disorders	54 (0.18%)
Depressed level of consciousness	Nervous system disorders	54 (0.18%)
Hallucination	Psychiatric disorders	53 (0.17%)
Hypokinesia	Nervous system disorders	53 (0.17%)
Sudden death	General disorders and administration site conditions	53 (0.17%)
Vaccination site discomfort	General disorders and administration site conditions	53 (0.17%)
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	52 (0.17%)
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	52 (0.17%)
Sinus headache	Nervous system disorders	52 (0.17%)
Face oedema	General disorders and administration site conditions	51 (0.17%)
Guillain-Barre syndrome	Nervous system disorders	51 (0.17%)
Paralysis	Nervous system disorders	50 (0.16%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Parosmia	Nervous system disorders	50 (0.16%)
Thrombophlebitis	Vascular disorders	50 (0.16%)
Exposure during pregnancy	Injury, poisoning and procedural complications	49 (0.16%)
Thrombophlebitis superficial	Vascular disorders	49 (0.16%)
Acute myocardial infarction	Cardiac disorders	48 (0.16%)
Blood glucose increased	Investigations	48 (0.16%)
COVID-19 pneumonia	Infections and infestations	48 (0.16%)
Dyskinesia	Nervous system disorders	48 (0.16%)
Flatulence	Gastrointestinal disorders	48 (0.16%)
Haematoma	Vascular disorders	48 (0.16%)
Lacrimation increased	Eye disorders	48 (0.16%)
Muscle twitching	Musculoskeletal and connective tissue disorders	48 (0.16%)
Bradycardia	Cardiac disorders	47 (0.15%)
Gastrointestinal disorder	Gastrointestinal disorders	47 (0.15%)
Hyperaesthesia	Nervous system disorders	47 (0.15%)
Respiratory failure	Respiratory, thoracic and mediastinal disorders	47 (0.15%)
Sensation of foreign body	General disorders and administration site conditions	47 (0.15%)
Bronchospasm	Respiratory, thoracic and mediastinal disorders	46 (0.15%)
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	46 (0.15%)
Toothache	Gastrointestinal disorders	46 (0.15%)
Axillary mass	Musculoskeletal and connective tissue disorders	45 (0.15%)
Dry throat	Respiratory, thoracic and mediastinal disorders	45 (0.15%)
Odynophagia	Gastrointestinal disorders	45 (0.15%)
Sensory disturbance	Nervous system disorders	45 (0.15%)
Skin burning sensation	Skin and subcutaneous tissue disorders	45 (0.15%)
Swelling of eyelid	Eye disorders	45 (0.15%)
Blindness	Eye disorders	44 (0.14%)
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	44 (0.14%)
Joint stiffness	Musculoskeletal and connective tissue disorders	44 (0.14%)
No adverse event	General disorders and administration site conditions	44 (0.14%)
Embolism	Vascular disorders	43 (0.14%)
Glossodynia	Gastrointestinal disorders	43 (0.14%)
Head injury	Injury, poisoning and procedural complications	43 (0.14%)
Immune thrombocytopenia	Blood and lymphatic system disorders	43 (0.14%)
Sinusitis	Infections and infestations	43 (0.14%)
Dry skin	Skin and subcutaneous tissue disorders	42 (0.14%)
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	42 (0.14%)
Deafness unilateral	Ear and labyrinth disorders	41 (0.13%)
Depressed mood	Psychiatric disorders	41 (0.13%)
Haematochezia	Gastrointestinal disorders	41 (0.13%)
Mouth ulceration	Gastrointestinal disorders	41 (0.13%)
Underdose	Injury, poisoning and procedural complications	41 (0.13%)
Fibrin D dimer increased	Investigations	40 (0.13%)
Heart rate irregular	Investigations	40 (0.13%)
Cardiac disorder	Cardiac disorders	39 (0.13%)
Cardiovascular disorder	Cardiac disorders	39 (0.13%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Depression	Psychiatric disorders	39 (0.13%)
Eye haemorrhage	Eye disorders	39 (0.13%)
Eye irritation	Eye disorders	39 (0.13%)
Hemiplegia	Nervous system disorders	39 (0.13%)
Product administered at inappropriate site	Injury, poisoning and procedural complications	39 (0.13%)
Acute kidney injury	Renal and urinary disorders	38 (0.12%)
Dermatitis allergic	Skin and subcutaneous tissue disorders	38 (0.12%)
Muscle tightness	Musculoskeletal and connective tissue disorders	38 (0.12%)
Product dose omission issue	Injury, poisoning and procedural complications	38 (0.12%)
Vaccination site haematoma	General disorders and administration site conditions	38 (0.12%)
Vaginal haemorrhage	Reproductive system and breast disorders	38 (0.12%)
Allergy to vaccine	Immune system disorders	37 (0.12%)
Eye disorder	Eye disorders	37 (0.12%)
Hyperventilation	Respiratory, thoracic and mediastinal disorders	37 (0.12%)
Poor quality sleep	Nervous system disorders	37 (0.12%)
Sensory loss	Nervous system disorders	37 (0.12%)
Cyanosis	Vascular disorders	36 (0.12%)
Heart rate decreased	Investigations	36 (0.12%)
Local reaction	General disorders and administration site conditions	36 (0.12%)
Lung disorder	Respiratory, thoracic and mediastinal disorders	36 (0.12%)
Migraine with aura	Nervous system disorders	36 (0.12%)
Ocular discomfort	Eye disorders	36 (0.12%)
Retching	Gastrointestinal disorders	36 (0.12%)
Agitation	Psychiatric disorders	35 (0.11%)
Chillblains	Injury, poisoning and procedural complications	35 (0.11%)
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	35 (0.11%)
Cardiac flutter	Cardiac disorders	34 (0.11%)
Dysuria	Renal and urinary disorders	34 (0.11%)
Feeding disorder	Metabolism and nutrition disorders	34 (0.11%)
Gastrointestinal pain	Gastrointestinal disorders	34 (0.11%)
Menstruation irregular	Reproductive system and breast disorders	34 (0.11%)
Panic attack	Psychiatric disorders	34 (0.11%)
Renal pain	Renal and urinary disorders	34 (0.11%)
Sepsis	Infections and infestations	34 (0.11%)
Vasculitis	Vascular disorders	34 (0.11%)
Asthenopia	Eye disorders	33 (0.11%)
Cardio-respiratory arrest	Cardiac disorders	33 (0.11%)
Eczema	Skin and subcutaneous tissue disorders	33 (0.11%)
Extrasystoles	Cardiac disorders	33 (0.11%)
Eyelid oedema	Eye disorders	33 (0.11%)
Nervous system disorder	Nervous system disorders	33 (0.11%)
Oral discomfort	Gastrointestinal disorders	33 (0.11%)
Product preparation error	Injury, poisoning and procedural complications	33 (0.11%)
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	33 (0.11%)
Skin disorder	Skin and subcutaneous tissue disorders	33 (0.11%)
Sudden hearing loss	Ear and labyrinth disorders	33 (0.11%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Unresponsive to stimuli	Nervous system disorders	33 (0.11%)
Alopecia	Skin and subcutaneous tissue disorders	32 (0.10%)
Anaemia	Blood and lymphatic system disorders	32 (0.10%)
Hyperglycaemia	Metabolism and nutrition disorders	32 (0.10%)
Lower respiratory tract infection	Infections and infestations	32 (0.10%)
Urinary incontinence	Renal and urinary disorders	32 (0.10%)
Appendicitis	Infections and infestations	31 (0.10%)
Cerebral thrombosis	Nervous system disorders	31 (0.10%)
Haemoptysis	Respiratory, thoracic and mediastinal disorders	31 (0.10%)
Hypothermia	General disorders and administration site conditions	31 (0.10%)
Hypoxia	Respiratory, thoracic and mediastinal disorders	31 (0.10%)
Pleural effusion	Respiratory, thoracic and mediastinal disorders	31 (0.10%)
Renal failure	Renal and urinary disorders	31 (0.10%)
Ear infection	Infections and infestations	30 (0.10%)
Eating disorder	Psychiatric disorders	30 (0.10%)
Oral pain	Gastrointestinal disorders	30 (0.10%)
Periorbital swelling	Eye disorders	30 (0.10%)
Phlebitis	Vascular disorders	30 (0.10%)
Abnormal dreams	Psychiatric disorders	29 (0.09%)
Breast swelling	Reproductive system and breast disorders	29 (0.09%)
Conjunctival haemorrhage	Eye disorders	29 (0.09%)
Generalised tonic-clonic seizure	Nervous system disorders	29 (0.09%)
Skin exfoliation	Skin and subcutaneous tissue disorders	29 (0.09%)
Tachypnoea	Respiratory, thoracic and mediastinal disorders	29 (0.09%)
Abdominal pain lower	Gastrointestinal disorders	28 (0.09%)
Hyperthermia	General disorders and administration site conditions	28 (0.09%)
Impaired work ability	Social circumstances	28 (0.09%)
Sinus tachycardia	Cardiac disorders	28 (0.09%)
Skin reaction	Skin and subcutaneous tissue disorders	28 (0.09%)
Stress	Psychiatric disorders	28 (0.09%)
Cerebral venous sinus thrombosis	Nervous system disorders	27 (0.09%)
Crying	General disorders and administration site conditions	27 (0.09%)
Dermatitis	Skin and subcutaneous tissue disorders	27 (0.09%)
Incorrect dose administered	Injury, poisoning and procedural complications	27 (0.09%)
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	27 (0.09%)
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	27 (0.09%)
Rectal haemorrhage	Gastrointestinal disorders	27 (0.09%)
Vaccination site haemorrhage	General disorders and administration site conditions	27 (0.09%)
Groin pain	Musculoskeletal and connective tissue disorders	26 (0.08%)
Motor dysfunction	Nervous system disorders	26 (0.08%)
Nightmare	Psychiatric disorders	26 (0.08%)
Photopsia	Eye disorders	26 (0.08%)
Pollakiuria	Renal and urinary disorders	26 (0.08%)
Altered state of consciousness	Nervous system disorders	25 (0.08%)
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	25 (0.08%)
Coordination abnormal	Nervous system disorders	25 (0.08%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Drug hypersensitivity	Immune system disorders	25 (0.08%)
Gastroesophageal reflux disease	Gastrointestinal disorders	25 (0.08%)
Injection site erythema	General disorders and administration site conditions	25 (0.08%)
Mental impairment	Nervous system disorders	25 (0.08%)
Rash maculo-papular	Skin and subcutaneous tissue disorders	25 (0.08%)
SARS-CoV-2 antibody test negative	Investigations	25 (0.08%)
Skin warm	Skin and subcutaneous tissue disorders	25 (0.08%)
Spinal pain	Musculoskeletal and connective tissue disorders	25 (0.08%)
Stomatitis	Gastrointestinal disorders	25 (0.08%)
Vaccination site lymphadenopathy	General disorders and administration site conditions	25 (0.08%)
White blood cell count increased	Investigations	25 (0.08%)
Aphonia	Respiratory, thoracic and mediastinal disorders	24 (0.08%)
Cluster headache	Nervous system disorders	24 (0.08%)
Drug interaction	General disorders and administration site conditions	24 (0.08%)
Dry eye	Eye disorders	24 (0.08%)
Injected limb mobility decreased	General disorders and administration site conditions	24 (0.08%)
Product storage error	Injury, poisoning and procedural complications	24 (0.08%)
Tongue oedema	Gastrointestinal disorders	24 (0.08%)
Troponin increased	Investigations	24 (0.08%)
Acne	Skin and subcutaneous tissue disorders	23 (0.07%)
Blood glucose decreased	Investigations	23 (0.07%)
Blood pressure abnormal	Investigations	23 (0.07%)
Body temperature abnormal	Investigations	23 (0.07%)
Body temperature decreased	Investigations	23 (0.07%)
Cystitis	Infections and infestations	23 (0.07%)
Diabetes mellitus	Metabolism and nutrition disorders	23 (0.07%)
Heart rate abnormal	Investigations	23 (0.07%)
Hypotonia	Nervous system disorders	23 (0.07%)
Hypovolaemic shock	Vascular disorders	23 (0.07%)
Lip oedema	Gastrointestinal disorders	23 (0.07%)
Lymphoedema	Vascular disorders	23 (0.07%)
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	23 (0.07%)
Rhinitis	Infections and infestations	23 (0.07%)
Sinus pain	Respiratory, thoracic and mediastinal disorders	23 (0.07%)
Venous thrombosis limb	Vascular disorders	23 (0.07%)
Acute coronary syndrome	Cardiac disorders	22 (0.07%)
Blood pressure systolic increased	Investigations	22 (0.07%)
Coagulopathy	Blood and lymphatic system disorders	22 (0.07%)
Expired product administered	Injury, poisoning and procedural complications	22 (0.07%)
Hallucination, visual	Psychiatric disorders	22 (0.07%)
Hepatic enzyme increased	Investigations	22 (0.07%)
Hyperacusis	Ear and labyrinth disorders	22 (0.07%)
Injection site swelling	General disorders and administration site conditions	22 (0.07%)
Middle insomnia	Psychiatric disorders	22 (0.07%)
Monoparesis	Nervous system disorders	22 (0.07%)
Mouth swelling	Gastrointestinal disorders	22 (0.07%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Pericardial effusion	Cardiac disorders	22 (0.07%)
Psoriasis	Skin and subcutaneous tissue disorders	22 (0.07%)
Purpura	Skin and subcutaneous tissue disorders	22 (0.07%)
Skin irritation	Skin and subcutaneous tissue disorders	22 (0.07%)
Bedridden	Social circumstances	21 (0.07%)
Blood pressure fluctuation	Vascular disorders	21 (0.07%)
Blood urine present	Investigations	21 (0.07%)
Cognitive disorder	Nervous system disorders	21 (0.07%)
Colitis	Gastrointestinal disorders	21 (0.07%)
Febrile convulsion	Nervous system disorders	21 (0.07%)
Grip strength decreased	Investigations	21 (0.07%)
Haemoglobin decreased	Investigations	21 (0.07%)
Limb injury	Injury, poisoning and procedural complications	21 (0.07%)
Menstrual disorder	Reproductive system and breast disorders	21 (0.07%)
Muscle strain	Injury, poisoning and procedural complications	21 (0.07%)
Pneumonia aspiration	Respiratory, thoracic and mediastinal disorders	21 (0.07%)
Respiratory rate increased	Investigations	21 (0.07%)
Vaccination site hypoaesthesia	General disorders and administration site conditions	21 (0.07%)
Autoimmune disorder	Immune system disorders	20 (0.07%)
Cerebral ischaemia	Nervous system disorders	20 (0.07%)
Chronic fatigue syndrome	General disorders and administration site conditions	20 (0.07%)
Conjunctival hyperaemia	Eye disorders	20 (0.07%)
Dysaesthesia	Nervous system disorders	20 (0.07%)
Dysentery	Infections and infestations	20 (0.07%)
Erysipelas	Infections and infestations	20 (0.07%)
Eyelid ptosis	Eye disorders	20 (0.07%)
Feeling drunk	General disorders and administration site conditions	20 (0.07%)
Haematuria	Renal and urinary disorders	20 (0.07%)
Hypopnoea	Respiratory, thoracic and mediastinal disorders	20 (0.07%)
Internal haemorrhage	Vascular disorders	20 (0.07%)
Mass	General disorders and administration site conditions	20 (0.07%)
Painful respiration	Respiratory, thoracic and mediastinal disorders	20 (0.07%)
Vaccination site urticaria	General disorders and administration site conditions	20 (0.07%)
Vertigo positional	Ear and labyrinth disorders	20 (0.07%)
Aphthous ulcer	Gastrointestinal disorders	19 (0.06%)
Diverticulitis	Infections and infestations	19 (0.06%)
Ischaemic cerebral infarction	Nervous system disorders	19 (0.06%)
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	19 (0.06%)
Rash vesicular	Skin and subcutaneous tissue disorders	19 (0.06%)
Retinal vein occlusion	Eye disorders	19 (0.06%)
Subarachnoid haemorrhage	Nervous system disorders	19 (0.06%)
Vaccination complication	Injury, poisoning and procedural complications	19 (0.06%)
Vaccine breakthrough infection	Infections and infestations	19 (0.06%)
Wrong product administered	Injury, poisoning and procedural complications	19 (0.06%)
Blindness unilateral	Eye disorders	18 (0.06%)
Body temperature	Investigations	18 (0.06%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bronchitis	Infections and infestations	18 (0.06%)
Choking	Respiratory, thoracic and mediastinal disorders	18 (0.06%)
Colitis ulcerative	Gastrointestinal disorders	18 (0.06%)
Dysmenorrhoea	Reproductive system and breast disorders	18 (0.06%)
Haematemesis	Gastrointestinal disorders	18 (0.06%)
Injury	Injury, poisoning and procedural complications	18 (0.06%)
Mental fatigue	Psychiatric disorders	18 (0.06%)
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	18 (0.06%)
Nerve injury	Injury, poisoning and procedural complications	18 (0.06%)
Ophthalmic herpes zoster	Infections and infestations	18 (0.06%)
Oral pruritus	Gastrointestinal disorders	18 (0.06%)
Renal impairment	Renal and urinary disorders	18 (0.06%)
Sinus disorder	Respiratory, thoracic and mediastinal disorders	18 (0.06%)
Status epilepticus	Nervous system disorders	18 (0.06%)
Tongue discomfort	Gastrointestinal disorders	18 (0.06%)
Vaccination site paraesthesia	General disorders and administration site conditions	18 (0.06%)
Breast mass	Reproductive system and breast disorders	17 (0.06%)
Bursitis	Musculoskeletal and connective tissue disorders	17 (0.06%)
Fear	Psychiatric disorders	17 (0.06%)
Gastric disorder	Gastrointestinal disorders	17 (0.06%)
Gingival bleeding	Gastrointestinal disorders	17 (0.06%)
Monoplegia	Nervous system disorders	17 (0.06%)
Post viral fatigue syndrome	Infections and infestations	17 (0.06%)
Raynaud's phenomenon	Vascular disorders	17 (0.06%)
Sluggishness	General disorders and administration site conditions	17 (0.06%)
Ventricular extrasystoles	Cardiac disorders	17 (0.06%)
Weight increased	Investigations	17 (0.06%)
White blood cell count decreased	Investigations	17 (0.06%)
Apathy	Psychiatric disorders	16 (0.05%)
Ataxia	Nervous system disorders	16 (0.05%)
Body temperature fluctuation	Investigations	16 (0.05%)
Conjunctivitis	Infections and infestations	16 (0.05%)
Ear swelling	Ear and labyrinth disorders	16 (0.05%)
Gastrointestinal haemorrhage	Gastrointestinal disorders	16 (0.05%)
Haemorrhagic stroke	Nervous system disorders	16 (0.05%)
Localised oedema	General disorders and administration site conditions	16 (0.05%)
Menstruation delayed	Reproductive system and breast disorders	16 (0.05%)
Nephrolithiasis	Renal and urinary disorders	16 (0.05%)
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	16 (0.05%)
Salivary hypersecretion	Gastrointestinal disorders	16 (0.05%)
Skin lesion	Skin and subcutaneous tissue disorders	16 (0.05%)
Skin swelling	Skin and subcutaneous tissue disorders	16 (0.05%)
Vaccination site hypersensitivity	General disorders and administration site conditions	16 (0.05%)
Viral infection	Infections and infestations	16 (0.05%)
Aggression	Psychiatric disorders	15 (0.05%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Alanine aminotransferase increased	Investigations	15 (0.05%)
Atrial flutter	Cardiac disorders	15 (0.05%)
Blepharospasm	Eye disorders	15 (0.05%)
Bradypnea	Psychiatric disorders	15 (0.05%)
Deafness neurosensory	Ear and labyrinth disorders	15 (0.05%)
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	15 (0.05%)
Fibromyalgia	Musculoskeletal and connective tissue disorders	15 (0.05%)
Hypoglycaemia	Metabolism and nutrition disorders	15 (0.05%)
Immune system disorder	Immune system disorders	15 (0.05%)
Intestinal ischaemia	Gastrointestinal disorders	15 (0.05%)
Labyrinthitis	Infections and infestations	15 (0.05%)
Leukopenia	Blood and lymphatic system disorders	15 (0.05%)
Mastitis	Infections and infestations	15 (0.05%)
Multiple sclerosis relapse	Nervous system disorders	15 (0.05%)
Pelvic pain	Reproductive system and breast disorders	15 (0.05%)
Respiratory tract infection	Infections and infestations	15 (0.05%)
Thinking abnormal	Psychiatric disorders	15 (0.05%)
Tongue disorder	Gastrointestinal disorders	15 (0.05%)
Venous thrombosis	Vascular disorders	15 (0.05%)
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	14 (0.05%)
Arthropathy	Musculoskeletal and connective tissue disorders	14 (0.05%)
Blood test abnormal	Investigations	14 (0.05%)
Chromaturia	Renal and urinary disorders	14 (0.05%)
Diarrhoea haemorrhagic	Gastrointestinal disorders	14 (0.05%)
Drug eruption	Skin and subcutaneous tissue disorders	14 (0.05%)
Ecchymosis	Skin and subcutaneous tissue disorders	14 (0.05%)
Erythema nodosum	Skin and subcutaneous tissue disorders	14 (0.05%)
Faeces discoloured	Gastrointestinal disorders	14 (0.05%)
Fluid retention	Metabolism and nutrition disorders	14 (0.05%)
Formication	Nervous system disorders	14 (0.05%)
Hemiparaesthesia	Nervous system disorders	14 (0.05%)
Hypersensitivity vasculitis	Skin and subcutaneous tissue disorders	14 (0.05%)
Incoherent	Nervous system disorders	14 (0.05%)
International normalised ratio increased	Investigations	14 (0.05%)
Jaundice	Hepatobiliary disorders	14 (0.05%)
Lip pain	Gastrointestinal disorders	14 (0.05%)
Metrorrhagia	Reproductive system and breast disorders	14 (0.05%)
Miliaria	Skin and subcutaneous tissue disorders	14 (0.05%)
Motion sickness	Ear and labyrinth disorders	14 (0.05%)
Near death experience	Psychiatric disorders	14 (0.05%)
Neutropenia	Blood and lymphatic system disorders	14 (0.05%)
Peripheral ischaemia	Vascular disorders	14 (0.05%)
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	14 (0.05%)
Pulmonary infarction	Respiratory, thoracic and mediastinal disorders	14 (0.05%)
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	14 (0.05%)
Restless legs syndrome	Nervous system disorders	14 (0.05%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Retinal artery occlusion	Eye disorders	14 (0.05%)
Seasonal allergy	Immune system disorders	14 (0.05%)
Skin haemorrhage	Skin and subcutaneous tissue disorders	14 (0.05%)
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	14 (0.05%)
Tendonitis	Musculoskeletal and connective tissue disorders	14 (0.05%)
Trigeminal neuralgia	Nervous system disorders	14 (0.05%)
Urinary retention	Renal and urinary disorders	14 (0.05%)
Vaccination site cellulitis	Infections and infestations	14 (0.05%)
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	13 (0.04%)
Emotional disorder	Psychiatric disorders	13 (0.04%)
Eye movement disorder	Eye disorders	13 (0.04%)
Gastritis	Gastrointestinal disorders	13 (0.04%)
Gout	Metabolism and nutrition disorders	13 (0.04%)
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	13 (0.04%)
Hyponatraemia	Metabolism and nutrition disorders	13 (0.04%)
Hypophagia	Metabolism and nutrition disorders	13 (0.04%)
Incontinence	Renal and urinary disorders	13 (0.04%)
Joint injury	Injury, poisoning and procedural complications	13 (0.04%)
Mental disorder	Psychiatric disorders	13 (0.04%)
Multiple sclerosis	Nervous system disorders	13 (0.04%)
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	13 (0.04%)
Nerve compression	Nervous system disorders	13 (0.04%)
Neurological symptom	Nervous system disorders	13 (0.04%)
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	13 (0.04%)
Photosensitivity reaction	Skin and subcutaneous tissue disorders	13 (0.04%)
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	13 (0.04%)
Secretion discharge	General disorders and administration site conditions	13 (0.04%)
Shock	Vascular disorders	13 (0.04%)
Sinus congestion	Respiratory, thoracic and mediastinal disorders	13 (0.04%)
Supraventricular tachycardia	Cardiac disorders	13 (0.04%)
Temperature intolerance	General disorders and administration site conditions	13 (0.04%)
Visual field defect	Nervous system disorders	13 (0.04%)
Vomiting projectile	Gastrointestinal disorders	13 (0.04%)
Abnormal behaviour	Psychiatric disorders	12 (0.04%)
Abscess	Infections and infestations	12 (0.04%)
Anal incontinence	Gastrointestinal disorders	12 (0.04%)
Breast tenderness	Reproductive system and breast disorders	12 (0.04%)
Cardiac failure congestive	Cardiac disorders	12 (0.04%)
Dementia	Nervous system disorders	12 (0.04%)
Encephalitis	Infections and infestations	12 (0.04%)
Erectile dysfunction	Reproductive system and breast disorders	12 (0.04%)
Erythema multiforme	Skin and subcutaneous tissue disorders	12 (0.04%)
Euphoric mood	Psychiatric disorders	12 (0.04%)
Flank pain	Musculoskeletal and connective tissue disorders	12 (0.04%)
Gingival pain	Gastrointestinal disorders	12 (0.04%)
Hypokalaemia	Metabolism and nutrition disorders	12 (0.04%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Injection site pruritus	General disorders and administration site conditions	12 (0.04%)
International normalised ratio decreased	Investigations	12 (0.04%)
Kidney infection	Infections and infestations	12 (0.04%)
Lymphopenia	Blood and lymphatic system disorders	12 (0.04%)
Meniere's disease	Ear and labyrinth disorders	12 (0.04%)
Micturition urgency	Renal and urinary disorders	12 (0.04%)
Pancreatitis acute	Gastrointestinal disorders	12 (0.04%)
Pancytopenia	Blood and lymphatic system disorders	12 (0.04%)
Paresis	Nervous system disorders	12 (0.04%)
Pharyngitis	Infections and infestations	12 (0.04%)
Postmenopausal haemorrhage	Reproductive system and breast disorders	12 (0.04%)
Product supply issue	Product issues	12 (0.04%)
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	12 (0.04%)
Respiratory rate decreased	Investigations	12 (0.04%)
Road traffic accident	Injury, poisoning and procedural complications	12 (0.04%)
Sciatica	Nervous system disorders	12 (0.04%)
Suicidal ideation	Psychiatric disorders	12 (0.04%)
Sweating fever	Infections and infestations	12 (0.04%)
Tonsillitis	Infections and infestations	12 (0.04%)
Vestibular neuronitis	Infections and infestations	12 (0.04%)
Abnormal sensation in eye	Eye disorders	11 (0.04%)
Amenorrhoea	Reproductive system and breast disorders	11 (0.04%)
Cardiac failure acute	Cardiac disorders	11 (0.04%)
Choking sensation	Respiratory, thoracic and mediastinal disorders	11 (0.04%)
Coma	Nervous system disorders	11 (0.04%)
Ear disorder	Ear and labyrinth disorders	11 (0.04%)
Electrocardiogram abnormal	Investigations	11 (0.04%)
Embolic stroke	Nervous system disorders	11 (0.04%)
Emotional distress	Psychiatric disorders	11 (0.04%)
Feeling jittery	General disorders and administration site conditions	11 (0.04%)
Gamma-glutamyltransferase increased	Investigations	11 (0.04%)
Gastroenteritis	Infections and infestations	11 (0.04%)
Giant cell arteritis	Vascular disorders	11 (0.04%)
Hepatic function abnormal	Hepatobiliary disorders	11 (0.04%)
Hyperthyroidism	Endocrine disorders	11 (0.04%)
Lip dry	Gastrointestinal disorders	11 (0.04%)
Listless	Psychiatric disorders	11 (0.04%)
Livedo reticularis	Skin and subcutaneous tissue disorders	11 (0.04%)
Mouth haemorrhage	Gastrointestinal disorders	11 (0.04%)
Muscle contractions involuntary	Nervous system disorders	11 (0.04%)
Muscle disorder	Musculoskeletal and connective tissue disorders	11 (0.04%)
Mydriasis	Eye disorders	11 (0.04%)
Neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (0.04%)
Optic neuritis	Nervous system disorders	11 (0.04%)
Panic reaction	Psychiatric disorders	11 (0.04%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	11 (0.04%)
Pneumonitis	Respiratory, thoracic and mediastinal disorders	11 (0.04%)
Polyarthritis	Musculoskeletal and connective tissue disorders	11 (0.04%)
Pulse abnormal	Investigations	11 (0.04%)
Rhinalgia	Respiratory, thoracic and mediastinal disorders	11 (0.04%)
SARS-CoV-2 antibody test positive	Investigations	11 (0.04%)
Skin sensitisation	Skin and subcutaneous tissue disorders	11 (0.04%)
Stridor	Respiratory, thoracic and mediastinal disorders	11 (0.04%)
Subdural haematoma	Injury, poisoning and procedural complications	11 (0.04%)
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	11 (0.04%)
Type I hypersensitivity	Immune system disorders	11 (0.04%)
Ventricular fibrillation	Cardiac disorders	11 (0.04%)
Visual acuity reduced	Eye disorders	11 (0.04%)
Wound	Injury, poisoning and procedural complications	11 (0.04%)
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Adverse event	General disorders and administration site conditions	10 (0.03%)
Anaphylactoid reaction	Immune system disorders	10 (0.03%)
Arthritis reactive	Musculoskeletal and connective tissue disorders	10 (0.03%)
Coronavirus infection	Infections and infestations	10 (0.03%)
Dermatitis bullous	Skin and subcutaneous tissue disorders	10 (0.03%)
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Dystonia	Nervous system disorders	10 (0.03%)
Ear pruritus	Ear and labyrinth disorders	10 (0.03%)
Eye discharge	Eye disorders	10 (0.03%)
Faeces soft	Gastrointestinal disorders	10 (0.03%)
Haemorrhagic disorder	Blood and lymphatic system disorders	10 (0.03%)
Hepatitis	Hepatobiliary disorders	10 (0.03%)
Herpes simplex	Infections and infestations	10 (0.03%)
Herpes virus infection	Infections and infestations	10 (0.03%)
Hypothyroidism	Endocrine disorders	10 (0.03%)
Impaired driving ability	Social circumstances	10 (0.03%)
Iridocyclitis	Eye disorders	10 (0.03%)
Irritable bowel syndrome	Gastrointestinal disorders	10 (0.03%)
Lymphangitis	Infections and infestations	10 (0.03%)
Multiple organ dysfunction syndrome	General disorders and administration site conditions	10 (0.03%)
Neutrophil count increased	Investigations	10 (0.03%)
Oral candidiasis	Infections and infestations	10 (0.03%)
Oral disorder	Gastrointestinal disorders	10 (0.03%)
Oral mucosal blistering	Gastrointestinal disorders	10 (0.03%)
Osteoarthritis	Musculoskeletal and connective tissue disorders	10 (0.03%)
Oxygen saturation abnormal	Investigations	10 (0.03%)
Periarthritis	Musculoskeletal and connective tissue disorders	10 (0.03%)
Petit mal epilepsy	Nervous system disorders	10 (0.03%)
Pharyngeal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Pneumothorax	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Product complaint	Product issues	10 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Psychomotor hyperactivity	Nervous system disorders	10 (0.03%)
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Septic shock	Infections and infestations	10 (0.03%)
Skin tightness	Skin and subcutaneous tissue disorders	10 (0.03%)
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	10 (0.03%)
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Tongue discoloration	Gastrointestinal disorders	10 (0.03%)
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	10 (0.03%)
Vaccination site discoloration	General disorders and administration site conditions	10 (0.03%)
Vlth nerve paralysis	Nervous system disorders	10 (0.03%)
Adverse drug reaction	General disorders and administration site conditions	9 (0.03%)
Apnoea	Respiratory, thoracic and mediastinal disorders	9 (0.03%)
Appendicitis perforated	Infections and infestations	9 (0.03%)
Aspartate aminotransferase increased	Investigations	9 (0.03%)
Blood creatinine increased	Investigations	9 (0.03%)
Blood potassium decreased	Investigations	9 (0.03%)
Blood sodium decreased	Investigations	9 (0.03%)
Breath sounds abnormal	Investigations	9 (0.03%)
Cerebral venous thrombosis	Nervous system disorders	9 (0.03%)
Dizziness exertional	Nervous system disorders	9 (0.03%)
Drooling	Nervous system disorders	9 (0.03%)
Energy increased	General disorders and administration site conditions	9 (0.03%)
Enlarged uvula	Gastrointestinal disorders	9 (0.03%)
Eructation	Gastrointestinal disorders	9 (0.03%)
Exercise tolerance decreased	General disorders and administration site conditions	9 (0.03%)
Facial bones fracture	Injury, poisoning and procedural complications	9 (0.03%)
Gingival swelling	Gastrointestinal disorders	9 (0.03%)
Glomerular filtration rate decreased	Investigations	9 (0.03%)
Interstitial lung disease	Respiratory, thoracic and mediastinal disorders	9 (0.03%)
Intussusception	Gastrointestinal disorders	9 (0.03%)
Leukocytosis	Blood and lymphatic system disorders	9 (0.03%)
Limb mass	Musculoskeletal and connective tissue disorders	9 (0.03%)
Lymph node abscess	Infections and infestations	9 (0.03%)
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	9 (0.03%)
Meningitis	Infections and infestations	9 (0.03%)
Myelitis transverse	Nervous system disorders	9 (0.03%)
Myositis	Musculoskeletal and connective tissue disorders	9 (0.03%)
Nystagmus	Nervous system disorders	9 (0.03%)
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	9 (0.03%)
Peripheral venous disease	Vascular disorders	9 (0.03%)
Pityriasis rosea	Skin and subcutaneous tissue disorders	9 (0.03%)
Platelet count increased	Investigations	9 (0.03%)
Polyneuropathy	Nervous system disorders	9 (0.03%)
Portal vein thrombosis	Hepatobiliary disorders	9 (0.03%)
Product quality issue	Product issues	9 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Rales	Respiratory, thoracic and mediastinal disorders	9 (0.03%)
Renal disorder	Renal and urinary disorders	9 (0.03%)
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	9 (0.03%)
Scab	Skin and subcutaneous tissue disorders	9 (0.03%)
Skin laceration	Injury, poisoning and procedural complications	9 (0.03%)
Skin mass	Skin and subcutaneous tissue disorders	9 (0.03%)
Tearfulness	Psychiatric disorders	9 (0.03%)
Trismus	Musculoskeletal and connective tissue disorders	9 (0.03%)
Upper respiratory tract infection	Infections and infestations	9 (0.03%)
Vitreous floaters	Eye disorders	9 (0.03%)
Abnormal faeces	Gastrointestinal disorders	8 (0.03%)
Blood blister	Skin and subcutaneous tissue disorders	8 (0.03%)
Blood creatine phosphokinase increased	Investigations	8 (0.03%)
Carpal tunnel syndrome	Nervous system disorders	8 (0.03%)
Chronic kidney disease	Renal and urinary disorders	8 (0.03%)
Concussion	Injury, poisoning and procedural complications	8 (0.03%)
Crohn's disease	Gastrointestinal disorders	8 (0.03%)
Delusion	Psychiatric disorders	8 (0.03%)
Dysphemia	Psychiatric disorders	8 (0.03%)
Dysphoria	Psychiatric disorders	8 (0.03%)
Face injury	Injury, poisoning and procedural complications	8 (0.03%)
Foreign body sensation in eyes	Eye disorders	8 (0.03%)
Genital herpes	Infections and infestations	8 (0.03%)
Hallucination, auditory	Psychiatric disorders	8 (0.03%)
Hepatocellular injury	Hepatobiliary disorders	8 (0.03%)
Infarction	Vascular disorders	8 (0.03%)
Injection site warmth	General disorders and administration site conditions	8 (0.03%)
Localised infection	Infections and infestations	8 (0.03%)
Lung infiltration	Respiratory, thoracic and mediastinal disorders	8 (0.03%)
Melaena	Gastrointestinal disorders	8 (0.03%)
Muscle swelling	Musculoskeletal and connective tissue disorders	8 (0.03%)
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	8 (0.03%)
Orthostatic hypotension	Vascular disorders	8 (0.03%)
Papule	Skin and subcutaneous tissue disorders	8 (0.03%)
Parkinson's disease	Nervous system disorders	8 (0.03%)
Peripheral circulatory failure	Vascular disorders	8 (0.03%)
Peripheral embolism	Vascular disorders	8 (0.03%)
Peripheral vascular disorder	Vascular disorders	8 (0.03%)
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	8 (0.03%)
Polyuria	Renal and urinary disorders	8 (0.03%)
Psychotic disorder	Psychiatric disorders	8 (0.03%)
Pyelonephritis	Infections and infestations	8 (0.03%)
Rash morbilliform	Skin and subcutaneous tissue disorders	8 (0.03%)
Red blood cell sedimentation rate increased	Investigations	8 (0.03%)
Retinal vein thrombosis	Eye disorders	8 (0.03%)
Rib fracture	Injury, poisoning and procedural complications	8 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Scratch	Injury, poisoning and procedural complications	8 (0.03%)
Skin infection	Infections and infestations	8 (0.03%)
Skin ulcer	Skin and subcutaneous tissue disorders	8 (0.03%)
Slow speech	Nervous system disorders	8 (0.03%)
Temperature regulation disorder	General disorders and administration site conditions	8 (0.03%)
Testicular pain	Reproductive system and breast disorders	8 (0.03%)
Tongue blistering	Gastrointestinal disorders	8 (0.03%)
Tongue pruritus	Gastrointestinal disorders	8 (0.03%)
Toxic skin eruption	Skin and subcutaneous tissue disorders	8 (0.03%)
Tunnel vision	Nervous system disorders	8 (0.03%)
Type 1 diabetes mellitus	Metabolism and nutrition disorders	8 (0.03%)
Vaccination site infection	Infections and infestations	8 (0.03%)
Vaccination site irritation	General disorders and administration site conditions	8 (0.03%)
Vaccination site joint erythema	General disorders and administration site conditions	8 (0.03%)
Vaccination site joint movement impairment	General disorders and administration site conditions	8 (0.03%)
Vasodilatation	Vascular disorders	8 (0.03%)
Ventricular tachycardia	Cardiac disorders	8 (0.03%)
Activated partial thromboplastin time prolonged	Investigations	7 (0.02%)
Asthmatic crisis	Respiratory, thoracic and mediastinal disorders	7 (0.02%)
Atrioventricular block	Cardiac disorders	7 (0.02%)
Autoimmune thyroiditis	Endocrine disorders	7 (0.02%)
Bradykinesia	Nervous system disorders	7 (0.02%)
Breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.02%)
Cardiac discomfort	Cardiac disorders	7 (0.02%)
Cardiogenic shock	Cardiac disorders	7 (0.02%)
Carotid artery occlusion	Nervous system disorders	7 (0.02%)
Cataract	Eye disorders	7 (0.02%)
Cerebral artery thrombosis	Nervous system disorders	7 (0.02%)
Coronary artery disease	Cardiac disorders	7 (0.02%)
Costochondritis	Musculoskeletal and connective tissue disorders	7 (0.02%)
Disseminated Bacillus Calmette-Guerin infection	Infections and infestations	7 (0.02%)
Facial asymmetry	Musculoskeletal and connective tissue disorders	7 (0.02%)
Functional gastrointestinal disorder	Gastrointestinal disorders	7 (0.02%)
Gastroenteritis viral	Infections and infestations	7 (0.02%)
Haemarthrosis	Musculoskeletal and connective tissue disorders	7 (0.02%)
Haemolytic anaemia	Blood and lymphatic system disorders	7 (0.02%)
Haemorrhage urinary tract	Renal and urinary disorders	7 (0.02%)
Hangover	General disorders and administration site conditions	7 (0.02%)
Herpes ophthalmic	Infections and infestations	7 (0.02%)
Herpes zoster oticus	Infections and infestations	7 (0.02%)
Hip fracture	Injury, poisoning and procedural complications	7 (0.02%)
Hyperleukocytosis	Blood and lymphatic system disorders	7 (0.02%)
Impaired quality of life	Social circumstances	7 (0.02%)
Injection site reaction	General disorders and administration site conditions	7 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Intestinal obstruction	Gastrointestinal disorders	7 (0.02%)
Ischaemia	Vascular disorders	7 (0.02%)
Laryngospasm	Respiratory, thoracic and mediastinal disorders	7 (0.02%)
Liver disorder	Hepatobiliary disorders	7 (0.02%)
Liver function test increased	Investigations	7 (0.02%)
Mesenteric vein thrombosis	Gastrointestinal disorders	7 (0.02%)
Myoclonus	Nervous system disorders	7 (0.02%)
Nasal dryness	Respiratory, thoracic and mediastinal disorders	7 (0.02%)
Nasal oedema	Respiratory, thoracic and mediastinal disorders	7 (0.02%)
Neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.02%)
Neuralgic amyotrophy	Nervous system disorders	7 (0.02%)
Neuritis	Nervous system disorders	7 (0.02%)
Oculomucocutaneous syndrome	Skin and subcutaneous tissue disorders	7 (0.02%)
Optic ischaemic neuropathy	Eye disorders	7 (0.02%)
Phlebitis superficial	Vascular disorders	7 (0.02%)
Rotator cuff syndrome	Musculoskeletal and connective tissue disorders	7 (0.02%)
Scar	Injury, poisoning and procedural complications	7 (0.02%)
Screaming	General disorders and administration site conditions	7 (0.02%)
Soft tissue swelling	Musculoskeletal and connective tissue disorders	7 (0.02%)
Sudden cardiac death	General disorders and administration site conditions	7 (0.02%)
Synovial cyst	Musculoskeletal and connective tissue disorders	7 (0.02%)
Tendon pain	Musculoskeletal and connective tissue disorders	7 (0.02%)
Tongue ulceration	Gastrointestinal disorders	7 (0.02%)
Trigger finger	Musculoskeletal and connective tissue disorders	7 (0.02%)
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	7 (0.02%)
Upper limb fracture	Injury, poisoning and procedural complications	7 (0.02%)
Urine output decreased	Investigations	7 (0.02%)
Vaccination site extravasation	General disorders and administration site conditions	7 (0.02%)
Vaccination site nodule	General disorders and administration site conditions	7 (0.02%)
Vitreous detachment	Eye disorders	7 (0.02%)
Yawning	Respiratory, thoracic and mediastinal disorders	7 (0.02%)
		7 (0.02%)
Abdominal tenderness	Gastrointestinal disorders	6 (0.02%)
Abortion missed	Pregnancy, puerperium and perinatal conditions	6 (0.02%)
Accidental exposure to product	Injury, poisoning and procedural complications	6 (0.02%)
Anal haemorrhage	Gastrointestinal disorders	6 (0.02%)
Atrioventricular block complete	Cardiac disorders	6 (0.02%)
Aura	Nervous system disorders	6 (0.02%)
Autoscopy	Psychiatric disorders	6 (0.02%)
Basedow's disease	Endocrine disorders	6 (0.02%)
Blindness transient	Eye disorders	6 (0.02%)
Blood alkaline phosphatase increased	Investigations	6 (0.02%)
Blood lactate dehydrogenase increased	Investigations	6 (0.02%)
Cardiopulmonary failure	Cardiac disorders	6 (0.02%)
Catarrh	Respiratory, thoracic and mediastinal disorders	6 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral artery occlusion	Nervous system disorders	6 (0.02%)
Cheilitis	Gastrointestinal disorders	6 (0.02%)
Cholestasis	Hepatobiliary disorders	6 (0.02%)
Demyelination	Nervous system disorders	6 (0.02%)
Dermatitis atopic	Skin and subcutaneous tissue disorders	6 (0.02%)
Disseminated intravascular coagulation	Blood and lymphatic system disorders	6 (0.02%)
Dysgraphia	Nervous system disorders	6 (0.02%)
Epigastric discomfort	Gastrointestinal disorders	6 (0.02%)
Erythema of eyelid	Eye disorders	6 (0.02%)
Eyelids pruritus	Eye disorders	6 (0.02%)
Facial discomfort	General disorders and administration site conditions	6 (0.02%)
Facial spasm	Nervous system disorders	6 (0.02%)
Food allergy	Immune system disorders	6 (0.02%)
Frequent bowel movements	Gastrointestinal disorders	6 (0.02%)
Gastric ulcer	Gastrointestinal disorders	6 (0.02%)
Gastrointestinal sounds abnormal	Gastrointestinal disorders	6 (0.02%)
Gingivitis	Infections and infestations	6 (0.02%)
Goitre	Endocrine disorders	6 (0.02%)
Haematocrit decreased	Investigations	6 (0.02%)
Haemorrhoids	Gastrointestinal disorders	6 (0.02%)
Heart rate	Investigations	6 (0.02%)
Immobile	Social circumstances	6 (0.02%)
Incomplete course of vaccination	Injury, poisoning and procedural complications	6 (0.02%)
Initial insomnia	Psychiatric disorders	6 (0.02%)
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	6 (0.02%)
Intestinal haemorrhage	Gastrointestinal disorders	6 (0.02%)
Intracranial pressure increased	Nervous system disorders	6 (0.02%)
Jaw disorder	Musculoskeletal and connective tissue disorders	6 (0.02%)
Joint effusion	Musculoskeletal and connective tissue disorders	6 (0.02%)
Joint lock	Musculoskeletal and connective tissue disorders	6 (0.02%)
Laryngeal discomfort	Respiratory, thoracic and mediastinal disorders	6 (0.02%)
Ligament sprain	Injury, poisoning and procedural complications	6 (0.02%)
Lip blister	Gastrointestinal disorders	6 (0.02%)
Lip disorder	Gastrointestinal disorders	6 (0.02%)
Lip pruritus	Gastrointestinal disorders	6 (0.02%)
Lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (0.02%)
Mastication disorder	Musculoskeletal and connective tissue disorders	6 (0.02%)
Mitral valve incompetence	Cardiac disorders	6 (0.02%)
Mood altered	Psychiatric disorders	6 (0.02%)
Muscle atrophy	Musculoskeletal and connective tissue disorders	6 (0.02%)
Muscle rigidity	Musculoskeletal and connective tissue disorders	6 (0.02%)
Myasthenia gravis	Nervous system disorders	6 (0.02%)
Narcolepsy	Nervous system disorders	6 (0.02%)
Nipple pain	Reproductive system and breast disorders	6 (0.02%)
Occupational exposure to product	Injury, poisoning and procedural complications	6 (0.02%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Ocular vascular disorder	Eye disorders	6 (0.02%)
Ophthalmic vein thrombosis	Eye disorders	6 (0.02%)
Palatal swelling	Gastrointestinal disorders	6 (0.02%)
Pancreatitis	Gastrointestinal disorders	6 (0.02%)
Paraparesis	Nervous system disorders	6 (0.02%)
Periorbital oedema	Eye disorders	6 (0.02%)
Peripheral artery thrombosis	Vascular disorders	6 (0.02%)
Piloerection	Skin and subcutaneous tissue disorders	6 (0.02%)
Pneumonia bacterial	Infections and infestations	6 (0.02%)
PO2 decreased	Investigations	6 (0.02%)
Polymenorrhoea	Reproductive system and breast disorders	6 (0.02%)
Poor peripheral circulation	Vascular disorders	6 (0.02%)
Pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	6 (0.02%)
Pulmonary hypertension	Respiratory, thoracic and mediastinal disorders	6 (0.02%)
Red blood cell count decreased	Investigations	6 (0.02%)
Reduced facial expression	Nervous system disorders	6 (0.02%)
Respiratory acidosis	Respiratory, thoracic and mediastinal disorders	6 (0.02%)
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	6 (0.02%)
Sarcoidosis	Immune system disorders	6 (0.02%)
Sjogren's syndrome	Musculoskeletal and connective tissue disorders	6 (0.02%)
Skin fissures	Skin and subcutaneous tissue disorders	6 (0.02%)
Sopor	Psychiatric disorders	6 (0.02%)
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	6 (0.02%)
Supraventricular extrasystoles	Cardiac disorders	6 (0.02%)
Thermal burn	Injury, poisoning and procedural complications	6 (0.02%)
Thyroid disorder	Endocrine disorders	6 (0.02%)
Urosepsis	Infections and infestations	6 (0.02%)
Vaccination site joint pain	General disorders and administration site conditions	6 (0.02%)
Vaccination site vesicles	General disorders and administration site conditions	6 (0.02%)
Varicose vein	Vascular disorders	6 (0.02%)
Accident	Injury, poisoning and procedural complications	5 (0.02%)
Accidental overdose	Injury, poisoning and procedural complications	5 (0.02%)
Activated partial thromboplastin time shortened	Investigations	5 (0.02%)
Acute abdomen	Gastrointestinal disorders	5 (0.02%)
Affect lability	Psychiatric disorders	5 (0.02%)
Allodynia	Nervous system disorders	5 (0.02%)
Amaurosis fugax	Eye disorders	5 (0.02%)
Anaesthesia	Nervous system disorders	5 (0.02%)
Ankle fracture	Injury, poisoning and procedural complications	5 (0.02%)
Anuria	Renal and urinary disorders	5 (0.02%)
Aortic dissection	Vascular disorders	5 (0.02%)
Arterial thrombosis	Vascular disorders	5 (0.02%)
Aspiration	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Autonomic nervous system imbalance	Nervous system disorders	5 (0.02%)
Bacterial infection	Infections and infestations	5 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bacterial test positive	Investigations	5 (0.02%)
Behaviour disorder	Psychiatric disorders	5 (0.02%)
Blood bilirubin increased	Investigations	5 (0.02%)
Blood cholesterol increased	Investigations	5 (0.02%)
Blood count abnormal	Investigations	5 (0.02%)
Blood potassium increased	Investigations	5 (0.02%)
Blood thyroid stimulating hormone increased	Investigations	5 (0.02%)
Blue toe syndrome	Vascular disorders	5 (0.02%)
Body height decreased	Investigations	5 (0.02%)
Bowel movement irregularity	Gastrointestinal disorders	5 (0.02%)
Cardiac asthma	Cardiac disorders	5 (0.02%)
Cardiomegaly	Cardiac disorders	5 (0.02%)
Cell death	Metabolism and nutrition disorders	5 (0.02%)
Cerebral haematoma	Nervous system disorders	5 (0.02%)
Chest injury	Injury, poisoning and procedural complications	5 (0.02%)
Colitis ischaemic	Gastrointestinal disorders	5 (0.02%)
Coronary artery thrombosis	Cardiac disorders	5 (0.02%)
Craniocerebral injury	Injury, poisoning and procedural complications	5 (0.02%)
Defaecation urgency	Gastrointestinal disorders	5 (0.02%)
Diplegia	Nervous system disorders	5 (0.02%)
Dissociation	Psychiatric disorders	5 (0.02%)
Ear congestion	Ear and labyrinth disorders	5 (0.02%)
Electrocardiogram ST segment elevation	Investigations	5 (0.02%)
Emphysema	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Endocrine ophthalmopathy	Eye disorders	5 (0.02%)
Eosinophilia	Blood and lymphatic system disorders	5 (0.02%)
Excessive cerumen production	Ear and labyrinth disorders	5 (0.02%)
Exposure via skin contact	Injury, poisoning and procedural complications	5 (0.02%)
Eye contusion	Injury, poisoning and procedural complications	5 (0.02%)
Eye infection	Infections and infestations	5 (0.02%)
Eye inflammation	Eye disorders	5 (0.02%)
Eye injury	Injury, poisoning and procedural complications	5 (0.02%)
Eyelid pain	Eye disorders	5 (0.02%)
Femur fracture	Injury, poisoning and procedural complications	5 (0.02%)
Foaming at mouth	General disorders and administration site conditions	5 (0.02%)
Foetal death	Pregnancy, puerperium and perinatal conditions	5 (0.02%)
Gaze palsy	Eye disorders	5 (0.02%)
Generalised oedema	General disorders and administration site conditions	5 (0.02%)
Glaucoma	Eye disorders	5 (0.02%)
Haemophagocytic lymphohistiocytosis	Immune system disorders	5 (0.02%)
Heart injury	Injury, poisoning and procedural complications	5 (0.02%)
Hepatitis acute	Hepatobiliary disorders	5 (0.02%)
Hyperaemia	Vascular disorders	5 (0.02%)
Hyperkalaemia	Metabolism and nutrition disorders	5 (0.02%)
Hypoaesthesia eye	Eye disorders	5 (0.02%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Illrd nerve paralysis	Nervous system disorders	5 (0.02%)
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Injection related reaction	Injury, poisoning and procedural complications	5 (0.02%)
Injection site inflammation	General disorders and administration site conditions	5 (0.02%)
Laboratory test abnormal	Investigations	5 (0.02%)
Lacunar stroke	Nervous system disorders	5 (0.02%)
Lip injury	Injury, poisoning and procedural complications	5 (0.02%)
Liver function test abnormal	Investigations	5 (0.02%)
Liver injury	Hepatobiliary disorders	5 (0.02%)
Lymphocyte count decreased	Investigations	5 (0.02%)
Major depression	Psychiatric disorders	5 (0.02%)
Measles	Infections and infestations	5 (0.02%)
Mental status changes	Psychiatric disorders	5 (0.02%)
Migraine without aura	Nervous system disorders	5 (0.02%)
Muscle discomfort	Musculoskeletal and connective tissue disorders	5 (0.02%)
Myelitis	Infections and infestations	5 (0.02%)
Nasal disorder	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Neck mass	Musculoskeletal and connective tissue disorders	5 (0.02%)
Nephrotic syndrome	Renal and urinary disorders	5 (0.02%)
Neutrophil count decreased	Investigations	5 (0.02%)
Neutrophilia	Blood and lymphatic system disorders	5 (0.02%)
Occipital neuralgia	Nervous system disorders	5 (0.02%)
Oedema mouth	Gastrointestinal disorders	5 (0.02%)
Palatal oedema	Gastrointestinal disorders	5 (0.02%)
Panic disorder	Psychiatric disorders	5 (0.02%)
Partial seizures	Nervous system disorders	5 (0.02%)
Physical deconditioning	General disorders and administration site conditions	5 (0.02%)
Pneumonia viral	Infections and infestations	5 (0.02%)
Postural orthostatic tachycardia syndrome	Cardiac disorders	5 (0.02%)
Premature baby	Pregnancy, puerperium and perinatal conditions	5 (0.02%)
Prostatitis	Reproductive system and breast disorders	5 (0.02%)
Pulmonary mass	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Pustule	Infections and infestations	5 (0.02%)
Reaction to excipient	Immune system disorders	5 (0.02%)
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	5 (0.02%)
Retinal haemorrhage	Eye disorders	5 (0.02%)
Retinal tear	Eye disorders	5 (0.02%)
Retinal vascular thrombosis	Eye disorders	5 (0.02%)
Sense of oppression	General disorders and administration site conditions	5 (0.02%)
Sialoadenitis	Infections and infestations	5 (0.02%)
Skin abrasion	Injury, poisoning and procedural complications	5 (0.02%)
Staphylococcal infection	Infections and infestations	5 (0.02%)
Sudden visual loss	Eye disorders	5 (0.02%)
Systemic inflammatory response syndrome	General disorders and administration site conditions	5 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Tension	Psychiatric disorders	5 (0.02%)
Tongue movement disturbance	Gastrointestinal disorders	5 (0.02%)
Tongue paralysis	Nervous system disorders	5 (0.02%)
Tooth infection	Infections and infestations	5 (0.02%)
Transaminases increased	Investigations	5 (0.02%)
Tricuspid valve incompetence	Cardiac disorders	5 (0.02%)
Trigeminal nerve disorder	Nervous system disorders	5 (0.02%)
Troponin T increased	Investigations	5 (0.02%)
Type IV hypersensitivity reaction	Immune system disorders	5 (0.02%)
Urine abnormality	Renal and urinary disorders	5 (0.02%)
Urine odour abnormal	Renal and urinary disorders	5 (0.02%)
Uveitis	Eye disorders	5 (0.02%)
Vaccination site joint swelling	General disorders and administration site conditions	5 (0.02%)
Varicella	Infections and infestations	5 (0.02%)
Vascular pain	Vascular disorders	5 (0.02%)
Vein disorder	Vascular disorders	5 (0.02%)
Vestibular migraine	Nervous system disorders	5 (0.02%)
Vitreous haemorrhage	Eye disorders	5 (0.02%)
Vulvovaginal pain	Reproductive system and breast disorders	5 (0.02%)
Walking aid user	Social circumstances	5 (0.02%)
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	5 (0.02%)
Wound haemorrhage	Injury, poisoning and procedural complications	5 (0.02%)
Abdominal infection	Infections and infestations	4 (0.01%)
Acidosis	Metabolism and nutrition disorders	4 (0.01%)
Administration site reaction	General disorders and administration site conditions	4 (0.01%)
Adrenocortical insufficiency acute	Endocrine disorders	4 (0.01%)
Allergic oedema	Immune system disorders	4 (0.01%)
Arthropod bite	Injury, poisoning and procedural complications	4 (0.01%)
Arthropod sting	Injury, poisoning and procedural complications	4 (0.01%)
Autoimmune haemolytic anaemia	Blood and lymphatic system disorders	4 (0.01%)
Back disorder	Musculoskeletal and connective tissue disorders	4 (0.01%)
Back injury	Injury, poisoning and procedural complications	4 (0.01%)
Basilar artery thrombosis	Nervous system disorders	4 (0.01%)
Bed rest	Surgical and medical procedures	4 (0.01%)
Bladder disorder	Renal and urinary disorders	4 (0.01%)
Blood calcium decreased	Investigations	4 (0.01%)
Blood disorder	Blood and lymphatic system disorders	4 (0.01%)
Blood glucose fluctuation	Investigations	4 (0.01%)
Blood pressure diastolic increased	Investigations	4 (0.01%)
Brain stem stroke	Nervous system disorders	4 (0.01%)
Breast discomfort	Reproductive system and breast disorders	4 (0.01%)
Breast inflammation	Reproductive system and breast disorders	4 (0.01%)
Breath odour	Gastrointestinal disorders	4 (0.01%)
Bundle branch block left	Cardiac disorders	4 (0.01%)
Bundle branch block right	Cardiac disorders	4 (0.01%)
Candida infection	Infections and infestations	4 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cardiac death	General disorders and administration site conditions	4 (0.01%)
Cardiac fibrillation	Cardiac disorders	4 (0.01%)
Cardiac murmur	Investigations	4 (0.01%)
Cardiospasm	Gastrointestinal disorders	4 (0.01%)
Carotid artery thrombosis	Nervous system disorders	4 (0.01%)
Cerebral artery embolism	Nervous system disorders	4 (0.01%)
Cervical radiculopathy	Nervous system disorders	4 (0.01%)
Chapped lips	Gastrointestinal disorders	4 (0.01%)
Cholelithiasis	Hepatobiliary disorders	4 (0.01%)
Chronic lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.01%)
Circadian rhythm sleep disorder	Nervous system disorders	4 (0.01%)
Clumsiness	Nervous system disorders	4 (0.01%)
Complex regional pain syndrome	Nervous system disorders	4 (0.01%)
Coronary artery stenosis	Cardiac disorders	4 (0.01%)
Counterfeit product administered	Injury, poisoning and procedural complications	4 (0.01%)
Daydreaming	Psychiatric disorders	4 (0.01%)
Deafness transitory	Ear and labyrinth disorders	4 (0.01%)
Decubitus ulcer	Skin and subcutaneous tissue disorders	4 (0.01%)
Dermo-hypodermatitis	Infections and infestations	4 (0.01%)
Diaphragmalgia	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Disease progression	General disorders and administration site conditions	4 (0.01%)
Disorganised speech	Psychiatric disorders	4 (0.01%)
Diverticulum intestinal	Gastrointestinal disorders	4 (0.01%)
Ear haemorrhage	Ear and labyrinth disorders	4 (0.01%)
Endometriosis	Reproductive system and breast disorders	4 (0.01%)
Enteritis	Gastrointestinal disorders	4 (0.01%)
Escherichia urinary tract infection	Infections and infestations	4 (0.01%)
Extrapyramidal disorder	Nervous system disorders	4 (0.01%)
Eyelid disorder	Eye disorders	4 (0.01%)
Eyelid function disorder	Eye disorders	4 (0.01%)
Eye oedema	Eye disorders	4 (0.01%)
Facial neuralgia	Nervous system disorders	4 (0.01%)
Fear of death	Psychiatric disorders	4 (0.01%)
Feeling of despair	Psychiatric disorders	4 (0.01%)
Fine motor skill dysfunction	Nervous system disorders	4 (0.01%)
Food aversion	Metabolism and nutrition disorders	4 (0.01%)
Food intolerance	Metabolism and nutrition disorders	4 (0.01%)
Fungal infection	Infections and infestations	4 (0.01%)
Gallbladder disorder	Hepatobiliary disorders	4 (0.01%)
Gastric haemorrhage	Gastrointestinal disorders	4 (0.01%)
Gastrointestinal motility disorder	Gastrointestinal disorders	4 (0.01%)
Gingival discomfort	Gastrointestinal disorders	4 (0.01%)
Haematoma muscle	Musculoskeletal and connective tissue disorders	4 (0.01%)
Haemodynamic instability	Vascular disorders	4 (0.01%)
Haemorrhage intracranial	Nervous system disorders	4 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Haemorrhagic diathesis	Blood and lymphatic system disorders	4 (0.01%)
Hair texture abnormal	Skin and subcutaneous tissue disorders	4 (0.01%)
Hemianopia homonymous	Nervous system disorders	4 (0.01%)
Hepatic pain	Hepatobiliary disorders	4 (0.01%)
Hordeolum	Infections and infestations	4 (0.01%)
Hunger	General disorders and administration site conditions	4 (0.01%)
Hyperbilirubinaemia	Hepatobiliary disorders	4 (0.01%)
Hypertensive emergency	Vascular disorders	4 (0.01%)
Hypertensive heart disease	Cardiac disorders	4 (0.01%)
Hyposmia	Nervous system disorders	4 (0.01%)
Idiopathic intracranial hypertension	Nervous system disorders	4 (0.01%)
Impaired gastric emptying	Gastrointestinal disorders	4 (0.01%)
Increased tendency to bruise	Blood and lymphatic system disorders	4 (0.01%)
Infectious mononucleosis	Infections and infestations	4 (0.01%)
Intentional product misuse	Injury, poisoning and procedural complications	4 (0.01%)
Intracranial aneurysm	Nervous system disorders	4 (0.01%)
Joint noise	Musculoskeletal and connective tissue disorders	4 (0.01%)
Joint warmth	Musculoskeletal and connective tissue disorders	4 (0.01%)
Lack of spontaneous speech	Psychiatric disorders	4 (0.01%)
Lagophthalmos	Eye disorders	4 (0.01%)
Language disorder	Nervous system disorders	4 (0.01%)
Left ventricular dysfunction	Cardiac disorders	4 (0.01%)
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.01%)
Loss of control of legs	General disorders and administration site conditions	4 (0.01%)
Lung opacity	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Lymph gland infection	Infections and infestations	4 (0.01%)
Maternal exposure before pregnancy	Injury, poisoning and procedural complications	4 (0.01%)
Metamorphopsia	Eye disorders	4 (0.01%)
Mucous stools	Gastrointestinal disorders	4 (0.01%)
Muscle contracture	Musculoskeletal and connective tissue disorders	4 (0.01%)
Mutism	Psychiatric disorders	4 (0.01%)
Myasthenia gravis crisis	Nervous system disorders	4 (0.01%)
Myocardial ischaemia	Cardiac disorders	4 (0.01%)
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Needle issue	Product issues	4 (0.01%)
Nephropathy	Renal and urinary disorders	4 (0.01%)
N-terminal prohormone brain natriuretic peptide increased	Investigations	4 (0.01%)
Nuchal rigidity	Musculoskeletal and connective tissue disorders	4 (0.01%)
Oligomenorrhoea	Reproductive system and breast disorders	4 (0.01%)
Oliguria	Renal and urinary disorders	4 (0.01%)
Oral mucosal eruption	Gastrointestinal disorders	4 (0.01%)
Parkinsonism	Nervous system disorders	4 (0.01%)
Parotid gland enlargement	Gastrointestinal disorders	4 (0.01%)
Pemphigoid	Skin and subcutaneous tissue disorders	4 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Peroneal nerve palsy	Nervous system disorders	4 (0.01%)
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Pharyngeal mass	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Platelet disorder	Blood and lymphatic system disorders	4 (0.01%)
Poisoning	Injury, poisoning and procedural complications	4 (0.01%)
Potentiating drug interaction	General disorders and administration site conditions	4 (0.01%)
Product administration error	Injury, poisoning and procedural complications	4 (0.01%)
Prostate cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.01%)
Prothrombin time prolonged	Investigations	4 (0.01%)
Pulmonary arterial pressure increased	Investigations	4 (0.01%)
Pulmonary haemorrhage	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Pulse absent	Investigations	4 (0.01%)
Pupils unequal	Eye disorders	4 (0.01%)
Renal cyst	Renal and urinary disorders	4 (0.01%)
Retinal detachment	Eye disorders	4 (0.01%)
Rheumatic disorder	Musculoskeletal and connective tissue disorders	4 (0.01%)
Sacroiliitis	Musculoskeletal and connective tissue disorders	4 (0.01%)
SARS-CoV-2 test negative	Investigations	4 (0.01%)
Scleritis	Eye disorders	4 (0.01%)
Skin temperature	Investigations	4 (0.01%)
Skin wrinkling	Skin and subcutaneous tissue disorders	4 (0.01%)
Sleep apnoea syndrome	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Sleep deficit	Nervous system disorders	4 (0.01%)
Sleep terror	Psychiatric disorders	4 (0.01%)
Snoring	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Splenic infarction	Blood and lymphatic system disorders	4 (0.01%)
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	4 (0.01%)
Stress cardiomyopathy	Cardiac disorders	4 (0.01%)
Superinfection bacterial	Infections and infestations	4 (0.01%)
Suspected counterfeit product	Product issues	4 (0.01%)
Tetany	Metabolism and nutrition disorders	4 (0.01%)
Thrombocytopenic purpura	Blood and lymphatic system disorders	4 (0.01%)
Thrombotic stroke	Nervous system disorders	4 (0.01%)
Thrombotic thrombocytopenic purpura	Blood and lymphatic system disorders	4 (0.01%)
Tongue biting	Nervous system disorders	4 (0.01%)
Tongue erythema	Gastrointestinal disorders	4 (0.01%)
Tonic convulsion	Nervous system disorders	4 (0.01%)
Tooth abscess	Infections and infestations	4 (0.01%)
Tooth disorder	Gastrointestinal disorders	4 (0.01%)
Tooth fracture	Injury, poisoning and procedural complications	4 (0.01%)
Toxicity to various agents	Injury, poisoning and procedural complications	4 (0.01%)
Troponin I increased	Investigations	4 (0.01%)
Type 2 diabetes mellitus	Metabolism and nutrition disorders	4 (0.01%)
Urticaria chronic	Skin and subcutaneous tissue disorders	4 (0.01%)
Uterine haemorrhage	Reproductive system and breast disorders	4 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vaccination site hyperaesthesia	General disorders and administration site conditions	4 (0.01%)
Vasoconstriction	Vascular disorders	4 (0.01%)
Ventricular hypokinesia	Cardiac disorders	4 (0.01%)
Vestibular disorder	Ear and labyrinth disorders	4 (0.01%)
Vitamin D decreased	Investigations	4 (0.01%)
Vitamin D deficiency	Metabolism and nutrition disorders	4 (0.01%)
Vulvovaginal candidiasis	Infections and infestations	4 (0.01%)
Abdominal mass	Gastrointestinal disorders	3 (0.01%)
Abdominal rigidity	Gastrointestinal disorders	3 (0.01%)
Abortion	Pregnancy, puerperium and perinatal conditions	3 (0.01%)
Acoustic neuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.01%)
Acute disseminated encephalomyelitis	Nervous system disorders	3 (0.01%)
Acute psychosis	Psychiatric disorders	3 (0.01%)
Administration site pain	General disorders and administration site conditions	3 (0.01%)
Adverse event following immunisation	Injury, poisoning and procedural complications	3 (0.01%)
Affective disorder	Psychiatric disorders	3 (0.01%)
Allergic cough	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Allergic reaction to excipient	Immune system disorders	3 (0.01%)
Aneurysm	Vascular disorders	3 (0.01%)
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	3 (0.01%)
Antibody test abnormal	Investigations	3 (0.01%)
Anticoagulation drug level below therapeutic	Investigations	3 (0.01%)
Aortic aneurysm	Vascular disorders	3 (0.01%)
Aortic embolus	Vascular disorders	3 (0.01%)
Aortic valve incompetence	Cardiac disorders	3 (0.01%)
Arterial occlusive disease	Vascular disorders	3 (0.01%)
Arteriosclerosis	Vascular disorders	3 (0.01%)
Asphyxia	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Atelectasis	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Attention deficit hyperactivity disorder	Psychiatric disorders	3 (0.01%)
Auditory disorder	Ear and labyrinth disorders	3 (0.01%)
Axillary lymphadenectomy	Surgical and medical procedures	3 (0.01%)
Bacterial sepsis	Infections and infestations	3 (0.01%)
Biliary colic	Hepatobiliary disorders	3 (0.01%)
Blepharitis	Eye disorders	3 (0.01%)
Blood cholesterol abnormal	Investigations	3 (0.01%)
Blood fibrinogen decreased	Investigations	3 (0.01%)
Blood fibrinogen increased	Investigations	3 (0.01%)
Blood iron decreased	Investigations	3 (0.01%)
Blood lactic acid increased	Investigations	3 (0.01%)
Blood pressure diastolic decreased	Investigations	3 (0.01%)
Blood pressure systolic decreased	Investigations	3 (0.01%)
Blood urea increased	Investigations	3 (0.01%)
Bloody discharge	Vascular disorders	3 (0.01%)
Bone disorder	Musculoskeletal and connective tissue disorders	3 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bone swelling	Musculoskeletal and connective tissue disorders	3 (0.01%)
Brain death	General disorders and administration site conditions	3 (0.01%)
Brain injury	Nervous system disorders	3 (0.01%)
Brain natriuretic peptide increased	Investigations	3 (0.01%)
Brain oedema	Nervous system disorders	3 (0.01%)
Brain stem infarction	Nervous system disorders	3 (0.01%)
Breast disorder	Reproductive system and breast disorders	3 (0.01%)
Bronchiectasis	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Bronchostenosis	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Cardiac tamponade	Cardiac disorders	3 (0.01%)
Cardiomyopathy	Cardiac disorders	3 (0.01%)
Cardiovascular insufficiency	Cardiac disorders	3 (0.01%)
Cerebellar infarction	Nervous system disorders	3 (0.01%)
Cerebellar stroke	Nervous system disorders	3 (0.01%)
Cerebral palsy	Congenital, familial and genetic disorders	3 (0.01%)
Cerebrovascular disorder	Nervous system disorders	3 (0.01%)
Cholecystitis	Hepatobiliary disorders	3 (0.01%)
Clonus	Nervous system disorders	3 (0.01%)
Coccydynia	Musculoskeletal and connective tissue disorders	3 (0.01%)
Cold-stimulus headache	Nervous system disorders	3 (0.01%)
Communication disorder	Psychiatric disorders	3 (0.01%)
Contraindicated product administered	Injury, poisoning and procedural complications	3 (0.01%)
Conversion disorder	Psychiatric disorders	3 (0.01%)
Coronary artery occlusion	Cardiac disorders	3 (0.01%)
COVID-19 immunisation	Surgical and medical procedures	3 (0.01%)
Creutzfeldt-Jakob disease	Infections and infestations	3 (0.01%)
Cyst	General disorders and administration site conditions	3 (0.01%)
Decreased activity	General disorders and administration site conditions	3 (0.01%)
Decreased interest	Psychiatric disorders	3 (0.01%)
Dermatitis contact	Skin and subcutaneous tissue disorders	3 (0.01%)
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	3 (0.01%)
Dermatomyositis	Skin and subcutaneous tissue disorders	3 (0.01%)
Disseminated varicella zoster virus infection	Infections and infestations	3 (0.01%)
Drug-induced liver injury	Hepatobiliary disorders	3 (0.01%)
Drug reaction with eosinophilia and systemic symptoms	Skin and subcutaneous tissue disorders	3 (0.01%)
Dysmetria	Nervous system disorders	3 (0.01%)
Embolic cerebral infarction	Nervous system disorders	3 (0.01%)
Embolism venous	Vascular disorders	3 (0.01%)
Enterocolitis	Gastrointestinal disorders	3 (0.01%)
Enuresis	Psychiatric disorders	3 (0.01%)
Essential hypertension	Vascular disorders	3 (0.01%)
Exophthalmos	Eye disorders	3 (0.01%)
External ear pain	Ear and labyrinth disorders	3 (0.01%)
Extremity necrosis	Vascular disorders	3 (0.01%)
Eyelid irritation	Eye disorders	3 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Facial nerve disorder	Nervous system disorders	3 (0.01%)
Fluid intake reduced	Metabolism and nutrition disorders	3 (0.01%)
Focal dyscognitive seizures	Nervous system disorders	3 (0.01%)
Food poisoning	Gastrointestinal disorders	3 (0.01%)
Foot fracture	Injury, poisoning and procedural complications	3 (0.01%)
Frustration tolerance decreased	Psychiatric disorders	3 (0.01%)
Furuncle	Infections and infestations	3 (0.01%)
Gastric dilatation	Gastrointestinal disorders	3 (0.01%)
Gastrointestinal necrosis	Gastrointestinal disorders	3 (0.01%)
Glomerulonephritis minimal lesion	Renal and urinary disorders	3 (0.01%)
Glossitis	Gastrointestinal disorders	3 (0.01%)
Grunting	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Habit cough	Psychiatric disorders	3 (0.01%)
Hallucinations, mixed	Psychiatric disorders	3 (0.01%)
Head titubation	Nervous system disorders	3 (0.01%)
Hemianaesthesia	Nervous system disorders	3 (0.01%)
Hemianopia	Nervous system disorders	3 (0.01%)
Hepatic cyst	Hepatobiliary disorders	3 (0.01%)
Hepatic enzyme abnormal	Investigations	3 (0.01%)
Hepatic steatosis	Hepatobiliary disorders	3 (0.01%)
Hepatomegaly	Hepatobiliary disorders	3 (0.01%)
Herpes simplex reactivation	Infections and infestations	3 (0.01%)
Herpes zoster meningoencephalitis	Infections and infestations	3 (0.01%)
Hiatus hernia	Gastrointestinal disorders	3 (0.01%)
Hyperlactacidaemia	Metabolism and nutrition disorders	3 (0.01%)
Hypernatraemia	Metabolism and nutrition disorders	3 (0.01%)
Hypertensive urgency	Vascular disorders	3 (0.01%)
Hypertonia	Nervous system disorders	3 (0.01%)
Hypomenorrhoea	Reproductive system and breast disorders	3 (0.01%)
Hypotonic-hyporesponsive episode	Nervous system disorders	3 (0.01%)
Hypoventilation	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Ileus paralytic	Gastrointestinal disorders	3 (0.01%)
Ill-defined disorder	General disorders and administration site conditions	3 (0.01%)
Immunodeficiency	Immune system disorders	3 (0.01%)
Impaired healing	General disorders and administration site conditions	3 (0.01%)
Injection site urticaria	General disorders and administration site conditions	3 (0.01%)
Inner ear disorder	Ear and labyrinth disorders	3 (0.01%)
Iron deficiency	Metabolism and nutrition disorders	3 (0.01%)
Irregular breathing	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Jugular vein thrombosis	Vascular disorders	3 (0.01%)
Keratitis	Eye disorders	3 (0.01%)
Large intestine infection	Infections and infestations	3 (0.01%)
Laryngitis	Infections and infestations	3 (0.01%)
Leukoencephalopathy	Nervous system disorders	3 (0.01%)
Lipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Lip ulceration	Gastrointestinal disorders	3 (0.01%)
Loss of libido	Psychiatric disorders	3 (0.01%)
Lower limb fracture	Injury, poisoning and procedural complications	3 (0.01%)
Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Lung neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.01%)
Lymph node palpable	Investigations	3 (0.01%)
Lymphocytosis	Blood and lymphatic system disorders	3 (0.01%)
Macroglossia	Congenital, familial and genetic disorders	3 (0.01%)
Macular oedema	Eye disorders	3 (0.01%)
Maculopathy	Eye disorders	3 (0.01%)
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	3 (0.01%)
Medication error	Injury, poisoning and procedural complications	3 (0.01%)
Meningitis aseptic	Infections and infestations	3 (0.01%)
Moaning	General disorders and administration site conditions	3 (0.01%)
Monoclonal gammopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.01%)
Monocytosis	Blood and lymphatic system disorders	3 (0.01%)
Mucosal dryness	General disorders and administration site conditions	3 (0.01%)
Muscle spasticity	Nervous system disorders	3 (0.01%)
Nail discolouration	Skin and subcutaneous tissue disorders	3 (0.01%)
Nipple swelling	Reproductive system and breast disorders	3 (0.01%)
Non-cardiac chest pain	General disorders and administration site conditions	3 (0.01%)
Noninfective gingivitis	Gastrointestinal disorders	3 (0.01%)
Oesophagitis	Gastrointestinal disorders	3 (0.01%)
Onychoclasia	Skin and subcutaneous tissue disorders	3 (0.01%)
Oral blood blister	Gastrointestinal disorders	3 (0.01%)
Oral lichen planus	Gastrointestinal disorders	3 (0.01%)
Oral mucosal erythema	Gastrointestinal disorders	3 (0.01%)
Oral mucosal exfoliation	Gastrointestinal disorders	3 (0.01%)
Orbital oedema	Eye disorders	3 (0.01%)
Orthopnoea	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Orthostatic intolerance	Nervous system disorders	3 (0.01%)
Otitis media	Infections and infestations	3 (0.01%)
Oversensing	Product issues	3 (0.01%)
Paraesthesia ear	Ear and labyrinth disorders	3 (0.01%)
Paranoia	Psychiatric disorders	3 (0.01%)
Parotitis	Infections and infestations	3 (0.01%)
Peak expiratory flow rate decreased	Investigations	3 (0.01%)
Pericardial haemorrhage	Cardiac disorders	3 (0.01%)
Periorbital pain	Eye disorders	3 (0.01%)
Peripheral sensory neuropathy	Nervous system disorders	3 (0.01%)
Personality change	Psychiatric disorders	3 (0.01%)
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Pigmentation disorder	Skin and subcutaneous tissue disorders	3 (0.01%)
Plantar fasciitis	Musculoskeletal and connective tissue disorders	3 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Platelet count abnormal	Investigations	3 (0.01%)
Pleurisy	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Polydipsia	Metabolism and nutrition disorders	3 (0.01%)
Posture abnormal	Musculoskeletal and connective tissue disorders	3 (0.01%)
Pre-existing condition improved	General disorders and administration site conditions	3 (0.01%)
Procalcitonin increased	Investigations	3 (0.01%)
Product colour issue	Product issues	3 (0.01%)
Proteinuria	Renal and urinary disorders	3 (0.01%)
Protein urine present	Investigations	3 (0.01%)
Pupil fixed	Eye disorders	3 (0.01%)
Q fever	Infections and infestations	3 (0.01%)
Quality of life decreased	Investigations	3 (0.01%)
Radial nerve palsy	Nervous system disorders	3 (0.01%)
Radial pulse abnormal	Investigations	3 (0.01%)
Rash pustular	Infections and infestations	3 (0.01%)
Renal colic	Renal and urinary disorders	3 (0.01%)
Renal infarct	Renal and urinary disorders	3 (0.01%)
Right ventricular failure	Cardiac disorders	3 (0.01%)
Salivary gland enlargement	Gastrointestinal disorders	3 (0.01%)
Salivary gland pain	Gastrointestinal disorders	3 (0.01%)
SARS-CoV-2 antibody test	Investigations	3 (0.01%)
SARS-CoV-2 test false positive	Investigations	3 (0.01%)
Sedation	Nervous system disorders	3 (0.01%)
Sensory level abnormal	Investigations	3 (0.01%)
Severe acute respiratory syndrome	Infections and infestations	3 (0.01%)
Shoulder injury related to vaccine administration	General disorders and administration site conditions	3 (0.01%)
Sickle cell anaemia with crisis	Blood and lymphatic system disorders	3 (0.01%)
Sitting disability	Social circumstances	3 (0.01%)
Skin erosion	Skin and subcutaneous tissue disorders	3 (0.01%)
Skin induration	Skin and subcutaneous tissue disorders	3 (0.01%)
Skin necrosis	Skin and subcutaneous tissue disorders	3 (0.01%)
Skin plaque	Skin and subcutaneous tissue disorders	3 (0.01%)
Sleep disorder due to a general medical condition	Psychiatric disorders	3 (0.01%)
Spinal cord ischaemia	Nervous system disorders	3 (0.01%)
Splenic rupture	Injury, poisoning and procedural complications	3 (0.01%)
Splenomegaly	Blood and lymphatic system disorders	3 (0.01%)
Sputum increased	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Sputum purulent	Infections and infestations	3 (0.01%)
Staphylococcal sepsis	Infections and infestations	3 (0.01%)
Staring	Psychiatric disorders	3 (0.01%)
Stenosis	General disorders and administration site conditions	3 (0.01%)
Strabismus	Eye disorders	3 (0.01%)
Stupor	Nervous system disorders	3 (0.01%)
Subclavian vein thrombosis	Vascular disorders	3 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Subcutaneous haematoma	Injury, poisoning and procedural complications	3 (0.01%)
Subdural haemorrhage	Injury, poisoning and procedural complications	3 (0.01%)
Sunburn	Injury, poisoning and procedural complications	3 (0.01%)
Superficial vein prominence	Vascular disorders	3 (0.01%)
Systemic immune activation	Immune system disorders	3 (0.01%)
Systemic lupus erythematosus rash	Skin and subcutaneous tissue disorders	3 (0.01%)
Tachyarrhythmia	Cardiac disorders	3 (0.01%)
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	3 (0.01%)
Tendon rupture	Injury, poisoning and procedural complications	3 (0.01%)
Tenosynovitis	Musculoskeletal and connective tissue disorders	3 (0.01%)
Testicular swelling	Reproductive system and breast disorders	3 (0.01%)
Thyroiditis subacute	Endocrine disorders	3 (0.01%)
Thyroid mass	Endocrine disorders	3 (0.01%)
Thyrotoxic crisis	Endocrine disorders	3 (0.01%)
Tongue coated	Gastrointestinal disorders	3 (0.01%)
Tongue dry	Gastrointestinal disorders	3 (0.01%)
Tongue eruption	Gastrointestinal disorders	3 (0.01%)
Tonic clonic movements	Nervous system disorders	3 (0.01%)
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Tooth extraction	Surgical and medical procedures	3 (0.01%)
Tracheal stenosis	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Tracheitis	Infections and infestations	3 (0.01%)
Transient aphasia	Nervous system disorders	3 (0.01%)
Transient global amnesia	Nervous system disorders	3 (0.01%)
Type III immune complex mediated reaction	Immune system disorders	3 (0.01%)
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	3 (0.01%)
Urinary tract infection bacterial	Infections and infestations	3 (0.01%)
Urine analysis abnormal	Investigations	3 (0.01%)
Urine ketone body present	Investigations	3 (0.01%)
Vaccination error	Injury, poisoning and procedural complications	3 (0.01%)
Vaccination site abscess	Infections and infestations	3 (0.01%)
Vaccination site coldness	General disorders and administration site conditions	3 (0.01%)
Vaccination site granuloma	General disorders and administration site conditions	3 (0.01%)
Vaccination site necrosis	General disorders and administration site conditions	3 (0.01%)
Vaccination site papule	General disorders and administration site conditions	3 (0.01%)
Vaccination site pustule	Infections and infestations	3 (0.01%)
Vascular injury	Injury, poisoning and procedural complications	3 (0.01%)
Vascular purpura	Skin and subcutaneous tissue disorders	3 (0.01%)
Vascular stent thrombosis	General disorders and administration site conditions	3 (0.01%)
Vasculitic rash	Skin and subcutaneous tissue disorders	3 (0.01%)
Venous injury	Injury, poisoning and procedural complications	3 (0.01%)
Vertebral artery dissection	Nervous system disorders	3 (0.01%)
Viral rash	Infections and infestations	3 (0.01%)
Vitamin B12 decreased	Investigations	3 (0.01%)
Vulvovaginal burning sensation	Reproductive system and breast disorders	3 (0.01%)
Walking disability	Social circumstances	3 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Weight fluctuation	Metabolism and nutrition disorders	3 (0.01%)
White blood cell count abnormal	Investigations	3 (0.01%)
White blood cells urine positive	Investigations	3 (0.01%)
Wound infection	Infections and infestations	3 (0.01%)
Yellow skin	Skin and subcutaneous tissue disorders	3 (0.01%)
Abdominal symptom	Gastrointestinal disorders	2 (0.01%)
Acquired haemophilia	Blood and lymphatic system disorders	2 (0.01%)
Acute febrile neutrophilic dermatosis	Skin and subcutaneous tissue disorders	2 (0.01%)
Acute generalised exanthematous pustulosis	Skin and subcutaneous tissue disorders	2 (0.01%)
Acute myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.01%)
Acute vestibular syndrome	Ear and labyrinth disorders	2 (0.01%)
Administration site movement impairment	General disorders and administration site conditions	2 (0.01%)
Age-related macular degeneration	Eye disorders	2 (0.01%)
Akinesia	Nervous system disorders	2 (0.01%)
Alcohol intolerance	Metabolism and nutrition disorders	2 (0.01%)
Allergy to arthropod sting	Immune system disorders	2 (0.01%)
Alopecia areata	Skin and subcutaneous tissue disorders	2 (0.01%)
Altered visual depth perception	Eye disorders	2 (0.01%)
Amylase increased	Investigations	2 (0.01%)
Anaemia macrocytic	Blood and lymphatic system disorders	2 (0.01%)
Anaemia vitamin B12 deficiency	Blood and lymphatic system disorders	2 (0.01%)
Anal pruritus	Gastrointestinal disorders	2 (0.01%)
Androgenetic alopecia	Skin and subcutaneous tissue disorders	2 (0.01%)
Anembryonic gestation	Pregnancy, puerperium and perinatal conditions	2 (0.01%)
Anger	Psychiatric disorders	2 (0.01%)
Angiopathy	Vascular disorders	2 (0.01%)
Anorectal discomfort	Gastrointestinal disorders	2 (0.01%)
Antibody test negative	Investigations	2 (0.01%)
Aortic arteriosclerosis	Vascular disorders	2 (0.01%)
Aortic stenosis	Vascular disorders	2 (0.01%)
Aortic valve calcification	Cardiac disorders	2 (0.01%)
Appetite disorder	Metabolism and nutrition disorders	2 (0.01%)
Application site erythema	General disorders and administration site conditions	2 (0.01%)
Areflexia	Nervous system disorders	2 (0.01%)
Arrhythmia supraventricular	Cardiac disorders	2 (0.01%)
Arterial disorder	Vascular disorders	2 (0.01%)
Arteriosclerosis coronary artery	Cardiac disorders	2 (0.01%)
Arteriovenous fistula thrombosis	Injury, poisoning and procedural complications	2 (0.01%)
Autoimmune hepatitis	Hepatobiliary disorders	2 (0.01%)
Autoimmune neutropenia	Blood and lymphatic system disorders	2 (0.01%)
Bacille Calmette-Guerin scar reactivation	Immune system disorders	2 (0.01%)
Bacterial vaginosis	Infections and infestations	2 (0.01%)
Basal ganglia stroke	Nervous system disorders	2 (0.01%)
Behcet's syndrome	Vascular disorders	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Benign prostatic hyperplasia	Reproductive system and breast disorders	2 (0.01%)
Biliary tract disorder	Hepatobiliary disorders	2 (0.01%)
Binocular eye movement disorder	Eye disorders	2 (0.01%)
Bladder discomfort	Renal and urinary disorders	2 (0.01%)
Bladder dysfunction	Renal and urinary disorders	2 (0.01%)
Blood bicarbonate decreased	Investigations	2 (0.01%)
Blood bilirubin abnormal	Investigations	2 (0.01%)
Blood creatinine abnormal	Investigations	2 (0.01%)
Blood folate decreased	Investigations	2 (0.01%)
Blood gases abnormal	Investigations	2 (0.01%)
Blood glucose abnormal	Investigations	2 (0.01%)
Blood iron increased	Investigations	2 (0.01%)
Blood phosphorus decreased	Investigations	2 (0.01%)
Blood pressure ambulatory increased	Investigations	2 (0.01%)
Blood pressure systolic abnormal	Investigations	2 (0.01%)
Blood triglycerides increased	Investigations	2 (0.01%)
Bone neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.01%)
Brachial plexus injury	Injury, poisoning and procedural complications	2 (0.01%)
Brain neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.01%)
Breast engorgement	Reproductive system and breast disorders	2 (0.01%)
Breast haematoma	Reproductive system and breast disorders	2 (0.01%)
Breast oedema	Reproductive system and breast disorders	2 (0.01%)
Bronchial obstruction	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Bruxism	Psychiatric disorders	2 (0.01%)
Burn oral cavity	Injury, poisoning and procedural complications	2 (0.01%)
Cachexia	Metabolism and nutrition disorders	2 (0.01%)
Cardiac failure chronic	Cardiac disorders	2 (0.01%)
Central nervous system lesion	Nervous system disorders	2 (0.01%)
Cerebellar ataxia	Nervous system disorders	2 (0.01%)
Cerebellar haematoma	Nervous system disorders	2 (0.01%)
Cerebellar haemorrhage	Nervous system disorders	2 (0.01%)
Cerebral disorder	Nervous system disorders	2 (0.01%)
Cervicobrachial syndrome	Nervous system disorders	2 (0.01%)
Change of bowel habit	Gastrointestinal disorders	2 (0.01%)
Chest crushing	Injury, poisoning and procedural complications	2 (0.01%)
Chest X-ray abnormal	Investigations	2 (0.01%)
Cholangitis	Hepatobiliary disorders	2 (0.01%)
Cholinergic syndrome	Nervous system disorders	2 (0.01%)
Chromatopsia	Eye disorders	2 (0.01%)
Circumoral oedema	Skin and subcutaneous tissue disorders	2 (0.01%)
Circumoral swelling	Skin and subcutaneous tissue disorders	2 (0.01%)
Clostridium difficile colitis	Infections and infestations	2 (0.01%)
Cold urticaria	Skin and subcutaneous tissue disorders	2 (0.01%)
Concomitant disease aggravated	General disorders and administration site conditions	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Conjunctival oedema	Eye disorders	2 (0.01%)
Corneal reflex decreased	Investigations	2 (0.01%)
Coronary artery dissection	Cardiac disorders	2 (0.01%)
Cranial nerve palsies multiple	Nervous system disorders	2 (0.01%)
C-reactive protein abnormal	Investigations	2 (0.01%)
Cutaneous vasculitis	Skin and subcutaneous tissue disorders	2 (0.01%)
Cystitis haemorrhagic	Renal and urinary disorders	2 (0.01%)
Dark circles under eyes	Eye disorders	2 (0.01%)
Deafness bilateral	Ear and labyrinth disorders	2 (0.01%)
Decreased embryo viability	Injury, poisoning and procedural complications	2 (0.01%)
Decreased vibratory sense	Nervous system disorders	2 (0.01%)
Delayed recovery from anaesthesia	Injury, poisoning and procedural complications	2 (0.01%)
Dementia Alzheimer's type	Nervous system disorders	2 (0.01%)
Demyelinating polyneuropathy	Nervous system disorders	2 (0.01%)
Dental caries	Gastrointestinal disorders	2 (0.01%)
Depersonalisation/derealisation disorder	Psychiatric disorders	2 (0.01%)
Derealisation	Psychiatric disorders	2 (0.01%)
Diabetic coma	Nervous system disorders	2 (0.01%)
Diabetic ketoacidosis	Metabolism and nutrition disorders	2 (0.01%)
Diaphragmatic disorder	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Diarrhoea infectious	Infections and infestations	2 (0.01%)
Dilatation atrial	Cardiac disorders	2 (0.01%)
Drowning	General disorders and administration site conditions	2 (0.01%)
Drug level increased	Investigations	2 (0.01%)
Duodenogastric reflux	Gastrointestinal disorders	2 (0.01%)
Dyschezia	Gastrointestinal disorders	2 (0.01%)
Dyschromatopsia	Eye disorders	2 (0.01%)
Dyslalia	Nervous system disorders	2 (0.01%)
Dyslexia	Nervous system disorders	2 (0.01%)
Electrocardiogram ST segment depression	Investigations	2 (0.01%)
Electrocardiogram T wave inversion	Investigations	2 (0.01%)
Encephalitis autoimmune	Nervous system disorders	2 (0.01%)
Encephalitis viral	Infections and infestations	2 (0.01%)
Encephalopathy	Nervous system disorders	2 (0.01%)
Enterococcal infection	Infections and infestations	2 (0.01%)
Enthesopathy	Musculoskeletal and connective tissue disorders	2 (0.01%)
Eosinophil count increased	Investigations	2 (0.01%)
Epicondylitis	Injury, poisoning and procedural complications	2 (0.01%)
Epiglottitis	Infections and infestations	2 (0.01%)
Erythema annulare	Skin and subcutaneous tissue disorders	2 (0.01%)
Escherichia bacteraemia	Infections and infestations	2 (0.01%)
Escherichia infection	Infections and infestations	2 (0.01%)
Exfoliative rash	Skin and subcutaneous tissue disorders	2 (0.01%)
Extraocular muscle disorder	Eye disorders	2 (0.01%)
Extraocular muscle paresis	Eye disorders	2 (0.01%)
Eyelid rash	Eye disorders	2 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Eye symptom	Eye disorders	2 (0.01%)
Faecal calprotectin increased	Investigations	2 (0.01%)
Faecaloma	Gastrointestinal disorders	2 (0.01%)
Faeces hard	Gastrointestinal disorders	2 (0.01%)
Feeling of relaxation	General disorders and administration site conditions	2 (0.01%)
Femoral neck fracture	Injury, poisoning and procedural complications	2 (0.01%)
Fever neonatal	General disorders and administration site conditions	2 (0.01%)
Fluid imbalance	Metabolism and nutrition disorders	2 (0.01%)
Fluid overload	Metabolism and nutrition disorders	2 (0.01%)
Foetal exposure during pregnancy	Injury, poisoning and procedural complications	2 (0.01%)
Foetal hypokinesia	Pregnancy, puerperium and perinatal conditions	2 (0.01%)
Food refusal	Metabolism and nutrition disorders	2 (0.01%)
Foot deformity	Musculoskeletal and connective tissue disorders	2 (0.01%)
Foreign body in throat	Injury, poisoning and procedural complications	2 (0.01%)
Fracture	Injury, poisoning and procedural complications	2 (0.01%)
Freezing phenomenon	Nervous system disorders	2 (0.01%)
Galactorrhoea	Reproductive system and breast disorders	2 (0.01%)
Gangrene	Infections and infestations	2 (0.01%)
Gastrointestinal hypermotility	Gastrointestinal disorders	2 (0.01%)
Gastrointestinal hypomotility	Gastrointestinal disorders	2 (0.01%)
Gastrointestinal tract irritation	Gastrointestinal disorders	2 (0.01%)
General physical condition abnormal	Investigations	2 (0.01%)
Genital haemorrhage	Reproductive system and breast disorders	2 (0.01%)
Glycosylated haemoglobin increased	Investigations	2 (0.01%)
Guttate psoriasis	Skin and subcutaneous tissue disorders	2 (0.01%)
Haemoglobin increased	Investigations	2 (0.01%)
Haemolysis	Blood and lymphatic system disorders	2 (0.01%)
Hallucination, olfactory	Psychiatric disorders	2 (0.01%)
Hand deformity	Musculoskeletal and connective tissue disorders	2 (0.01%)
Hand dermatitis	Skin and subcutaneous tissue disorders	2 (0.01%)
Head banging	Psychiatric disorders	2 (0.01%)
Heart valve incompetence	Cardiac disorders	2 (0.01%)
Hemiplegic migraine	Nervous system disorders	2 (0.01%)
Henoch-Schonlein purpura	Skin and subcutaneous tissue disorders	2 (0.01%)
Hepatic failure	Hepatobiliary disorders	2 (0.01%)
Hepatitis cholestatic	Hepatobiliary disorders	2 (0.01%)
Hepatitis viral	Infections and infestations	2 (0.01%)
Herpes zoster cutaneous disseminated	Infections and infestations	2 (0.01%)
Herpes zoster reactivation	Infections and infestations	2 (0.01%)
HIV test false positive	Investigations	2 (0.01%)
HIV test positive	Investigations	2 (0.01%)
Humerus fracture	Injury, poisoning and procedural complications	2 (0.01%)
Hydrocephalus	Nervous system disorders	2 (0.01%)
Hyperaesthesia teeth	Gastrointestinal disorders	2 (0.01%)
Hypercapnia	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Hyperuricaemia	Metabolism and nutrition disorders	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hypocalcaemia	Metabolism and nutrition disorders	2 (0.01%)
Hyponatraemic syndrome	Metabolism and nutrition disorders	2 (0.01%)
Hyporeflexia	Nervous system disorders	2 (0.01%)
Hypotensive crisis	Vascular disorders	2 (0.01%)
Hypovitaminosis	Metabolism and nutrition disorders	2 (0.01%)
Illrd nerve disorder	Nervous system disorders	2 (0.01%)
Immunisation	Surgical and medical procedures	2 (0.01%)
Immunisation anxiety related reaction	Psychiatric disorders	2 (0.01%)
Immunisation reaction	Immune system disorders	2 (0.01%)
Immunoglobulins increased	Investigations	2 (0.01%)
Inadequate aseptic technique in use of product	Injury, poisoning and procedural complications	2 (0.01%)
Inappropriate affect	Psychiatric disorders	2 (0.01%)
Increased appetite	Metabolism and nutrition disorders	2 (0.01%)
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Infant irritability	Nervous system disorders	2 (0.01%)
Inflammatory bowel disease	Gastrointestinal disorders	2 (0.01%)
Inflammatory pain	General disorders and administration site conditions	2 (0.01%)
Injection site bruising	General disorders and administration site conditions	2 (0.01%)
Injection site discomfort	General disorders and administration site conditions	2 (0.01%)
Injection site mass	General disorders and administration site conditions	2 (0.01%)
Injection site muscle weakness	General disorders and administration site conditions	2 (0.01%)
Injection site rash	General disorders and administration site conditions	2 (0.01%)
Intentional product use issue	Injury, poisoning and procedural complications	2 (0.01%)
International normalised ratio abnormal	Investigations	2 (0.01%)
Intervertebral disc disorder	Musculoskeletal and connective tissue disorders	2 (0.01%)
Intracardiac thrombus	Cardiac disorders	2 (0.01%)
Intraocular pressure increased	Investigations	2 (0.01%)
Intraventricular haemorrhage	Nervous system disorders	2 (0.01%)
Intrusive thoughts	Psychiatric disorders	2 (0.01%)
Iritis	Eye disorders	2 (0.01%)
Joint dislocation	Injury, poisoning and procedural complications	2 (0.01%)
Lactation disorder	Reproductive system and breast disorders	2 (0.01%)
Lacunar infarction	Nervous system disorders	2 (0.01%)
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Larynx irritation	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Left ventricular failure	Cardiac disorders	2 (0.01%)
Left ventricular hypertrophy	Cardiac disorders	2 (0.01%)
Leukocyturia	Renal and urinary disorders	2 (0.01%)
Lhermitte's sign	Nervous system disorders	2 (0.01%)
Lichenoid keratosis	Skin and subcutaneous tissue disorders	2 (0.01%)
Lip erythema	Gastrointestinal disorders	2 (0.01%)
Lip haemorrhage	Gastrointestinal disorders	2 (0.01%)
Liquid product physical issue	Product issues	2 (0.01%)
Lung consolidation	Respiratory, thoracic and mediastinal disorders	2 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Lyme disease	Infections and infestations	2 (0.01%)
Macule	Skin and subcutaneous tissue disorders	2 (0.01%)
Magnetic resonance imaging brain abnormal	Investigations	2 (0.01%)
Malignant hypertension	Vascular disorders	2 (0.01%)
Mania	Psychiatric disorders	2 (0.01%)
Mean cell haemoglobin concentration decreased	Investigations	2 (0.01%)
Mean cell volume decreased	Investigations	2 (0.01%)
Melanoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.01%)
Meningism	Nervous system disorders	2 (0.01%)
Meningitis viral	Infections and infestations	2 (0.01%)
Meningoencephalitis herpetic	Infections and infestations	2 (0.01%)
Meningoradiculitis	Nervous system disorders	2 (0.01%)
Menopausal symptoms	Reproductive system and breast disorders	2 (0.01%)
Menopause	Social circumstances	2 (0.01%)
Menstrual discomfort	Reproductive system and breast disorders	2 (0.01%)
Mesenteric artery thrombosis	Gastrointestinal disorders	2 (0.01%)
Metabolic acidosis	Metabolism and nutrition disorders	2 (0.01%)
Monocyte count increased	Investigations	2 (0.01%)
Mood swings	Psychiatric disorders	2 (0.01%)
Mouth injury	Injury, poisoning and procedural complications	2 (0.01%)
Mucosal discolouration	General disorders and administration site conditions	2 (0.01%)
Multi-organ disorder	General disorders and administration site conditions	2 (0.01%)
Muscle mass	Musculoskeletal and connective tissue disorders	2 (0.01%)
Myalgia intercostal	Musculoskeletal and connective tissue disorders	2 (0.01%)
Myocardial necrosis marker increased	Investigations	2 (0.01%)
Nasal herpes	Infections and infestations	2 (0.01%)
Neck injury	Injury, poisoning and procedural complications	2 (0.01%)
Necrosis	General disorders and administration site conditions	2 (0.01%)
Neurologic neglect syndrome	Nervous system disorders	2 (0.01%)
Neuromyelitis optica spectrum disorder	Nervous system disorders	2 (0.01%)
Nitrite urine present	Investigations	2 (0.01%)
Nocturia	Renal and urinary disorders	2 (0.01%)
Nocturnal dyspnoea	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
No reaction on previous exposure to drug	General disorders and administration site conditions	2 (0.01%)
Obstructive pancreatitis	Gastrointestinal disorders	2 (0.01%)
Ocular myasthenia	Eye disorders	2 (0.01%)
Oculofacial paralysis	Nervous system disorders	2 (0.01%)
Oedema mucosal	General disorders and administration site conditions	2 (0.01%)
Oral dysaesthesia	Gastrointestinal disorders	2 (0.01%)
Oral fungal infection	Infections and infestations	2 (0.01%)
Oral mucosa erosion	Gastrointestinal disorders	2 (0.01%)
Oral mucosal roughening	Gastrointestinal disorders	2 (0.01%)
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Osteonecrosis of jaw	Musculoskeletal and connective tissue disorders	2 (0.01%)
Ovarian cyst	Reproductive system and breast disorders	2 (0.01%)
Oxygen saturation increased	Investigations	2 (0.01%)
Pancreatic carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.01%)
Pancreatic disorder	Gastrointestinal disorders	2 (0.01%)
Paraplegia	Nervous system disorders	2 (0.01%)
Parophthalmia	Eye disorders	2 (0.01%)
Patella fracture	Injury, poisoning and procedural complications	2 (0.01%)
Pelvic fracture	Injury, poisoning and procedural complications	2 (0.01%)
Pelvic mass	General disorders and administration site conditions	2 (0.01%)
Pelvic venous thrombosis	Vascular disorders	2 (0.01%)
Pemphigus	Skin and subcutaneous tissue disorders	2 (0.01%)
Performance status decreased	General disorders and administration site conditions	2 (0.01%)
Perineal pain	Reproductive system and breast disorders	2 (0.01%)
Peripheral artery occlusion	Vascular disorders	2 (0.01%)
Pharyngeal cyst	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Pharyngeal haemorrhage	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Pharyngeal stenosis	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Pneumothorax spontaneous	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Polychondritis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Polyp	General disorders and administration site conditions	2 (0.01%)
Poor feeding infant	Metabolism and nutrition disorders	2 (0.01%)
Posterior reversible encephalopathy syndrome	Nervous system disorders	2 (0.01%)
Post herpetic neuralgia	Nervous system disorders	2 (0.01%)
Post thrombotic syndrome	Vascular disorders	2 (0.01%)
Pregnancy with contraceptive device	Pregnancy, puerperium and perinatal conditions	2 (0.01%)
Premature labour	Pregnancy, puerperium and perinatal conditions	2 (0.01%)
Premenstrual syndrome	Reproductive system and breast disorders	2 (0.01%)
Prerenal failure	Renal and urinary disorders	2 (0.01%)
Procedural dizziness	Injury, poisoning and procedural complications	2 (0.01%)
Proctalgia	Gastrointestinal disorders	2 (0.01%)
Proctitis	Gastrointestinal disorders	2 (0.01%)
Prostatomegaly	Reproductive system and breast disorders	2 (0.01%)
Prothrombin time shortened	Investigations	2 (0.01%)
Pseudoallergic reaction	General disorders and administration site conditions	2 (0.01%)
Pseudomonas infection	Infections and infestations	2 (0.01%)
Psychiatric symptom	Psychiatric disorders	2 (0.01%)
Psychomotor skills impaired	Nervous system disorders	2 (0.01%)
Pulmonary arterial hypertension	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Puncture site pain	General disorders and administration site conditions	2 (0.01%)
Pupillary disorder	Eye disorders	2 (0.01%)
Quadriplegia	Nervous system disorders	2 (0.01%)
Radiculopathy	Nervous system disorders	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Reaction to preservatives	Immune system disorders	2 (0.01%)
Recall phenomenon	Injury, poisoning and procedural complications	2 (0.01%)
Red blood cells urine positive	Investigations	2 (0.01%)
Reflexes abnormal	Nervous system disorders	2 (0.01%)
Renal haemorrhage	Renal and urinary disorders	2 (0.01%)
Respiratory alkalosis	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Respiratory tract infection viral	Infections and infestations	2 (0.01%)
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Retinal exudates	Eye disorders	2 (0.01%)
Retinal fovea disorder	Eye disorders	2 (0.01%)
Retinal injury	Injury, poisoning and procedural complications	2 (0.01%)
Retinal migraine	Nervous system disorders	2 (0.01%)
Retrograde amnesia	Nervous system disorders	2 (0.01%)
Rheumatoid factor increased	Investigations	2 (0.01%)
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Right ventricular dilatation	Cardiac disorders	2 (0.01%)
Salivary gland disorder	Gastrointestinal disorders	2 (0.01%)
Scarlet fever	Infections and infestations	2 (0.01%)
Schizophrenia	Psychiatric disorders	2 (0.01%)
Scleroderma	Musculoskeletal and connective tissue disorders	2 (0.01%)
Scrotal pain	Reproductive system and breast disorders	2 (0.01%)
Seizure like phenomena	Nervous system disorders	2 (0.01%)
Self-injurious ideation	Psychiatric disorders	2 (0.01%)
Sensitivity to weather change	General disorders and administration site conditions	2 (0.01%)
Septic arthritis staphylococcal	Infections and infestations	2 (0.01%)
Serum sickness	Immune system disorders	2 (0.01%)
Shock haemorrhagic	Vascular disorders	2 (0.01%)
Sinus arrest	Cardiac disorders	2 (0.01%)
Sinus bradycardia	Cardiac disorders	2 (0.01%)
Sinus rhythm	Investigations	2 (0.01%)
Skin hypertrophy	Skin and subcutaneous tissue disorders	2 (0.01%)
Skin striae	Skin and subcutaneous tissue disorders	2 (0.01%)
Skin weeping	Skin and subcutaneous tissue disorders	2 (0.01%)
Sleep talking	Psychiatric disorders	2 (0.01%)
Slow response to stimuli	Nervous system disorders	2 (0.01%)
Small intestinal obstruction	Gastrointestinal disorders	2 (0.01%)
Somatic symptom disorder	Psychiatric disorders	2 (0.01%)
Speech sound disorder	Psychiatric disorders	2 (0.01%)
Spinal cord infarction	Nervous system disorders	2 (0.01%)
Spinal disorder	Musculoskeletal and connective tissue disorders	2 (0.01%)
Spinal fracture	Injury, poisoning and procedural complications	2 (0.01%)
Spinal osteoarthritis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Spleen disorder	Blood and lymphatic system disorders	2 (0.01%)
Spondylitis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Spontaneous haematoma	Blood and lymphatic system disorders	2 (0.01%)
Staphylococcal bacteraemia	Infections and infestations	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Stiff tongue	Gastrointestinal disorders	2 (0.01%)
Stillbirth	Pregnancy, puerperium and perinatal conditions	2 (0.01%)
Subcutaneous abscess	Infections and infestations	2 (0.01%)
Submaxillary gland enlargement	Gastrointestinal disorders	2 (0.01%)
Sudden onset of sleep	Nervous system disorders	2 (0.01%)
Suicide attempt	Psychiatric disorders	2 (0.01%)
Superinfection	Infections and infestations	2 (0.01%)
Superior sagittal sinus thrombosis	Nervous system disorders	2 (0.01%)
Symptom recurrence	General disorders and administration site conditions	2 (0.01%)
Tachycardia paroxysmal	Cardiac disorders	2 (0.01%)
Tardive dyskinesia	Nervous system disorders	2 (0.01%)
Terminal insomnia	Psychiatric disorders	2 (0.01%)
Thalamic infarction	Nervous system disorders	2 (0.01%)
Therapeutic product effect delayed	General disorders and administration site conditions	2 (0.01%)
Thermal burns of eye	Injury, poisoning and procedural complications	2 (0.01%)
Throat clearing	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Thrombocytosis	Blood and lymphatic system disorders	2 (0.01%)
Thrombosed varicose vein	Vascular disorders	2 (0.01%)
Thrombotic cerebral infarction	Nervous system disorders	2 (0.01%)
Thrombotic microangiopathy	Blood and lymphatic system disorders	2 (0.01%)
Thyroiditis	Endocrine disorders	2 (0.01%)
Thyroid pain	Endocrine disorders	2 (0.01%)
Thyroxine free increased	Investigations	2 (0.01%)
Tic	Psychiatric disorders	2 (0.01%)
Tooth injury	Injury, poisoning and procedural complications	2 (0.01%)
Total lung capacity decreased	Investigations	2 (0.01%)
Toxocariasis	Infections and infestations	2 (0.01%)
Tracheal obstruction	Injury, poisoning and procedural complications	2 (0.01%)
Tumour marker increased	Investigations	2 (0.01%)
Underweight	Metabolism and nutrition disorders	2 (0.01%)
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Urine flow decreased	Renal and urinary disorders	2 (0.01%)
Urticaria papular	Skin and subcutaneous tissue disorders	2 (0.01%)
Urticaria thermal	Skin and subcutaneous tissue disorders	2 (0.01%)
Uvulitis	Gastrointestinal disorders	2 (0.01%)
Vaccination site joint discomfort	General disorders and administration site conditions	2 (0.01%)
Vaccination site joint inflammation	General disorders and administration site conditions	2 (0.01%)
Vaccination site macule	General disorders and administration site conditions	2 (0.01%)
Vascular occlusion	Vascular disorders	2 (0.01%)
Vasoplegia syndrome	Injury, poisoning and procedural complications	2 (0.01%)
Vein discolouration	Vascular disorders	2 (0.01%)
Vein rupture	Vascular disorders	2 (0.01%)
Vena cava thrombosis	Vascular disorders	2 (0.01%)
Viral labyrinthitis	Infections and infestations	2 (0.01%)
Vitamin B12 increased	Investigations	2 (0.01%)
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vulval haemorrhage	Reproductive system and breast disorders	2 (0.01%)
Vulvovaginal mycotic infection	Infections and infestations	2 (0.01%)
Vulvovaginal ulceration	Reproductive system and breast disorders	2 (0.01%)
Water pollution	Social circumstances	2 (0.01%)
White blood cell disorder	Blood and lymphatic system disorders	2 (0.01%)
White matter lesion	Nervous system disorders	2 (0.01%)
Xerophthalmia	Eye disorders	2 (0.01%)
Abdominal adhesions	Gastrointestinal disorders	1 (0.00%)
Abdominal lymphadenopathy	Blood and lymphatic system disorders	1 (0.00%)
Abdominal migraine	Gastrointestinal disorders	1 (0.00%)
Abdominal wall haemorrhage	Gastrointestinal disorders	1 (0.00%)
Abnormal clotting factor	Blood and lymphatic system disorders	1 (0.00%)
Abnormal loss of weight	Metabolism and nutrition disorders	1 (0.00%)
Abortion induced	Surgical and medical procedures	1 (0.00%)
Abscess limb	Infections and infestations	1 (0.00%)
Abscess neck	Infections and infestations	1 (0.00%)
Abscess oral	Infections and infestations	1 (0.00%)
Acarodermatitis	Infections and infestations	1 (0.00%)
Accident at work	Injury, poisoning and procedural complications	1 (0.00%)
Accommodation disorder	Eye disorders	1 (0.00%)
Achlorhydria	Gastrointestinal disorders	1 (0.00%)
Activated partial thromboplastin time abnormal	Investigations	1 (0.00%)
Acute cardiac event	Cardiac disorders	1 (0.00%)
Acute endocarditis	Infections and infestations	1 (0.00%)
Acute hepatic failure	Hepatobiliary disorders	1 (0.00%)
Acute left ventricular failure	Cardiac disorders	1 (0.00%)
Acute lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Acute macular outer retinopathy	Eye disorders	1 (0.00%)
Acute motor axonal neuropathy	Nervous system disorders	1 (0.00%)
Acute phase reaction	General disorders and administration site conditions	1 (0.00%)
Acute right ventricular failure	Cardiac disorders	1 (0.00%)
Acute sinusitis	Infections and infestations	1 (0.00%)
Acute stress disorder	Psychiatric disorders	1 (0.00%)
Adenopathy syphilitic	Infections and infestations	1 (0.00%)
Adjustment disorder with depressed mood	Psychiatric disorders	1 (0.00%)
Administration site discomfort	General disorders and administration site conditions	1 (0.00%)
Administration site hypoaesthesia	General disorders and administration site conditions	1 (0.00%)
Administration site irritation	General disorders and administration site conditions	1 (0.00%)
Administration site swelling	General disorders and administration site conditions	1 (0.00%)
Adnexa uteri pain	Reproductive system and breast disorders	1 (0.00%)
Adrenal disorder	Endocrine disorders	1 (0.00%)
Adrenal insufficiency	Endocrine disorders	1 (0.00%)
Adrenal mass	Endocrine disorders	1 (0.00%)
Adrenomegaly	Endocrine disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Adverse reaction	General disorders and administration site conditions	1 (0.00%)
Aerophagia	Gastrointestinal disorders	1 (0.00%)
African trypanosomiasis	Infections and infestations	1 (0.00%)
Agnosia	Nervous system disorders	1 (0.00%)
Agranulocytosis	Blood and lymphatic system disorders	1 (0.00%)
Air embolism	Vascular disorders	1 (0.00%)
Akathisia	Nervous system disorders	1 (0.00%)
Albuminuria	Renal and urinary disorders	1 (0.00%)
Allergy to arthropod bite	Immune system disorders	1 (0.00%)
Allergy to chemicals	Immune system disorders	1 (0.00%)
Alopecia totalis	Skin and subcutaneous tissue disorders	1 (0.00%)
Alpha tumour necrosis factor increased	Investigations	1 (0.00%)
Alveolitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Amaurosis	Eye disorders	1 (0.00%)
Amblyopia	Eye disorders	1 (0.00%)
Amnesic disorder	Nervous system disorders	1 (0.00%)
Amniotic cavity infection	Infections and infestations	1 (0.00%)
Amyotrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Anaemia megaloblastic	Blood and lymphatic system disorders	1 (0.00%)
Anaesthesia dolorosa	Nervous system disorders	1 (0.00%)
Anamnestic reaction	Immune system disorders	1 (0.00%)
Anaphylactoid shock	Immune system disorders	1 (0.00%)
Anaphylaxis prophylaxis	Surgical and medical procedures	1 (0.00%)
Anencephaly	Congenital, familial and genetic disorders	1 (0.00%)
Angina bullosa haemorrhagica	Gastrointestinal disorders	1 (0.00%)
Angina unstable	Cardiac disorders	1 (0.00%)
Angiokeratoma	Skin and subcutaneous tissue disorders	1 (0.00%)
Angle closure glaucoma	Eye disorders	1 (0.00%)
Angular cheilitis	Gastrointestinal disorders	1 (0.00%)
Anhedonia	Psychiatric disorders	1 (0.00%)
Animal bite	Injury, poisoning and procedural complications	1 (0.00%)
Anisometropia	Eye disorders	1 (0.00%)
Anorectal disorder	Gastrointestinal disorders	1 (0.00%)
Anterograde amnesia	Nervous system disorders	1 (0.00%)
Antibody test normal	Investigations	1 (0.00%)
Anti-glomerular basement membrane disease	Renal and urinary disorders	1 (0.00%)
Anti Kell antibody test positive	Investigations	1 (0.00%)
Antinuclear antibody increased	Investigations	1 (0.00%)
Antinuclear antibody positive	Investigations	1 (0.00%)
Antiphospholipid antibodies positive	Investigations	1 (0.00%)
Antiphospholipid syndrome	Blood and lymphatic system disorders	1 (0.00%)
Anti-platelet antibody	Investigations	1 (0.00%)
Anti-thyroid antibody	Investigations	1 (0.00%)
Anti-thyroid antibody positive	Investigations	1 (0.00%)
Anxiety disorder	Psychiatric disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Aortic dilatation	Vascular disorders	1 (0.00%)
Aortic disorder	Vascular disorders	1 (0.00%)
Aortic valve stenosis	Cardiac disorders	1 (0.00%)
Aortitis	Vascular disorders	1 (0.00%)
Apallic syndrome	Nervous system disorders	1 (0.00%)
Aplastic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Appendix disorder	Gastrointestinal disorders	1 (0.00%)
Application site swelling	General disorders and administration site conditions	1 (0.00%)
Application site vesicles	General disorders and administration site conditions	1 (0.00%)
Apraxia	Nervous system disorders	1 (0.00%)
Apyalism	Gastrointestinal disorders	1 (0.00%)
Arteriosclerotic retinopathy	Eye disorders	1 (0.00%)
Arteriospasm coronary	Cardiac disorders	1 (0.00%)
Arteriovenous fistula	Vascular disorders	1 (0.00%)
Arteriovenous graft thrombosis	Injury, poisoning and procedural complications	1 (0.00%)
Arthritis infective	Infections and infestations	1 (0.00%)
Arthritis viral	Infections and infestations	1 (0.00%)
Arthrodesis	Surgical and medical procedures	1 (0.00%)
Ascites	Gastrointestinal disorders	1 (0.00%)
Asterixis	Nervous system disorders	1 (0.00%)
Atonic seizures	Nervous system disorders	1 (0.00%)
Atrial septal defect	Congenital, familial and genetic disorders	1 (0.00%)
Atrial tachycardia	Cardiac disorders	1 (0.00%)
Atrial thrombosis	Cardiac disorders	1 (0.00%)
Atrioventricular block first degree	Cardiac disorders	1 (0.00%)
Atrioventricular block second degree	Cardiac disorders	1 (0.00%)
Atrophy	General disorders and administration site conditions	1 (0.00%)
Atypical haemolytic uraemic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Atypical pneumonia	Infections and infestations	1 (0.00%)
Audiogram abnormal	Investigations	1 (0.00%)
Auricular swelling	Ear and labyrinth disorders	1 (0.00%)
Autism spectrum disorder	Psychiatric disorders	1 (0.00%)
Autoimmune anaemia	Blood and lymphatic system disorders	1 (0.00%)
Autoimmune arthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Autoimmune hypothyroidism	Endocrine disorders	1 (0.00%)
Autoimmune thyroid disorder	Endocrine disorders	1 (0.00%)
Autonomic neuropathy	Nervous system disorders	1 (0.00%)
Autophony	Ear and labyrinth disorders	1 (0.00%)
Aversion	Psychiatric disorders	1 (0.00%)
Avulsion fracture	Injury, poisoning and procedural complications	1 (0.00%)
Axillary vein thrombosis	Vascular disorders	1 (0.00%)
Axonal neuropathy	Nervous system disorders	1 (0.00%)
Bacteraemia	Infections and infestations	1 (0.00%)
Bacterial pyelonephritis	Infections and infestations	1 (0.00%)
Bacterial test	Investigations	1 (0.00%)
Barrett's oesophagus	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Basal ganglia haemorrhage	Nervous system disorders	1 (0.00%)
Basal ganglia infarction	Nervous system disorders	1 (0.00%)
Base excess decreased	Investigations	1 (0.00%)
Basilar artery occlusion	Nervous system disorders	1 (0.00%)
Basilar migraine	Nervous system disorders	1 (0.00%)
Basophil count decreased	Investigations	1 (0.00%)
B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bicytopenia	Blood and lymphatic system disorders	1 (0.00%)
Biliary cyst	Hepatobiliary disorders	1 (0.00%)
Biliary dilatation	Hepatobiliary disorders	1 (0.00%)
Bilirubinuria	Renal and urinary disorders	1 (0.00%)
Biopsy	Investigations	1 (0.00%)
Bipolar disorder	Psychiatric disorders	1 (0.00%)
Bipolar I disorder	Psychiatric disorders	1 (0.00%)
Bladder dilatation	Renal and urinary disorders	1 (0.00%)
Bladder neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bladder pain	Renal and urinary disorders	1 (0.00%)
Bleeding varicose vein	Vascular disorders	1 (0.00%)
Blood albumin decreased	Investigations	1 (0.00%)
Blood alcohol decreased	Investigations	1 (0.00%)
Blood bicarbonate increased	Investigations	1 (0.00%)
Blood cholesterol	Investigations	1 (0.00%)
Blood chromium increased	Investigations	1 (0.00%)
Blood copper increased	Investigations	1 (0.00%)
Blood creatine increased	Investigations	1 (0.00%)
Blood creatine phosphokinase abnormal	Investigations	1 (0.00%)
Blood culture positive	Investigations	1 (0.00%)
Blood electrolytes decreased	Investigations	1 (0.00%)
Blood folate increased	Investigations	1 (0.00%)
Blood follicle stimulating hormone increased	Investigations	1 (0.00%)
Blood glucose	Investigations	1 (0.00%)
Blood growth hormone abnormal	Investigations	1 (0.00%)
Blood immunoglobulin E increased	Investigations	1 (0.00%)
Blood immunoglobulin M abnormal	Investigations	1 (0.00%)
Blood insulin increased	Investigations	1 (0.00%)
Blood loss anaemia	Blood and lymphatic system disorders	1 (0.00%)
Blood parathyroid hormone increased	Investigations	1 (0.00%)
Blood pH	Investigations	1 (0.00%)
Blood pH decreased	Investigations	1 (0.00%)
Blood pH increased	Investigations	1 (0.00%)
Blood pressure immeasurable	Investigations	1 (0.00%)
Blood pressure measurement	Investigations	1 (0.00%)
Blood pressure orthostatic increased	Investigations	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Blood sodium increased	Investigations	1 (0.00%)
Blood thrombin	Investigations	1 (0.00%)
Blood thyroid stimulating hormone decreased	Investigations	1 (0.00%)
Blood triglycerides abnormal	Investigations	1 (0.00%)
Blood urea abnormal	Investigations	1 (0.00%)
Blood uric acid increased	Investigations	1 (0.00%)
Body fat disorder	Metabolism and nutrition disorders	1 (0.00%)
Bone density abnormal	Investigations	1 (0.00%)
Bone density decreased	Investigations	1 (0.00%)
Bone development abnormal	Musculoskeletal and connective tissue disorders	1 (0.00%)
Bone marrow oedema	Blood and lymphatic system disorders	1 (0.00%)
Bradycardia	Cardiac disorders	1 (0.00%)
Bradypnoea	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Brain cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Brain compression	Nervous system disorders	1 (0.00%)
Brain contusion	Injury, poisoning and procedural complications	1 (0.00%)
Brain herniation	Injury, poisoning and procedural complications	1 (0.00%)
Brain hypoxia	Nervous system disorders	1 (0.00%)
Brain stem haemorrhage	Nervous system disorders	1 (0.00%)
Brain stem ischaemia	Nervous system disorders	1 (0.00%)
Breast cancer stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cellulitis	Infections and infestations	1 (0.00%)
Breast cyst	Reproductive system and breast disorders	1 (0.00%)
Breast enlargement	Reproductive system and breast disorders	1 (0.00%)
Breast induration	Reproductive system and breast disorders	1 (0.00%)
Breast prosthesis user	Social circumstances	1 (0.00%)
Breathing-related sleep disorder	Psychiatric disorders	1 (0.00%)
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial oedema	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial secretion retention	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchiolitis	Infections and infestations	1 (0.00%)
Bronchitis chronic	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchopneumopathy	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bulbar palsy	Nervous system disorders	1 (0.00%)
Bundle branch block	Cardiac disorders	1 (0.00%)
Burning mouth syndrome	Gastrointestinal disorders	1 (0.00%)
Burn oesophageal	Injury, poisoning and procedural complications	1 (0.00%)
Burns second degree	Injury, poisoning and procedural complications	1 (0.00%)
Butterfly rash	Skin and subcutaneous tissue disorders	1 (0.00%)
Caffeine consumption	Social circumstances	1 (0.00%)
Capillaritis	Skin and subcutaneous tissue disorders	1 (0.00%)
Capillary disorder	Vascular disorders	1 (0.00%)
Capillary fragility	Vascular disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Capillary nail refill test abnormal	Investigations	1 (0.00%)
Carbon dioxide decreased	Investigations	1 (0.00%)
Carbon dioxide increased	Investigations	1 (0.00%)
Carbon monoxide poisoning	Injury, poisoning and procedural complications	1 (0.00%)
Cardiac hypertrophy	Cardiac disorders	1 (0.00%)
Cardio-respiratory distress	Cardiac disorders	1 (0.00%)
Cardiothoracic ratio increased	Investigations	1 (0.00%)
Carotid arteriosclerosis	Nervous system disorders	1 (0.00%)
Carotid artery disease	Nervous system disorders	1 (0.00%)
Carotid artery dissection	Nervous system disorders	1 (0.00%)
Carotid artery stenosis	Nervous system disorders	1 (0.00%)
Cataplexy	Nervous system disorders	1 (0.00%)
Cavernous sinus thrombosis	Infections and infestations	1 (0.00%)
Cell marker decreased	Investigations	1 (0.00%)
Cells in urine	Investigations	1 (0.00%)
Central nervous system inflammation	Nervous system disorders	1 (0.00%)
Central nervous system vasculitis	Nervous system disorders	1 (0.00%)
Central venous pressure abnormal	Investigations	1 (0.00%)
Central vision loss	Eye disorders	1 (0.00%)
Cephalhaematoma	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Cerebellar ischaemia	Nervous system disorders	1 (0.00%)
Cerebellar syndrome	Nervous system disorders	1 (0.00%)
Cerebral amyloid angiopathy	Nervous system disorders	1 (0.00%)
Cerebral arteriosclerosis	Nervous system disorders	1 (0.00%)
Cerebral atrophy	Nervous system disorders	1 (0.00%)
Cerebral congestion	Nervous system disorders	1 (0.00%)
Cerebral microangiopathy	Nervous system disorders	1 (0.00%)
Cerebral ventricle collapse	Injury, poisoning and procedural complications	1 (0.00%)
Cerebrospinal fluid leakage	Nervous system disorders	1 (0.00%)
Cerebrovascular insufficiency	Nervous system disorders	1 (0.00%)
Cerumen impaction	Ear and labyrinth disorders	1 (0.00%)
Cervical cord compression	Nervous system disorders	1 (0.00%)
Cervical dysplasia	Reproductive system and breast disorders	1 (0.00%)
Cervicogenic headache	Nervous system disorders	1 (0.00%)
Cervix haematoma uterine	Reproductive system and breast disorders	1 (0.00%)
Chalazion	Eye disorders	1 (0.00%)
Change in sustained attention	Psychiatric disorders	1 (0.00%)
Cholecystitis acute	Hepatobiliary disorders	1 (0.00%)
Cholecystitis infective	Infections and infestations	1 (0.00%)
Choluria	Renal and urinary disorders	1 (0.00%)
Chondrocalcinosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Chorioretinopathy	Eye disorders	1 (0.00%)
Chronic gastritis	Gastrointestinal disorders	1 (0.00%)
Chronic inflammatory demyelinating polyradiculoneuropathy	Nervous system disorders	1 (0.00%)
Chronic sinusitis	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Citrobacter infection	Infections and infestations	1 (0.00%)
Claudication of jaw muscles	Vascular disorders	1 (0.00%)
Clavicle fracture	Injury, poisoning and procedural complications	1 (0.00%)
Clinomania	Psychiatric disorders	1 (0.00%)
Clostridium difficile infection	Infections and infestations	1 (0.00%)
Clostridium test positive	Investigations	1 (0.00%)
Coagulation factor increased	Investigations	1 (0.00%)
Coeliac disease	Gastrointestinal disorders	1 (0.00%)
Colitis microscopic	Gastrointestinal disorders	1 (0.00%)
Colon cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Coma scale abnormal	Investigations	1 (0.00%)
Complement factor C3 increased	Investigations	1 (0.00%)
Completed suicide	Psychiatric disorders	1 (0.00%)
Complicated appendicitis	Infections and infestations	1 (0.00%)
Congenital multiplex arthrogyriposis	Congenital, familial and genetic disorders	1 (0.00%)
Conjunctivitis allergic	Eye disorders	1 (0.00%)
Conjunctivitis bacterial	Infections and infestations	1 (0.00%)
Conjunctivitis viral	Infections and infestations	1 (0.00%)
Consciousness fluctuating	Nervous system disorders	1 (0.00%)
Contraceptive diaphragm	Surgical and medical procedures	1 (0.00%)
Contraindicated product prescribed	Injury, poisoning and procedural complications	1 (0.00%)
Conus medullaris syndrome	Nervous system disorders	1 (0.00%)
Convulsions local	Nervous system disorders	1 (0.00%)
Coombs negative haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Coombs positive haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Corneal dystrophy	Congenital, familial and genetic disorders	1 (0.00%)
Corneal infection	Infections and infestations	1 (0.00%)
Coronary artery insufficiency	Cardiac disorders	1 (0.00%)
Coronavirus test positive	Investigations	1 (0.00%)
Cor pulmonale acute	Cardiac disorders	1 (0.00%)
Cramp-fasciculation syndrome	Nervous system disorders	1 (0.00%)
Crepitations	General disorders and administration site conditions	1 (0.00%)
CSF immunoglobulin increased	Investigations	1 (0.00%)
CSF polymorphonuclear cell count increased	Investigations	1 (0.00%)
CSF protein increased	Investigations	1 (0.00%)
Culture urine positive	Investigations	1 (0.00%)
Cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	1 (0.00%)
Cutaneous sarcoidosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Cystitis bacterial	Infections and infestations	1 (0.00%)
Cystitis escherichia	Infections and infestations	1 (0.00%)
Cystitis interstitial	Renal and urinary disorders	1 (0.00%)
Cystitis noninfective	Renal and urinary disorders	1 (0.00%)
Cytomegalovirus infection	Infections and infestations	1 (0.00%)
Cytomegalovirus test positive	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Dacryocystitis	Infections and infestations	1 (0.00%)
Dactylitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Dairy intolerance	Metabolism and nutrition disorders	1 (0.00%)
Decreased insulin requirement	Metabolism and nutrition disorders	1 (0.00%)
Defaecation disorder	Gastrointestinal disorders	1 (0.00%)
Defect conduction intraventricular	Cardiac disorders	1 (0.00%)
Deficiency anaemia	Blood and lymphatic system disorders	1 (0.00%)
Deja vu	Psychiatric disorders	1 (0.00%)
Delirium febrile	Psychiatric disorders	1 (0.00%)
Delusional perception	Psychiatric disorders	1 (0.00%)
Dental discomfort	Gastrointestinal disorders	1 (0.00%)
Dental paraesthesia	Gastrointestinal disorders	1 (0.00%)
Dependent rubor	Vascular disorders	1 (0.00%)
Depression suicidal	Psychiatric disorders	1 (0.00%)
Dermal cyst	Skin and subcutaneous tissue disorders	1 (0.00%)
Dermal filler injection	Surgical and medical procedures	1 (0.00%)
Dermatitis diaper	Skin and subcutaneous tissue disorders	1 (0.00%)
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	1 (0.00%)
Dermatitis infected	Infections and infestations	1 (0.00%)
Dermatochalasis	Eye disorders	1 (0.00%)
Dermatophytosis of nail	Infections and infestations	1 (0.00%)
Device leakage	Product issues	1 (0.00%)
Device pacing issue	Product issues	1 (0.00%)
Device related infection	Infections and infestations	1 (0.00%)
Diabetic complication	Metabolism and nutrition disorders	1 (0.00%)
Diabetic hyperosmolar coma	Nervous system disorders	1 (0.00%)
Diffuse alopecia	Skin and subcutaneous tissue disorders	1 (0.00%)
Diffuse large B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Digestive enzyme abnormal	Investigations	1 (0.00%)
Dilatation ventricular	Cardiac disorders	1 (0.00%)
Discoloured vomit	Gastrointestinal disorders	1 (0.00%)
Discouragement	Psychiatric disorders	1 (0.00%)
Dissociative amnesia	Psychiatric disorders	1 (0.00%)
Diverticulum	Gastrointestinal disorders	1 (0.00%)
Drainage	Surgical and medical procedures	1 (0.00%)
Dreamy state	Nervous system disorders	1 (0.00%)
Drug abuse	Psychiatric disorders	1 (0.00%)
Drug effective for unapproved indication	General disorders and administration site conditions	1 (0.00%)
Drug level fluctuating	Investigations	1 (0.00%)
Drug screen positive	Investigations	1 (0.00%)
Dry age-related macular degeneration	Eye disorders	1 (0.00%)
Dumping syndrome	Gastrointestinal disorders	1 (0.00%)
Duodenal ulcer haemorrhage	Gastrointestinal disorders	1 (0.00%)
Dupuytren's contracture	Musculoskeletal and connective tissue disorders	1 (0.00%)
Dysacusis	Ear and labyrinth disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Dysdiadochokinesis	Nervous system disorders	1 (0.00%)
Dyslipidaemia	Metabolism and nutrition disorders	1 (0.00%)
Dyspraxia	Nervous system disorders	1 (0.00%)
Dyssomnia	Psychiatric disorders	1 (0.00%)
Ear canal erythema	Ear and labyrinth disorders	1 (0.00%)
Ear infection viral	Infections and infestations	1 (0.00%)
Ear injury	Injury, poisoning and procedural complications	1 (0.00%)
Ear, nose and throat examination abnormal	Investigations	1 (0.00%)
Eastern Cooperative Oncology Group performance status worsened	Investigations	1 (0.00%)
Eating disorder symptom	Metabolism and nutrition disorders	1 (0.00%)
Eczema asteatotic	Skin and subcutaneous tissue disorders	1 (0.00%)
Eczema eyelids	Eye disorders	1 (0.00%)
Eczema herpeticum	Infections and infestations	1 (0.00%)
Eczema nummular	Skin and subcutaneous tissue disorders	1 (0.00%)
Effusion	General disorders and administration site conditions	1 (0.00%)
Ejection fraction decreased	Investigations	1 (0.00%)
Electric shock	Injury, poisoning and procedural complications	1 (0.00%)
Electrocardiogram normal	Investigations	1 (0.00%)
Electrocardiogram PR shortened	Investigations	1 (0.00%)
Electrocardiogram QRS complex prolonged	Investigations	1 (0.00%)
Electrocardiogram QRS complex shortened	Investigations	1 (0.00%)
Electrocardiogram repolarisation abnormality	Investigations	1 (0.00%)
Electrocardiogram ST-T change	Investigations	1 (0.00%)
Electrocardiogram T wave abnormal	Investigations	1 (0.00%)
Electrolyte imbalance	Metabolism and nutrition disorders	1 (0.00%)
Electromyogram abnormal	Investigations	1 (0.00%)
Embedded device	Product issues	1 (0.00%)
Embolism arterial	Vascular disorders	1 (0.00%)
Emotional poverty	Psychiatric disorders	1 (0.00%)
End stage renal disease	Renal and urinary disorders	1 (0.00%)
Enteritis infectious	Infections and infestations	1 (0.00%)
Enterocolitis haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Eosinophil count decreased	Investigations	1 (0.00%)
Eosinophilic bronchitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Eosinophilic oesophagitis	Gastrointestinal disorders	1 (0.00%)
Ephelides	Skin and subcutaneous tissue disorders	1 (0.00%)
Episcleritis	Eye disorders	1 (0.00%)
Epstein-Barr virus antibody positive	Investigations	1 (0.00%)
Erection increased	Reproductive system and breast disorders	1 (0.00%)
Erythema ab igne	Skin and subcutaneous tissue disorders	1 (0.00%)
Escherichia test positive	Investigations	1 (0.00%)
Essential tremor	Nervous system disorders	1 (0.00%)
Eustachian tube dysfunction	Ear and labyrinth disorders	1 (0.00%)
Evans syndrome	Blood and lymphatic system disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Exaggerated startle response	Nervous system disorders	1 (0.00%)
Excessive ocular convergence	Eye disorders	1 (0.00%)
Exercise electrocardiogram abnormal	Investigations	1 (0.00%)
Exertional headache	Nervous system disorders	1 (0.00%)
Exposure to contaminated water	Injury, poisoning and procedural complications	1 (0.00%)
Exposure to extreme temperature	Injury, poisoning and procedural complications	1 (0.00%)
Exposure via eye contact	Injury, poisoning and procedural complications	1 (0.00%)
Extensor plantar response	Nervous system disorders	1 (0.00%)
Eye allergy	Eye disorders	1 (0.00%)
Eye colour change	Eye disorders	1 (0.00%)
Eye haematoma	Eye disorders	1 (0.00%)
Eyelid bleeding	Eye disorders	1 (0.00%)
Eyelid contusion	Injury, poisoning and procedural complications	1 (0.00%)
Eyelid myoclonus	Eye disorders	1 (0.00%)
Eyelid sensory disorder	Eye disorders	1 (0.00%)
Eyelid vascular disorder	Eye disorders	1 (0.00%)
Eye ulcer	Eye disorders	1 (0.00%)
Factitious disorder	Psychiatric disorders	1 (0.00%)
Factor II mutation	Congenital, familial and genetic disorders	1 (0.00%)
Factor V Leiden mutation	Congenital, familial and genetic disorders	1 (0.00%)
Faecal vomiting	Gastrointestinal disorders	1 (0.00%)
Faeces pale	Gastrointestinal disorders	1 (0.00%)
Failed in vitro fertilisation	Injury, poisoning and procedural complications	1 (0.00%)
False negative investigation result	Investigations	1 (0.00%)
False positive investigation result	Investigations	1 (0.00%)
Fasting	Social circumstances	1 (0.00%)
Fear of falling	Psychiatric disorders	1 (0.00%)
Fear of injection	Psychiatric disorders	1 (0.00%)
Female sexual dysfunction	Reproductive system and breast disorders	1 (0.00%)
Fibrin degradation products increased	Investigations	1 (0.00%)
Fibrinolysis	Investigations	1 (0.00%)
Fibromuscular dysplasia	Vascular disorders	1 (0.00%)
Fibrosis	General disorders and administration site conditions	1 (0.00%)
Finger deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Flashback	Psychiatric disorders	1 (0.00%)
Flat affect	Psychiatric disorders	1 (0.00%)
Foetal growth restriction	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Foetal heart rate decreased	Investigations	1 (0.00%)
Foetal malformation	Congenital, familial and genetic disorders	1 (0.00%)
Folliculitis	Infections and infestations	1 (0.00%)
Food craving	Metabolism and nutrition disorders	1 (0.00%)
Foreign body in gastrointestinal tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in mouth	Injury, poisoning and procedural complications	1 (0.00%)
Foveal reflex abnormal	Investigations	1 (0.00%)
Full blood count abnormal	Investigations	1 (0.00%)
Full blood count increased	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Fungal peritonitis	Infections and infestations	1 (0.00%)
Fungal skin infection	Infections and infestations	1 (0.00%)
Galactostasis	Reproductive system and breast disorders	1 (0.00%)
Gallbladder oedema	Hepatobiliary disorders	1 (0.00%)
Gastric antral vascular ectasia	Gastrointestinal disorders	1 (0.00%)
Gastric pH decreased	Investigations	1 (0.00%)
Gastritis erosive	Gastrointestinal disorders	1 (0.00%)
Gastroenteritis bacterial	Infections and infestations	1 (0.00%)
Gastroenteritis norovirus	Infections and infestations	1 (0.00%)
Gastroenteritis rotavirus	Infections and infestations	1 (0.00%)
Gastrointestinal carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gastrointestinal infection	Infections and infestations	1 (0.00%)
Gastrointestinal injury	Injury, poisoning and procedural complications	1 (0.00%)
Gastrointestinal mucosal disorder	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal oedema	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal somatic symptom disorder	Psychiatric disorders	1 (0.00%)
Gastrointestinal surgery	Surgical and medical procedures	1 (0.00%)
Gastrointestinal viral infection	Infections and infestations	1 (0.00%)
Gastrointestinal wall thickening	Gastrointestinal disorders	1 (0.00%)
Gastroschisis	Congenital, familial and genetic disorders	1 (0.00%)
Generalised anxiety disorder	Psychiatric disorders	1 (0.00%)
General symptom	General disorders and administration site conditions	1 (0.00%)
Genital herpes zoster	Infections and infestations	1 (0.00%)
Genital paraesthesia	Reproductive system and breast disorders	1 (0.00%)
Genital swelling	Reproductive system and breast disorders	1 (0.00%)
Gestational diabetes	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Gingival blister	Gastrointestinal disorders	1 (0.00%)
Gingival discolouration	Gastrointestinal disorders	1 (0.00%)
Gingival disorder	Gastrointestinal disorders	1 (0.00%)
Gingival pruritus	Gastrointestinal disorders	1 (0.00%)
Glassy eyes	General disorders and administration site conditions	1 (0.00%)
Glossopharyngeal nerve disorder	Nervous system disorders	1 (0.00%)
Glycopenia	Metabolism and nutrition disorders	1 (0.00%)
Gouty tophus	Musculoskeletal and connective tissue disorders	1 (0.00%)
Graft versus host disease	Immune system disorders	1 (0.00%)
Granulocytes abnormal	Investigations	1 (0.00%)
Granuloma annulare	Skin and subcutaneous tissue disorders	1 (0.00%)
Granuloma skin	Skin and subcutaneous tissue disorders	1 (0.00%)
Grief reaction	Psychiatric disorders	1 (0.00%)
Gynaecomastia	Reproductive system and breast disorders	1 (0.00%)
Haematocrit increased	Investigations	1 (0.00%)
Haematology test abnormal	Investigations	1 (0.00%)
Haemospermia	Reproductive system and breast disorders	1 (0.00%)
Haemoglobin abnormal	Investigations	1 (0.00%)
Haemoglobinuria	Renal and urinary disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Haemoperitoneum	Gastrointestinal disorders	1 (0.00%)
Haemorrhage in pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Haemorrhagic transformation stroke	Nervous system disorders	1 (0.00%)
Haemorrhagic urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Hair disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Hair growth abnormal	Skin and subcutaneous tissue disorders	1 (0.00%)
Haptoglobin increased	Investigations	1 (0.00%)
Head deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Heart alternation	Cardiac disorders	1 (0.00%)
Heart sounds abnormal	Investigations	1 (0.00%)
Heat illness	Injury, poisoning and procedural complications	1 (0.00%)
Heat oedema	Injury, poisoning and procedural complications	1 (0.00%)
Helplessness	Psychiatric disorders	1 (0.00%)
Hemiapraxia	Nervous system disorders	1 (0.00%)
Hemihyperaesthesia	Nervous system disorders	1 (0.00%)
Hepatic cirrhosis	Hepatobiliary disorders	1 (0.00%)
Hepatic haemorrhage	Hepatobiliary disorders	1 (0.00%)
Hepatic infarction	Hepatobiliary disorders	1 (0.00%)
Hepatitis A	Infections and infestations	1 (0.00%)
Hepatitis A virus test positive	Investigations	1 (0.00%)
Hepatitis B	Infections and infestations	1 (0.00%)
Hepatitis B virus test positive	Investigations	1 (0.00%)
Hepatitis D	Infections and infestations	1 (0.00%)
Hepatojugular reflux	Cardiac disorders	1 (0.00%)
Hereditary neuropathy with liability to pressure palsies	Congenital, familial and genetic disorders	1 (0.00%)
Hernia repair	Surgical and medical procedures	1 (0.00%)
Herpangina	Infections and infestations	1 (0.00%)
Herpes dermatitis	Infections and infestations	1 (0.00%)
Herpes pharyngitis	Infections and infestations	1 (0.00%)
Herpes simplex encephalitis	Infections and infestations	1 (0.00%)
Herpes simplex test positive	Investigations	1 (0.00%)
Herpes virus test	Investigations	1 (0.00%)
Herpes zoster meningitis	Infections and infestations	1 (0.00%)
Heterophoria	Eye disorders	1 (0.00%)
Hiccups	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
High density lipoprotein decreased	Investigations	1 (0.00%)
HIV antibody positive	Investigations	1 (0.00%)
HIV test negative	Investigations	1 (0.00%)
Hormone level abnormal	Investigations	1 (0.00%)
Horner's syndrome	Nervous system disorders	1 (0.00%)
Hostility	Psychiatric disorders	1 (0.00%)
Huntington's disease	Congenital, familial and genetic disorders	1 (0.00%)
Hypercalcaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperchloraemia	Metabolism and nutrition disorders	1 (0.00%)
Hypercholesterolaemia	Metabolism and nutrition disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Hypercoagulation	Blood and lymphatic system disorders	1 (0.00%)
Hypercreatininaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperferritinaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperintensity in brain deep nuclei	Nervous system disorders	1 (0.00%)
Hyperoxia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hyperreflexia	Nervous system disorders	1 (0.00%)
Hypertensive encephalopathy	Nervous system disorders	1 (0.00%)
Hypertriglyceridaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypertrophic cardiomyopathy	Congenital, familial and genetic disorders	1 (0.00%)
Hypervigilance	Psychiatric disorders	1 (0.00%)
Hypoalbuminaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypogammaglobulinaemia	Immune system disorders	1 (0.00%)
Hypogeusia	Nervous system disorders	1 (0.00%)
Hypoglossal nerve paresis	Nervous system disorders	1 (0.00%)
Hypokalaemic syndrome	Metabolism and nutrition disorders	1 (0.00%)
Hypoperfusion	Vascular disorders	1 (0.00%)
Hypotony of eye	Eye disorders	1 (0.00%)
Hysterectomy	Surgical and medical procedures	1 (0.00%)
Idiopathic pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
IgA nephropathy	Renal and urinary disorders	1 (0.00%)
Illrd nerve paresis	Nervous system disorders	1 (0.00%)
Ileectomy	Surgical and medical procedures	1 (0.00%)
Illusion	Psychiatric disorders	1 (0.00%)
Immobilisation syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Immune-mediated adverse reaction	Immune system disorders	1 (0.00%)
Immune-mediated hepatic disorder	Hepatobiliary disorders	1 (0.00%)
Immune-mediated hepatitis	Hepatobiliary disorders	1 (0.00%)
Immunodeficiency common variable	Immune system disorders	1 (0.00%)
Immunology test	Investigations	1 (0.00%)
Immunology test abnormal	Investigations	1 (0.00%)
Impaired self-care	General disorders and administration site conditions	1 (0.00%)
Imperception	Psychiatric disorders	1 (0.00%)
Impetigo	Infections and infestations	1 (0.00%)
Inability to crawl	Nervous system disorders	1 (0.00%)
Inadequate analgesia	General disorders and administration site conditions	1 (0.00%)
Incision site pain	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect dosage administered	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect dose administered by device	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect product administration duration	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect product formulation administered	Injury, poisoning and procedural complications	1 (0.00%)
Indifference	Psychiatric disorders	1 (0.00%)
Infective exacerbation of bronchiectasis	Infections and infestations	1 (0.00%)
Infective spondylitis	Infections and infestations	1 (0.00%)
Inferior vena caval occlusion	Vascular disorders	1 (0.00%)
Infertility female	Reproductive system and breast disorders	1 (0.00%)
Inflammation of wound	Injury, poisoning and procedural complications	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Inflammatory marker increased	Investigations	1 (0.00%)
Infusion related reaction	Injury, poisoning and procedural complications	1 (0.00%)
Infusion site warmth	General disorders and administration site conditions	1 (0.00%)
Injection site cellulitis	Infections and infestations	1 (0.00%)
Injection site extravasation	General disorders and administration site conditions	1 (0.00%)
Injection site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Injection site hypoaesthesia	General disorders and administration site conditions	1 (0.00%)
Injection site nodule	General disorders and administration site conditions	1 (0.00%)
Injection site oedema	General disorders and administration site conditions	1 (0.00%)
Injection site pustule	Infections and infestations	1 (0.00%)
Injection site vesicles	General disorders and administration site conditions	1 (0.00%)
Injury associated with device	General disorders and administration site conditions	1 (0.00%)
Insulin resistance	Metabolism and nutrition disorders	1 (0.00%)
Insulin resistant diabetes	Metabolism and nutrition disorders	1 (0.00%)
Intentional self-injury	Psychiatric disorders	1 (0.00%)
Intention tremor	Nervous system disorders	1 (0.00%)
Intercostal neuralgia	Nervous system disorders	1 (0.00%)
Internal hernia	Gastrointestinal disorders	1 (0.00%)
International normalised ratio fluctuation	Investigations	1 (0.00%)
Intervertebral disc compression	Musculoskeletal and connective tissue disorders	1 (0.00%)
Intervertebral disc degeneration	Musculoskeletal and connective tissue disorders	1 (0.00%)
Intestinal infarction	Gastrointestinal disorders	1 (0.00%)
Intestinal perforation	Gastrointestinal disorders	1 (0.00%)
Intracranial mass	Nervous system disorders	1 (0.00%)
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Invasive ductal breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Iron deficiency anaemia	Blood and lymphatic system disorders	1 (0.00%)
Irregular sleep wake rhythm disorder	Nervous system disorders	1 (0.00%)
Ischaemic cardiomyopathy	Cardiac disorders	1 (0.00%)
Ischaemic limb pain	Vascular disorders	1 (0.00%)
Itching scar	Skin and subcutaneous tissue disorders	1 (0.00%)
IVth nerve disorder	Nervous system disorders	1 (0.00%)
IVth nerve paralysis	Nervous system disorders	1 (0.00%)
Jaundice cholestatic	Hepatobiliary disorders	1 (0.00%)
Jaw clicking	Musculoskeletal and connective tissue disorders	1 (0.00%)
Job dissatisfaction	Social circumstances	1 (0.00%)
Joint abscess	Infections and infestations	1 (0.00%)
Joint laxity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Kaposi's varicelliform eruption	Infections and infestations	1 (0.00%)
Keratoconus	Eye disorders	1 (0.00%)
Kidney transplant rejection	Immune system disorders	1 (0.00%)
Lacrimation disorder	Eye disorders	1 (0.00%)
Lactic acidosis	Metabolism and nutrition disorders	1 (0.00%)
Large intestine perforation	Gastrointestinal disorders	1 (0.00%)
Laryngeal dyspnoea	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Laryngeal obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Lateral medullary syndrome	Nervous system disorders	1 (0.00%)
Lateropulsion	Nervous system disorders	1 (0.00%)
Laziness	Psychiatric disorders	1 (0.00%)
Left atrial dilatation	Cardiac disorders	1 (0.00%)
Left ventricular dilatation	Cardiac disorders	1 (0.00%)
Leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lid margin discharge	Eye disorders	1 (0.00%)
Ligament disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ligamentitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ligament pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ligament rupture	Injury, poisoning and procedural complications	1 (0.00%)
Limbal swelling	Eye disorders	1 (0.00%)
Limb crushing injury	Injury, poisoning and procedural complications	1 (0.00%)
Limb immobilisation	Surgical and medical procedures	1 (0.00%)
Limb operation	Surgical and medical procedures	1 (0.00%)
Lipase decreased	Investigations	1 (0.00%)
Lipase increased	Investigations	1 (0.00%)
Lip haematoma	Gastrointestinal disorders	1 (0.00%)
Listeria test positive	Investigations	1 (0.00%)
Liver tenderness	Hepatobiliary disorders	1 (0.00%)
Lividity	Skin and subcutaneous tissue disorders	1 (0.00%)
Locked-in syndrome	Nervous system disorders	1 (0.00%)
Logorrhoea	Psychiatric disorders	1 (0.00%)
Loose body in joint	Musculoskeletal and connective tissue disorders	1 (0.00%)
Loose tooth	Gastrointestinal disorders	1 (0.00%)
Low density lipoprotein increased	Investigations	1 (0.00%)
Lung hyperinflation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Lupus myositis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Lymphadenopathy mediastinal	Blood and lymphatic system disorders	1 (0.00%)
Lymphangiectasia	Vascular disorders	1 (0.00%)
Lymphangiopathy	Vascular disorders	1 (0.00%)
Lymphatic disorder	Blood and lymphatic system disorders	1 (0.00%)
Lymphatic obstruction	Blood and lymphatic system disorders	1 (0.00%)
Lymphocyte count increased	Investigations	1 (0.00%)
Lymphoproliferative disorder	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Macular degeneration	Eye disorders	1 (0.00%)
Macular hole	Eye disorders	1 (0.00%)
Macular rupture	Eye disorders	1 (0.00%)
Madarosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Magnetic resonance imaging abnormal	Investigations	1 (0.00%)
Malignant pleural effusion	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Malnutrition	Metabolism and nutrition disorders	1 (0.00%)
Mammogram abnormal	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Marasmus	Metabolism and nutrition disorders	1 (0.00%)
Mastoid disorder	Ear and labyrinth disorders	1 (0.00%)
Mean cell haemoglobin decreased	Investigations	1 (0.00%)
Mean cell volume increased	Investigations	1 (0.00%)
Mean platelet volume decreased	Investigations	1 (0.00%)
Meningioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Meningitis herpes	Infections and infestations	1 (0.00%)
Meningorrhagia	Nervous system disorders	1 (0.00%)
Mesenteric abscess	Infections and infestations	1 (0.00%)
Mesenteric artery aneurysm	Gastrointestinal disorders	1 (0.00%)
Metabolic disorder	Metabolism and nutrition disorders	1 (0.00%)
Metastasis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Metastatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Methylenetetrahydrofolate reductase gene mutation	Congenital, familial and genetic disorders	1 (0.00%)
Microangiopathic haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Microembolism	Vascular disorders	1 (0.00%)
Microscopic polyangiitis	Vascular disorders	1 (0.00%)
Microvascular coronary artery disease	Cardiac disorders	1 (0.00%)
Micturition disorder	Renal and urinary disorders	1 (0.00%)
Migraine prophylaxis	Surgical and medical procedures	1 (0.00%)
Miosis	Eye disorders	1 (0.00%)
Misophonia	Ear and labyrinth disorders	1 (0.00%)
Mitral valve calcification	Cardiac disorders	1 (0.00%)
Mitral valve disease	Cardiac disorders	1 (0.00%)
Mitral valve stenosis	Cardiac disorders	1 (0.00%)
Mononeuropathy multiplex	Nervous system disorders	1 (0.00%)
Morganella infection	Infections and infestations	1 (0.00%)
Morning sickness	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Mouth cyst	Gastrointestinal disorders	1 (0.00%)
Mucocutaneous disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Mucosal disorder	General disorders and administration site conditions	1 (0.00%)
Mucosal haemorrhage	General disorders and administration site conditions	1 (0.00%)
Mucosal inflammation	General disorders and administration site conditions	1 (0.00%)
Multimorbidity	General disorders and administration site conditions	1 (0.00%)
Multiple allergies	Immune system disorders	1 (0.00%)
Multiple sclerosis relapse prophylaxis	Surgical and medical procedures	1 (0.00%)
Mumps	Infections and infestations	1 (0.00%)
Muscle injury	Injury, poisoning and procedural complications	1 (0.00%)
Muscle rupture	Injury, poisoning and procedural complications	1 (0.00%)
Muscle strength abnormal	Investigations	1 (0.00%)
Myelodysplastic syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Myelopathy	Nervous system disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Myocardial rupture	Cardiac disorders	1 (0.00%)
Myocardial strain	Investigations	1 (0.00%)
Myoclonic epilepsy	Nervous system disorders	1 (0.00%)
Myoglobinuria	Renal and urinary disorders	1 (0.00%)
Myopathy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Myopia	Eye disorders	1 (0.00%)
Myringitis	Infections and infestations	1 (0.00%)
Nail pigmentation	Skin and subcutaneous tissue disorders	1 (0.00%)
Nail ridging	Skin and subcutaneous tissue disorders	1 (0.00%)
Nasal abscess	Infections and infestations	1 (0.00%)
Nasal injury	Injury, poisoning and procedural complications	1 (0.00%)
Nasal odour	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Necrotising colitis	Gastrointestinal disorders	1 (0.00%)
Necrotising fasciitis	Infections and infestations	1 (0.00%)
Necrotising retinitis	Eye disorders	1 (0.00%)
Negative thoughts	Psychiatric disorders	1 (0.00%)
Neoplasm progression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Nerve conduction studies abnormal	Investigations	1 (0.00%)
Neurodermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Neurological decompensation	Nervous system disorders	1 (0.00%)
Neuromuscular pain	Nervous system disorders	1 (0.00%)
Neuronal neuropathy	Nervous system disorders	1 (0.00%)
Neurosensory hypoacusis	Ear and labyrinth disorders	1 (0.00%)
Neutrophil count abnormal	Investigations	1 (0.00%)
Neutrophilic dermatosis	Skin and subcutaneous tissue disorders	1 (0.00%)
NIH stroke scale score decreased	Investigations	1 (0.00%)
Nipple disorder	Reproductive system and breast disorders	1 (0.00%)
Nipple exudate bloody	Reproductive system and breast disorders	1 (0.00%)
Nipple infection	Infections and infestations	1 (0.00%)
Non-Hodgkin's lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Noninfective sialoadenitis	Gastrointestinal disorders	1 (0.00%)
Non-pitting oedema	General disorders and administration site conditions	1 (0.00%)
Non-tobacco user	Social circumstances	1 (0.00%)
Normal pressure hydrocephalus	Nervous system disorders	1 (0.00%)
Normochromic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Normochromic normocytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Ocular dysmetria	Eye disorders	1 (0.00%)
Ocular icterus	Hepatobiliary disorders	1 (0.00%)
Oedema blister	Skin and subcutaneous tissue disorders	1 (0.00%)
Oedema genital	Reproductive system and breast disorders	1 (0.00%)
Oesophageal achalasia	Gastrointestinal disorders	1 (0.00%)
Oesophageal pain	Gastrointestinal disorders	1 (0.00%)
Oesophageal rupture	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Oesophageal stenosis	Gastrointestinal disorders	1 (0.00%)
Oesophageal ulcer haemorrhage	Gastrointestinal disorders	1 (0.00%)
Oligodendroglioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Omphalitis	Infections and infestations	1 (0.00%)
Oophoritis	Infections and infestations	1 (0.00%)
Ophthalmic artery thrombosis	Eye disorders	1 (0.00%)
Ophthalmological examination abnormal	Investigations	1 (0.00%)
Ophthalmoplegia	Eye disorders	1 (0.00%)
Ophthalmoplegic migraine	Nervous system disorders	1 (0.00%)
Opisthotonus	Nervous system disorders	1 (0.00%)
Optic atrophy	Eye disorders	1 (0.00%)
Optic nerve disorder	Eye disorders	1 (0.00%)
Optic nerve infarction	Eye disorders	1 (0.00%)
Oral mucosa haematoma	Gastrointestinal disorders	1 (0.00%)
Oral pigmentation	Gastrointestinal disorders	1 (0.00%)
Oral purpura	Gastrointestinal disorders	1 (0.00%)
Orchitis	Infections and infestations	1 (0.00%)
Organ failure	General disorders and administration site conditions	1 (0.00%)
Oropharyngeal candidiasis	Infections and infestations	1 (0.00%)
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Orthostatic tremor	Nervous system disorders	1 (0.00%)
Oscillopsia	Eye disorders	1 (0.00%)
Osteitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Osteoarthropathy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Osteochondritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Osteoporosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Otitis externa	Infections and infestations	1 (0.00%)
Ovarian disorder	Reproductive system and breast disorders	1 (0.00%)
Ovarian enlargement	Reproductive system and breast disorders	1 (0.00%)
Oxygen consumption decreased	Investigations	1 (0.00%)
Oxygen saturation	Investigations	1 (0.00%)
Palatal disorder	Gastrointestinal disorders	1 (0.00%)
Palindromic rheumatism	Musculoskeletal and connective tissue disorders	1 (0.00%)
Palmar erythema	Skin and subcutaneous tissue disorders	1 (0.00%)
Palpable purpura	Skin and subcutaneous tissue disorders	1 (0.00%)
Pancreatitis chronic	Gastrointestinal disorders	1 (0.00%)
Panniculitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Papilloedema	Eye disorders	1 (0.00%)
Paraesthesia mucosal	Nervous system disorders	1 (0.00%)
Parainfluenzae viral laryngotracheobronchitis	Infections and infestations	1 (0.00%)
Paramnesia	Psychiatric disorders	1 (0.00%)
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Paratracheal lymphadenopathy	Blood and lymphatic system disorders	1 (0.00%)
Parvovirus infection	Infections and infestations	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Patellofemoral pain syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Paternal exposure before pregnancy	Injury, poisoning and procedural complications	1 (0.00%)
Patient elopement	Nervous system disorders	1 (0.00%)
Patient uncooperative	Social circumstances	1 (0.00%)
PCO2 abnormal	Investigations	1 (0.00%)
PCO2 decreased	Investigations	1 (0.00%)
Peak expiratory flow rate	Investigations	1 (0.00%)
Pelvic discomfort	Reproductive system and breast disorders	1 (0.00%)
Penile haemorrhage	Reproductive system and breast disorders	1 (0.00%)
Peptic ulcer haemorrhage	Gastrointestinal disorders	1 (0.00%)
Pericardial disease	Cardiac disorders	1 (0.00%)
Perioral dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Periorbital cellulitis	Infections and infestations	1 (0.00%)
Periorbital discomfort	Eye disorders	1 (0.00%)
Periorbital disorder	Eye disorders	1 (0.00%)
Periorbital haematoma	Injury, poisoning and procedural complications	1 (0.00%)
Peripheral arterial occlusive disease	Vascular disorders	1 (0.00%)
Peripheral artery stenosis	Vascular disorders	1 (0.00%)
Peripheral motor neuropathy	Nervous system disorders	1 (0.00%)
Peripheral nerve palsy	Nervous system disorders	1 (0.00%)
Peripheral nerve paresis	Nervous system disorders	1 (0.00%)
Peripheral paralysis	Nervous system disorders	1 (0.00%)
Peripheral vein stenosis	Vascular disorders	1 (0.00%)
Peripheral vein thrombus extension	Vascular disorders	1 (0.00%)
Peritonitis	Infections and infestations	1 (0.00%)
Peritonsillar abscess	Infections and infestations	1 (0.00%)
Persecutory delusion	Psychiatric disorders	1 (0.00%)
Persistent generalised lymphadenopathy	Infections and infestations	1 (0.00%)
Persistent postural-perceptual dizziness	Nervous system disorders	1 (0.00%)
Pharyngeal lesion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pharyngeal pustule	Infections and infestations	1 (0.00%)
Pharyngitis bacterial	Infections and infestations	1 (0.00%)
Pharyngitis streptococcal	Infections and infestations	1 (0.00%)
Pharyngotonsillitis	Infections and infestations	1 (0.00%)
Phlebitis deep	Vascular disorders	1 (0.00%)
Phobia	Psychiatric disorders	1 (0.00%)
Pigmentary glaucoma	Eye disorders	1 (0.00%)
Pineal gland cyst	Nervous system disorders	1 (0.00%)
Pityriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Pityriasis lichenoides et varioliformis acuta	Skin and subcutaneous tissue disorders	1 (0.00%)
Plantar erythema	Skin and subcutaneous tissue disorders	1 (0.00%)
Plasma viscosity abnormal	Investigations	1 (0.00%)
Pleocytosis	Nervous system disorders	1 (0.00%)
Pleuropericarditis	Cardiac disorders	1 (0.00%)
Pneumatosis	General disorders and administration site conditions	1 (0.00%)
Pneumonia staphylococcal	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Polychromasia	Blood and lymphatic system disorders	1 (0.00%)
Polymerase chain reaction positive	Investigations	1 (0.00%)
Polyserositis	General disorders and administration site conditions	1 (0.00%)
Poor venous access	Vascular disorders	1 (0.00%)
Porphyria	Congenital, familial and genetic disorders	1 (0.00%)
Positron emission tomogram	Investigations	1 (0.00%)
Postictal paralysis	Nervous system disorders	1 (0.00%)
Post procedural constipation	Injury, poisoning and procedural complications	1 (0.00%)
Post procedural haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Post stroke epilepsy	Nervous system disorders	1 (0.00%)
Post-traumatic stress disorder	Psychiatric disorders	1 (0.00%)
Pre-eclampsia	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy test positive	Investigations	1 (0.00%)
Prehypertension	Vascular disorders	1 (0.00%)
Premature menarche	Endocrine disorders	1 (0.00%)
Prinzmetal angina	Cardiac disorders	1 (0.00%)
Procedural pain	Injury, poisoning and procedural complications	1 (0.00%)
Product contamination physical	Product issues	1 (0.00%)
Product dispensing issue	Injury, poisoning and procedural complications	1 (0.00%)
Product dose omission in error	Injury, poisoning and procedural complications	1 (0.00%)
Product label confusion	Injury, poisoning and procedural complications	1 (0.00%)
Product leakage	Product issues	1 (0.00%)
Product residue present	Investigations	1 (0.00%)
Product use in unapproved indication	Injury, poisoning and procedural complications	1 (0.00%)
Progressive supranuclear palsy	Nervous system disorders	1 (0.00%)
Prohormone brain natriuretic peptide increased	Investigations	1 (0.00%)
Prolapse	General disorders and administration site conditions	1 (0.00%)
Prostatic abscess	Infections and infestations	1 (0.00%)
Prostatic disorder	Reproductive system and breast disorders	1 (0.00%)
Prostatic pain	Reproductive system and breast disorders	1 (0.00%)
Protein C increased	Investigations	1 (0.00%)
Protein total decreased	Investigations	1 (0.00%)
Prothrombin level abnormal	Investigations	1 (0.00%)
Prothrombin level decreased	Investigations	1 (0.00%)
Prothrombin time ratio increased	Investigations	1 (0.00%)
Prurigo	Skin and subcutaneous tissue disorders	1 (0.00%)
Pseudomonal sepsis	Infections and infestations	1 (0.00%)
Psychogenic seizure	Nervous system disorders	1 (0.00%)
Psychomotor retardation	Psychiatric disorders	1 (0.00%)
Pulmonary alveolar haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary artery dilatation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary artery occlusion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary artery thrombosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary calcification	Respiratory, thoracic and mediastinal disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Pulmonary function test	Investigations	1 (0.00%)
Pulmonary function test decreased	Investigations	1 (0.00%)
Pulmonary hypertensive crisis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary microemboli	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary sarcoidosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary sepsis	Infections and infestations	1 (0.00%)
Pulmonary tuberculosis	Infections and infestations	1 (0.00%)
Pulmonary venous thrombosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulpitis dental	Infections and infestations	1 (0.00%)
Pulseless electrical activity	Cardiac disorders	1 (0.00%)
Pulse pressure decreased	Investigations	1 (0.00%)
Pulse volume decreased	Investigations	1 (0.00%)
Puncture site bruise	General disorders and administration site conditions	1 (0.00%)
Puncture site swelling	General disorders and administration site conditions	1 (0.00%)
Pupillary light reflex tests abnormal	Investigations	1 (0.00%)
Pupillary reflex impaired	Eye disorders	1 (0.00%)
Purging	Psychiatric disorders	1 (0.00%)
Purple glove syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Pustular psoriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Quadrantanopia	Nervous system disorders	1 (0.00%)
Quadripareisis	Nervous system disorders	1 (0.00%)
Radiculitis brachial	Nervous system disorders	1 (0.00%)
Rash neonatal	Skin and subcutaneous tissue disorders	1 (0.00%)
Reaction to colouring	Immune system disorders	1 (0.00%)
Reactogenicity event	General disorders and administration site conditions	1 (0.00%)
Recalled product administered	Injury, poisoning and procedural complications	1 (0.00%)
Rectal abscess	Infections and infestations	1 (0.00%)
Rectal injury	Injury, poisoning and procedural complications	1 (0.00%)
Rectal tenesmus	Gastrointestinal disorders	1 (0.00%)
Red blood cell abnormality	Blood and lymphatic system disorders	1 (0.00%)
Red blood cell count abnormal	Investigations	1 (0.00%)
Red blood cell count increased	Investigations	1 (0.00%)
Red blood cell sedimentation rate abnormal	Investigations	1 (0.00%)
Red blood cells urine	Investigations	1 (0.00%)
Reflux gastritis	Gastrointestinal disorders	1 (0.00%)
Relapsing fever	Infections and infestations	1 (0.00%)
Renal atrophy	Renal and urinary disorders	1 (0.00%)
Renal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Renal injury	Renal and urinary disorders	1 (0.00%)
Renal transplant failure	Immune system disorders	1 (0.00%)
Renal tubular disorder	Renal and urinary disorders	1 (0.00%)
Renal tubular necrosis	Renal and urinary disorders	1 (0.00%)
Respiratory disorder neonatal	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory fume inhalation disorder	Injury, poisoning and procedural complications	1 (0.00%)
Respiratory tract infection bacterial	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Resuscitation	Surgical and medical procedures	1 (0.00%)
Reticulocyte count decreased	Investigations	1 (0.00%)
Retinal aneurysm	Eye disorders	1 (0.00%)
Retinal disorder	Eye disorders	1 (0.00%)
Retinal drusen	Eye disorders	1 (0.00%)
Retinal oedema	Eye disorders	1 (0.00%)
Retinal vascular occlusion	Eye disorders	1 (0.00%)
Retinal vasculitis	Eye disorders	1 (0.00%)
Retinopathy	Eye disorders	1 (0.00%)
Retroperitoneal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Rheumatic fever	Musculoskeletal and connective tissue disorders	1 (0.00%)
Rhinovirus infection	Infections and infestations	1 (0.00%)
Root canal infection	Infections and infestations	1 (0.00%)
Rosacea	Skin and subcutaneous tissue disorders	1 (0.00%)
Salmonella test positive	Investigations	1 (0.00%)
SARS-CoV-1 test positive	Investigations	1 (0.00%)
Scalloped tongue	Gastrointestinal disorders	1 (0.00%)
Scapula fracture	Injury, poisoning and procedural complications	1 (0.00%)
Scar pain	Skin and subcutaneous tissue disorders	1 (0.00%)
Scintillating scotoma	Eye disorders	1 (0.00%)
Scleral disorder	Eye disorders	1 (0.00%)
Scleral haemorrhage	Eye disorders	1 (0.00%)
Scoliosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Scrotal erythema	Reproductive system and breast disorders	1 (0.00%)
Seborrhoea	Skin and subcutaneous tissue disorders	1 (0.00%)
Secondary adrenocortical insufficiency	Endocrine disorders	1 (0.00%)
Secondary hypertension	Vascular disorders	1 (0.00%)
Secondary transmission	Infections and infestations	1 (0.00%)
Sedation complication	Injury, poisoning and procedural complications	1 (0.00%)
Semen discolouration	Reproductive system and breast disorders	1 (0.00%)
Sensation of blood flow	General disorders and administration site conditions	1 (0.00%)
Sensitisation	Immune system disorders	1 (0.00%)
Sensorimotor disorder	Nervous system disorders	1 (0.00%)
Serology negative	Investigations	1 (0.00%)
Serositis	General disorders and administration site conditions	1 (0.00%)
Serum ferritin abnormal	Investigations	1 (0.00%)
Serum ferritin decreased	Investigations	1 (0.00%)
Serum ferritin increased	Investigations	1 (0.00%)
Shock symptom	Vascular disorders	1 (0.00%)
Sigmoidoscopy abnormal	Investigations	1 (0.00%)
Silent thyroiditis	Endocrine disorders	1 (0.00%)
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Skeletal injury	Injury, poisoning and procedural complications	1 (0.00%)
Skin bacterial infection	Infections and infestations	1 (0.00%)
Skin depigmentation	Skin and subcutaneous tissue disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Skin discharge	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin hyperpigmentation	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin indentation	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin injury	Injury, poisoning and procedural complications	1 (0.00%)
Skin odour abnormal	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin turgor decreased	Investigations	1 (0.00%)
Skin wound	Injury, poisoning and procedural complications	1 (0.00%)
Skull fracture	Injury, poisoning and procedural complications	1 (0.00%)
Sleep attacks	Psychiatric disorders	1 (0.00%)
Sleep paralysis	Nervous system disorders	1 (0.00%)
Small for dates baby	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Small intestinal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Soft tissue atrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Soft tissue inflammation	General disorders and administration site conditions	1 (0.00%)
Soft tissue injury	Injury, poisoning and procedural complications	1 (0.00%)
Solar dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Solar lentigo	Skin and subcutaneous tissue disorders	1 (0.00%)
Soliloquy	Psychiatric disorders	1 (0.00%)
Somnambulism	Psychiatric disorders	1 (0.00%)
Spinal column injury	Injury, poisoning and procedural complications	1 (0.00%)
Spinal compression fracture	Injury, poisoning and procedural complications	1 (0.00%)
Spinal cord compression	Nervous system disorders	1 (0.00%)
Spinal epidural haemorrhage	Nervous system disorders	1 (0.00%)
Spinal meningeal cyst	Nervous system disorders	1 (0.00%)
Spinal stenosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Splenic artery embolisation	Surgical and medical procedures	1 (0.00%)
Splenic haemorrhage	Blood and lymphatic system disorders	1 (0.00%)
Splenic vein thrombosis	Blood and lymphatic system disorders	1 (0.00%)
Splenitis	Blood and lymphatic system disorders	1 (0.00%)
Splinter	Injury, poisoning and procedural complications	1 (0.00%)
Sputum retention	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Staphylococcal abscess	Infections and infestations	1 (0.00%)
Starvation	Metabolism and nutrition disorders	1 (0.00%)
Stasis dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Steatorrhoea	Gastrointestinal disorders	1 (0.00%)
Sternal fracture	Injury, poisoning and procedural complications	1 (0.00%)
Sticky skin	Skin and subcutaneous tissue disorders	1 (0.00%)
Stiff person syndrome	Nervous system disorders	1 (0.00%)
Still's disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Streptococcal abscess	Infections and infestations	1 (0.00%)
Streptococcal infection	Infections and infestations	1 (0.00%)
Stress urinary incontinence	Renal and urinary disorders	1 (0.00%)
Subacute inflammatory demyelinating polyneuropathy	Nervous system disorders	1 (0.00%)
Subclavian vein stenosis	Vascular disorders	1 (0.00%)
Subileus	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Sudden infant death syndrome	General disorders and administration site conditions	1 (0.00%)
Suicidal behaviour	Psychiatric disorders	1 (0.00%)
Suppressed lactation	Reproductive system and breast disorders	1 (0.00%)
Syringe issue	Product issues	1 (0.00%)
Teeth brittle	Gastrointestinal disorders	1 (0.00%)
Teething	Gastrointestinal disorders	1 (0.00%)
Telangiectasia	Skin and subcutaneous tissue disorders	1 (0.00%)
Temperature difference of extremities	Investigations	1 (0.00%)
Temporal lobe epilepsy	Nervous system disorders	1 (0.00%)
Tendon injury	Injury, poisoning and procedural complications	1 (0.00%)
Tenosynovitis stenosans	Musculoskeletal and connective tissue disorders	1 (0.00%)
Terminal state	General disorders and administration site conditions	1 (0.00%)
Testicular neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Testis discomfort	Reproductive system and breast disorders	1 (0.00%)
Tetanus	Infections and infestations	1 (0.00%)
Therapeutic procedure	Surgical and medical procedures	1 (0.00%)
Therapeutic product effect decreased	General disorders and administration site conditions	1 (0.00%)
Thrombectomy	Surgical and medical procedures	1 (0.00%)
Thromboangiitis obliterans	Vascular disorders	1 (0.00%)
Thrombolysis	Surgical and medical procedures	1 (0.00%)
Thrombosis in device	Product issues	1 (0.00%)
Thrombosis mesenteric vessel	Gastrointestinal disorders	1 (0.00%)
Thyroglossal cyst	Congenital, familial and genetic disorders	1 (0.00%)
Thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Thyroidectomy	Surgical and medical procedures	1 (0.00%)
Thyroid function test abnormal	Investigations	1 (0.00%)
Thyroid hormones increased	Investigations	1 (0.00%)
Thyroxine free decreased	Investigations	1 (0.00%)
Tidal volume decreased	Investigations	1 (0.00%)
Time perception altered	Psychiatric disorders	1 (0.00%)
Tinea pedis	Infections and infestations	1 (0.00%)
Tongue cyst	Gastrointestinal disorders	1 (0.00%)
Tongue fungal infection	Infections and infestations	1 (0.00%)
Tongue haemorrhage	Gastrointestinal disorders	1 (0.00%)
Tongue rough	Gastrointestinal disorders	1 (0.00%)
Tongue spasm	Gastrointestinal disorders	1 (0.00%)
Tonsillar cyst	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tonsillar disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tonsillar erythema	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tonsillitis bacterial	Infections and infestations	1 (0.00%)
Tooth discolouration	Gastrointestinal disorders	1 (0.00%)
Tooth erosion	Gastrointestinal disorders	1 (0.00%)
Torticollis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Tourette's disorder	Congenital, familial and genetic disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Toxic epidermal necrolysis	Skin and subcutaneous tissue disorders	1 (0.00%)
Toxic neuropathy	Nervous system disorders	1 (0.00%)
Toxoplasma serology positive	Investigations	1 (0.00%)
Toxoplasmosis	Infections and infestations	1 (0.00%)
Trance	Psychiatric disorders	1 (0.00%)
Transaminases decreased	Investigations	1 (0.00%)
Transferrin decreased	Investigations	1 (0.00%)
Transfusion reaction	Injury, poisoning and procedural complications	1 (0.00%)
Transverse sinus stenosis	Nervous system disorders	1 (0.00%)
Transverse sinus thrombosis	Nervous system disorders	1 (0.00%)
Traumatic haematoma	Injury, poisoning and procedural complications	1 (0.00%)
Trigeminal nerve paresis	Nervous system disorders	1 (0.00%)
Trigeminal palsy	Nervous system disorders	1 (0.00%)
Tri-iodothyronine free decreased	Investigations	1 (0.00%)
Triple negative breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Troponin	Investigations	1 (0.00%)
Tumefactive multiple sclerosis	Nervous system disorders	1 (0.00%)
Tympanic membrane hyperaemia	Ear and labyrinth disorders	1 (0.00%)
Type II hypersensitivity	Immune system disorders	1 (0.00%)
Type V hyperlipidaemia	Congenital, familial and genetic disorders	1 (0.00%)
Typical aura without headache	Nervous system disorders	1 (0.00%)
Ulcer	General disorders and administration site conditions	1 (0.00%)
Ulnar nerve palsy	Nervous system disorders	1 (0.00%)
Ulnar neuritis	Nervous system disorders	1 (0.00%)
Umbilical haematoma	Skin and subcutaneous tissue disorders	1 (0.00%)
Undersensing	Product issues	1 (0.00%)
Urinary bladder haemorrhage	Renal and urinary disorders	1 (0.00%)
Urinary tract discomfort	Renal and urinary disorders	1 (0.00%)
Urinary tract infection pseudomonal	Infections and infestations	1 (0.00%)
Urinary tract inflammation	Renal and urinary disorders	1 (0.00%)
Urine leukocyte esterase positive	Investigations	1 (0.00%)
Urine output	Investigations	1 (0.00%)
Urine porphobilinogen increased	Investigations	1 (0.00%)
Urogenital haemorrhage	Renal and urinary disorders	1 (0.00%)
Urogenital infection bacterial	Infections and infestations	1 (0.00%)
Urticaria vesiculosa	Skin and subcutaneous tissue disorders	1 (0.00%)
Uterine pain	Reproductive system and breast disorders	1 (0.00%)
Vaccination site calcification	General disorders and administration site conditions	1 (0.00%)
Vaccination site discharge	General disorders and administration site conditions	1 (0.00%)
Vaccination site dryness	General disorders and administration site conditions	1 (0.00%)
Vaccination site dysaesthesia	General disorders and administration site conditions	1 (0.00%)
Vaccination site eczema	General disorders and administration site conditions	1 (0.00%)
Vaccination site exfoliation	General disorders and administration site conditions	1 (0.00%)
Vaccination site joint warmth	General disorders and administration site conditions	1 (0.00%)
Vaccination site pallor	General disorders and administration site conditions	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vaccination site phlebitis	General disorders and administration site conditions	1 (0.00%)
Vaccination site recall reaction	General disorders and administration site conditions	1 (0.00%)
Vaccination site scar	General disorders and administration site conditions	1 (0.00%)
Vaccination site streaking	General disorders and administration site conditions	1 (0.00%)
Vaccination site thrombosis	General disorders and administration site conditions	1 (0.00%)
Vaginal cyst	Reproductive system and breast disorders	1 (0.00%)
Vaginal disorder	Reproductive system and breast disorders	1 (0.00%)
Vaginal infection	Infections and infestations	1 (0.00%)
Vaginal ulceration	Reproductive system and breast disorders	1 (0.00%)
Vagus nerve disorder	Nervous system disorders	1 (0.00%)
Varicella virus test positive	Investigations	1 (0.00%)
Varicella zoster virus infection	Infections and infestations	1 (0.00%)
Varicocele	Reproductive system and breast disorders	1 (0.00%)
Vascular dementia	Nervous system disorders	1 (0.00%)
Vascular encephalopathy	Nervous system disorders	1 (0.00%)
Vascular headache	Nervous system disorders	1 (0.00%)
Vascular rupture	Vascular disorders	1 (0.00%)
Vascular stenosis	Vascular disorders	1 (0.00%)
Vasculitis necrotising	Vascular disorders	1 (0.00%)
Vasospasm	Vascular disorders	1 (0.00%)
Venous occlusion	Vascular disorders	1 (0.00%)
Venous oxygen saturation decreased	Investigations	1 (0.00%)
Venous thrombosis in pregnancy	Vascular disorders	1 (0.00%)
Ventricular arrhythmia	Cardiac disorders	1 (0.00%)
Ventricular dysfunction	Cardiac disorders	1 (0.00%)
Ventricular enlargement	Cardiac disorders	1 (0.00%)
Ventricular failure	Cardiac disorders	1 (0.00%)
Ventricular hypertrophy	Cardiac disorders	1 (0.00%)
Vertebral artery stenosis	Nervous system disorders	1 (0.00%)
Vertebral lesion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Vertebrobasilar stroke	Nervous system disorders	1 (0.00%)
Vertigo labyrinthine	Ear and labyrinth disorders	1 (0.00%)
Viral keratouveitis	Infections and infestations	1 (0.00%)
Viral sepsis	Infections and infestations	1 (0.00%)
Viral test positive	Investigations	1 (0.00%)
Virologic failure	Infections and infestations	1 (0.00%)
Visual acuity reduced transiently	Eye disorders	1 (0.00%)
Visual perseveration	Nervous system disorders	1 (0.00%)
Visual snow syndrome	Eye disorders	1 (0.00%)
Vitamin D	Investigations	1 (0.00%)
Vlth nerve paresis	Nervous system disorders	1 (0.00%)
Vitiligo	Skin and subcutaneous tissue disorders	1 (0.00%)
Vulval ulceration	Reproductive system and breast disorders	1 (0.00%)
Vulvitis	Infections and infestations	1 (0.00%)
Vulvovaginal discomfort	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal swelling	Reproductive system and breast disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Weight loss poor	Metabolism and nutrition disorders	1 (0.00%)
Wheat-free diet	Surgical and medical procedures	1 (0.00%)
White blood cells urine	Investigations	1 (0.00%)
White coat hypertension	Vascular disorders	1 (0.00%)
Withdrawal syndrome	General disorders and administration site conditions	1 (0.00%)
Wound complication	Injury, poisoning and procedural complications	1 (0.00%)
Wound secretion	Injury, poisoning and procedural complications	1 (0.00%)
X-ray abnormal	Investigations	1 (0.00%)



**APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

BNT162B2 - ALL

Reporting Period: Through 29-APR-2021

Total Number of Cases: 109692 (100%) (ALL) / 109692 (OVERALL)

Total Number of Adverse Events (PT): 415068 (ALL)

**NON CT**

Total Number of Cases: 109692

Total Number of Adverse Events (PT): 415068

		Number of Cases	Percentage (%)
<b>Sex</b>			
	FEMALE	77724	70.9 %
	MALE	25445	23.2 %
	NO DATA	6522	5.9 %
	UNK	1	0.0 %
<b>Age Range</b>			
Min = 0.0 Years	0 to 27 days	19	0.0 %
Max = 895.0 Years*	28 days to 23 months	128	0.1 %
	2 to 11 years	65	0.1 %
Mean = 52	12 to 17 years	217	0.2 %
Median = 50.0	18 - 30 years	12673	11.6 %
Standard Deviation = 19.28	31 - 50 years	34530	31.5 %
n = 93079	51 - 64 years	21938	20.0 %
	65 - 74 years	9314	8.5 %
	Greater than or equal to 75 years	14707	13.4 %
	Unknown	16079	14.7 %
	N/A - age range only applies to post-birth patients	22	0.0 %
<b>Country Where Event Occurred</b>			
	UNITED KINGDOM	33430	30.5 %
	UNITED STATES	27497	25.1 %
	ITALY	11167	10.2 %
	FRANCE	5427	4.9 %
	GERMANY	3992	3.6 %
	JAPAN	2476	2.3 %
	SPAIN	2459	2.2 %
	PORTUGAL	2322	2.1 %
	NETHERLANDS	2286	2.1 %
	MEXICO	2064	1.9 %
	SWEDEN	1422	1.3 %
	BELGIUM	1405	1.3 %
	DENMARK	1176	1.1 %
	GREECE	1170	1.1 %
	ISRAEL	1153	1.1 %
	CZECH REPUBLIC	999	0.9 %
	ROMANIA	961	0.9 %

\*Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP



		Number of Cases	Percentage (%)
<b>Country Where Event Occured</b>			
	AUSTRIA	769	0.7 %
	POLAND	761	0.7 %
	CANADA	730	0.7 %
	NORWAY	645	0.6 %
	FINLAND	601	0.5 %
	IRELAND	580	0.5 %
	HUNGARY	473	0.4 %
	AUSTRALIA	390	0.4 %
	SWITZERLAND	326	0.3 %
	CROATIA	305	0.3 %
	SLOVAKIA	286	0.3 %
	LATVIA	212	0.2 %
	BULGARIA	209	0.2 %
	COSTA RICA	173	0.2 %
	ESTONIA	162	0.1 %
	SLOVENIA	145	0.1 %
	LUXEMBOURG	132	0.1 %
	CHILE	128	0.1 %
	CYPRUS	122	0.1 %
	ICELAND	122	0.1 %
	SERBIA	113	0.1 %
	HONG KONG	106	0.1 %
	SINGAPORE	105	0.1 %
	MALTA	90	0.1 %
	LITHUANIA	83	0.1 %
	PUERTO RICO	79	0.1 %
	COLOMBIA	61	0.1 %
	UNITED ARAB EMIRATES	58	0.1 %
	LEBANON	54	0.0 %
	SAUDI ARABIA	37	0.0 %
	ECUADOR	28	0.0 %
	PANAMA	27	0.0 %
	QATAR	21	0.0 %
	TURKEY	21	0.0 %
	JORDAN	15	0.0 %
	PERU	13	0.0 %
	MALAYSIA	11	0.0 %
	MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	10	0.0 %
	NEW ZEALAND	10	0.0 %
	BERMUDA	8	0.0 %
	KUWAIT	7	0.0 %
	TUNISIA	6	0.0 %

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		Number of Cases	Percentage (%)
<b>Country Where Event Occured</b>			
	BAHRAIN	5	0.0 %
	ARGENTINA	4	0.0 %
	NORTHERN MARIANA ISLANDS	4	0.0 %
	ALBANIA	3	0.0 %
	INDIA	3	0.0 %
	OMAN	3	0.0 %
	ANGOLA	2	0.0 %
	FRENCH POLYNESIA	2	0.0 %
	GEORGIA	2	0.0 %
	HOLY SEE (VATICAN CITY STATE)	2	0.0 %
	IRAQ	2	0.0 %
	TURKS AND CAICOS ISLANDS	2	0.0 %
	UNITED STATES MINOR OUTLYING ISLANDS	2	0.0 %
	AFGHANISTAN	1	0.0 %
	AMERICAN SAMOA	1	0.0 %
	ANDORRA	1	0.0 %
	BOSNIA AND HERZEGOVINA	1	0.0 %
	BRAZIL	1	0.0 %
	CAYMAN ISLANDS	1	0.0 %
	EGYPT	1	0.0 %
	FRENCH SOUTHERN TERRITORIES	1	0.0 %
	GUINEA	1	0.0 %
	KOREA, REPUBLIC OF (SOUTH KOREA)	1	0.0 %
	LIECHTENSTEIN	1	0.0 %
	MACAO	1	0.0 %
	MONACO	1	0.0 %
	SWAZILAND	1	0.0 %
	UKRAINE	1	0.0 %
	URUGUAY	1	0.0 %
<b>Source</b>			
	Clinical Study	435	0.4 %
	Literature - Non Study	97	0.1 %
	Literature - Study	28	0.0 %
	Solicited	22	0.0 %
	Spontaneous	109110	99.5 %
<b>Case Seriousness</b>			
	SERIOUS	57352	52.3 %
	NONSERIOUS	52340	47.7 %
<b>HP/Medically Confirmed</b>			
	Yes	61946	56.5 %
	No	47746	43.5 %
<b>Special Populations</b>	<b>Pregnant/Breastfeeding Women</b>		
	Yes	1036	0.9 %

\*Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP

		Number of Cases	Percentage (%)
	<b>Pediatric Non EIU</b>		
	Yes	284	0.3 %
	<b>Elderly</b>		
	Yes	24022	21.9 %
	<b>Race/Ethnicity</b>		
	ASIAN - HISPANIC OR LATINO	18	0.0 %
	ASIAN - NO DATA	1142	1.0 %
	ASIAN - NOT HISPANIC OR LATINO	615	0.6 %
	ASIAN - OTHER	1	0.0 %
	BLACK - HISPANIC OR LATINO	32	0.0 %
	BLACK - NO DATA	615	0.6 %
	BLACK - NOT HISPANIC OR LATINO	380	0.3 %
	BLACK - OTHER	7	0.0 %
	CAUCASIAN - HISPANIC OR LATINO	538	0.5 %
	CAUCASIAN - NO DATA	7292	6.6 %
	CAUCASIAN - NOT HISPANIC OR LATINO	6869	6.3 %
	CAUCASIAN - OTHER	24	0.0 %
	NATIVE AMERICAN - HISPANIC OR LATINO	20	0.0 %
	NATIVE AMERICAN - NO DATA	104	0.1 %
	NATIVE AMERICAN - NOT HISPANIC OR LATINO	37	0.0 %
	NATIVE AMERICAN - OTHER	2	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO	6	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA	16	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	29	0.0 %
	NO DATA - HISPANIC OR LATINO	761	0.7 %
	NO DATA - NO DATA	90804	82.8 %
	NO DATA - NOT HISPANIC OR LATINO	229	0.2 %
	NO DATA - OTHER	151	0.1 %

\*Age incorrectly captured as '90 decades' in one case has been amended to '9 decades' after the DLP

**APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

BNT162B2 - ALL

Reporting Period: Through 29-APR-2021

Total Number of Cases: 109692 (100%) (ALL) / 109692 (OVERALL)

Total Number of Adverse Events (PT): 415068 (ALL)

**NON CT**

Total Number of Cases: 109692

Total Number of Adverse Events (PT): 415068

Preferred Term	System Organ Class (SOC)	Number of Cases
Headache	Nervous system disorders	25526 (23.27%)
Pyrexia	General disorders and administration site conditions	19385 (17.67%)
Fatigue	General disorders and administration site conditions	18540 (16.90%)
Chills	General disorders and administration site conditions	13285 (12.11%)
Myalgia	Musculoskeletal and connective tissue disorders	13094 (11.94%)
Nausea	Gastrointestinal disorders	12843 (11.71%)
Vaccination site pain	General disorders and administration site conditions	11928 (10.87%)
Pain in extremity	Musculoskeletal and connective tissue disorders	10348 (9.43%)
Arthralgia	Musculoskeletal and connective tissue disorders	9740 (8.88%)
Dizziness	Nervous system disorders	8704 (7.93%)
Pain	General disorders and administration site conditions	8656 (7.89%)
Malaise	General disorders and administration site conditions	8001 (7.29%)
Asthenia	General disorders and administration site conditions	6600 (6.02%)
Lymphadenopathy	Blood and lymphatic system disorders	5643 (5.14%)
Dyspnoea	Respiratory, thoracic and mediastinal disorders	5185 (4.73%)
COVID-19	Infections and infestations	5125 (4.67%)
Diarrhoea	Gastrointestinal disorders	4669 (4.26%)
Vomiting	Gastrointestinal disorders	4307 (3.93%)
Pruritus	Skin and subcutaneous tissue disorders	3845 (3.51%)
Paraesthesia	Nervous system disorders	3710 (3.38%)
Rash	Skin and subcutaneous tissue disorders	3668 (3.34%)
Drug ineffective	General disorders and administration site conditions	3566 (3.25%)
Cough	Respiratory, thoracic and mediastinal disorders	2853 (2.60%)
Erythema	Skin and subcutaneous tissue disorders	2806 (2.56%)
Influenza like illness	General disorders and administration site conditions	2518 (2.30%)
Hypoesthesia	Nervous system disorders	2475 (2.26%)
Tachycardia	Cardiac disorders	2381 (2.17%)
Vaccination site erythema	General disorders and administration site conditions	2278 (2.08%)
Feeling abnormal	General disorders and administration site conditions	2199 (2.00%)
Vaccination site swelling	General disorders and administration site conditions	2197 (2.00%)
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	2146 (1.96%)
Urticaria	Skin and subcutaneous tissue disorders	2141 (1.95%)
Hyperhidrosis	Skin and subcutaneous tissue disorders	2125 (1.94%)
Back pain	Musculoskeletal and connective tissue disorders	2066 (1.88%)
Chest pain	General disorders and administration site conditions	1994 (1.82%)
Anaphylactic reaction	Immune system disorders	1965 (1.79%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Off label use	Injury, poisoning and procedural complications	1930 (1.76%)
Hypertension	Vascular disorders	1898 (1.73%)
Palpitations	Cardiac disorders	1870 (1.70%)
Peripheral swelling	General disorders and administration site conditions	1800 (1.64%)
Syncope	Nervous system disorders	1789 (1.63%)
Feeling hot	General disorders and administration site conditions	1727 (1.57%)
Tremor	Nervous system disorders	1707 (1.56%)
Decreased appetite	Metabolism and nutrition disorders	1673 (1.53%)
Neck pain	Musculoskeletal and connective tissue disorders	1662 (1.52%)
Abdominal pain	Gastrointestinal disorders	1525 (1.39%)
Migraine	Nervous system disorders	1501 (1.37%)
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	1496 (1.36%)
Insomnia	Psychiatric disorders	1482 (1.35%)
Chest discomfort	General disorders and administration site conditions	1413 (1.29%)
Vertigo	Ear and labyrinth disorders	1411 (1.29%)
Somnolence	Nervous system disorders	1410 (1.29%)
Hypersensitivity	Immune system disorders	1401 (1.28%)
Swelling	General disorders and administration site conditions	1365 (1.24%)
Feeling cold	General disorders and administration site conditions	1362 (1.24%)
Heart rate increased	Investigations	1356 (1.24%)
Abdominal pain upper	Gastrointestinal disorders	1330 (1.21%)
Injection site pain	General disorders and administration site conditions	1330 (1.21%)
Facial paralysis	Nervous system disorders	1276 (1.16%)
Paraesthesia oral	Gastrointestinal disorders	1272 (1.16%)
Lethargy	Nervous system disorders	1237 (1.13%)
Blood pressure increased	Investigations	1192 (1.09%)
Illness	General disorders and administration site conditions	1185 (1.08%)
Axillary pain	General disorders and administration site conditions	1122 (1.02%)
Loss of consciousness	Nervous system disorders	1121 (1.02%)
Vaccination site warmth	General disorders and administration site conditions	1116 (1.02%)
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	1109 (1.01%)
Muscular weakness	Musculoskeletal and connective tissue disorders	1106 (1.01%)
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	1080 (0.98%)
Product use issue	Injury, poisoning and procedural complications	1073 (0.98%)
Dysgeusia	Nervous system disorders	1006 (0.92%)
Herpes zoster	Infections and infestations	1001 (0.91%)
Limb discomfort	Musculoskeletal and connective tissue disorders	983 (0.90%)
Body temperature increased	Investigations	980 (0.89%)
Lymph node pain	Blood and lymphatic system disorders	945 (0.86%)
Swelling face	General disorders and administration site conditions	926 (0.84%)
Tinnitus	Ear and labyrinth disorders	909 (0.83%)
Hypotension	Vascular disorders	899 (0.82%)
Respiratory distress	Respiratory, thoracic and mediastinal disorders	894 (0.82%)
Vaccination site pruritus	General disorders and administration site conditions	891 (0.81%)
Presyncope	Nervous system disorders	878 (0.80%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Flushing	Vascular disorders	874 (0.80%)
Poor quality product administered	Injury, poisoning and procedural complications	871 (0.79%)
Death	General disorders and administration site conditions	860 (0.78%)
Condition aggravated	General disorders and administration site conditions	854 (0.78%)
Confusional state	Psychiatric disorders	854 (0.78%)
Influenza	Infections and infestations	793 (0.72%)
Muscle spasms	Musculoskeletal and connective tissue disorders	777 (0.71%)
Vision blurred	Eye disorders	773 (0.70%)
Hot flush	Vascular disorders	766 (0.70%)
Nasopharyngitis	Infections and infestations	753 (0.69%)
Gait disturbance	General disorders and administration site conditions	749 (0.68%)
Anxiety	Psychiatric disorders	724 (0.66%)
Eye pain	Eye disorders	708 (0.65%)
Rash erythematous	Skin and subcutaneous tissue disorders	708 (0.65%)
Fall	Injury, poisoning and procedural complications	707 (0.64%)
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	690 (0.63%)
Cerebrovascular accident	Nervous system disorders	687 (0.63%)
Sensitive skin	Skin and subcutaneous tissue disorders	684 (0.62%)
Rash pruritic	Skin and subcutaneous tissue disorders	682 (0.62%)
Dysphagia	Gastrointestinal disorders	664 (0.61%)
Hypoaesthesia oral	Gastrointestinal disorders	657 (0.60%)
Seizure	Nervous system disorders	650 (0.59%)
Throat tightness	Respiratory, thoracic and mediastinal disorders	647 (0.59%)
Vaccination failure	Injury, poisoning and procedural complications	645 (0.59%)
Burning sensation	Nervous system disorders	624 (0.57%)
Lip swelling	Gastrointestinal disorders	616 (0.56%)
Abdominal discomfort	Gastrointestinal disorders	588 (0.54%)
Oxygen saturation decreased	Investigations	585 (0.53%)
Ear pain	Ear and labyrinth disorders	584 (0.53%)
Discomfort	General disorders and administration site conditions	583 (0.53%)
Vaccination site reaction	General disorders and administration site conditions	583 (0.53%)
Cold sweat	Skin and subcutaneous tissue disorders	578 (0.53%)
Throat irritation	Respiratory, thoracic and mediastinal disorders	578 (0.53%)
Swollen tongue	Gastrointestinal disorders	574 (0.52%)
Bone pain	Musculoskeletal and connective tissue disorders	568 (0.52%)
Suspected COVID-19	Infections and infestations	549 (0.50%)
SARS-CoV-2 test positive	Investigations	543 (0.50%)
Incorrect route of product administration	Injury, poisoning and procedural complications	542 (0.49%)
Disease recurrence	General disorders and administration site conditions	541 (0.49%)
Nasal congestion	Respiratory, thoracic and mediastinal disorders	536 (0.49%)
Dry mouth	Gastrointestinal disorders	522 (0.48%)
Atrial fibrillation	Cardiac disorders	501 (0.46%)
Balance disorder	Nervous system disorders	497 (0.45%)
Ageusia	Nervous system disorders	486 (0.44%)
Angioedema	Skin and subcutaneous tissue disorders	485 (0.44%)
Product temperature excursion issue	Product issues	468 (0.43%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Pneumonia	Infections and infestations	466 (0.42%)
Epistaxis	Respiratory, thoracic and mediastinal disorders	443 (0.40%)
Inflammation	General disorders and administration site conditions	442 (0.40%)
Vaccination site inflammation	General disorders and administration site conditions	434 (0.40%)
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	433 (0.39%)
Contusion	Injury, poisoning and procedural complications	432 (0.39%)
Visual impairment	Eye disorders	432 (0.39%)
Wheezing	Respiratory, thoracic and mediastinal disorders	429 (0.39%)
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	426 (0.39%)
Thrombosis	Vascular disorders	423 (0.39%)
Pallor	Vascular disorders	420 (0.38%)
Disturbance in attention	Nervous system disorders	416 (0.38%)
Mobility decreased	Musculoskeletal and connective tissue disorders	412 (0.38%)
Night sweats	Skin and subcutaneous tissue disorders	410 (0.37%)
General physical health deterioration	General disorders and administration site conditions	407 (0.37%)
Hypertensive crisis	Vascular disorders	407 (0.37%)
Deep vein thrombosis	Vascular disorders	406 (0.37%)
Dysphonia	Respiratory, thoracic and mediastinal disorders	400 (0.36%)
Peripheral coldness	Vascular disorders	399 (0.36%)
Head discomfort	Nervous system disorders	397 (0.36%)
Anosmia	Nervous system disorders	389 (0.35%)
Joint swelling	Musculoskeletal and connective tissue disorders	388 (0.35%)
Rash macular	Skin and subcutaneous tissue disorders	388 (0.35%)
Vaccination site mass	General disorders and administration site conditions	385 (0.35%)
Asthma	Respiratory, thoracic and mediastinal disorders	380 (0.35%)
Overdose	Injury, poisoning and procedural complications	380 (0.35%)
Sleep disorder	Psychiatric disorders	380 (0.35%)
Eye swelling	Eye disorders	372 (0.34%)
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	372 (0.34%)
Arrhythmia	Cardiac disorders	371 (0.34%)
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	369 (0.34%)
Vaccination site oedema	General disorders and administration site conditions	368 (0.34%)
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	367 (0.33%)
Extensive swelling of vaccinated limb	General disorders and administration site conditions	359 (0.33%)
Neuralgia	Nervous system disorders	358 (0.33%)
Oedema	General disorders and administration site conditions	342 (0.31%)
Hyperpyrexia	General disorders and administration site conditions	339 (0.31%)
Underdose	Injury, poisoning and procedural complications	336 (0.31%)
Blood pressure decreased	Investigations	334 (0.30%)
Dizziness postural	Nervous system disorders	332 (0.30%)
Vaccination site rash	General disorders and administration site conditions	323 (0.29%)
Vaccination site induration	General disorders and administration site conditions	321 (0.29%)
Feeling of body temperature change	General disorders and administration site conditions	320 (0.29%)
Myocardial infarction	Cardiac disorders	319 (0.29%)
Disorientation	Psychiatric disorders	307 (0.28%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Loss of personal independence in daily activities	Social circumstances	307 (0.28%)
Photophobia	Eye disorders	307 (0.28%)
Speech disorder	Nervous system disorders	297 (0.27%)
Hypersomnia	Nervous system disorders	294 (0.27%)
Exposure via breast milk	Injury, poisoning and procedural complications	288 (0.26%)
Product preparation issue	Injury, poisoning and procedural complications	287 (0.26%)
Cardiac failure	Cardiac disorders	283 (0.26%)
Vaccination site movement impairment	General disorders and administration site conditions	283 (0.26%)
Product preparation error	Injury, poisoning and procedural complications	282 (0.26%)
Dehydration	Metabolism and nutrition disorders	280 (0.26%)
Cardiac arrest	Cardiac disorders	276 (0.25%)
Pain in jaw	Musculoskeletal and connective tissue disorders	273 (0.25%)
Oedema peripheral	General disorders and administration site conditions	271 (0.25%)
Sneezing	Respiratory, thoracic and mediastinal disorders	270 (0.25%)
Wrong technique in product usage process	Injury, poisoning and procedural complications	270 (0.25%)
Tenderness	General disorders and administration site conditions	269 (0.25%)
Nervousness	Psychiatric disorders	264 (0.24%)
Movement disorder	Nervous system disorders	263 (0.24%)
Ocular hyperaemia	Eye disorders	263 (0.24%)
Transient ischaemic attack	Nervous system disorders	263 (0.24%)
Taste disorder	Nervous system disorders	261 (0.24%)
Dyspepsia	Gastrointestinal disorders	257 (0.23%)
Asymptomatic COVID-19	Infections and infestations	249 (0.23%)
Facial paresis	Nervous system disorders	248 (0.23%)
C-reactive protein increased	Investigations	247 (0.23%)
Facial pain	General disorders and administration site conditions	247 (0.23%)
Urinary tract infection	Infections and infestations	246 (0.22%)
Depressed level of consciousness	Nervous system disorders	245 (0.22%)
Breast pain	Reproductive system and breast disorders	243 (0.22%)
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	240 (0.22%)
Lacrimation increased	Eye disorders	239 (0.22%)
Eye pruritus	Eye disorders	237 (0.22%)
Dysarthria	Nervous system disorders	236 (0.22%)
Epilepsy	Nervous system disorders	236 (0.22%)
Anaphylactic shock	Immune system disorders	235 (0.21%)
Vaccination site bruising	General disorders and administration site conditions	235 (0.21%)
Blister	Skin and subcutaneous tissue disorders	234 (0.21%)
Thirst	General disorders and administration site conditions	232 (0.21%)
Oral herpes	Infections and infestations	230 (0.21%)
Pain of skin	Skin and subcutaneous tissue disorders	228 (0.21%)
Gait inability	General disorders and administration site conditions	225 (0.21%)
Abdominal distension	Gastrointestinal disorders	223 (0.20%)
Nodule	General disorders and administration site conditions	221 (0.20%)
Sudden death	General disorders and administration site conditions	219 (0.20%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Muscle twitching	Musculoskeletal and connective tissue disorders	215 (0.20%)
Allergy to vaccine	Immune system disorders	213 (0.19%)
Restlessness	Psychiatric disorders	213 (0.19%)
Bronchospasm	Respiratory, thoracic and mediastinal disorders	212 (0.19%)
Irritability	Psychiatric disorders	212 (0.19%)
Ear discomfort	Ear and labyrinth disorders	208 (0.19%)
Face oedema	General disorders and administration site conditions	208 (0.19%)
Tension headache	Nervous system disorders	208 (0.19%)
Thrombocytopenia	Blood and lymphatic system disorders	208 (0.19%)
Aphasia	Nervous system disorders	207 (0.19%)
Blood glucose increased	Investigations	207 (0.19%)
Bradycardia	Cardiac disorders	207 (0.19%)
Cellulitis	Infections and infestations	207 (0.19%)
Lymphadenitis	Blood and lymphatic system disorders	207 (0.19%)
Dysstasia	Nervous system disorders	206 (0.19%)
Neuropathy peripheral	Nervous system disorders	204 (0.19%)
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	199 (0.18%)
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	198 (0.18%)
Haemorrhage	Vascular disorders	197 (0.18%)
Arthritis	Musculoskeletal and connective tissue disorders	196 (0.18%)
Deafness	Ear and labyrinth disorders	196 (0.18%)
Eye irritation	Eye disorders	196 (0.18%)
Induration	General disorders and administration site conditions	196 (0.18%)
Rash papular	Skin and subcutaneous tissue disorders	196 (0.18%)
Diplopia	Eye disorders	194 (0.18%)
Vaccination site discomfort	General disorders and administration site conditions	194 (0.18%)
Hallucination	Psychiatric disorders	189 (0.17%)
Sensation of foreign body	General disorders and administration site conditions	189 (0.17%)
Dysentery	Infections and infestations	188 (0.17%)
Hypoacusis	Ear and labyrinth disorders	188 (0.17%)
Ischaemic stroke	Nervous system disorders	187 (0.17%)
Memory impairment	Nervous system disorders	187 (0.17%)
Weight decreased	Investigations	186 (0.17%)
Circulatory collapse	Vascular disorders	185 (0.17%)
Constipation	Gastrointestinal disorders	184 (0.17%)
Joint stiffness	Musculoskeletal and connective tissue disorders	182 (0.17%)
Productive cough	Respiratory, thoracic and mediastinal disorders	181 (0.17%)
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	180 (0.16%)
Muscle fatigue	Musculoskeletal and connective tissue disorders	178 (0.16%)
COVID-19 pneumonia	Infections and infestations	177 (0.16%)
Muscle tightness	Musculoskeletal and connective tissue disorders	175 (0.16%)
Retching	Gastrointestinal disorders	175 (0.16%)
Infection	Infections and infestations	174 (0.16%)
Odynophagia	Gastrointestinal disorders	174 (0.16%)
Skin burning sensation	Skin and subcutaneous tissue disorders	174 (0.16%)
Hemiparesis	Nervous system disorders	172 (0.16%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Poor quality sleep	Nervous system disorders	172 (0.16%)
Skin discolouration	Skin and subcutaneous tissue disorders	172 (0.16%)
Angina pectoris	Cardiac disorders	168 (0.15%)
Delirium	Psychiatric disorders	168 (0.15%)
Hyperaesthesia	Nervous system disorders	167 (0.15%)
Tachypnoea	Respiratory, thoracic and mediastinal disorders	166 (0.15%)
Lip oedema	Gastrointestinal disorders	162 (0.15%)
Parosmia	Nervous system disorders	159 (0.14%)
Myocarditis	Cardiac disorders	157 (0.14%)
Flatulence	Gastrointestinal disorders	156 (0.14%)
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	156 (0.14%)
Agitation	Psychiatric disorders	155 (0.14%)
Exposure during pregnancy	Injury, poisoning and procedural complications	153 (0.14%)
SARS-CoV-2 antibody test negative	Investigations	153 (0.14%)
Depressed mood	Psychiatric disorders	152 (0.14%)
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	152 (0.14%)
Dry throat	Respiratory, thoracic and mediastinal disorders	151 (0.14%)
Hyperthermia	General disorders and administration site conditions	150 (0.14%)
Injection site oedema	General disorders and administration site conditions	150 (0.14%)
Paralysis	Nervous system disorders	150 (0.14%)
Product administered at inappropriate site	Injury, poisoning and procedural complications	150 (0.14%)
Respiratory failure	Respiratory, thoracic and mediastinal disorders	150 (0.14%)
Swelling of eyelid	Eye disorders	149 (0.14%)
Sinus headache	Nervous system disorders	148 (0.13%)
Gastrointestinal disorder	Gastrointestinal disorders	147 (0.13%)
Renal pain	Renal and urinary disorders	147 (0.13%)
Pericarditis	Cardiac disorders	146 (0.13%)
Sensory disturbance	Nervous system disorders	146 (0.13%)
Vaccination site paraesthesia	General disorders and administration site conditions	146 (0.13%)
Petechiae	Skin and subcutaneous tissue disorders	145 (0.13%)
Amnesia	Nervous system disorders	143 (0.13%)
Vaccination complication	Injury, poisoning and procedural complications	143 (0.13%)
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	141 (0.13%)
Glossodynia	Gastrointestinal disorders	140 (0.13%)
Dermatitis allergic	Skin and subcutaneous tissue disorders	139 (0.13%)
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	137 (0.12%)
Cardiovascular disorder	Cardiac disorders	136 (0.12%)
Mouth ulceration	Gastrointestinal disorders	136 (0.12%)
Therapeutic response unexpected	General disorders and administration site conditions	135 (0.12%)
Cerebral haemorrhage	Nervous system disorders	134 (0.12%)
Injection site erythema	General disorders and administration site conditions	130 (0.12%)
Oral discomfort	Gastrointestinal disorders	130 (0.12%)
Vaccination site haematoma	General disorders and administration site conditions	130 (0.12%)
Hypothermia	General disorders and administration site conditions	129 (0.12%)
Unresponsive to stimuli	Nervous system disorders	129 (0.12%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Toothache	Gastrointestinal disorders	128 (0.12%)
Depression	Psychiatric disorders	127 (0.12%)
Heart rate irregular	Investigations	126 (0.11%)
Hyperventilation	Respiratory, thoracic and mediastinal disorders	126 (0.11%)
Vaccination site urticaria	General disorders and administration site conditions	126 (0.11%)
Acute kidney injury	Renal and urinary disorders	125 (0.11%)
Cyanosis	Vascular disorders	125 (0.11%)
No adverse event	General disorders and administration site conditions	125 (0.11%)
Feeding disorder	Metabolism and nutrition disorders	124 (0.11%)
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	124 (0.11%)
Tongue oedema	Gastrointestinal disorders	124 (0.11%)
Heart rate decreased	Investigations	123 (0.11%)
Menorrhagia	Reproductive system and breast disorders	123 (0.11%)
Sinusitis	Infections and infestations	123 (0.11%)
Eyelid oedema	Eye disorders	122 (0.11%)
Head injury	Injury, poisoning and procedural complications	122 (0.11%)
Local reaction	General disorders and administration site conditions	122 (0.11%)
Skin warm	Skin and subcutaneous tissue disorders	122 (0.11%)
Spinal pain	Musculoskeletal and connective tissue disorders	122 (0.11%)
Acute myocardial infarction	Cardiac disorders	121 (0.11%)
Asthenopia	Eye disorders	121 (0.11%)
Vaccination site lymphadenopathy	General disorders and administration site conditions	121 (0.11%)
Axillary mass	Musculoskeletal and connective tissue disorders	120 (0.11%)
Periorbital swelling	Eye disorders	120 (0.11%)
Cerebral infarction	Nervous system disorders	119 (0.11%)
Crying	General disorders and administration site conditions	118 (0.11%)
Hypokinesia	Nervous system disorders	118 (0.11%)
Hypoxia	Respiratory, thoracic and mediastinal disorders	118 (0.11%)
Impaired work ability	Social circumstances	117 (0.11%)
Middle insomnia	Psychiatric disorders	116 (0.11%)
Sinus tachycardia	Cardiac disorders	116 (0.11%)
Haematochezia	Gastrointestinal disorders	115 (0.10%)
Haematoma	Vascular disorders	115 (0.10%)
Oral pain	Gastrointestinal disorders	115 (0.10%)
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	113 (0.10%)
Platelet count decreased	Investigations	112 (0.10%)
Dyskinesia	Nervous system disorders	111 (0.10%)
Extrasystoles	Cardiac disorders	111 (0.10%)
Sensory loss	Nervous system disorders	111 (0.10%)
Rash maculo-papular	Skin and subcutaneous tissue disorders	110 (0.10%)
Guillain-Barre syndrome	Nervous system disorders	109 (0.10%)
Skin disorder	Skin and subcutaneous tissue disorders	109 (0.10%)
Dry skin	Skin and subcutaneous tissue disorders	108 (0.10%)
Migraine with aura	Nervous system disorders	108 (0.10%)
Mouth swelling	Gastrointestinal disorders	108 (0.10%)
Eczema	Skin and subcutaneous tissue disorders	106 (0.10%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Eye disorder	Eye disorders	106 (0.10%)
Generalised tonic-clonic seizure	Nervous system disorders	106 (0.10%)
Nightmare	Psychiatric disorders	106 (0.10%)
Vaginal haemorrhage	Reproductive system and breast disorders	106 (0.10%)
Hypoglycaemia	Metabolism and nutrition disorders	105 (0.10%)
Lower respiratory tract infection	Infections and infestations	105 (0.10%)
Sepsis	Infections and infestations	105 (0.10%)
Blindness	Eye disorders	104 (0.09%)
Urinary incontinence	Renal and urinary disorders	104 (0.09%)
Hyperglycaemia	Metabolism and nutrition disorders	103 (0.09%)
Gastrointestinal pain	Gastrointestinal disorders	102 (0.09%)
Abnormal dreams	Psychiatric disorders	100 (0.09%)
Injection site swelling	General disorders and administration site conditions	100 (0.09%)
Vaccination site hypoaesthesia	General disorders and administration site conditions	100 (0.09%)
Abdominal pain lower	Gastrointestinal disorders	99 (0.09%)
Body temperature abnormal	Investigations	99 (0.09%)
Vaccination site haemorrhage	General disorders and administration site conditions	99 (0.09%)
Deafness unilateral	Ear and labyrinth disorders	98 (0.09%)
Drug hypersensitivity	Immune system disorders	98 (0.09%)
Injected limb mobility decreased	General disorders and administration site conditions	98 (0.09%)
Ocular discomfort	Eye disorders	98 (0.09%)
Gastrooesophageal reflux disease	Gastrointestinal disorders	97 (0.09%)
Incorrect dose administered	Injury, poisoning and procedural complications	97 (0.09%)
Rhinitis	Infections and infestations	97 (0.09%)
Cognitive disorder	Nervous system disorders	96 (0.09%)
Nervous system disorder	Nervous system disorders	96 (0.09%)
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	96 (0.09%)
Dry eye	Eye disorders	95 (0.09%)
Immune thrombocytopenia	Blood and lymphatic system disorders	95 (0.09%)
Panic attack	Psychiatric disorders	95 (0.09%)
Respiratory rate increased	Investigations	95 (0.09%)
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	94 (0.09%)
Cardiac flutter	Cardiac disorders	93 (0.08%)
Conjunctivitis	Infections and infestations	93 (0.08%)
Lung disorder	Respiratory, thoracic and mediastinal disorders	93 (0.08%)
Stress	Psychiatric disorders	93 (0.08%)
Cardiac disorder	Cardiac disorders	92 (0.08%)
Feeling drunk	General disorders and administration site conditions	92 (0.08%)
SARS-CoV-2 antibody test positive	Investigations	92 (0.08%)
Body temperature decreased	Investigations	91 (0.08%)
Mental impairment	Nervous system disorders	91 (0.08%)
Renal failure	Renal and urinary disorders	91 (0.08%)
Cardio-respiratory arrest	Cardiac disorders	90 (0.08%)
Dysaesthesia	Nervous system disorders	90 (0.08%)
Dysuria	Renal and urinary disorders	90 (0.08%)
Photopsia	Eye disorders	89 (0.08%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Eating disorder	Psychiatric disorders	88 (0.08%)
Aphonia	Respiratory, thoracic and mediastinal disorders	87 (0.08%)
Skin reaction	Skin and subcutaneous tissue disorders	87 (0.08%)
Accidental overdose	Injury, poisoning and procedural complications	86 (0.08%)
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	86 (0.08%)
Lymphoedema	Vascular disorders	86 (0.08%)
Stomatitis	Gastrointestinal disorders	85 (0.08%)
Hemiplegia	Nervous system disorders	84 (0.08%)
Oral pruritus	Gastrointestinal disorders	83 (0.08%)
White blood cell count increased	Investigations	83 (0.08%)
Altered state of consciousness	Nervous system disorders	82 (0.07%)
Conjunctival haemorrhage	Eye disorders	82 (0.07%)
Localised oedema	General disorders and administration site conditions	82 (0.07%)
Tongue discomfort	Gastrointestinal disorders	82 (0.07%)
Groin pain	Musculoskeletal and connective tissue disorders	81 (0.07%)
Pollakiuria	Renal and urinary disorders	81 (0.07%)
Skin exfoliation	Skin and subcutaneous tissue disorders	81 (0.07%)
Eye haemorrhage	Eye disorders	80 (0.07%)
Sinus pain	Respiratory, thoracic and mediastinal disorders	80 (0.07%)
Blood pressure fluctuation	Vascular disorders	79 (0.07%)
Skin lesion	Skin and subcutaneous tissue disorders	79 (0.07%)
Pneumonia aspiration	Respiratory, thoracic and mediastinal disorders	78 (0.07%)
Tongue disorder	Gastrointestinal disorders	78 (0.07%)
Cluster headache	Nervous system disorders	77 (0.07%)
Alopecia	Skin and subcutaneous tissue disorders	76 (0.07%)
Anaemia	Blood and lymphatic system disorders	76 (0.07%)
Dermatitis	Skin and subcutaneous tissue disorders	76 (0.07%)
Mental fatigue	Psychiatric disorders	76 (0.07%)
Vaccination site hypersensitivity	General disorders and administration site conditions	76 (0.07%)
Blood pressure systolic increased	Investigations	75 (0.07%)
Rash vesicular	Skin and subcutaneous tissue disorders	75 (0.07%)
Haemoglobin decreased	Investigations	74 (0.07%)
Monoplegia	Nervous system disorders	74 (0.07%)
Vaccination site cellulitis	Infections and infestations	74 (0.07%)
Aphthous ulcer	Gastrointestinal disorders	73 (0.07%)
Febrile convulsion	Nervous system disorders	73 (0.07%)
Bedridden	Social circumstances	72 (0.07%)
Blood glucose decreased	Investigations	72 (0.07%)
Rectal haemorrhage	Gastrointestinal disorders	72 (0.07%)
Appendicitis	Infections and infestations	71 (0.06%)
Coordination abnormal	Nervous system disorders	71 (0.06%)
Ear infection	Infections and infestations	71 (0.06%)
Fibrin D dimer increased	Investigations	71 (0.06%)
Product dose omission issue	Injury, poisoning and procedural complications	71 (0.06%)
Haemoptysis	Respiratory, thoracic and mediastinal disorders	70 (0.06%)
Heart rate abnormal	Investigations	70 (0.06%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Ventricular extrasystoles	Cardiac disorders	70 (0.06%)
Hypotonia	Nervous system disorders	69 (0.06%)
Pleural effusion	Respiratory, thoracic and mediastinal disorders	69 (0.06%)
Skin irritation	Skin and subcutaneous tissue disorders	69 (0.06%)
Mass	General disorders and administration site conditions	68 (0.06%)
Menstruation irregular	Reproductive system and breast disorders	68 (0.06%)
Motor dysfunction	Nervous system disorders	68 (0.06%)
Sudden hearing loss	Ear and labyrinth disorders	68 (0.06%)
Blood pressure abnormal	Investigations	67 (0.06%)
Breast swelling	Reproductive system and breast disorders	67 (0.06%)
Painful respiration	Respiratory, thoracic and mediastinal disorders	67 (0.06%)
Bronchitis	Infections and infestations	65 (0.06%)
Sciatica	Nervous system disorders	64 (0.06%)
Thrombophlebitis superficial	Vascular disorders	64 (0.06%)
Vasculitis	Vascular disorders	64 (0.06%)
Eyelid ptosis	Eye disorders	63 (0.06%)
Urinary retention	Renal and urinary disorders	63 (0.06%)
Fear	Psychiatric disorders	62 (0.06%)
Hemiparaesthesia	Nervous system disorders	62 (0.06%)
Hyperacusis	Ear and labyrinth disorders	62 (0.06%)
International normalised ratio increased	Investigations	62 (0.06%)
Menstrual disorder	Reproductive system and breast disorders	62 (0.06%)
Sinus disorder	Respiratory, thoracic and mediastinal disorders	62 (0.06%)
Apathy	Psychiatric disorders	61 (0.06%)
Haematemesis	Gastrointestinal disorders	61 (0.06%)
Limb injury	Injury, poisoning and procedural complications	61 (0.06%)
Salivary hypersecretion	Gastrointestinal disorders	61 (0.06%)
Vaccination site joint movement impairment	General disorders and administration site conditions	61 (0.06%)
Feeling jittery	General disorders and administration site conditions	60 (0.05%)
Formication	Nervous system disorders	60 (0.05%)
Shock	Vascular disorders	60 (0.05%)
Hypopnoea	Respiratory, thoracic and mediastinal disorders	59 (0.05%)
Lip pruritus	Gastrointestinal disorders	59 (0.05%)
Sinus congestion	Respiratory, thoracic and mediastinal disorders	59 (0.05%)
Thrombophlebitis	Vascular disorders	59 (0.05%)
Troponin increased	Investigations	59 (0.05%)
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	58 (0.05%)
Cystitis	Infections and infestations	58 (0.05%)
Drug interaction	General disorders and administration site conditions	58 (0.05%)
Monoparesis	Nervous system disorders	58 (0.05%)
Muscle contractions involuntary	Nervous system disorders	58 (0.05%)
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	58 (0.05%)
Sweating fever	Infections and infestations	58 (0.05%)
Vertigo positional	Ear and labyrinth disorders	58 (0.05%)
Wrong product administered	Injury, poisoning and procedural complications	58 (0.05%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Diabetes mellitus	Metabolism and nutrition disorders	57 (0.05%)
Embolism	Vascular disorders	57 (0.05%)
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	57 (0.05%)
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	57 (0.05%)
Thinking abnormal	Psychiatric disorders	57 (0.05%)
Blood urine present	Investigations	56 (0.05%)
Gingival pain	Gastrointestinal disorders	56 (0.05%)
Haematuria	Renal and urinary disorders	56 (0.05%)
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	56 (0.05%)
Photosensitivity reaction	Skin and subcutaneous tissue disorders	56 (0.05%)
Gout	Metabolism and nutrition disorders	55 (0.05%)
Supraventricular tachycardia	Cardiac disorders	55 (0.05%)
Flank pain	Musculoskeletal and connective tissue disorders	54 (0.05%)
Hallucination, visual	Psychiatric disorders	54 (0.05%)
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	54 (0.05%)
Chillblains	Injury, poisoning and procedural complications	53 (0.05%)
Menstruation delayed	Reproductive system and breast disorders	53 (0.05%)
Muscle strain	Injury, poisoning and procedural complications	53 (0.05%)
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	53 (0.05%)
Psoriasis	Skin and subcutaneous tissue disorders	53 (0.05%)
Purpura	Skin and subcutaneous tissue disorders	53 (0.05%)
Anaphylactoid reaction	Immune system disorders	52 (0.05%)
Arthropathy	Musculoskeletal and connective tissue disorders	52 (0.05%)
Expired product administered	Injury, poisoning and procedural complications	52 (0.05%)
Fibromyalgia	Musculoskeletal and connective tissue disorders	52 (0.05%)
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	52 (0.05%)
Choking	Respiratory, thoracic and mediastinal disorders	51 (0.05%)
Chromaturia	Renal and urinary disorders	51 (0.05%)
Injection site pruritus	General disorders and administration site conditions	51 (0.05%)
Stridor	Respiratory, thoracic and mediastinal disorders	51 (0.05%)
Tongue pruritus	Gastrointestinal disorders	51 (0.05%)
Vaccination site discolouration	General disorders and administration site conditions	51 (0.05%)
Accidental exposure to product	Injury, poisoning and procedural complications	50 (0.05%)
Acute coronary syndrome	Cardiac disorders	50 (0.05%)
Administration site pain	General disorders and administration site conditions	50 (0.05%)
Eructation	Gastrointestinal disorders	50 (0.05%)
Gastric disorder	Gastrointestinal disorders	50 (0.05%)
Metrorrhagia	Reproductive system and breast disorders	50 (0.05%)
Skin swelling	Skin and subcutaneous tissue disorders	50 (0.05%)
Neutropenia	Blood and lymphatic system disorders	49 (0.04%)
Pericardial effusion	Cardiac disorders	49 (0.04%)
Pharyngeal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	49 (0.04%)
Raynaud's phenomenon	Vascular disorders	49 (0.04%)
Restless legs syndrome	Nervous system disorders	49 (0.04%)
Alanine aminotransferase increased	Investigations	48 (0.04%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Labyrinthitis	Infections and infestations	48 (0.04%)
Lip pain	Gastrointestinal disorders	48 (0.04%)
Livedo reticularis	Skin and subcutaneous tissue disorders	48 (0.04%)
Multiple sclerosis	Nervous system disorders	48 (0.04%)
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	48 (0.04%)
Respiratory tract infection	Infections and infestations	48 (0.04%)
Sluggishness	General disorders and administration site conditions	48 (0.04%)
Trigeminal neuralgia	Nervous system disorders	48 (0.04%)
Type I hypersensitivity	Immune system disorders	48 (0.04%)
Acne	Skin and subcutaneous tissue disorders	47 (0.04%)
Autoimmune disorder	Immune system disorders	47 (0.04%)
Dementia	Nervous system disorders	47 (0.04%)
Ear swelling	Ear and labyrinth disorders	47 (0.04%)
Grip strength decreased	Investigations	47 (0.04%)
Immune system disorder	Immune system disorders	47 (0.04%)
Laryngospasm	Respiratory, thoracic and mediastinal disorders	47 (0.04%)
Pelvic pain	Reproductive system and breast disorders	47 (0.04%)
Phlebitis	Vascular disorders	47 (0.04%)
Status epilepticus	Nervous system disorders	47 (0.04%)
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	47 (0.04%)
Dysmenorrhoea	Reproductive system and breast disorders	46 (0.04%)
Faeces discoloured	Gastrointestinal disorders	46 (0.04%)
Ophthalmic herpes zoster	Infections and infestations	46 (0.04%)
Temperature regulation disorder	General disorders and administration site conditions	46 (0.04%)
Vaccination site joint pain	General disorders and administration site conditions	46 (0.04%)
Vomiting projectile	Gastrointestinal disorders	46 (0.04%)
Body temperature fluctuation	Investigations	45 (0.04%)
Erythema multiforme	Skin and subcutaneous tissue disorders	45 (0.04%)
Hangover	General disorders and administration site conditions	45 (0.04%)
Herpes simplex	Infections and infestations	45 (0.04%)
Hypophagia	Metabolism and nutrition disorders	45 (0.04%)
Multiple organ dysfunction syndrome	General disorders and administration site conditions	45 (0.04%)
Palatal oedema	Gastrointestinal disorders	45 (0.04%)
Product storage error	Injury, poisoning and procedural complications	45 (0.04%)
Pulse abnormal	Investigations	45 (0.04%)
Vaccination site nodule	General disorders and administration site conditions	45 (0.04%)
Visual field defect	Nervous system disorders	45 (0.04%)
Blepharospasm	Eye disorders	44 (0.04%)
Cerebral thrombosis	Nervous system disorders	44 (0.04%)
Coagulopathy	Blood and lymphatic system disorders	44 (0.04%)
Lymphopenia	Blood and lymphatic system disorders	44 (0.04%)
Bradypnea	Psychiatric disorders	43 (0.04%)
Irritable bowel syndrome	Gastrointestinal disorders	43 (0.04%)
Muscle rigidity	Musculoskeletal and connective tissue disorders	43 (0.04%)
Periarthritis	Musculoskeletal and connective tissue disorders	43 (0.04%)
Viral infection	Infections and infestations	43 (0.04%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Anaesthesia	Nervous system disorders	42 (0.04%)
Diverticulitis	Infections and infestations	42 (0.04%)
Ear pruritus	Ear and labyrinth disorders	42 (0.04%)
Hypokalaemia	Metabolism and nutrition disorders	42 (0.04%)
Neurological symptom	Nervous system disorders	42 (0.04%)
Panic reaction	Psychiatric disorders	42 (0.04%)
Pharyngitis	Infections and infestations	42 (0.04%)
Product colour issue	Product issues	42 (0.04%)
Abnormal faeces	Gastrointestinal disorders	41 (0.04%)
Bursitis	Musculoskeletal and connective tissue disorders	41 (0.04%)
Conjunctival hyperaemia	Eye disorders	41 (0.04%)
Diarrhoea haemorrhagic	Gastrointestinal disorders	41 (0.04%)
Erysipelas	Infections and infestations	41 (0.04%)
Eye movement disorder	Eye disorders	41 (0.04%)
Jaundice	Hepatobiliary disorders	41 (0.04%)
Multiple sclerosis relapse	Nervous system disorders	41 (0.04%)
Nerve injury	Injury, poisoning and procedural complications	41 (0.04%)
Petit mal epilepsy	Nervous system disorders	41 (0.04%)
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	41 (0.04%)
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	41 (0.04%)
Skin tightness	Skin and subcutaneous tissue disorders	41 (0.04%)
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	41 (0.04%)
Choking sensation	Respiratory, thoracic and mediastinal disorders	40 (0.04%)
Coma	Nervous system disorders	40 (0.04%)
Emotional disorder	Psychiatric disorders	40 (0.04%)
Gastroenteritis	Infections and infestations	40 (0.04%)
Mental disorder	Psychiatric disorders	40 (0.04%)
Peripheral vascular disorder	Vascular disorders	40 (0.04%)
Post viral fatigue syndrome	Infections and infestations	40 (0.04%)
Renal impairment	Renal and urinary disorders	40 (0.04%)
Exposure via skin contact	Injury, poisoning and procedural complications	39 (0.04%)
Hepatic enzyme increased	Investigations	39 (0.04%)
Herpes virus infection	Infections and infestations	39 (0.04%)
Hypovolaemic shock	Vascular disorders	39 (0.04%)
Impaired driving ability	Social circumstances	39 (0.04%)
Oral mucosal blistering	Gastrointestinal disorders	39 (0.04%)
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	39 (0.04%)
Pneumonitis	Respiratory, thoracic and mediastinal disorders	39 (0.04%)
White blood cell count decreased	Investigations	39 (0.04%)
Frequent bowel movements	Gastrointestinal disorders	38 (0.03%)
Gastritis	Gastrointestinal disorders	38 (0.03%)
Gastrointestinal haemorrhage	Gastrointestinal disorders	38 (0.03%)
Limb mass	Musculoskeletal and connective tissue disorders	38 (0.03%)
Liquid product physical issue	Product issues	38 (0.03%)
Motion sickness	Ear and labyrinth disorders	38 (0.03%)
Tendonitis	Musculoskeletal and connective tissue disorders	38 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Ear disorder	Ear and labyrinth disorders	37 (0.03%)
Fluid retention	Metabolism and nutrition disorders	37 (0.03%)
Haemorrhagic stroke	Nervous system disorders	37 (0.03%)
Incontinence	Renal and urinary disorders	37 (0.03%)
Miliaria	Skin and subcutaneous tissue disorders	37 (0.03%)
Nerve compression	Nervous system disorders	37 (0.03%)
Paresis	Nervous system disorders	37 (0.03%)
Subarachnoid haemorrhage	Nervous system disorders	37 (0.03%)
Tonsillitis	Infections and infestations	37 (0.03%)
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	36 (0.03%)
Ataxia	Nervous system disorders	36 (0.03%)
Colitis ulcerative	Gastrointestinal disorders	36 (0.03%)
Deafness neurosensory	Ear and labyrinth disorders	36 (0.03%)
Drug eruption	Skin and subcutaneous tissue disorders	36 (0.03%)
Erectile dysfunction	Reproductive system and breast disorders	36 (0.03%)
Hemianaesthesia	Nervous system disorders	36 (0.03%)
Ischaemic cerebral infarction	Nervous system disorders	36 (0.03%)
Neuritis	Nervous system disorders	36 (0.03%)
Periorbital oedema	Eye disorders	36 (0.03%)
Rales	Respiratory, thoracic and mediastinal disorders	36 (0.03%)
Red blood cell sedimentation rate increased	Investigations	36 (0.03%)
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	36 (0.03%)
Vaccination site infection	Infections and infestations	36 (0.03%)
Vitreous floaters	Eye disorders	36 (0.03%)
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	35 (0.03%)
Adverse drug reaction	General disorders and administration site conditions	35 (0.03%)
Anal incontinence	Gastrointestinal disorders	35 (0.03%)
Cerebral venous sinus thrombosis	Nervous system disorders	35 (0.03%)
Chronic fatigue syndrome	General disorders and administration site conditions	35 (0.03%)
Colitis	Gastrointestinal disorders	35 (0.03%)
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	35 (0.03%)
Leukocytosis	Blood and lymphatic system disorders	35 (0.03%)
Product administration error	Injury, poisoning and procedural complications	35 (0.03%)
Product complaint	Product issues	35 (0.03%)
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	35 (0.03%)
Vestibular neuronitis	Infections and infestations	35 (0.03%)
Weight increased	Investigations	35 (0.03%)
Gingival bleeding	Gastrointestinal disorders	34 (0.03%)
Lip dry	Gastrointestinal disorders	34 (0.03%)
Myelitis transverse	Nervous system disorders	34 (0.03%)
Myoclonus	Nervous system disorders	34 (0.03%)
Oral disorder	Gastrointestinal disorders	34 (0.03%)
Orthostatic hypotension	Vascular disorders	34 (0.03%)
Papule	Skin and subcutaneous tissue disorders	34 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Rhinalgia	Respiratory, thoracic and mediastinal disorders	34 (0.03%)
Aggression	Psychiatric disorders	33 (0.03%)
Atrial flutter	Cardiac disorders	33 (0.03%)
Blood potassium decreased	Investigations	33 (0.03%)
Cardiac failure congestive	Cardiac disorders	33 (0.03%)
Dermatitis bullous	Skin and subcutaneous tissue disorders	33 (0.03%)
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	33 (0.03%)
Encephalitis	Infections and infestations	33 (0.03%)
Initial insomnia	Psychiatric disorders	33 (0.03%)
Mastitis	Infections and infestations	33 (0.03%)
Myositis	Musculoskeletal and connective tissue disorders	33 (0.03%)
Neck mass	Musculoskeletal and connective tissue disorders	33 (0.03%)
Nuchal rigidity	Musculoskeletal and connective tissue disorders	33 (0.03%)
Nystagmus	Nervous system disorders	33 (0.03%)
Oral candidiasis	Infections and infestations	33 (0.03%)
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	33 (0.03%)
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	33 (0.03%)
Ventricular fibrillation	Cardiac disorders	33 (0.03%)
Blindness unilateral	Eye disorders	32 (0.03%)
Breast mass	Reproductive system and breast disorders	32 (0.03%)
Injection site reaction	General disorders and administration site conditions	32 (0.03%)
Injection site warmth	General disorders and administration site conditions	32 (0.03%)
Localised infection	Infections and infestations	32 (0.03%)
Muscle contracture	Musculoskeletal and connective tissue disorders	32 (0.03%)
Nasal oedema	Respiratory, thoracic and mediastinal disorders	32 (0.03%)
Near death experience	Psychiatric disorders	32 (0.03%)
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	32 (0.03%)
Optic neuritis	Nervous system disorders	32 (0.03%)
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	32 (0.03%)
Vaccination site vesicles	General disorders and administration site conditions	32 (0.03%)
Arthritis reactive	Musculoskeletal and connective tissue disorders	31 (0.03%)
Asthmatic crisis	Respiratory, thoracic and mediastinal disorders	31 (0.03%)
Cerebral ischaemia	Nervous system disorders	31 (0.03%)
Eye oedema	Eye disorders	31 (0.03%)
Gingival swelling	Gastrointestinal disorders	31 (0.03%)
Leukopenia	Blood and lymphatic system disorders	31 (0.03%)
Psychomotor hyperactivity	Nervous system disorders	31 (0.03%)
Seasonal allergy	Immune system disorders	31 (0.03%)
Secretion discharge	General disorders and administration site conditions	31 (0.03%)
Visual acuity reduced	Eye disorders	31 (0.03%)
		31 (0.03%)
Antibody test abnormal	Investigations	30 (0.03%)
Blood creatine phosphokinase increased	Investigations	30 (0.03%)
Cardiogenic shock	Cardiac disorders	30 (0.03%)
Euphoric mood	Psychiatric disorders	30 (0.03%)
Hallucination, auditory	Psychiatric disorders	30 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Incomplete course of vaccination	Injury, poisoning and procedural complications	30 (0.03%)
Nephrolithiasis	Renal and urinary disorders	30 (0.03%)
Renal disorder	Renal and urinary disorders	30 (0.03%)
Suicidal ideation	Psychiatric disorders	30 (0.03%)
Temperature intolerance	General disorders and administration site conditions	30 (0.03%)
Tunnel vision	Nervous system disorders	30 (0.03%)
Uveitis	Eye disorders	30 (0.03%)
Venous thrombosis limb	Vascular disorders	30 (0.03%)
Wound	Injury, poisoning and procedural complications	30 (0.03%)
Abnormal sensation in eye	Eye disorders	29 (0.03%)
Blood glucose fluctuation	Investigations	29 (0.03%)
Body height decreased	Investigations	29 (0.03%)
Breast tenderness	Reproductive system and breast disorders	29 (0.03%)
Emotional distress	Psychiatric disorders	29 (0.03%)
Eye discharge	Eye disorders	29 (0.03%)
Hypotonic-hyporesponsive episode	Nervous system disorders	29 (0.03%)
Injury	Injury, poisoning and procedural complications	29 (0.03%)
Joint effusion	Musculoskeletal and connective tissue disorders	29 (0.03%)
Micturition urgency	Renal and urinary disorders	29 (0.03%)
Muscle disorder	Musculoskeletal and connective tissue disorders	29 (0.03%)
Osteoarthritis	Musculoskeletal and connective tissue disorders	29 (0.03%)
Septic shock	Infections and infestations	29 (0.03%)
Tension	Psychiatric disorders	29 (0.03%)
Upper respiratory tract infection	Infections and infestations	29 (0.03%)
Body temperature	Investigations	28 (0.03%)
Hyponatraemia	Metabolism and nutrition disorders	28 (0.03%)
Incoherent	Nervous system disorders	28 (0.03%)
Injection site urticaria	General disorders and administration site conditions	28 (0.03%)
Joint injury	Injury, poisoning and procedural complications	28 (0.03%)
Lymphangitis	Infections and infestations	28 (0.03%)
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	28 (0.03%)
Product supply issue	Product issues	28 (0.03%)
Scratch	Injury, poisoning and procedural complications	28 (0.03%)
Abnormal behaviour	Psychiatric disorders	27 (0.02%)
Apnoea	Respiratory, thoracic and mediastinal disorders	27 (0.02%)
Coronavirus infection	Infections and infestations	27 (0.02%)
Dizziness exertional	Nervous system disorders	27 (0.02%)
Electrocardiogram abnormal	Investigations	27 (0.02%)
Facial discomfort	General disorders and administration site conditions	27 (0.02%)
Intestinal ischaemia	Gastrointestinal disorders	27 (0.02%)
Lip blister	Gastrointestinal disorders	27 (0.02%)
Muscle discomfort	Musculoskeletal and connective tissue disorders	27 (0.02%)
Myocardial ischaemia	Cardiac disorders	27 (0.02%)
Neutrophil count increased	Investigations	27 (0.02%)
Oxygen saturation abnormal	Investigations	27 (0.02%)
Pancreatitis	Gastrointestinal disorders	27 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Retinal vein occlusion	Eye disorders	27 (0.02%)
Skin laceration	Injury, poisoning and procedural complications	27 (0.02%)
Skin mass	Skin and subcutaneous tissue disorders	27 (0.02%)
Aspartate aminotransferase increased	Investigations	26 (0.02%)
Blindness transient	Eye disorders	26 (0.02%)
Cardiac failure acute	Cardiac disorders	26 (0.02%)
Crohn's disease	Gastrointestinal disorders	26 (0.02%)
Enlarged uvula	Gastrointestinal disorders	26 (0.02%)
Faeces soft	Gastrointestinal disorders	26 (0.02%)
Glossitis	Gastrointestinal disorders	26 (0.02%)
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	26 (0.02%)
Kidney infection	Infections and infestations	26 (0.02%)
Mood altered	Psychiatric disorders	26 (0.02%)
Muscle swelling	Musculoskeletal and connective tissue disorders	26 (0.02%)
Oedema mouth	Gastrointestinal disorders	26 (0.02%)
Palatal swelling	Gastrointestinal disorders	26 (0.02%)
Pancreatitis acute	Gastrointestinal disorders	26 (0.02%)
Pustule	Infections and infestations	26 (0.02%)
Respiratory rate decreased	Investigations	26 (0.02%)
Tongue ulceration	Gastrointestinal disorders	26 (0.02%)
Vaccination site hyperaesthesia	General disorders and administration site conditions	26 (0.02%)
Ventricular tachycardia	Cardiac disorders	26 (0.02%)
Blood creatinine increased	Investigations	25 (0.02%)
Dissociation	Psychiatric disorders	25 (0.02%)
Eye inflammation	Eye disorders	25 (0.02%)
Foreign body sensation in eyes	Eye disorders	25 (0.02%)
Glomerular filtration rate decreased	Investigations	25 (0.02%)
Herpes ophthalmic	Infections and infestations	25 (0.02%)
International normalised ratio decreased	Investigations	25 (0.02%)
Lip disorder	Gastrointestinal disorders	25 (0.02%)
Mydriasis	Eye disorders	25 (0.02%)
Piloerection	Skin and subcutaneous tissue disorders	25 (0.02%)
Pityriasis rosea	Skin and subcutaneous tissue disorders	25 (0.02%)
Pleurisy	Respiratory, thoracic and mediastinal disorders	25 (0.02%)
Polyarthritis	Musculoskeletal and connective tissue disorders	25 (0.02%)
Polyuria	Renal and urinary disorders	25 (0.02%)
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	25 (0.02%)
Pulmonary infarction	Respiratory, thoracic and mediastinal disorders	25 (0.02%)
Rash morbilliform	Skin and subcutaneous tissue disorders	25 (0.02%)
Trismus	Musculoskeletal and connective tissue disorders	25 (0.02%)
Aspiration	Respiratory, thoracic and mediastinal disorders	24 (0.02%)
Drooling	Nervous system disorders	24 (0.02%)
Erythema of eyelid	Eye disorders	24 (0.02%)
Eye injury	Injury, poisoning and procedural complications	24 (0.02%)
Gastrointestinal sounds abnormal	Gastrointestinal disorders	24 (0.02%)
Melaena	Gastrointestinal disorders	24 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Meniere's disease	Ear and labyrinth disorders	24 (0.02%)
Product quality issue	Product issues	24 (0.02%)
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	24 (0.02%)
Systemic inflammatory response syndrome	General disorders and administration site conditions	24 (0.02%)
Tearfulness	Psychiatric disorders	24 (0.02%)
Vaccination site joint erythema	General disorders and administration site conditions	24 (0.02%)
Amenorrhoea	Reproductive system and breast disorders	23 (0.02%)
Breath sounds abnormal	Investigations	23 (0.02%)
Costochondritis	Musculoskeletal and connective tissue disorders	23 (0.02%)
Erythema nodosum	Skin and subcutaneous tissue disorders	23 (0.02%)
Eye contusion	Injury, poisoning and procedural complications	23 (0.02%)
Eyelid pain	Eye disorders	23 (0.02%)
Eyelids pruritus	Eye disorders	23 (0.02%)
Facial nerve disorder	Nervous system disorders	23 (0.02%)
Facial spasm	Nervous system disorders	23 (0.02%)
Hepatitis	Hepatobiliary disorders	23 (0.02%)
Hyperaemia	Vascular disorders	23 (0.02%)
Hyposmia	Nervous system disorders	23 (0.02%)
Listless	Psychiatric disorders	23 (0.02%)
Pancytopenia	Blood and lymphatic system disorders	23 (0.02%)
Platelet count increased	Investigations	23 (0.02%)
Polyneuropathy	Nervous system disorders	23 (0.02%)
Reaction to excipient	Immune system disorders	23 (0.02%)
Sleep disorder due to a general medical condition	Psychiatric disorders	23 (0.02%)
Synovial cyst	Musculoskeletal and connective tissue disorders	23 (0.02%)
Tongue dry	Gastrointestinal disorders	23 (0.02%)
Vaccination site irritation	General disorders and administration site conditions	23 (0.02%)
Venous thrombosis	Vascular disorders	23 (0.02%)
Blood pressure diastolic increased	Investigations	22 (0.02%)
Cheilitis	Gastrointestinal disorders	22 (0.02%)
Delusion	Psychiatric disorders	22 (0.02%)
Exercise tolerance decreased	General disorders and administration site conditions	22 (0.02%)
Gamma-glutamyltransferase increased	Investigations	22 (0.02%)
Hunger	General disorders and administration site conditions	22 (0.02%)
Hyperthyroidism	Endocrine disorders	22 (0.02%)
Hypothyroidism	Endocrine disorders	22 (0.02%)
Internal haemorrhage	Vascular disorders	22 (0.02%)
Partial seizures	Nervous system disorders	22 (0.02%)
Peripheral ischaemia	Vascular disorders	22 (0.02%)
Product packaging quantity issue	Product issues	22 (0.02%)
Sedation	Nervous system disorders	22 (0.02%)
Skin ulcer	Skin and subcutaneous tissue disorders	22 (0.02%)
Tachyarrhythmia	Cardiac disorders	22 (0.02%)
Tongue discolouration	Gastrointestinal disorders	22 (0.02%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Urosepsis	Infections and infestations	22 (0.02%)
Vitreous detachment	Eye disorders	22 (0.02%)
Abscess	Infections and infestations	21 (0.02%)
Aura	Nervous system disorders	21 (0.02%)
Blood test abnormal	Investigations	21 (0.02%)
Bowel movement irregularity	Gastrointestinal disorders	21 (0.02%)
Concussion	Injury, poisoning and procedural complications	21 (0.02%)
Defaecation urgency	Gastrointestinal disorders	21 (0.02%)
Face injury	Injury, poisoning and procedural complications	21 (0.02%)
Gastroenteritis viral	Infections and infestations	21 (0.02%)
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	21 (0.02%)
Haemorrhoids	Gastrointestinal disorders	21 (0.02%)
Hypersensitivity vasculitis	Skin and subcutaneous tissue disorders	21 (0.02%)
Injection related reaction	Injury, poisoning and procedural complications	21 (0.02%)
Mouth haemorrhage	Gastrointestinal disorders	21 (0.02%)
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	21 (0.02%)
Parkinson's disease	Nervous system disorders	21 (0.02%)
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	21 (0.02%)
Road traffic accident	Injury, poisoning and procedural complications	21 (0.02%)
Scab	Skin and subcutaneous tissue disorders	21 (0.02%)
Vaccination site extravasation	General disorders and administration site conditions	21 (0.02%)
Adverse event	General disorders and administration site conditions	20 (0.02%)
Anuria	Renal and urinary disorders	20 (0.02%)
Autoimmune thyroiditis	Endocrine disorders	20 (0.02%)
Blood sodium decreased	Investigations	20 (0.02%)
Bradykinesia	Nervous system disorders	20 (0.02%)
Dysphemia	Psychiatric disorders	20 (0.02%)
Dystonia	Nervous system disorders	20 (0.02%)
Ecchymosis	Skin and subcutaneous tissue disorders	20 (0.02%)
Eye infection	Infections and infestations	20 (0.02%)
Interstitial lung disease	Respiratory, thoracic and mediastinal disorders	20 (0.02%)
Liver function test increased	Investigations	20 (0.02%)
Lung infiltration	Respiratory, thoracic and mediastinal disorders	20 (0.02%)
Neuralgic amyotrophy	Nervous system disorders	20 (0.02%)
Nipple pain	Reproductive system and breast disorders	20 (0.02%)
Personality change	Psychiatric disorders	20 (0.02%)
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	20 (0.02%)
Skin haemorrhage	Skin and subcutaneous tissue disorders	20 (0.02%)
Skin sensitisation	Skin and subcutaneous tissue disorders	20 (0.02%)
Tendon pain	Musculoskeletal and connective tissue disorders	20 (0.02%)
Transaminases increased	Investigations	20 (0.02%)
Type IV hypersensitivity reaction	Immune system disorders	20 (0.02%)
Vasodilatation	Vascular disorders	20 (0.02%)
Vlth nerve paralysis	Nervous system disorders	20 (0.02%)
Atrioventricular block complete	Cardiac disorders	19 (0.02%)
Bone swelling	Musculoskeletal and connective tissue disorders	19 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bundle branch block right	Cardiac disorders	19 (0.02%)
Communication disorder	Psychiatric disorders	19 (0.02%)
Energy increased	General disorders and administration site conditions	19 (0.02%)
Facial neuralgia	Nervous system disorders	19 (0.02%)
Giant cell arteritis	Vascular disorders	19 (0.02%)
Goitre	Endocrine disorders	19 (0.02%)
Haemorrhage urinary tract	Renal and urinary disorders	19 (0.02%)
Hepatic pain	Hepatobiliary disorders	19 (0.02%)
Hepatocellular injury	Hepatobiliary disorders	19 (0.02%)
Hip fracture	Injury, poisoning and procedural complications	19 (0.02%)
Hypoaesthesia eye	Eye disorders	19 (0.02%)
Iridocyclitis	Eye disorders	19 (0.02%)
Laryngitis	Infections and infestations	19 (0.02%)
Loss of control of legs	General disorders and administration site conditions	19 (0.02%)
Mastication disorder	Musculoskeletal and connective tissue disorders	19 (0.02%)
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	19 (0.02%)
Medication error	Injury, poisoning and procedural complications	19 (0.02%)
Needle issue	Product issues	19 (0.02%)
Pneumonia bacterial	Infections and infestations	19 (0.02%)
Polymenorrhoea	Reproductive system and breast disorders	19 (0.02%)
Retinal artery occlusion	Eye disorders	19 (0.02%)
Sense of oppression	General disorders and administration site conditions	19 (0.02%)
Supraventricular extrasystoles	Cardiac disorders	19 (0.02%)
Trigeminal nerve disorder	Nervous system disorders	19 (0.02%)
Vaccination site joint swelling	General disorders and administration site conditions	19 (0.02%)
Vaccine breakthrough infection	Infections and infestations	19 (0.02%)
Abdominal rigidity	Gastrointestinal disorders	18 (0.02%)
Arteriosclerosis	Vascular disorders	18 (0.02%)
Blood glucose abnormal	Investigations	18 (0.02%)
Chronic kidney disease	Renal and urinary disorders	18 (0.02%)
Diabetic ketoacidosis	Metabolism and nutrition disorders	18 (0.02%)
Functional gastrointestinal disorder	Gastrointestinal disorders	18 (0.02%)
Hyperleukocytosis	Blood and lymphatic system disorders	18 (0.02%)
Hypernatraemia	Metabolism and nutrition disorders	18 (0.02%)
Hypogeusia	Nervous system disorders	18 (0.02%)
Injection site rash	General disorders and administration site conditions	18 (0.02%)
Intestinal obstruction	Gastrointestinal disorders	18 (0.02%)
Ligament sprain	Injury, poisoning and procedural complications	18 (0.02%)
Liver function test abnormal	Investigations	18 (0.02%)
Lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	18 (0.02%)
Meningitis	Infections and infestations	18 (0.02%)
Myelitis	Infections and infestations	18 (0.02%)
Neurogenic shock	Vascular disorders	18 (0.02%)
Paranoia	Psychiatric disorders	18 (0.02%)
Pemphigoid	Skin and subcutaneous tissue disorders	18 (0.02%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Postmenopausal haemorrhage	Reproductive system and breast disorders	18 (0.02%)
Postural orthostatic tachycardia syndrome	Cardiac disorders	18 (0.02%)
Psychotic disorder	Psychiatric disorders	18 (0.02%)
Allodynia	Nervous system disorders	17 (0.02%)
Blood blister	Skin and subcutaneous tissue disorders	17 (0.02%)
Breath odour	Gastrointestinal disorders	17 (0.02%)
Diplegia	Nervous system disorders	17 (0.02%)
Epigastric discomfort	Gastrointestinal disorders	17 (0.02%)
Furuncle	Infections and infestations	17 (0.02%)
Herpes zoster oticus	Infections and infestations	17 (0.02%)
Irregular breathing	Respiratory, thoracic and mediastinal disorders	17 (0.02%)
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	17 (0.02%)
Myasthenia gravis	Nervous system disorders	17 (0.02%)
Nasal dryness	Respiratory, thoracic and mediastinal disorders	17 (0.02%)
Neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17 (0.02%)
Occupational exposure to product	Injury, poisoning and procedural complications	17 (0.02%)
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	17 (0.02%)
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	17 (0.02%)
Sudden cardiac death	General disorders and administration site conditions	17 (0.02%)
Tongue blistering	Gastrointestinal disorders	17 (0.02%)
Tonic clonic movements	Nervous system disorders	17 (0.02%)
Tonic convulsion	Nervous system disorders	17 (0.02%)
Viral rash	Infections and infestations	17 (0.02%)
Yawning	Respiratory, thoracic and mediastinal disorders	17 (0.02%)
Yellow skin	Skin and subcutaneous tissue disorders	17 (0.02%)
Asphyxia	Respiratory, thoracic and mediastinal disorders	16 (0.01%)
Autonomic nervous system imbalance	Nervous system disorders	16 (0.01%)
Blood alkaline phosphatase increased	Investigations	16 (0.01%)
Blood bilirubin increased	Investigations	16 (0.01%)
Blood thyroid stimulating hormone increased	Investigations	16 (0.01%)
Brain oedema	Nervous system disorders	16 (0.01%)
Cardiac discomfort	Cardiac disorders	16 (0.01%)
Catarrh	Respiratory, thoracic and mediastinal disorders	16 (0.01%)
Dermatitis atopic	Skin and subcutaneous tissue disorders	16 (0.01%)
Embolic stroke	Nervous system disorders	16 (0.01%)
Eyelid function disorder	Eye disorders	16 (0.01%)
Fluid intake reduced	Metabolism and nutrition disorders	16 (0.01%)
Food allergy	Immune system disorders	16 (0.01%)
Genital herpes	Infections and infestations	16 (0.01%)
Gingivitis	Infections and infestations	16 (0.01%)
Haematocrit decreased	Investigations	16 (0.01%)
Hordeolum	Infections and infestations	16 (0.01%)
Immobile	Social circumstances	16 (0.01%)
Injection site discomfort	General disorders and administration site conditions	16 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Joint lock	Musculoskeletal and connective tissue disorders	16 (0.01%)
Lip erythema	Gastrointestinal disorders	16 (0.01%)
Lymphocyte count decreased	Investigations	16 (0.01%)
Mechanical urticaria	Skin and subcutaneous tissue disorders	16 (0.01%)
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	16 (0.01%)
Nephrotic syndrome	Renal and urinary disorders	16 (0.01%)
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	16 (0.01%)
Paraparesis	Nervous system disorders	16 (0.01%)
Peroneal nerve palsy	Nervous system disorders	16 (0.01%)
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	16 (0.01%)
Polydipsia	Metabolism and nutrition disorders	16 (0.01%)
Product leakage	Product issues	16 (0.01%)
Pyelonephritis	Infections and infestations	16 (0.01%)
Q fever	Infections and infestations	16 (0.01%)
Red blood cell count decreased	Investigations	16 (0.01%)
Slow speech	Nervous system disorders	16 (0.01%)
Sopor	Psychiatric disorders	16 (0.01%)
Stupor	Nervous system disorders	16 (0.01%)
Testicular pain	Reproductive system and breast disorders	16 (0.01%)
Tongue coated	Gastrointestinal disorders	16 (0.01%)
Type 1 diabetes mellitus	Metabolism and nutrition disorders	16 (0.01%)
Upper limb fracture	Injury, poisoning and procedural complications	16 (0.01%)
Urine output decreased	Investigations	16 (0.01%)
Anger	Psychiatric disorders	15 (0.01%)
Atelectasis	Respiratory, thoracic and mediastinal disorders	15 (0.01%)
Back disorder	Musculoskeletal and connective tissue disorders	15 (0.01%)
Blood cholesterol increased	Investigations	15 (0.01%)
Blood lactic acid increased	Investigations	15 (0.01%)
Blood pressure diastolic decreased	Investigations	15 (0.01%)
Cerebral haematoma	Nervous system disorders	15 (0.01%)
Cervicobrachial syndrome	Nervous system disorders	15 (0.01%)
Coronary artery disease	Cardiac disorders	15 (0.01%)
Hepatic function abnormal	Hepatobiliary disorders	15 (0.01%)
Herpes zoster reactivation	Infections and infestations	15 (0.01%)
Hyperkalaemia	Metabolism and nutrition disorders	15 (0.01%)
Hypertonia	Nervous system disorders	15 (0.01%)
Hyporeflexia	Nervous system disorders	15 (0.01%)
Infarction	Vascular disorders	15 (0.01%)
Inflammatory marker increased	Investigations	15 (0.01%)
Injection site induration	General disorders and administration site conditions	15 (0.01%)
Laryngeal discomfort	Respiratory, thoracic and mediastinal disorders	15 (0.01%)
Lymph node palpable	Investigations	15 (0.01%)
Metamorphopsia	Eye disorders	15 (0.01%)
Mood swings	Psychiatric disorders	15 (0.01%)
Neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Neutrophil count decreased	Investigations	15 (0.01%)
Noninfective gingivitis	Gastrointestinal disorders	15 (0.01%)
Occipital neuralgia	Nervous system disorders	15 (0.01%)
Parotitis	Infections and infestations	15 (0.01%)
Peripheral sensory neuropathy	Nervous system disorders	15 (0.01%)
Poor peripheral circulation	Vascular disorders	15 (0.01%)
Rash pustular	Infections and infestations	15 (0.01%)
Rib fracture	Injury, poisoning and procedural complications	15 (0.01%)
Scar	Injury, poisoning and procedural complications	15 (0.01%)
Sialoadenitis	Infections and infestations	15 (0.01%)
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	15 (0.01%)
Throat clearing	Respiratory, thoracic and mediastinal disorders	15 (0.01%)
Tongue eruption	Gastrointestinal disorders	15 (0.01%)
Tongue erythema	Gastrointestinal disorders	15 (0.01%)
Urine odour abnormal	Renal and urinary disorders	15 (0.01%)
Administration site oedema	General disorders and administration site conditions	14 (0.01%)
Anal haemorrhage	Gastrointestinal disorders	14 (0.01%)
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	14 (0.01%)
Appetite disorder	Metabolism and nutrition disorders	14 (0.01%)
Behaviour disorder	Psychiatric disorders	14 (0.01%)
Blepharitis	Eye disorders	14 (0.01%)
Breast discomfort	Reproductive system and breast disorders	14 (0.01%)
Cardiopulmonary failure	Cardiac disorders	14 (0.01%)
Chapped lips	Gastrointestinal disorders	14 (0.01%)
Cholestasis	Hepatobiliary disorders	14 (0.01%)
Demyelination	Nervous system disorders	14 (0.01%)
Derealisation	Psychiatric disorders	14 (0.01%)
Encephalopathy	Nervous system disorders	14 (0.01%)
Eyelid disorder	Eye disorders	14 (0.01%)
Generalised oedema	General disorders and administration site conditions	14 (0.01%)
Haemolytic anaemia	Blood and lymphatic system disorders	14 (0.01%)
Hepatitis acute	Hepatobiliary disorders	14 (0.01%)
Immunisation anxiety related reaction	Psychiatric disorders	14 (0.01%)
Injection site inflammation	General disorders and administration site conditions	14 (0.01%)
Injection site paraesthesia	General disorders and administration site conditions	14 (0.01%)
Jaw disorder	Musculoskeletal and connective tissue disorders	14 (0.01%)
Joint warmth	Musculoskeletal and connective tissue disorders	14 (0.01%)
Liver disorder	Hepatobiliary disorders	14 (0.01%)
Liver injury	Hepatobiliary disorders	14 (0.01%)
Meningitis aseptic	Infections and infestations	14 (0.01%)
Muscle spasticity	Nervous system disorders	14 (0.01%)
Oral mucosal erythema	Gastrointestinal disorders	14 (0.01%)
Palmar erythema	Skin and subcutaneous tissue disorders	14 (0.01%)
Peripheral circulatory failure	Vascular disorders	14 (0.01%)
Radiculopathy	Nervous system disorders	14 (0.01%)
Reduced facial expression	Nervous system disorders	14 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Rotator cuff syndrome	Musculoskeletal and connective tissue disorders	14 (0.01%)
Skin abrasion	Injury, poisoning and procedural complications	14 (0.01%)
Subdural haematoma	Injury, poisoning and procedural complications	14 (0.01%)
Tooth infection	Infections and infestations	14 (0.01%)
Use of accessory respiratory muscles	Respiratory, thoracic and mediastinal disorders	14 (0.01%)
Varicose vein	Vascular disorders	14 (0.01%)
Vestibular disorder	Ear and labyrinth disorders	14 (0.01%)
Adnexa uteri pain	Reproductive system and breast disorders	13 (0.01%)
Adrenocortical insufficiency acute	Endocrine disorders	13 (0.01%)
Anaesthesia oral	Gastrointestinal disorders	13 (0.01%)
Arrhythmia supraventricular	Cardiac disorders	13 (0.01%)
Bladder disorder	Renal and urinary disorders	13 (0.01%)
Blood lactate dehydrogenase increased	Investigations	13 (0.01%)
Brain injury	Nervous system disorders	13 (0.01%)
Breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (0.01%)
Candida infection	Infections and infestations	13 (0.01%)
Cerebral disorder	Nervous system disorders	13 (0.01%)
Disease progression	General disorders and administration site conditions	13 (0.01%)
Dysgraphia	Nervous system disorders	13 (0.01%)
Dysphoria	Psychiatric disorders	13 (0.01%)
Ear congestion	Ear and labyrinth disorders	13 (0.01%)
Emphysema	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Eosinophil count increased	Investigations	13 (0.01%)
Facial asymmetry	Musculoskeletal and connective tissue disorders	13 (0.01%)
Facial bones fracture	Injury, poisoning and procedural complications	13 (0.01%)
Femur fracture	Injury, poisoning and procedural complications	13 (0.01%)
Fine motor skill dysfunction	Nervous system disorders	13 (0.01%)
Foaming at mouth	General disorders and administration site conditions	13 (0.01%)
Gastrointestinal motility disorder	Gastrointestinal disorders	13 (0.01%)
General physical condition abnormal	Investigations	13 (0.01%)
Glaucoma	Eye disorders	13 (0.01%)
Heart injury	Injury, poisoning and procedural complications	13 (0.01%)
Hyperaesthesia teeth	Gastrointestinal disorders	13 (0.01%)
Hypertensive emergency	Vascular disorders	13 (0.01%)
Illrd nerve paralysis	Nervous system disorders	13 (0.01%)
Increased tendency to bruise	Blood and lymphatic system disorders	13 (0.01%)
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	13 (0.01%)
Intussusception	Gastrointestinal disorders	13 (0.01%)
Metabolic acidosis	Metabolism and nutrition disorders	13 (0.01%)
Oral mucosal eruption	Gastrointestinal disorders	13 (0.01%)
Orthopnoea	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Periorbital pain	Eye disorders	13 (0.01%)
Physical deconditioning	General disorders and administration site conditions	13 (0.01%)
Potentiating drug interaction	General disorders and administration site conditions	13 (0.01%)
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	13 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Sarcoidosis	Immune system disorders	13 (0.01%)
Screaming	General disorders and administration site conditions	13 (0.01%)
Sjogren's syndrome	Musculoskeletal and connective tissue disorders	13 (0.01%)
Sleep deficit	Nervous system disorders	13 (0.01%)
Snoring	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	13 (0.01%)
Tooth disorder	Gastrointestinal disorders	13 (0.01%)
Torticollis	Musculoskeletal and connective tissue disorders	13 (0.01%)
Vaccination site abscess	Infections and infestations	13 (0.01%)
Vaccination site coldness	General disorders and administration site conditions	13 (0.01%)
Vasoconstriction	Vascular disorders	13 (0.01%)
Vein disorder	Vascular disorders	13 (0.01%)
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	13 (0.01%)
Abdominal tenderness	Gastrointestinal disorders	12 (0.01%)
Abortion missed	Pregnancy, puerperium and perinatal conditions	12 (0.01%)
Allergic oedema	Immune system disorders	12 (0.01%)
Allergic reaction to excipient	Immune system disorders	12 (0.01%)
Atrioventricular block	Cardiac disorders	12 (0.01%)
Blood urea increased	Investigations	12 (0.01%)
Cachexia	Metabolism and nutrition disorders	12 (0.01%)
Cardiac fibrillation	Cardiac disorders	12 (0.01%)
Carpal tunnel syndrome	Nervous system disorders	12 (0.01%)
Clonus	Nervous system disorders	12 (0.01%)
Clumsiness	Nervous system disorders	12 (0.01%)
Disorganised speech	Psychiatric disorders	12 (0.01%)
Disseminated Bacillus Calmette-Guerin infection	Infections and infestations	12 (0.01%)
Food aversion	Metabolism and nutrition disorders	12 (0.01%)
Food refusal	Metabolism and nutrition disorders	12 (0.01%)
Frustration tolerance decreased	Psychiatric disorders	12 (0.01%)
Gallbladder disorder	Hepatobiliary disorders	12 (0.01%)
Gaze palsy	Eye disorders	12 (0.01%)
Heart rate	Investigations	12 (0.01%)
Hiccups	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Ischaemia	Vascular disorders	12 (0.01%)
Left ventricular failure	Cardiac disorders	12 (0.01%)
Mucosal dryness	General disorders and administration site conditions	12 (0.01%)
Mutism	Psychiatric disorders	12 (0.01%)
Nail discolouration	Skin and subcutaneous tissue disorders	12 (0.01%)
Narcolepsy	Nervous system disorders	12 (0.01%)
Oliguria	Renal and urinary disorders	12 (0.01%)
Oral dysaesthesia	Gastrointestinal disorders	12 (0.01%)
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Pneumothorax	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Proteinuria	Renal and urinary disorders	12 (0.01%)
Pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	12 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Salivary gland enlargement	Gastrointestinal disorders	12 (0.01%)
Sunburn	Injury, poisoning and procedural complications	12 (0.01%)
Thermal burn	Injury, poisoning and procedural complications	12 (0.01%)
Thyroid disorder	Endocrine disorders	12 (0.01%)
Tongue movement disturbance	Gastrointestinal disorders	12 (0.01%)
Toxicity to various agents	Injury, poisoning and procedural complications	12 (0.01%)
Toxic skin eruption	Skin and subcutaneous tissue disorders	12 (0.01%)
Urinary tract infection bacterial	Infections and infestations	12 (0.01%)
Varicella	Infections and infestations	12 (0.01%)
Vitamin D deficiency	Metabolism and nutrition disorders	12 (0.01%)
Vulvovaginal candidiasis	Infections and infestations	12 (0.01%)
Activated partial thromboplastin time prolonged	Investigations	11 (0.01%)
Acute abdomen	Gastrointestinal disorders	11 (0.01%)
Arterial thrombosis	Vascular disorders	11 (0.01%)
Arthropod bite	Injury, poisoning and procedural complications	11 (0.01%)
Bacterial infection	Infections and infestations	11 (0.01%)
Blood count abnormal	Investigations	11 (0.01%)
Bundle branch block left	Cardiac disorders	11 (0.01%)
Cardiomyopathy	Cardiac disorders	11 (0.01%)
Cerebral venous thrombosis	Nervous system disorders	11 (0.01%)
Decreased activity	General disorders and administration site conditions	11 (0.01%)
Decreased interest	Psychiatric disorders	11 (0.01%)
Dementia Alzheimer's type	Nervous system disorders	11 (0.01%)
Dental discomfort	Gastrointestinal disorders	11 (0.01%)
Enteritis	Gastrointestinal disorders	11 (0.01%)
Eosinophilia	Blood and lymphatic system disorders	11 (0.01%)
Episcleritis	Eye disorders	11 (0.01%)
Fungal infection	Infections and infestations	11 (0.01%)
Grunting	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Haemorrhage intracranial	Nervous system disorders	11 (0.01%)
Haemorrhagic disorder	Blood and lymphatic system disorders	11 (0.01%)
Hyporesponsive to stimuli	Nervous system disorders	11 (0.01%)
Immunodeficiency	Immune system disorders	11 (0.01%)
Impaired quality of life	Social circumstances	11 (0.01%)
Joint dislocation	Injury, poisoning and procedural complications	11 (0.01%)
Joint noise	Musculoskeletal and connective tissue disorders	11 (0.01%)
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Lymph node abscess	Infections and infestations	11 (0.01%)
Macule	Skin and subcutaneous tissue disorders	11 (0.01%)
Meningitis viral	Infections and infestations	11 (0.01%)
Monocyte count increased	Investigations	11 (0.01%)
Mucous stools	Gastrointestinal disorders	11 (0.01%)
Muscle atrophy	Musculoskeletal and connective tissue disorders	11 (0.01%)
Neutrophilia	Blood and lymphatic system disorders	11 (0.01%)
Panic disorder	Psychiatric disorders	11 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Peripheral venous disease	Vascular disorders	11 (0.01%)
Quality of life decreased	Investigations	11 (0.01%)
Respiratory acidosis	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
SARS-CoV-2 test false positive	Investigations	11 (0.01%)
Sinus bradycardia	Cardiac disorders	11 (0.01%)
Sitting disability	Social circumstances	11 (0.01%)
Skin infection	Infections and infestations	11 (0.01%)
Splenomegaly	Blood and lymphatic system disorders	11 (0.01%)
Staphylococcal infection	Infections and infestations	11 (0.01%)
Tenosynovitis	Musculoskeletal and connective tissue disorders	11 (0.01%)
Terminal insomnia	Psychiatric disorders	11 (0.01%)
Tetany	Metabolism and nutrition disorders	11 (0.01%)
Transient global amnesia	Nervous system disorders	11 (0.01%)
Trigger finger	Musculoskeletal and connective tissue disorders	11 (0.01%)
Ulcer	General disorders and administration site conditions	11 (0.01%)
Urine analysis abnormal	Investigations	11 (0.01%)
Vaccination site macule	General disorders and administration site conditions	11 (0.01%)
Vascular purpura	Skin and subcutaneous tissue disorders	11 (0.01%)
Wound haemorrhage	Injury, poisoning and procedural complications	11 (0.01%)
Aortic dissection	Vascular disorders	10 (0.01%)
Appendicitis perforated	Infections and infestations	10 (0.01%)
Autoscopy	Psychiatric disorders	10 (0.01%)
Basedow's disease	Endocrine disorders	10 (0.01%)
Bladder pain	Renal and urinary disorders	10 (0.01%)
Blood iron decreased	Investigations	10 (0.01%)
Blue toe syndrome	Vascular disorders	10 (0.01%)
Cataract	Eye disorders	10 (0.01%)
Cervical radiculopathy	Nervous system disorders	10 (0.01%)
Chest injury	Injury, poisoning and procedural complications	10 (0.01%)
Circumoral oedema	Skin and subcutaneous tissue disorders	10 (0.01%)
Complex regional pain syndrome	Nervous system disorders	10 (0.01%)
Concomitant disease aggravated	General disorders and administration site conditions	10 (0.01%)
Coronary artery stenosis	Cardiac disorders	10 (0.01%)
Diaphragmalgia	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Eyelid irritation	Eye disorders	10 (0.01%)
Feeling of despair	Psychiatric disorders	10 (0.01%)
Foetal death	Pregnancy, puerperium and perinatal conditions	10 (0.01%)
Hepatic failure	Hepatobiliary disorders	10 (0.01%)
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (0.01%)
Lipase increased	Investigations	10 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Mesenteric vein thrombosis	Gastrointestinal disorders	10 (0.01%)
Mitral valve incompetence	Cardiac disorders	10 (0.01%)
Morning sickness	Pregnancy, puerperium and perinatal conditions	10 (0.01%)
Mucosal disorder	General disorders and administration site conditions	10 (0.01%)
Nasal disorder	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Oesophageal pain	Gastrointestinal disorders	10 (0.01%)
Parotid gland enlargement	Gastrointestinal disorders	10 (0.01%)
Peripheral embolism	Vascular disorders	10 (0.01%)
Pharyngeal mass	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Pharyngitis streptococcal	Infections and infestations	10 (0.01%)
Post herpetic neuralgia	Nervous system disorders	10 (0.01%)
Premature baby	Pregnancy, puerperium and perinatal conditions	10 (0.01%)
Pupils unequal	Eye disorders	10 (0.01%)
Radiculitis brachial	Nervous system disorders	10 (0.01%)
Respiratory depression	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Salivary gland pain	Gastrointestinal disorders	10 (0.01%)
Tachycardia paroxysmal	Cardiac disorders	10 (0.01%)
Tic	Psychiatric disorders	10 (0.01%)
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	10 (0.01%)
Vaccination site papule	General disorders and administration site conditions	10 (0.01%)
Vasculitic rash	Skin and subcutaneous tissue disorders	10 (0.01%)
Vestibular migraine	Nervous system disorders	10 (0.01%)
Vulvovaginal pain	Reproductive system and breast disorders	10 (0.01%)
Abdominal symptom	Gastrointestinal disorders	9 (0.01%)
Accident	Injury, poisoning and procedural complications	9 (0.01%)
Acute disseminated encephalomyelitis	Nervous system disorders	9 (0.01%)
Affect lability	Psychiatric disorders	9 (0.01%)
Amaurosis fugax	Eye disorders	9 (0.01%)
Antibody test negative	Investigations	9 (0.01%)
Auditory disorder	Ear and labyrinth disorders	9 (0.01%)
Auricular swelling	Ear and labyrinth disorders	9 (0.01%)
Autoimmune haemolytic anaemia	Blood and lymphatic system disorders	9 (0.01%)
Bacille Calmette-Guerin scar reactivation	Immune system disorders	9 (0.01%)
Bacterial test positive	Investigations	9 (0.01%)
Blood calcium decreased	Investigations	9 (0.01%)
Blood disorder	Blood and lymphatic system disorders	9 (0.01%)
Blood potassium increased	Investigations	9 (0.01%)
Blood pressure systolic decreased	Investigations	9 (0.01%)
Bone disorder	Musculoskeletal and connective tissue disorders	9 (0.01%)
Bronchiectasis	Respiratory, thoracic and mediastinal disorders	9 (0.01%)
Cardiac death	General disorders and administration site conditions	9 (0.01%)
Cardiomegaly	Cardiac disorders	9 (0.01%)
Cholecystitis	Hepatobiliary disorders	9 (0.01%)
Cholelithiasis	Hepatobiliary disorders	9 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Coma scale abnormal	Investigations	9 (0.01%)
Contraindicated product administered	Injury, poisoning and procedural complications	9 (0.01%)
Cranial nerve disorder	Nervous system disorders	9 (0.01%)
Craniocerebral injury	Injury, poisoning and procedural complications	9 (0.01%)
Deafness transitory	Ear and labyrinth disorders	9 (0.01%)
Dermatomyositis	Skin and subcutaneous tissue disorders	9 (0.01%)
Electrocardiogram ST segment elevation	Investigations	9 (0.01%)
Femoral neck fracture	Injury, poisoning and procedural complications	9 (0.01%)
Foreign body in throat	Injury, poisoning and procedural complications	9 (0.01%)
Fracture	Injury, poisoning and procedural complications	9 (0.01%)
Gastric haemorrhage	Gastrointestinal disorders	9 (0.01%)
Gastric ulcer	Gastrointestinal disorders	9 (0.01%)
Gastrointestinal hypermotility	Gastrointestinal disorders	9 (0.01%)
Gingival discomfort	Gastrointestinal disorders	9 (0.01%)
Glomerulonephritis minimal lesion	Renal and urinary disorders	9 (0.01%)
Hallucinations, mixed	Psychiatric disorders	9 (0.01%)
Hypomenorrhoea	Reproductive system and breast disorders	9 (0.01%)
Infectious mononucleosis	Infections and infestations	9 (0.01%)
Injection site bruising	General disorders and administration site conditions	9 (0.01%)
Injection site infection	Infections and infestations	9 (0.01%)
Injection site mass	General disorders and administration site conditions	9 (0.01%)
Inner ear disorder	Ear and labyrinth disorders	9 (0.01%)
Intestinal haemorrhage	Gastrointestinal disorders	9 (0.01%)
Intracranial pressure increased	Nervous system disorders	9 (0.01%)
Intraocular pressure increased	Investigations	9 (0.01%)
Laboratory test abnormal	Investigations	9 (0.01%)
Language disorder	Nervous system disorders	9 (0.01%)
Lung opacity	Respiratory, thoracic and mediastinal disorders	9 (0.01%)
Lymphocytosis	Blood and lymphatic system disorders	9 (0.01%)
Mania	Psychiatric disorders	9 (0.01%)
Meningism	Nervous system disorders	9 (0.01%)
Mental status changes	Psychiatric disorders	9 (0.01%)
Miosis	Eye disorders	9 (0.01%)
Moaning	General disorders and administration site conditions	9 (0.01%)
Myocardial necrosis marker increased	Investigations	9 (0.01%)
N-terminal prohormone brain natriuretic peptide increased	Investigations	9 (0.01%)
Oedema mucosal	General disorders and administration site conditions	9 (0.01%)
Parkinsonism	Nervous system disorders	9 (0.01%)
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	9 (0.01%)
Pigmentation disorder	Skin and subcutaneous tissue disorders	9 (0.01%)
Portal vein thrombosis	Hepatobiliary disorders	9 (0.01%)
Pre-existing condition improved	General disorders and administration site conditions	9 (0.01%)
Proctalgia	Gastrointestinal disorders	9 (0.01%)
Pulmonary hypertension	Respiratory, thoracic and mediastinal disorders	9 (0.01%)
Pulse absent	Investigations	9 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Respiratory fatigue	Respiratory, thoracic and mediastinal disorders	9 (0.01%)
Retinal migraine	Nervous system disorders	9 (0.01%)
Retinal tear	Eye disorders	9 (0.01%)
Rheumatic disorder	Musculoskeletal and connective tissue disorders	9 (0.01%)
SARS-CoV-2 test negative	Investigations	9 (0.01%)
Scleritis	Eye disorders	9 (0.01%)
Shoulder injury related to vaccine administration	General disorders and administration site conditions	9 (0.01%)
Skin erosion	Skin and subcutaneous tissue disorders	9 (0.01%)
Skin fissures	Skin and subcutaneous tissue disorders	9 (0.01%)
Sleep terror	Psychiatric disorders	9 (0.01%)
Soft tissue swelling	Musculoskeletal and connective tissue disorders	9 (0.01%)
Somatic symptom disorder	Psychiatric disorders	9 (0.01%)
Staring	Psychiatric disorders	9 (0.01%)
Strabismus	Eye disorders	9 (0.01%)
Stress cardiomyopathy	Cardiac disorders	9 (0.01%)
Subcutaneous abscess	Infections and infestations	9 (0.01%)
Syringe issue	Product issues	9 (0.01%)
Thermal burns of eye	Injury, poisoning and procedural complications	9 (0.01%)
Thyroiditis subacute	Endocrine disorders	9 (0.01%)
Tongue biting	Nervous system disorders	9 (0.01%)
Troponin T increased	Investigations	9 (0.01%)
Vaginal discharge	Reproductive system and breast disorders	9 (0.01%)
Vascular pain	Vascular disorders	9 (0.01%)
Vitamin D decreased	Investigations	9 (0.01%)
Walking disability	Social circumstances	9 (0.01%)
Acidosis	Metabolism and nutrition disorders	8 (0.01%)
Acute vestibular syndrome	Ear and labyrinth disorders	8 (0.01%)
Allergic cough	Respiratory, thoracic and mediastinal disorders	8 (0.01%)
Angiopathy	Vascular disorders	8 (0.01%)
Atrial tachycardia	Cardiac disorders	8 (0.01%)
Back injury	Injury, poisoning and procedural complications	8 (0.01%)
Brain death	General disorders and administration site conditions	8 (0.01%)
Cardiac murmur	Investigations	8 (0.01%)
Carotid artery occlusion	Nervous system disorders	8 (0.01%)
Cerebellar stroke	Nervous system disorders	8 (0.01%)
Coronary artery thrombosis	Cardiac disorders	8 (0.01%)
Daydreaming	Psychiatric disorders	8 (0.01%)
Decubitus ulcer	Skin and subcutaneous tissue disorders	8 (0.01%)
Dermatitis contact	Skin and subcutaneous tissue disorders	8 (0.01%)
Dermo-hypodermatitis	Infections and infestations	8 (0.01%)
Disseminated intravascular coagulation	Blood and lymphatic system disorders	8 (0.01%)
Electrocardiogram T wave inversion	Investigations	8 (0.01%)
Electrolyte imbalance	Metabolism and nutrition disorders	8 (0.01%)
Enuresis	Psychiatric disorders	8 (0.01%)
Excessive cerumen production	Ear and labyrinth disorders	8 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Extrapyramidal disorder	Nervous system disorders	8 (0.01%)
Eye paraesthesia	Eye disorders	8 (0.01%)
Folliculitis	Infections and infestations	8 (0.01%)
Gastrointestinal necrosis	Gastrointestinal disorders	8 (0.01%)
Glassy eyes	General disorders and administration site conditions	8 (0.01%)
Haemarthrosis	Musculoskeletal and connective tissue disorders	8 (0.01%)
Haemophagocytic lymphohistiocytosis	Immune system disorders	8 (0.01%)
Hallucination, olfactory	Psychiatric disorders	8 (0.01%)
Hemidysaesthesia	Nervous system disorders	8 (0.01%)
Hyperbilirubinaemia	Hepatobiliary disorders	8 (0.01%)
Hyperchlorhydria	Gastrointestinal disorders	8 (0.01%)
Hypertensive heart disease	Cardiac disorders	8 (0.01%)
Hypocalcaemia	Metabolism and nutrition disorders	8 (0.01%)
Hypotensive crisis	Vascular disorders	8 (0.01%)
Hypoventilation	Respiratory, thoracic and mediastinal disorders	8 (0.01%)
Increased appetite	Metabolism and nutrition disorders	8 (0.01%)
Infant irritability	Nervous system disorders	8 (0.01%)
Inflammatory pain	General disorders and administration site conditions	8 (0.01%)
Injection site haemorrhage	General disorders and administration site conditions	8 (0.01%)
Intentional product misuse	Injury, poisoning and procedural complications	8 (0.01%)
Keratitis	Eye disorders	8 (0.01%)
Lack of spontaneous speech	Psychiatric disorders	8 (0.01%)
Limb immobilisation	Surgical and medical procedures	8 (0.01%)
Lividity	Skin and subcutaneous tissue disorders	8 (0.01%)
Lymph gland infection	Infections and infestations	8 (0.01%)
Macroglossia	Congenital, familial and genetic disorders	8 (0.01%)
Macular degeneration	Eye disorders	8 (0.01%)
Maternal exposure before pregnancy	Injury, poisoning and procedural complications	8 (0.01%)
Micturition disorder	Renal and urinary disorders	8 (0.01%)
Nipple swelling	Reproductive system and breast disorders	8 (0.01%)
Occupational exposure to SARS-CoV-2	Injury, poisoning and procedural complications	8 (0.01%)
Oculomucocutaneous syndrome	Skin and subcutaneous tissue disorders	8 (0.01%)
Optic ischaemic neuropathy	Eye disorders	8 (0.01%)
Oral blood blister	Gastrointestinal disorders	8 (0.01%)
Oversensing	Product issues	8 (0.01%)
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	8 (0.01%)
Peripheral artery thrombosis	Vascular disorders	8 (0.01%)
Phlebitis superficial	Vascular disorders	8 (0.01%)
Plantar fasciitis	Musculoskeletal and connective tissue disorders	8 (0.01%)
Pneumonia viral	Infections and infestations	8 (0.01%)
PO2 decreased	Investigations	8 (0.01%)
Prostatitis	Reproductive system and breast disorders	8 (0.01%)
Prothrombin time prolonged	Investigations	8 (0.01%)
Pulmonary mass	Respiratory, thoracic and mediastinal disorders	8 (0.01%)
Pupil fixed	Eye disorders	8 (0.01%)
Retinal haemorrhage	Eye disorders	8 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Retinal vein thrombosis	Eye disorders	8 (0.01%)
Rosacea	Skin and subcutaneous tissue disorders	8 (0.01%)
Seizure like phenomena	Nervous system disorders	8 (0.01%)
Sensory level abnormal	Investigations	8 (0.01%)
Skin plaque	Skin and subcutaneous tissue disorders	8 (0.01%)
Sleep apnoea syndrome	Respiratory, thoracic and mediastinal disorders	8 (0.01%)
Sleep paralysis	Nervous system disorders	8 (0.01%)
Spinal disorder	Musculoskeletal and connective tissue disorders	8 (0.01%)
Sudden visual loss	Eye disorders	8 (0.01%)
Suppressed lactation	Reproductive system and breast disorders	8 (0.01%)
Tachyphrenia	Psychiatric disorders	8 (0.01%)
Testicular swelling	Reproductive system and breast disorders	8 (0.01%)
Tongue paralysis	Nervous system disorders	8 (0.01%)
Tooth abscess	Infections and infestations	8 (0.01%)
Troponin I increased	Investigations	8 (0.01%)
Type 2 diabetes mellitus	Metabolism and nutrition disorders	8 (0.01%)
Urine abnormality	Renal and urinary disorders	8 (0.01%)
Uterine haemorrhage	Reproductive system and breast disorders	8 (0.01%)
Vaccination site discharge	General disorders and administration site conditions	8 (0.01%)
Vaccination site scab	General disorders and administration site conditions	8 (0.01%)
Acute febrile neutrophilic dermatosis	Skin and subcutaneous tissue disorders	7 (0.01%)
Acute myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Aortic aneurysm	Vascular disorders	7 (0.01%)
Aortic arteriosclerosis	Vascular disorders	7 (0.01%)
Areflexia	Nervous system disorders	7 (0.01%)
Arteriosclerosis coronary artery	Cardiac disorders	7 (0.01%)
Ascites	Gastrointestinal disorders	7 (0.01%)
Basilar artery thrombosis	Nervous system disorders	7 (0.01%)
Biliary colic	Hepatobiliary disorders	7 (0.01%)
Bladder discomfort	Renal and urinary disorders	7 (0.01%)
Blood chloride increased	Investigations	7 (0.01%)
Breast oedema	Reproductive system and breast disorders	7 (0.01%)
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Butterfly rash	Skin and subcutaneous tissue disorders	7 (0.01%)
Cardiovascular insufficiency	Cardiac disorders	7 (0.01%)
Cerebellar infarction	Nervous system disorders	7 (0.01%)
Cerebellar syndrome	Nervous system disorders	7 (0.01%)
Cerebral artery thrombosis	Nervous system disorders	7 (0.01%)
Cerebrovascular disorder	Nervous system disorders	7 (0.01%)
Circumoral swelling	Skin and subcutaneous tissue disorders	7 (0.01%)
Conjunctival irritation	Eye disorders	7 (0.01%)
Conjunctivitis allergic	Eye disorders	7 (0.01%)
Consciousness fluctuating	Nervous system disorders	7 (0.01%)
Cyst	General disorders and administration site conditions	7 (0.01%)
Cystitis haemorrhagic	Renal and urinary disorders	7 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Deafness bilateral	Ear and labyrinth disorders	7 (0.01%)
Demyelinating polyneuropathy	Nervous system disorders	7 (0.01%)
Depersonalisation/derealisation disorder	Psychiatric disorders	7 (0.01%)
Diet refusal	Metabolism and nutrition disorders	7 (0.01%)
Epicondylitis	Injury, poisoning and procedural complications	7 (0.01%)
Escherichia infection	Infections and infestations	7 (0.01%)
Escherichia urinary tract infection	Infections and infestations	7 (0.01%)
Essential hypertension	Vascular disorders	7 (0.01%)
Exfoliative rash	Skin and subcutaneous tissue disorders	7 (0.01%)
External ear pain	Ear and labyrinth disorders	7 (0.01%)
Eye allergy	Eye disorders	7 (0.01%)
Eyelid rash	Eye disorders	7 (0.01%)
Fear of death	Psychiatric disorders	7 (0.01%)
Food poisoning	Gastrointestinal disorders	7 (0.01%)
Gastric dilatation	Gastrointestinal disorders	7 (0.01%)
Heat stroke	Injury, poisoning and procedural complications	7 (0.01%)
Hepatomegaly	Hepatobiliary disorders	7 (0.01%)
Hypertensive urgency	Vascular disorders	7 (0.01%)
Ileus paralytic	Gastrointestinal disorders	7 (0.01%)
Immunisation	Surgical and medical procedures	7 (0.01%)
Impaired healing	General disorders and administration site conditions	7 (0.01%)
Injection site haematoma	General disorders and administration site conditions	7 (0.01%)
Insulin resistance	Metabolism and nutrition disorders	7 (0.01%)
Intracranial aneurysm	Nervous system disorders	7 (0.01%)
Iritis	Eye disorders	7 (0.01%)
Ketoacidosis	Metabolism and nutrition disorders	7 (0.01%)
Lacunar stroke	Nervous system disorders	7 (0.01%)
Lagophthalmos	Eye disorders	7 (0.01%)
Larynx irritation	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Laziness	Psychiatric disorders	7 (0.01%)
Leukoencephalopathy	Nervous system disorders	7 (0.01%)
Lip injury	Injury, poisoning and procedural complications	7 (0.01%)
Lung neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Macular oedema	Eye disorders	7 (0.01%)
Major depression	Psychiatric disorders	7 (0.01%)
Metastases to lymph nodes	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Muscle injury	Injury, poisoning and procedural complications	7 (0.01%)
Non-cardiac chest pain	General disorders and administration site conditions	7 (0.01%)
Oral mucosal exfoliation	Gastrointestinal disorders	7 (0.01%)
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Otitis externa	Infections and infestations	7 (0.01%)
Otitis media	Infections and infestations	7 (0.01%)
Paraesthesia ear	Ear and labyrinth disorders	7 (0.01%)
Paraesthesia mucosal	Nervous system disorders	7 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Peak expiratory flow rate decreased	Investigations	7 (0.01%)
Pemphigus	Skin and subcutaneous tissue disorders	7 (0.01%)
Performance status decreased	General disorders and administration site conditions	7 (0.01%)
Poisoning	Injury, poisoning and procedural complications	7 (0.01%)
Premenstrual syndrome	Reproductive system and breast disorders	7 (0.01%)
Prostate cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Psychiatric symptom	Psychiatric disorders	7 (0.01%)
Pulmonary sepsis	Infections and infestations	7 (0.01%)
Pulse volume decreased	Investigations	7 (0.01%)
Quadriplegia	Nervous system disorders	7 (0.01%)
Renal cyst	Renal and urinary disorders	7 (0.01%)
Retinal detachment	Eye disorders	7 (0.01%)
Rhonchi	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Sacroiliitis	Musculoskeletal and connective tissue disorders	7 (0.01%)
Scleral discoloration	Eye disorders	7 (0.01%)
Sensitisation	Immune system disorders	7 (0.01%)
Shock symptom	Vascular disorders	7 (0.01%)
Skin temperature	Investigations	7 (0.01%)
Slow response to stimuli	Nervous system disorders	7 (0.01%)
Spinal osteoarthritis	Musculoskeletal and connective tissue disorders	7 (0.01%)
Subclavian vein thrombosis	Vascular disorders	7 (0.01%)
Superinfection bacterial	Infections and infestations	7 (0.01%)
Suspected counterfeit product	Product issues	7 (0.01%)
Thyroid pain	Endocrine disorders	7 (0.01%)
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Tonsillitis bacterial	Infections and infestations	7 (0.01%)
Tracheitis	Infections and infestations	7 (0.01%)
Vaccination error	Injury, poisoning and procedural complications	7 (0.01%)
Vascular dementia	Nervous system disorders	7 (0.01%)
Vascular headache	Nervous system disorders	7 (0.01%)
Ventricular arrhythmia	Cardiac disorders	7 (0.01%)
White matter lesion	Nervous system disorders	7 (0.01%)
Abdominal infection	Infections and infestations	6 (0.01%)
Activated partial thromboplastin time shortened	Investigations	6 (0.01%)
Administration site reaction	General disorders and administration site conditions	6 (0.01%)
Angina unstable	Cardiac disorders	6 (0.01%)
Anorectal discomfort	Gastrointestinal disorders	6 (0.01%)
Arthropod sting	Injury, poisoning and procedural complications	6 (0.01%)
Band sensation	Nervous system disorders	6 (0.01%)
Blood albumin decreased	Investigations	6 (0.01%)
Brain stem stroke	Nervous system disorders	6 (0.01%)
Brain stem syndrome	Nervous system disorders	6 (0.01%)
Breast enlargement	Reproductive system and breast disorders	6 (0.01%)
Breast inflammation	Reproductive system and breast disorders	6 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bruxism	Psychiatric disorders	6 (0.01%)
Burn oral cavity	Injury, poisoning and procedural complications	6 (0.01%)
Cardiac asthma	Cardiac disorders	6 (0.01%)
Central nervous system lesion	Nervous system disorders	6 (0.01%)
Cerebral artery occlusion	Nervous system disorders	6 (0.01%)
Cerebral atrophy	Nervous system disorders	6 (0.01%)
Chest X-ray abnormal	Investigations	6 (0.01%)
Cholinergic syndrome	Nervous system disorders	6 (0.01%)
Coeliac disease	Gastrointestinal disorders	6 (0.01%)
Colitis ischaemic	Gastrointestinal disorders	6 (0.01%)
Corneal reflex decreased	Investigations	6 (0.01%)
Coronary artery occlusion	Cardiac disorders	6 (0.01%)
Crepitations	General disorders and administration site conditions	6 (0.01%)
Cutaneous symptom	Skin and subcutaneous tissue disorders	6 (0.01%)
Cutaneous vasculitis	Skin and subcutaneous tissue disorders	6 (0.01%)
Dermatitis acneiform	Skin and subcutaneous tissue disorders	6 (0.01%)
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	6 (0.01%)
Dyshidrotic eczema	Skin and subcutaneous tissue disorders	6 (0.01%)
Ear haemorrhage	Ear and labyrinth disorders	6 (0.01%)
Electric shock	Injury, poisoning and procedural complications	6 (0.01%)
Endocrine ophthalmopathy	Eye disorders	6 (0.01%)
Endometriosis	Reproductive system and breast disorders	6 (0.01%)
Enterocolitis	Gastrointestinal disorders	6 (0.01%)
Eosinophil count decreased	Investigations	6 (0.01%)
Epstein-Barr virus infection reactivation	Infections and infestations	6 (0.01%)
Exophthalmos	Eye disorders	6 (0.01%)
Faeces pale	Gastrointestinal disorders	6 (0.01%)
Gingival disorder	Gastrointestinal disorders	6 (0.01%)
Haemodynamic instability	Vascular disorders	6 (0.01%)
Haemorrhagic diathesis	Blood and lymphatic system disorders	6 (0.01%)
Hand fracture	Injury, poisoning and procedural complications	6 (0.01%)
Head titubation	Nervous system disorders	6 (0.01%)
Hemianopia	Nervous system disorders	6 (0.01%)
Hemianopia homonymous	Nervous system disorders	6 (0.01%)
Hepatitis cholestatic	Hepatobiliary disorders	6 (0.01%)
Herpes simplex reactivation	Infections and infestations	6 (0.01%)
Hiatus hernia	Gastrointestinal disorders	6 (0.01%)
Hormone level abnormal	Investigations	6 (0.01%)
Hypercapnia	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Hyperreflexia	Nervous system disorders	6 (0.01%)
Hypertransaminaemia	Hepatobiliary disorders	6 (0.01%)
Hypoperfusion	Vascular disorders	6 (0.01%)
Idiopathic intracranial hypertension	Nervous system disorders	6 (0.01%)
Ill-defined disorder	General disorders and administration site conditions	6 (0.01%)
Illusion	Psychiatric disorders	6 (0.01%)
Immunisation reaction	Immune system disorders	6 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Impaired gastric emptying	Gastrointestinal disorders	6 (0.01%)
International normalised ratio abnormal	Investigations	6 (0.01%)
Irritability postvaccinal	General disorders and administration site conditions	6 (0.01%)
Itching scar	Skin and subcutaneous tissue disorders	6 (0.01%)
IVth nerve paralysis	Nervous system disorders	6 (0.01%)
Jaw clicking	Musculoskeletal and connective tissue disorders	6 (0.01%)
Lactic acidosis	Metabolism and nutrition disorders	6 (0.01%)
Lacunar infarction	Nervous system disorders	6 (0.01%)
Laryngeal dyspnoea	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Laryngeal obstruction	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Left ventricular dysfunction	Cardiac disorders	6 (0.01%)
Left ventricular hypertrophy	Cardiac disorders	6 (0.01%)
Leukocyturia	Renal and urinary disorders	6 (0.01%)
Lipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (0.01%)
Lip ulceration	Gastrointestinal disorders	6 (0.01%)
Loss of libido	Psychiatric disorders	6 (0.01%)
Lower limb fracture	Injury, poisoning and procedural complications	6 (0.01%)
Lyme disease	Infections and infestations	6 (0.01%)
Malignant hypertension	Vascular disorders	6 (0.01%)
Malnutrition	Metabolism and nutrition disorders	6 (0.01%)
Migraine without aura	Nervous system disorders	6 (0.01%)
Monocytosis	Blood and lymphatic system disorders	6 (0.01%)
Myalgia intercostal	Musculoskeletal and connective tissue disorders	6 (0.01%)
Myasthenia gravis crisis	Nervous system disorders	6 (0.01%)
Nasal herpes	Infections and infestations	6 (0.01%)
Nephropathy	Renal and urinary disorders	6 (0.01%)
Noninfective encephalitis	Nervous system disorders	6 (0.01%)
Ocular vascular disorder	Eye disorders	6 (0.01%)
Oesophageal spasm	Gastrointestinal disorders	6 (0.01%)
Oligomenorrhoea	Reproductive system and breast disorders	6 (0.01%)
Ophthalmic vein thrombosis	Eye disorders	6 (0.01%)
Oral fungal infection	Infections and infestations	6 (0.01%)
Orbital oedema	Eye disorders	6 (0.01%)
Orchitis	Infections and infestations	6 (0.01%)
Oropharyngeal spasm	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Papilloedema	Eye disorders	6 (0.01%)
Pelvic fracture	Injury, poisoning and procedural complications	6 (0.01%)
Pericardial haemorrhage	Cardiac disorders	6 (0.01%)
Pityriasis	Skin and subcutaneous tissue disorders	6 (0.01%)
Platelet disorder	Blood and lymphatic system disorders	6 (0.01%)
Postictal state	Nervous system disorders	6 (0.01%)
Posture abnormal	Musculoskeletal and connective tissue disorders	6 (0.01%)
Product label confusion	Injury, poisoning and procedural complications	6 (0.01%)
Protein urine present	Investigations	6 (0.01%)
Pruritus allergic	Skin and subcutaneous tissue disorders	6 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Pulpitis dental	Infections and infestations	6 (0.01%)
Pulseless electrical activity	Cardiac disorders	6 (0.01%)
Retinal vascular thrombosis	Eye disorders	6 (0.01%)
Scrotal pain	Reproductive system and breast disorders	6 (0.01%)
Sensation of blood flow	General disorders and administration site conditions	6 (0.01%)
Sensitivity to weather change	General disorders and administration site conditions	6 (0.01%)
Sensorimotor disorder	Nervous system disorders	6 (0.01%)
Serum sickness	Immune system disorders	6 (0.01%)
Severe acute respiratory syndrome	Infections and infestations	6 (0.01%)
Skin induration	Skin and subcutaneous tissue disorders	6 (0.01%)
Skin injury	Injury, poisoning and procedural complications	6 (0.01%)
Skin odour abnormal	Skin and subcutaneous tissue disorders	6 (0.01%)
Sleep talking	Psychiatric disorders	6 (0.01%)
Small intestinal obstruction	Gastrointestinal disorders	6 (0.01%)
Sputum increased	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Sputum purulent	Infections and infestations	6 (0.01%)
Staphylococcal sepsis	Infections and infestations	6 (0.01%)
Stiff tongue	Gastrointestinal disorders	6 (0.01%)
Sudden onset of sleep	Nervous system disorders	6 (0.01%)
Suicide attempt	Psychiatric disorders	6 (0.01%)
Synovitis	Musculoskeletal and connective tissue disorders	6 (0.01%)
Systemic lupus erythematosus rash	Skin and subcutaneous tissue disorders	6 (0.01%)
Systolic hypertension	Vascular disorders	6 (0.01%)
Thrombocytopenic purpura	Blood and lymphatic system disorders	6 (0.01%)
Thrombotic stroke	Nervous system disorders	6 (0.01%)
Thrombotic thrombocytopenic purpura	Blood and lymphatic system disorders	6 (0.01%)
Thyroiditis	Endocrine disorders	6 (0.01%)
Thyroid mass	Endocrine disorders	6 (0.01%)
Tricuspid valve incompetence	Cardiac disorders	6 (0.01%)
Urticaria chronic	Skin and subcutaneous tissue disorders	6 (0.01%)
Urticaria papular	Skin and subcutaneous tissue disorders	6 (0.01%)
Uvulitis	Gastrointestinal disorders	6 (0.01%)
Vaccination site necrosis	General disorders and administration site conditions	6 (0.01%)
Vaginal infection	Infections and infestations	6 (0.01%)
Vulvovaginal burning sensation	Reproductive system and breast disorders	6 (0.01%)
Walking aid user	Social circumstances	6 (0.01%)
Weight fluctuation	Metabolism and nutrition disorders	6 (0.01%)
Accommodation disorder	Eye disorders	5 (0.00%)
Acute cardiac event	Cardiac disorders	5 (0.00%)
Affective disorder	Psychiatric disorders	5 (0.00%)
Alopecia areata	Skin and subcutaneous tissue disorders	5 (0.00%)
Amylase increased	Investigations	5 (0.00%)
Anal sphincter atony	Gastrointestinal disorders	5 (0.00%)
Aneurysm	Vascular disorders	5 (0.00%)
Ankle fracture	Injury, poisoning and procedural complications	5 (0.00%)
Antinuclear antibody positive	Investigations	5 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Aortic stenosis	Vascular disorders	5 (0.00%)
Application site pain	General disorders and administration site conditions	5 (0.00%)
Arterial occlusive disease	Vascular disorders	5 (0.00%)
Arteriospasm coronary	Cardiac disorders	5 (0.00%)
Atypical pneumonia	Infections and infestations	5 (0.00%)
Bacterial sepsis	Infections and infestations	5 (0.00%)
Basal ganglia haemorrhage	Nervous system disorders	5 (0.00%)
Behcet's syndrome	Vascular disorders	5 (0.00%)
Blood creatine increased	Investigations	5 (0.00%)
Blood phosphorus decreased	Investigations	5 (0.00%)
Blood triglycerides increased	Investigations	5 (0.00%)
Blood uric acid increased	Investigations	5 (0.00%)
Booster dose missed	Injury, poisoning and procedural complications	5 (0.00%)
Brain natriuretic peptide increased	Investigations	5 (0.00%)
Brain neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Breast disorder	Reproductive system and breast disorders	5 (0.00%)
Bronchial obstruction	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Bronchostenosis	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Burning sensation mucosal	Nervous system disorders	5 (0.00%)
Cardiac failure chronic	Cardiac disorders	5 (0.00%)
Cardiac tamponade	Cardiac disorders	5 (0.00%)
Carotid artery thrombosis	Nervous system disorders	5 (0.00%)
Cell death	Metabolism and nutrition disorders	5 (0.00%)
Cerebral artery embolism	Nervous system disorders	5 (0.00%)
Chorea	Nervous system disorders	5 (0.00%)
Chromatopsia	Eye disorders	5 (0.00%)
Chronic lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Circadian rhythm sleep disorder	Nervous system disorders	5 (0.00%)
Coagulation time prolonged	Investigations	5 (0.00%)
Cold-stimulus headache	Nervous system disorders	5 (0.00%)
Conjunctival oedema	Eye disorders	5 (0.00%)
Conversion disorder	Psychiatric disorders	5 (0.00%)
Coronavirus test positive	Investigations	5 (0.00%)
COVID-19 immunisation	Surgical and medical procedures	5 (0.00%)
Dermal cyst	Skin and subcutaneous tissue disorders	5 (0.00%)
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	5 (0.00%)
Diabetic metabolic decompensation	Metabolism and nutrition disorders	5 (0.00%)
Discoloured vomit	Gastrointestinal disorders	5 (0.00%)
Disseminated varicella zoster virus infection	Infections and infestations	5 (0.00%)
Diverticulum intestinal	Gastrointestinal disorders	5 (0.00%)
Drowning	General disorders and administration site conditions	5 (0.00%)
Drug-induced liver injury	Hepatobiliary disorders	5 (0.00%)
Ejection fraction decreased	Investigations	5 (0.00%)
Electrocardiogram QT prolonged	Investigations	5 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Electrocardiogram ST segment depression	Investigations	5 (0.00%)
Embolism venous	Vascular disorders	5 (0.00%)
Epiglottic oedema	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Extraocular muscle paresis	Eye disorders	5 (0.00%)
Eye haematoma	Eye disorders	5 (0.00%)
Eyelid sensory disorder	Eye disorders	5 (0.00%)
Faecaloma	Gastrointestinal disorders	5 (0.00%)
Food craving	Metabolism and nutrition disorders	5 (0.00%)
Food intolerance	Metabolism and nutrition disorders	5 (0.00%)
Freezing phenomenon	Nervous system disorders	5 (0.00%)
Full blood count abnormal	Investigations	5 (0.00%)
Gingival erythema	Gastrointestinal disorders	5 (0.00%)
Glycosylated haemoglobin increased	Investigations	5 (0.00%)
Haematoma muscle	Musculoskeletal and connective tissue disorders	5 (0.00%)
Haemoglobin increased	Investigations	5 (0.00%)
Hand deformity	Musculoskeletal and connective tissue disorders	5 (0.00%)
Hand dermatitis	Skin and subcutaneous tissue disorders	5 (0.00%)
Head banging	Psychiatric disorders	5 (0.00%)
Heart sounds abnormal	Investigations	5 (0.00%)
Hemiplegic migraine	Nervous system disorders	5 (0.00%)
Hepatic cyst	Hepatobiliary disorders	5 (0.00%)
Hepatic steatosis	Hepatobiliary disorders	5 (0.00%)
Herpes zoster cutaneous disseminated	Infections and infestations	5 (0.00%)
Huntington's disease	Congenital, familial and genetic disorders	5 (0.00%)
Hypertrophic cardiomyopathy	Congenital, familial and genetic disorders	5 (0.00%)
Hypoaesthesia teeth	Gastrointestinal disorders	5 (0.00%)
Injection site extravasation	General disorders and administration site conditions	5 (0.00%)
Intracardiac thrombus	Cardiac disorders	5 (0.00%)
Iron deficiency	Metabolism and nutrition disorders	5 (0.00%)
Joint instability	Musculoskeletal and connective tissue disorders	5 (0.00%)
Jugular vein thrombosis	Vascular disorders	5 (0.00%)
Logorrhoea	Psychiatric disorders	5 (0.00%)
Lymphocyte count increased	Investigations	5 (0.00%)
Maculopathy	Eye disorders	5 (0.00%)
Mean cell haemoglobin decreased	Investigations	5 (0.00%)
Mean cell volume decreased	Investigations	5 (0.00%)
Measles	Infections and infestations	5 (0.00%)
Menopausal symptoms	Reproductive system and breast disorders	5 (0.00%)
Microembolism	Vascular disorders	5 (0.00%)
Mononeuropathy	Nervous system disorders	5 (0.00%)
Mouth injury	Injury, poisoning and procedural complications	5 (0.00%)
Myofascial pain syndrome	Musculoskeletal and connective tissue disorders	5 (0.00%)
Myosclerosis	Musculoskeletal and connective tissue disorders	5 (0.00%)
Nasal injury	Injury, poisoning and procedural complications	5 (0.00%)
Neck injury	Injury, poisoning and procedural complications	5 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Necrosis	General disorders and administration site conditions	5 (0.00%)
Neoplasm progression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Neurodermatitis	Skin and subcutaneous tissue disorders	5 (0.00%)
Nocturia	Renal and urinary disorders	5 (0.00%)
Onychoclasia	Skin and subcutaneous tissue disorders	5 (0.00%)
Orthostatic intolerance	Nervous system disorders	5 (0.00%)
Overweight	Metabolism and nutrition disorders	5 (0.00%)
Pelvic venous thrombosis	Vascular disorders	5 (0.00%)
Phonophobia	Psychiatric disorders	5 (0.00%)
Plicated tongue	Gastrointestinal disorders	5 (0.00%)
Post procedural complication	Injury, poisoning and procedural complications	5 (0.00%)
Prostatomegaly	Reproductive system and breast disorders	5 (0.00%)
Prurigo	Skin and subcutaneous tissue disorders	5 (0.00%)
Psychogenic seizure	Nervous system disorders	5 (0.00%)
Psychomotor skills impaired	Nervous system disorders	5 (0.00%)
Pulmonary arterial pressure increased	Investigations	5 (0.00%)
Pulmonary artery thrombosis	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Pulmonary haemorrhage	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Puncture site pain	General disorders and administration site conditions	5 (0.00%)
Pupillary disorder	Eye disorders	5 (0.00%)
Radial pulse abnormal	Investigations	5 (0.00%)
Reaction to preservatives	Immune system disorders	5 (0.00%)
Renal colic	Renal and urinary disorders	5 (0.00%)
Respiratory alkalosis	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Retrograde amnesia	Nervous system disorders	5 (0.00%)
Right ventricular failure	Cardiac disorders	5 (0.00%)
Ruptured cerebral aneurysm	Nervous system disorders	5 (0.00%)
Salivary gland disorder	Gastrointestinal disorders	5 (0.00%)
Serum ferritin increased	Investigations	5 (0.00%)
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Skin depigmentation	Skin and subcutaneous tissue disorders	5 (0.00%)
Skin hypertrophy	Skin and subcutaneous tissue disorders	5 (0.00%)
Skin necrosis	Skin and subcutaneous tissue disorders	5 (0.00%)
Skin weeping	Skin and subcutaneous tissue disorders	5 (0.00%)
Skin wrinkling	Skin and subcutaneous tissue disorders	5 (0.00%)
Small intestinal haemorrhage	Gastrointestinal disorders	5 (0.00%)
Splenic infarction	Blood and lymphatic system disorders	5 (0.00%)
Streptococcal infection	Infections and infestations	5 (0.00%)
Superficial vein prominence	Vascular disorders	5 (0.00%)
Suspected product quality issue	Product issues	5 (0.00%)
Systemic immune activation	Immune system disorders	5 (0.00%)
Teething	Gastrointestinal disorders	5 (0.00%)
Tendon disorder	Musculoskeletal and connective tissue disorders	5 (0.00%)
Tendon injury	Injury, poisoning and procedural complications	5 (0.00%)
Thrombocytosis	Blood and lymphatic system disorders	5 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Thunderclap headache	Nervous system disorders	5 (0.00%)
Thyroid function test abnormal	Investigations	5 (0.00%)
Tonsillar disorder	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Tooth fracture	Injury, poisoning and procedural complications	5 (0.00%)
Toxic epidermal necrolysis	Skin and subcutaneous tissue disorders	5 (0.00%)
Ulcerative keratitis	Eye disorders	5 (0.00%)
Urinary tract inflammation	Renal and urinary disorders	5 (0.00%)
Urine flow decreased	Renal and urinary disorders	5 (0.00%)
Urine output increased	Investigations	5 (0.00%)
Vaccination site eczema	General disorders and administration site conditions	5 (0.00%)
Vaccination site injury	General disorders and administration site conditions	5 (0.00%)
Vaccination site joint inflammation	General disorders and administration site conditions	5 (0.00%)
Vaccination site pustule	Infections and infestations	5 (0.00%)
Vein discolouration	Vascular disorders	5 (0.00%)
Vein rupture	Vascular disorders	5 (0.00%)
Viral labyrinthitis	Infections and infestations	5 (0.00%)
Vitamin B12 decreased	Investigations	5 (0.00%)
Vitreous haemorrhage	Eye disorders	5 (0.00%)
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Vulvovaginal swelling	Reproductive system and breast disorders	5 (0.00%)
White blood cells urine positive	Investigations	5 (0.00%)
Abortion	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Accidental underdose	Injury, poisoning and procedural complications	4 (0.00%)
Acoustic neuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Acquired haemophilia	Blood and lymphatic system disorders	4 (0.00%)
Acoustic neuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Acquired haemophilia	Blood and lymphatic system disorders	4 (0.00%)
Adrenal disorder	Endocrine disorders	4 (0.00%)
Adrenal insufficiency	Endocrine disorders	4 (0.00%)
Adverse event following immunisation	Injury, poisoning and procedural complications	4 (0.00%)
Adverse reaction	General disorders and administration site conditions	4 (0.00%)
Agranulocytosis	Blood and lymphatic system disorders	4 (0.00%)
Akathisia	Nervous system disorders	4 (0.00%)
Aneurysm ruptured	Vascular disorders	4 (0.00%)
Angular cheilitis	Gastrointestinal disorders	4 (0.00%)
Aortic valve incompetence	Cardiac disorders	4 (0.00%)
Aptyalism	Gastrointestinal disorders	4 (0.00%)
Atonic seizures	Nervous system disorders	4 (0.00%)
Atrioventricular block first degree	Cardiac disorders	4 (0.00%)
Axonal neuropathy	Nervous system disorders	4 (0.00%)
Bacteraemia	Infections and infestations	4 (0.00%)
Basal ganglia stroke	Nervous system disorders	4 (0.00%)
Bed rest	Surgical and medical procedures	4 (0.00%)
Biliary tract disorder	Hepatobiliary disorders	4 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bladder dysfunction	Renal and urinary disorders	4 (0.00%)
Bladder spasm	Renal and urinary disorders	4 (0.00%)
Blood bicarbonate decreased	Investigations	4 (0.00%)
Blood chloride decreased	Investigations	4 (0.00%)
Blood fibrinogen decreased	Investigations	4 (0.00%)
Blood fibrinogen increased	Investigations	4 (0.00%)
Blood magnesium decreased	Investigations	4 (0.00%)
Blood pH increased	Investigations	4 (0.00%)
Blood thyroid stimulating hormone decreased	Investigations	4 (0.00%)
Bloody discharge	Vascular disorders	4 (0.00%)
Bone neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Brachial plexus injury	Injury, poisoning and procedural complications	4 (0.00%)
Brain stem haemorrhage	Nervous system disorders	4 (0.00%)
Breast cyst	Reproductive system and breast disorders	4 (0.00%)
Breast discharge	Reproductive system and breast disorders	4 (0.00%)
Bronchopneumopathy	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Capillary nail refill test abnormal	Investigations	4 (0.00%)
Cardiac valve disease	Cardiac disorders	4 (0.00%)
Cardiospasm	Gastrointestinal disorders	4 (0.00%)
Carotid artery dissection	Nervous system disorders	4 (0.00%)
Catatonia	Psychiatric disorders	4 (0.00%)
Cerebellar ataxia	Nervous system disorders	4 (0.00%)
Cerebellar haemorrhage	Nervous system disorders	4 (0.00%)
Chronic inflammatory demyelinating polyradiculoneuropathy	Nervous system disorders	4 (0.00%)
Chronic respiratory failure	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Circumstance or information capable of leading to device use error	Injury, poisoning and procedural complications	4 (0.00%)
Clonic convulsion	Nervous system disorders	4 (0.00%)
Clostridium difficile colitis	Infections and infestations	4 (0.00%)
Coccydynia	Musculoskeletal and connective tissue disorders	4 (0.00%)
Congestive cardiomyopathy	Cardiac disorders	4 (0.00%)
Conjunctivitis bacterial	Infections and infestations	4 (0.00%)
Costovertebral angle tenderness	Renal and urinary disorders	4 (0.00%)
Counterfeit product administered	Injury, poisoning and procedural complications	4 (0.00%)
C-reactive protein abnormal	Investigations	4 (0.00%)
Creutzfeldt-Jakob disease	Infections and infestations	4 (0.00%)
Dark circles under eyes	Eye disorders	4 (0.00%)
Delusional perception	Psychiatric disorders	4 (0.00%)
Dermatitis herpetiformis	Skin and subcutaneous tissue disorders	4 (0.00%)
Dermatitis infected	Infections and infestations	4 (0.00%)
Dermatosis	Skin and subcutaneous tissue disorders	4 (0.00%)
Diastolic hypertension	Vascular disorders	4 (0.00%)
Discharge	General disorders and administration site conditions	4 (0.00%)
Diverticulum	Gastrointestinal disorders	4 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Duodenogastric reflux	Gastrointestinal disorders	4 (0.00%)
Dyschezia	Gastrointestinal disorders	4 (0.00%)
Dyschromatopsia	Eye disorders	4 (0.00%)
Dyslalia	Nervous system disorders	4 (0.00%)
Dyslexia	Nervous system disorders	4 (0.00%)
Dyslipidaemia	Metabolism and nutrition disorders	4 (0.00%)
Dysmetria	Nervous system disorders	4 (0.00%)
Eczema herpeticum	Infections and infestations	4 (0.00%)
Electrocardiogram repolarisation abnormality	Investigations	4 (0.00%)
Embolic cerebral infarction	Nervous system disorders	4 (0.00%)
Endocarditis	Infections and infestations	4 (0.00%)
Essential tremor	Nervous system disorders	4 (0.00%)
Eustachian tube dysfunction	Ear and labyrinth disorders	4 (0.00%)
Exertional headache	Nervous system disorders	4 (0.00%)
Extensor plantar response	Nervous system disorders	4 (0.00%)
Eye colour change	Eye disorders	4 (0.00%)
Fear of injection	Psychiatric disorders	4 (0.00%)
Flat affect	Psychiatric disorders	4 (0.00%)
Fluid overload	Metabolism and nutrition disorders	4 (0.00%)
Focal dyscognitive seizures	Nervous system disorders	4 (0.00%)
Foetal exposure during pregnancy	Injury, poisoning and procedural complications	4 (0.00%)
Foetal growth restriction	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Foot deformity	Musculoskeletal and connective tissue disorders	4 (0.00%)
Foot fracture	Injury, poisoning and procedural complications	4 (0.00%)
Fungal skin infection	Infections and infestations	4 (0.00%)
Galactorrhoea	Reproductive system and breast disorders	4 (0.00%)
Genital haemorrhage	Reproductive system and breast disorders	4 (0.00%)
Gingival blister	Gastrointestinal disorders	4 (0.00%)
Guttate psoriasis	Skin and subcutaneous tissue disorders	4 (0.00%)
Haematocrit increased	Investigations	4 (0.00%)
Haemolysis	Blood and lymphatic system disorders	4 (0.00%)
Hair texture abnormal	Skin and subcutaneous tissue disorders	4 (0.00%)
Heat oedema	Injury, poisoning and procedural complications	4 (0.00%)
Henoch-Schonlein purpura	Skin and subcutaneous tissue disorders	4 (0.00%)
Hepatic cirrhosis	Hepatobiliary disorders	4 (0.00%)
Hepatic enzyme abnormal	Investigations	4 (0.00%)
Hepatitis viral	Infections and infestations	4 (0.00%)
Herpes simplex encephalitis	Infections and infestations	4 (0.00%)
Hidradenitis	Skin and subcutaneous tissue disorders	4 (0.00%)
Histamine level increased	Investigations	4 (0.00%)
Horner's syndrome	Nervous system disorders	4 (0.00%)
Hypercalcaemia	Metabolism and nutrition disorders	4 (0.00%)
Hypertonic bladder	Renal and urinary disorders	4 (0.00%)
Immune-mediated adverse reaction	Immune system disorders	4 (0.00%)
Incorrect dosage administered	Injury, poisoning and procedural complications	4 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Increased viscosity of bronchial secretion	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Indifference	Psychiatric disorders	4 (0.00%)
Infantile vomiting	Gastrointestinal disorders	4 (0.00%)
Inflammatory bowel disease	Gastrointestinal disorders	4 (0.00%)
Injection site hypersensitivity	General disorders and administration site conditions	4 (0.00%)
Injection site muscle weakness	General disorders and administration site conditions	4 (0.00%)
Intentional product use issue	Injury, poisoning and procedural complications	4 (0.00%)
Intercostal neuralgia	Nervous system disorders	4 (0.00%)
Intranasal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Iron deficiency anaemia	Blood and lymphatic system disorders	4 (0.00%)
Large intestine infection	Infections and infestations	4 (0.00%)
Lichenoid keratosis	Skin and subcutaneous tissue disorders	4 (0.00%)
Lip discolouration	Gastrointestinal disorders	4 (0.00%)
Lip exfoliation	Gastrointestinal disorders	4 (0.00%)
Lip haemorrhage	Gastrointestinal disorders	4 (0.00%)
Low density lipoprotein increased	Investigations	4 (0.00%)
Madarosis	Skin and subcutaneous tissue disorders	4 (0.00%)
Marasmus	Metabolism and nutrition disorders	4 (0.00%)
Mast cell activation syndrome	Blood and lymphatic system disorders	4 (0.00%)
Mean cell haemoglobin concentration decreased	Investigations	4 (0.00%)
Monocyte count decreased	Investigations	4 (0.00%)
Multi-organ disorder	General disorders and administration site conditions	4 (0.00%)
Muscle rupture	Injury, poisoning and procedural complications	4 (0.00%)
Myelosuppression	Blood and lymphatic system disorders	4 (0.00%)
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Neurologic neglect syndrome	Nervous system disorders	4 (0.00%)
Neutrophil count abnormal	Investigations	4 (0.00%)
Nocturnal dyspnoea	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Non-Hodgkin's lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Oesophageal disorder	Gastrointestinal disorders	4 (0.00%)
Ophthalmic herpes simplex	Infections and infestations	4 (0.00%)
Oral mucosa erosion	Gastrointestinal disorders	4 (0.00%)
Osteomyelitis	Infections and infestations	4 (0.00%)
Palatal disorder	Gastrointestinal disorders	4 (0.00%)
Pancreatic disorder	Gastrointestinal disorders	4 (0.00%)
Paraplegia	Nervous system disorders	4 (0.00%)
Patient elopement	Nervous system disorders	4 (0.00%)
Periorbital discomfort	Eye disorders	4 (0.00%)
Peritonitis	Infections and infestations	4 (0.00%)
Pernio-like erythema	Skin and subcutaneous tissue disorders	4 (0.00%)
Persistent postural-perceptual dizziness	Nervous system disorders	4 (0.00%)
Pleocytosis	Nervous system disorders	4 (0.00%)
Polychondritis	Musculoskeletal and connective tissue disorders	4 (0.00%)
Polymerase chain reaction positive	Investigations	4 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Post-traumatic stress disorder	Psychiatric disorders	4 (0.00%)
Pregnancy	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Procedural dizziness	Injury, poisoning and procedural complications	4 (0.00%)
Procedural nausea	Injury, poisoning and procedural complications	4 (0.00%)
Protein total decreased	Investigations	4 (0.00%)
Pruritus genital	Reproductive system and breast disorders	4 (0.00%)
Psychotic symptom	Psychiatric disorders	4 (0.00%)
Pulmonary arterial hypertension	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Red blood cells urine positive	Investigations	4 (0.00%)
Renal haemorrhage	Renal and urinary disorders	4 (0.00%)
Renal infarct	Renal and urinary disorders	4 (0.00%)
Retinal disorder	Eye disorders	4 (0.00%)
Rheumatoid factor increased	Investigations	4 (0.00%)
Rhinovirus infection	Infections and infestations	4 (0.00%)
SARS-CoV-2 antibody test	Investigations	4 (0.00%)
Scar pain	Skin and subcutaneous tissue disorders	4 (0.00%)
Seizure cluster	Nervous system disorders	4 (0.00%)
Self-injurious ideation	Psychiatric disorders	4 (0.00%)
Sense of a foreshortened future	Psychiatric disorders	4 (0.00%)
Serum ferritin decreased	Investigations	4 (0.00%)
Sinus arrest	Cardiac disorders	4 (0.00%)
Sinus rhythm	Investigations	4 (0.00%)
Sleep attacks	Psychiatric disorders	4 (0.00%)
Soft tissue infection	Infections and infestations	4 (0.00%)
Spinal cord disorder	Nervous system disorders	4 (0.00%)
Spondylitis	Musculoskeletal and connective tissue disorders	4 (0.00%)
Stenosis	General disorders and administration site conditions	4 (0.00%)
Subcutaneous haematoma	Injury, poisoning and procedural complications	4 (0.00%)
Subdural haemorrhage	Injury, poisoning and procedural complications	4 (0.00%)
Subileus	Gastrointestinal disorders	4 (0.00%)
Submaxillary gland enlargement	Gastrointestinal disorders	4 (0.00%)
Superior sagittal sinus thrombosis	Nervous system disorders	4 (0.00%)
Temperature difference of extremities	Investigations	4 (0.00%)
Thalamic infarction	Nervous system disorders	4 (0.00%)
Thrombotic microangiopathy	Blood and lymphatic system disorders	4 (0.00%)
Tongue spasm	Gastrointestinal disorders	4 (0.00%)
Tonsillar erythema	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Tooth injury	Injury, poisoning and procedural complications	4 (0.00%)
Transient aphasia	Nervous system disorders	4 (0.00%)
Type III immune complex mediated reaction	Immune system disorders	4 (0.00%)
Ulnar nerve injury	Injury, poisoning and procedural complications	4 (0.00%)
Urticaria thermal	Skin and subcutaneous tissue disorders	4 (0.00%)
Uterine pain	Reproductive system and breast disorders	4 (0.00%)
Vaccination site dermatitis	General disorders and administration site conditions	4 (0.00%)
Vaccination site dysaesthesia	General disorders and administration site conditions	4 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vaccination site scar	General disorders and administration site conditions	4 (0.00%)
Vaccination site thrombosis	General disorders and administration site conditions	4 (0.00%)
Varicella zoster virus infection	Infections and infestations	4 (0.00%)
Vascular encephalopathy	Nervous system disorders	4 (0.00%)
Vascular injury	Injury, poisoning and procedural complications	4 (0.00%)
Vena cava thrombosis	Vascular disorders	4 (0.00%)
Ventricular hypokinesia	Cardiac disorders	4 (0.00%)
Vertebral artery dissection	Nervous system disorders	4 (0.00%)
Viral pharyngitis	Infections and infestations	4 (0.00%)
Vitreous disorder	Eye disorders	4 (0.00%)
Vulval haemorrhage	Reproductive system and breast disorders	4 (0.00%)
Vulvovaginal mycotic infection	Infections and infestations	4 (0.00%)
Wound complication	Injury, poisoning and procedural complications	4 (0.00%)
Wound infection	Infections and infestations	4 (0.00%)
Abdominal mass	Gastrointestinal disorders	3 (0.00%)
Abdominal wall haemorrhage	Gastrointestinal disorders	3 (0.00%)
Abnormal loss of weight	Metabolism and nutrition disorders	3 (0.00%)
Abnormal weight gain	Metabolism and nutrition disorders	3 (0.00%)
Abortion induced	Surgical and medical procedures	3 (0.00%)
Abscess oral	Infections and infestations	3 (0.00%)
Acarodermatitis	Infections and infestations	3 (0.00%)
Acoustic neuritis	Nervous system disorders	3 (0.00%)
Acute generalised exanthematous pustulosis	Skin and subcutaneous tissue disorders	3 (0.00%)
Acute hepatic failure	Hepatobiliary disorders	3 (0.00%)
Acute leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Acute psychosis	Psychiatric disorders	3 (0.00%)
Acute stress disorder	Psychiatric disorders	3 (0.00%)
Administration site erythema	General disorders and administration site conditions	3 (0.00%)
Administration site swelling	General disorders and administration site conditions	3 (0.00%)
Adrenomegaly	Endocrine disorders	3 (0.00%)
Aerophagia	Gastrointestinal disorders	3 (0.00%)
Age-related macular degeneration	Eye disorders	3 (0.00%)
Airway burns	Injury, poisoning and procedural complications	3 (0.00%)
Akinesia	Nervous system disorders	3 (0.00%)
Alcohol intolerance	Metabolism and nutrition disorders	3 (0.00%)
Allergic respiratory symptom	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Allergy to arthropod sting	Immune system disorders	3 (0.00%)
Amnestic disorder	Nervous system disorders	3 (0.00%)
Anaemia vitamin B12 deficiency	Blood and lymphatic system disorders	3 (0.00%)
Anal pruritus	Gastrointestinal disorders	3 (0.00%)
Anaphylactoid shock	Immune system disorders	3 (0.00%)
Angle closure glaucoma	Eye disorders	3 (0.00%)
Anterograde amnesia	Nervous system disorders	3 (0.00%)
Anticoagulation drug level below therapeutic	Investigations	3 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Antiphospholipid syndrome	Blood and lymphatic system disorders	3 (0.00%)
Anti-thyroid antibody positive	Investigations	3 (0.00%)
Anxiety disorder	Psychiatric disorders	3 (0.00%)
Aortic aneurysm rupture	Vascular disorders	3 (0.00%)
Aortic embolus	Vascular disorders	3 (0.00%)
Aortic valve stenosis	Cardiac disorders	3 (0.00%)
Apallic syndrome	Nervous system disorders	3 (0.00%)
Application site erythema	General disorders and administration site conditions	3 (0.00%)
Apraxia	Nervous system disorders	3 (0.00%)
Arteriovenous fistula thrombosis	Injury, poisoning and procedural complications	3 (0.00%)
Asthma exercise induced	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Attention deficit hyperactivity disorder	Psychiatric disorders	3 (0.00%)
Autoimmune hepatitis	Hepatobiliary disorders	3 (0.00%)
Axillary lymphadenectomy	Surgical and medical procedures	3 (0.00%)
Azotaemia	Renal and urinary disorders	3 (0.00%)
Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Binocular eye movement disorder	Eye disorders	3 (0.00%)
Bipolar disorder	Psychiatric disorders	3 (0.00%)
Blister infected	Infections and infestations	3 (0.00%)
Blood calcium increased	Investigations	3 (0.00%)
Blood cholesterol abnormal	Investigations	3 (0.00%)
Blood creatinine abnormal	Investigations	3 (0.00%)
Blood creatinine decreased	Investigations	3 (0.00%)
Blood folate decreased	Investigations	3 (0.00%)
Blood immunoglobulin G decreased	Investigations	3 (0.00%)
Blood immunoglobulin M increased	Investigations	3 (0.00%)
Blood iron increased	Investigations	3 (0.00%)
Blood pressure immeasurable	Investigations	3 (0.00%)
Blood pressure inadequately controlled	Vascular disorders	3 (0.00%)
Blood sodium increased	Investigations	3 (0.00%)
Blood urine	Investigations	3 (0.00%)
Brachial plexopathy	Nervous system disorders	3 (0.00%)
Brain hypoxia	Nervous system disorders	3 (0.00%)
Brain stem infarction	Nervous system disorders	3 (0.00%)
Breast abscess	Infections and infestations	3 (0.00%)
Breast engorgement	Reproductive system and breast disorders	3 (0.00%)
Breast induration	Reproductive system and breast disorders	3 (0.00%)
Breath sounds	Investigations	3 (0.00%)
Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Bronchiolitis	Infections and infestations	3 (0.00%)
Bronchitis bacterial	Infections and infestations	3 (0.00%)
Burning mouth syndrome	Gastrointestinal disorders	3 (0.00%)
Burns second degree	Injury, poisoning and procedural complications	3 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Capillary fragility	Vascular disorders	3 (0.00%)
Cartilage injury	Injury, poisoning and procedural complications	3 (0.00%)
Cerebral palsy	Congenital, familial and genetic disorders	3 (0.00%)
Chalazion	Eye disorders	3 (0.00%)
Change of bowel habit	Gastrointestinal disorders	3 (0.00%)
Chest crushing	Injury, poisoning and procedural complications	3 (0.00%)
Cholangitis	Hepatobiliary disorders	3 (0.00%)
Choroidal neovascularisation	Eye disorders	3 (0.00%)
Chronic gastritis	Gastrointestinal disorders	3 (0.00%)
Clostridium difficile infection	Infections and infestations	3 (0.00%)
Cold urticaria	Skin and subcutaneous tissue disorders	3 (0.00%)
Colitis microscopic	Gastrointestinal disorders	3 (0.00%)
Complication associated with device	General disorders and administration site conditions	3 (0.00%)
Congestive hepatopathy	Hepatobiliary disorders	3 (0.00%)
Contraindication to vaccination	Social circumstances	3 (0.00%)
Convulsions local	Nervous system disorders	3 (0.00%)
CSF protein increased	Investigations	3 (0.00%)
Decreased immune responsiveness	Immune system disorders	3 (0.00%)
Decreased vibratory sense	Nervous system disorders	3 (0.00%)
Delirium febrile	Psychiatric disorders	3 (0.00%)
Dental caries	Gastrointestinal disorders	3 (0.00%)
Dental paraesthesia	Gastrointestinal disorders	3 (0.00%)
Diabetic coma	Nervous system disorders	3 (0.00%)
Diabetic complication	Metabolism and nutrition disorders	3 (0.00%)
Diaphragmatic disorder	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Diaphragmatic spasm	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Dilatation atrial	Cardiac disorders	3 (0.00%)
Dreamy state	Nervous system disorders	3 (0.00%)
Drug reaction with eosinophilia and systemic symptoms	Skin and subcutaneous tissue disorders	3 (0.00%)
Ear canal erythema	Ear and labyrinth disorders	3 (0.00%)
Eating disorder symptom	Metabolism and nutrition disorders	3 (0.00%)
Eczema eyelids	Eye disorders	3 (0.00%)
Eczema nummular	Skin and subcutaneous tissue disorders	3 (0.00%)
Electrocardiogram QRS complex shortened	Investigations	3 (0.00%)
Enanthema	General disorders and administration site conditions	3 (0.00%)
Encephalitis viral	Infections and infestations	3 (0.00%)
Enterococcal infection	Infections and infestations	3 (0.00%)
Enthesopathy	Musculoskeletal and connective tissue disorders	3 (0.00%)
Epiglottitis	Infections and infestations	3 (0.00%)
Epstein-Barr virus infection	Infections and infestations	3 (0.00%)
Erythema annulare	Skin and subcutaneous tissue disorders	3 (0.00%)
Escherichia bacteraemia	Infections and infestations	3 (0.00%)
Escherichia sepsis	Infections and infestations	3 (0.00%)
Exposure via eye contact	Injury, poisoning and procedural complications	3 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Extra dose administered	Injury, poisoning and procedural complications	3 (0.00%)
Extremity necrosis	Vascular disorders	3 (0.00%)
Eyelid myoclonus	Eye disorders	3 (0.00%)
Faecal vomiting	Gastrointestinal disorders	3 (0.00%)
Fasciitis	Musculoskeletal and connective tissue disorders	3 (0.00%)
Fear of falling	Psychiatric disorders	3 (0.00%)
Febrile infection	Infections and infestations	3 (0.00%)
Feeling of relaxation	General disorders and administration site conditions	3 (0.00%)
Finger deformity	Musculoskeletal and connective tissue disorders	3 (0.00%)
Fixed eruption	Skin and subcutaneous tissue disorders	3 (0.00%)
Fluid imbalance	Metabolism and nutrition disorders	3 (0.00%)
Foetal heart rate abnormal	Investigations	3 (0.00%)
Frostbite	Injury, poisoning and procedural complications	3 (0.00%)
Gangrene	Infections and infestations	3 (0.00%)
Gastric pH decreased	Investigations	3 (0.00%)
Gastrointestinal hypomotility	Gastrointestinal disorders	3 (0.00%)
Generalised anxiety disorder	Psychiatric disorders	3 (0.00%)
General symptom	General disorders and administration site conditions	3 (0.00%)
Genital herpes zoster	Infections and infestations	3 (0.00%)
Genital pain	Reproductive system and breast disorders	3 (0.00%)
Genital ulceration	Reproductive system and breast disorders	3 (0.00%)
Gingival discolouration	Gastrointestinal disorders	3 (0.00%)
Glomerulonephritis	Renal and urinary disorders	3 (0.00%)
Granulomatous lymphadenitis	Blood and lymphatic system disorders	3 (0.00%)
Habit cough	Psychiatric disorders	3 (0.00%)
Haemoglobin abnormal	Investigations	3 (0.00%)
Haemothorax	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Helplessness	Psychiatric disorders	3 (0.00%)
Hemihyperaesthesia	Nervous system disorders	3 (0.00%)
Hepatic lesion	Hepatobiliary disorders	3 (0.00%)
Herpes dermatitis	Infections and infestations	3 (0.00%)
Herpes zoster infection neurological	Infections and infestations	3 (0.00%)
Herpes zoster meningoencephalitis	Infections and infestations	3 (0.00%)
HIV test false positive	Investigations	3 (0.00%)
Hypercholesterolaemia	Metabolism and nutrition disorders	3 (0.00%)
Hyperlactacidaemia	Metabolism and nutrition disorders	3 (0.00%)
Hyperphagia	Metabolism and nutrition disorders	3 (0.00%)
Hypertrophy of tongue papillae	Gastrointestinal disorders	3 (0.00%)
Hypervigilance	Psychiatric disorders	3 (0.00%)
Hypoalbuminaemia	Metabolism and nutrition disorders	3 (0.00%)
Hypokalaemic syndrome	Metabolism and nutrition disorders	3 (0.00%)
Hypovitaminosis	Metabolism and nutrition disorders	3 (0.00%)
Illrd nerve disorder	Nervous system disorders	3 (0.00%)
Immunoglobulins increased	Investigations	3 (0.00%)
Impaired self-care	General disorders and administration site conditions	3 (0.00%)
Impetigo	Infections and infestations	3 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Inappropriate affect	Psychiatric disorders	3 (0.00%)
Incision site pain	Injury, poisoning and procedural complications	3 (0.00%)
Infective exacerbation of chronic obstructive airways disease	Infections and infestations	3 (0.00%)
Infusion related reaction	Injury, poisoning and procedural complications	3 (0.00%)
Infusion site pain	General disorders and administration site conditions	3 (0.00%)
Injection site discolouration	General disorders and administration site conditions	3 (0.00%)
Injection site joint pain	General disorders and administration site conditions	3 (0.00%)
Injury associated with device	General disorders and administration site conditions	3 (0.00%)
Inspiratory capacity decreased	Investigations	3 (0.00%)
Intentional dose omission	Injury, poisoning and procedural complications	3 (0.00%)
Intentional self-injury	Psychiatric disorders	3 (0.00%)
Intercepted medication error	Injury, poisoning and procedural complications	3 (0.00%)
Intervertebral disc disorder	Musculoskeletal and connective tissue disorders	3 (0.00%)
Intestinal infarction	Gastrointestinal disorders	3 (0.00%)
Intestinal perforation	Gastrointestinal disorders	3 (0.00%)
Intraventricular haemorrhage	Nervous system disorders	3 (0.00%)
Intrusive thoughts	Psychiatric disorders	3 (0.00%)
Irregular sleep wake rhythm disorder	Nervous system disorders	3 (0.00%)
Joint contracture	Musculoskeletal and connective tissue disorders	3 (0.00%)
Jugular vein distension	Vascular disorders	3 (0.00%)
Klebsiella infection	Infections and infestations	3 (0.00%)
Labile blood pressure	Vascular disorders	3 (0.00%)
Lactation disorder	Reproductive system and breast disorders	3 (0.00%)
Lhermitte's sign	Nervous system disorders	3 (0.00%)
Lichen planus	Skin and subcutaneous tissue disorders	3 (0.00%)
Loss of proprioception	Nervous system disorders	3 (0.00%)
Lung consolidation	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Magnetic resonance imaging brain abnormal	Investigations	3 (0.00%)
Mean cell volume increased	Investigations	3 (0.00%)
Meningeal disorder	Nervous system disorders	3 (0.00%)
Mesenteric artery thrombosis	Gastrointestinal disorders	3 (0.00%)
Metabolic disorder	Metabolism and nutrition disorders	3 (0.00%)
Monoclonal gammopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Morose	Psychiatric disorders	3 (0.00%)
Mouth breathing	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Mouth cyst	Gastrointestinal disorders	3 (0.00%)
Mucosal haemorrhage	General disorders and administration site conditions	3 (0.00%)
Mucosal inflammation	General disorders and administration site conditions	3 (0.00%)
Mumps	Infections and infestations	3 (0.00%)
Muscle mass	Musculoskeletal and connective tissue disorders	3 (0.00%)
Muscle oedema	Musculoskeletal and connective tissue disorders	3 (0.00%)
Muscle strength abnormal	Investigations	3 (0.00%)
Myelodysplastic syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Myelopathy	Nervous system disorders	3 (0.00%)
Myocardial hypoxia	Cardiac disorders	3 (0.00%)
Myocardial rupture	Cardiac disorders	3 (0.00%)
Myopia	Eye disorders	3 (0.00%)
Nasal odour	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Necrotising fasciitis	Infections and infestations	3 (0.00%)
Negative thoughts	Psychiatric disorders	3 (0.00%)
Neuromuscular pain	Nervous system disorders	3 (0.00%)
Neuromyelitis optica spectrum disorder	Nervous system disorders	3 (0.00%)
Neuromyopathy	Nervous system disorders	3 (0.00%)
Neutrophilic dermatosis	Skin and subcutaneous tissue disorders	3 (0.00%)
Nitrite urine present	Investigations	3 (0.00%)
Noninfective sialoadenitis	Gastrointestinal disorders	3 (0.00%)
Non-pitting oedema	General disorders and administration site conditions	3 (0.00%)
Normochromic normocytic anaemia	Blood and lymphatic system disorders	3 (0.00%)
Obstruction	General disorders and administration site conditions	3 (0.00%)
Obstructive pancreatitis	Gastrointestinal disorders	3 (0.00%)
Ocular myasthenia	Eye disorders	3 (0.00%)
Oesophagitis	Gastrointestinal disorders	3 (0.00%)
Ophthalmoplegia	Eye disorders	3 (0.00%)
Optic neuropathy	Eye disorders	3 (0.00%)
Oral lichen planus	Gastrointestinal disorders	3 (0.00%)
Oral mucosal roughening	Gastrointestinal disorders	3 (0.00%)
Oral viral infection	Infections and infestations	3 (0.00%)
Osteoporosis	Musculoskeletal and connective tissue disorders	3 (0.00%)
Ovarian cyst	Reproductive system and breast disorders	3 (0.00%)
Palpable purpura	Skin and subcutaneous tissue disorders	3 (0.00%)
Pancreatic carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Panniculitis	Skin and subcutaneous tissue disorders	3 (0.00%)
Paresis cranial nerve	Nervous system disorders	3 (0.00%)
Pelvic haemorrhage	Reproductive system and breast disorders	3 (0.00%)
Perineal pain	Reproductive system and breast disorders	3 (0.00%)
Perioral dermatitis	Skin and subcutaneous tissue disorders	3 (0.00%)
Periorbital cellulitis	Infections and infestations	3 (0.00%)
Periorbital disorder	Eye disorders	3 (0.00%)
Periorbital haematoma	Injury, poisoning and procedural complications	3 (0.00%)
Peripheral motor neuropathy	Nervous system disorders	3 (0.00%)
Persistent depressive disorder	Psychiatric disorders	3 (0.00%)
Pertussis	Infections and infestations	3 (0.00%)
Phantom limb syndrome	Nervous system disorders	3 (0.00%)
Pharyngeal enanthema	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Pharyngeal haemorrhage	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Plantar erythema	Skin and subcutaneous tissue disorders	3 (0.00%)
Platelet count abnormal	Investigations	3 (0.00%)
Pneumonia pneumococcal	Infections and infestations	3 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Pneumonia staphylococcal	Infections and infestations	3 (0.00%)
Pneumothorax spontaneous	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Polymyositis	Musculoskeletal and connective tissue disorders	3 (0.00%)
Polyp	General disorders and administration site conditions	3 (0.00%)
Poor feeding infant	Metabolism and nutrition disorders	3 (0.00%)
Posterior reversible encephalopathy syndrome	Nervous system disorders	3 (0.00%)
Post-traumatic neck syndrome	Injury, poisoning and procedural complications	3 (0.00%)
Premature labour	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Prerenal failure	Renal and urinary disorders	3 (0.00%)
Pressure of speech	Psychiatric disorders	3 (0.00%)
Primary cough headache	Nervous system disorders	3 (0.00%)
Procalcitonin increased	Investigations	3 (0.00%)
Procedural pain	Injury, poisoning and procedural complications	3 (0.00%)
Proctitis	Gastrointestinal disorders	3 (0.00%)
Product container issue	Product issues	3 (0.00%)
Product contamination physical	Product issues	3 (0.00%)
Product dose omission in error	Injury, poisoning and procedural complications	3 (0.00%)
Product prescribing error	Injury, poisoning and procedural complications	3 (0.00%)
Product use in unapproved indication	Injury, poisoning and procedural complications	3 (0.00%)
Prolonged expiration	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Prostatic specific antigen increased	Investigations	3 (0.00%)
Pulmonary sarcoidosis	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Pupillary reflex impaired	Eye disorders	3 (0.00%)
Quadriplegia	Nervous system disorders	3 (0.00%)
Radial nerve palsy	Nervous system disorders	3 (0.00%)
Reading disorder	Psychiatric disorders	3 (0.00%)
Rectal discharge	Gastrointestinal disorders	3 (0.00%)
Rectal tenesmus	Gastrointestinal disorders	3 (0.00%)
Red blood cell count increased	Investigations	3 (0.00%)
Red cell distribution width increased	Investigations	3 (0.00%)
Reflexes abnormal	Nervous system disorders	3 (0.00%)
Reflux gastritis	Gastrointestinal disorders	3 (0.00%)
Regurgitation	Gastrointestinal disorders	3 (0.00%)
Respiratory tract infection viral	Infections and infestations	3 (0.00%)
Scarlet fever	Infections and infestations	3 (0.00%)
Schizophrenia	Psychiatric disorders	3 (0.00%)
Scintillating scotoma	Eye disorders	3 (0.00%)
Scrotal erythema	Reproductive system and breast disorders	3 (0.00%)
Scrotal swelling	Reproductive system and breast disorders	3 (0.00%)
Sickle cell anaemia with crisis	Blood and lymphatic system disorders	3 (0.00%)
Skeletal injury	Injury, poisoning and procedural complications	3 (0.00%)
Skin indentation	Skin and subcutaneous tissue disorders	3 (0.00%)
Skin laxity	Skin and subcutaneous tissue disorders	3 (0.00%)
Skin oedema	Skin and subcutaneous tissue disorders	3 (0.00%)
Skin striae	Skin and subcutaneous tissue disorders	3 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Somnambulism	Psychiatric disorders	3 (0.00%)
Spinal compression fracture	Injury, poisoning and procedural complications	3 (0.00%)
Spinal cord ischaemia	Nervous system disorders	3 (0.00%)
Spinal stenosis	Musculoskeletal and connective tissue disorders	3 (0.00%)
Splenic rupture	Injury, poisoning and procedural complications	3 (0.00%)
Spontaneous haematoma	Blood and lymphatic system disorders	3 (0.00%)
Staphylococcal bacteraemia	Infections and infestations	3 (0.00%)
Stereotypy	Psychiatric disorders	3 (0.00%)
Streptococcus test positive	Investigations	3 (0.00%)
Symptom recurrence	General disorders and administration site conditions	3 (0.00%)
Tardive dyskinesia	Nervous system disorders	3 (0.00%)
Tendon rupture	Injury, poisoning and procedural complications	3 (0.00%)
Terminal state	General disorders and administration site conditions	3 (0.00%)
Thrombosis mesenteric vessel	Gastrointestinal disorders	3 (0.00%)
Thyroiditis acute	Endocrine disorders	3 (0.00%)
Thyrotoxic crisis	Endocrine disorders	3 (0.00%)
Thyroxine free increased	Investigations	3 (0.00%)
Tongue haematoma	Gastrointestinal disorders	3 (0.00%)
Tongue injury	Injury, poisoning and procedural complications	3 (0.00%)
Tooth extraction	Surgical and medical procedures	3 (0.00%)
Tracheal obstruction	Injury, poisoning and procedural complications	3 (0.00%)
Tracheal pain	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Tracheal stenosis	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Trichoglossia	Gastrointestinal disorders	3 (0.00%)
Trigeminal neuritis	Nervous system disorders	3 (0.00%)
Tri-iodothyronine decreased	Investigations	3 (0.00%)
Tuberculosis	Infections and infestations	3 (0.00%)
Underweight	Metabolism and nutrition disorders	3 (0.00%)
Urine ketone body present	Investigations	3 (0.00%)
Urine output	Investigations	3 (0.00%)
Vaccination site anaesthesia	General disorders and administration site conditions	3 (0.00%)
Vaccination site dryness	General disorders and administration site conditions	3 (0.00%)
Vaccination site granuloma	General disorders and administration site conditions	3 (0.00%)
Vaccination site joint discomfort	General disorders and administration site conditions	3 (0.00%)
Vaccination site pallor	General disorders and administration site conditions	3 (0.00%)
Vaginal disorder	Reproductive system and breast disorders	3 (0.00%)
Vagus nerve disorder	Nervous system disorders	3 (0.00%)
Vascular stent thrombosis	General disorders and administration site conditions	3 (0.00%)
Vasospasm	Vascular disorders	3 (0.00%)
Venous injury	Injury, poisoning and procedural complications	3 (0.00%)
Ventricular hypertrophy	Cardiac disorders	3 (0.00%)
Vertigo labyrinthine	Ear and labyrinth disorders	3 (0.00%)
Viral upper respiratory tract infection	Infections and infestations	3 (0.00%)
Vocal cord paralysis	Nervous system disorders	3 (0.00%)
Volvulus	Gastrointestinal disorders	3 (0.00%)
Vulvovaginal pruritus	Reproductive system and breast disorders	3 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vulvovaginal ulceration	Reproductive system and breast disorders	3 (0.00%)
Water pollution	Social circumstances	3 (0.00%)
White blood cell count abnormal	Investigations	3 (0.00%)
White blood cells urine	Investigations	3 (0.00%)
Withdrawal hypertension	Vascular disorders	3 (0.00%)
Withdrawal syndrome	General disorders and administration site conditions	3 (0.00%)
Wound secretion	Injury, poisoning and procedural complications	3 (0.00%)
Wrist fracture	Injury, poisoning and procedural complications	3 (0.00%)
Wrong schedule	Injury, poisoning and procedural complications	3 (0.00%)
Xerophthalmia	Eye disorders	3 (0.00%)
Abdominal adhesions	Gastrointestinal disorders	2 (0.00%)
Abdominal lymphadenopathy	Blood and lymphatic system disorders	2 (0.00%)
Abnormal clotting factor	Blood and lymphatic system disorders	2 (0.00%)
Acne pustular	Infections and infestations	2 (0.00%)
Acute left ventricular failure	Cardiac disorders	2 (0.00%)
Acute macular outer retinopathy	Eye disorders	2 (0.00%)
Acute motor axonal neuropathy	Nervous system disorders	2 (0.00%)
Adenopathy syphilitic	Infections and infestations	2 (0.00%)
Administration site joint movement impairment	General disorders and administration site conditions	2 (0.00%)
Administration site movement impairment	General disorders and administration site conditions	2 (0.00%)
Administration site pruritus	General disorders and administration site conditions	2 (0.00%)
Adrenal mass	Endocrine disorders	2 (0.00%)
African trypanosomiasis	Infections and infestations	2 (0.00%)
Alanine aminotransferase decreased	Investigations	2 (0.00%)
Albuminuria	Renal and urinary disorders	2 (0.00%)
Alcohol interaction	General disorders and administration site conditions	2 (0.00%)
Alcohol poisoning	Injury, poisoning and procedural complications	2 (0.00%)
Alexia	Nervous system disorders	2 (0.00%)
Allergic sinusitis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Allergy to chemicals	Immune system disorders	2 (0.00%)
Altered visual depth perception	Eye disorders	2 (0.00%)
Amaurosis	Eye disorders	2 (0.00%)
Amblyopia	Eye disorders	2 (0.00%)
Anaemia macrocytic	Blood and lymphatic system disorders	2 (0.00%)
Androgenetic alopecia	Skin and subcutaneous tissue disorders	2 (0.00%)
Anembryonic gestation	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Animal bite	Injury, poisoning and procedural complications	2 (0.00%)
Anisocytosis	Blood and lymphatic system disorders	2 (0.00%)
Antisynthetase syndrome	Musculoskeletal and connective tissue disorders	2 (0.00%)
Aortic valve calcification	Cardiac disorders	2 (0.00%)
Aortitis	Vascular disorders	2 (0.00%)
Apnoeic attack	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Application site coldness	General disorders and administration site conditions	2 (0.00%)
Application site vesicles	General disorders and administration site conditions	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Arterial disorder	Vascular disorders	2 (0.00%)
Arterial rupture	Vascular disorders	2 (0.00%)
Arthritis allergic	Musculoskeletal and connective tissue disorders	2 (0.00%)
Arthritis bacterial	Infections and infestations	2 (0.00%)
Arthritis viral	Infections and infestations	2 (0.00%)
Atrial septal defect	Congenital, familial and genetic disorders	2 (0.00%)
Atrial thrombosis	Cardiac disorders	2 (0.00%)
Atrophy	General disorders and administration site conditions	2 (0.00%)
Autoimmune neutropenia	Blood and lymphatic system disorders	2 (0.00%)
Autophony	Ear and labyrinth disorders	2 (0.00%)
Axillary vein thrombosis	Vascular disorders	2 (0.00%)
Bacterial pyelonephritis	Infections and infestations	2 (0.00%)
Bacterial vaginosis	Infections and infestations	2 (0.00%)
Basal ganglia infarction	Nervous system disorders	2 (0.00%)
Basilar artery occlusion	Nervous system disorders	2 (0.00%)
Basophil count decreased	Investigations	2 (0.00%)
Basophil count increased	Investigations	2 (0.00%)
Benign prostatic hyperplasia	Reproductive system and breast disorders	2 (0.00%)
Bladder sphincter atony	Renal and urinary disorders	2 (0.00%)
Blood bilirubin abnormal	Investigations	2 (0.00%)
Blood bilirubin decreased	Investigations	2 (0.00%)
Blood copper increased	Investigations	2 (0.00%)
Blood creatine phosphokinase MB increased	Investigations	2 (0.00%)
Blood gases abnormal	Investigations	2 (0.00%)
Blood glucose	Investigations	2 (0.00%)
Blood growth hormone abnormal	Investigations	2 (0.00%)
Blood immunoglobulin E increased	Investigations	2 (0.00%)
Blood immunoglobulin G increased	Investigations	2 (0.00%)
Blood ketone body increased	Investigations	2 (0.00%)
Blood pH	Investigations	2 (0.00%)
Blood pressure ambulatory increased	Investigations	2 (0.00%)
Blood pressure systolic	Investigations	2 (0.00%)
Blood pressure systolic abnormal	Investigations	2 (0.00%)
Bone contusion	Injury, poisoning and procedural complications	2 (0.00%)
Bone marrow oedema	Blood and lymphatic system disorders	2 (0.00%)
Bradycardia	Cardiac disorders	2 (0.00%)
Bradypnoea	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Brain compression	Nervous system disorders	2 (0.00%)
Brain contusion	Injury, poisoning and procedural complications	2 (0.00%)
Brain scan abnormal	Investigations	2 (0.00%)
Brain stem ischaemia	Nervous system disorders	2 (0.00%)
Breakthrough pain	General disorders and administration site conditions	2 (0.00%)
Breast haematoma	Reproductive system and breast disorders	2 (0.00%)
Breast milk discolouration	Reproductive system and breast disorders	2 (0.00%)
Bronchial oedema	Respiratory, thoracic and mediastinal disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Bronchial secretion retention	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bundle branch block	Cardiac disorders	2 (0.00%)
Burn oesophageal	Injury, poisoning and procedural complications	2 (0.00%)
Capillaritis	Skin and subcutaneous tissue disorders	2 (0.00%)
Capillary disorder	Vascular disorders	2 (0.00%)
Carbohydrate antigen 125 increased	Investigations	2 (0.00%)
Carbon dioxide increased	Investigations	2 (0.00%)
Carcinoembryonic antigen increased	Investigations	2 (0.00%)
Cardiac hypertrophy	Cardiac disorders	2 (0.00%)
Cardio-respiratory distress	Cardiac disorders	2 (0.00%)
Carotid arteriosclerosis	Nervous system disorders	2 (0.00%)
Carotid artery stenosis	Nervous system disorders	2 (0.00%)
Carotid bruit	Investigations	2 (0.00%)
Cataplexy	Nervous system disorders	2 (0.00%)
Central pain syndrome	Nervous system disorders	2 (0.00%)
Central vision loss	Eye disorders	2 (0.00%)
Cerebellar haematoma	Nervous system disorders	2 (0.00%)
Cerebral amyloid angiopathy	Nervous system disorders	2 (0.00%)
Cerebral ventricle collapse	Injury, poisoning and procedural complications	2 (0.00%)
Cerebrospinal fluid leakage	Nervous system disorders	2 (0.00%)
Cerumen impaction	Ear and labyrinth disorders	2 (0.00%)
Cervical spinal stenosis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Cervicogenic headache	Nervous system disorders	2 (0.00%)
Cholecystitis infective	Infections and infestations	2 (0.00%)
Choluria	Renal and urinary disorders	2 (0.00%)
Chondritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Chorioretinopathy	Eye disorders	2 (0.00%)
Citrobacter infection	Infections and infestations	2 (0.00%)
Clavicle fracture	Injury, poisoning and procedural complications	2 (0.00%)
Coccidioidomycosis	Infections and infestations	2 (0.00%)
Colon cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Complement factor C3 increased	Investigations	2 (0.00%)
Complicated appendicitis	Infections and infestations	2 (0.00%)
Conjunctivitis viral	Infections and infestations	2 (0.00%)
Coombs negative haemolytic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Corneal disorder	Eye disorders	2 (0.00%)
Corneal infection	Infections and infestations	2 (0.00%)
Corneal opacity	Eye disorders	2 (0.00%)
Coronary artery dissection	Cardiac disorders	2 (0.00%)
Cor pulmonale	Cardiac disorders	2 (0.00%)
Cor pulmonale acute	Cardiac disorders	2 (0.00%)
Cortisol decreased	Investigations	2 (0.00%)
Cranial nerve palsies multiple	Nervous system disorders	2 (0.00%)
Cranial nerve paralysis	Nervous system disorders	2 (0.00%)
CT hypotension complex	Vascular disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Culture urine positive	Investigations	2 (0.00%)
Cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	2 (0.00%)
Cutaneous sarcoidosis	Skin and subcutaneous tissue disorders	2 (0.00%)
Cystitis interstitial	Renal and urinary disorders	2 (0.00%)
Cystitis noninfective	Renal and urinary disorders	2 (0.00%)
Cytomegalovirus infection	Infections and infestations	2 (0.00%)
Cytomegalovirus test positive	Investigations	2 (0.00%)
Decreased embryo viability	Injury, poisoning and procedural complications	2 (0.00%)
Decreased nasolabial fold	Musculoskeletal and connective tissue disorders	2 (0.00%)
Defaecation disorder	Gastrointestinal disorders	2 (0.00%)
Delayed recovery from anaesthesia	Injury, poisoning and procedural complications	2 (0.00%)
Dental restoration failure	Injury, poisoning and procedural complications	2 (0.00%)
Depression suicidal	Psychiatric disorders	2 (0.00%)
Dermatitis diaper	Skin and subcutaneous tissue disorders	2 (0.00%)
Device related infection	Infections and infestations	2 (0.00%)
Diarrhoea infectious	Infections and infestations	2 (0.00%)
Diastolic hypotension	Vascular disorders	2 (0.00%)
Dilatation ventricular	Cardiac disorders	2 (0.00%)
Discouragement	Psychiatric disorders	2 (0.00%)
Dissociative disorder	Psychiatric disorders	2 (0.00%)
Distractibility	Psychiatric disorders	2 (0.00%)
Disturbance in social behaviour	Psychiatric disorders	2 (0.00%)
Drainage	Surgical and medical procedures	2 (0.00%)
Dropped head syndrome	Nervous system disorders	2 (0.00%)
Drug level increased	Investigations	2 (0.00%)
Duodenal ulcer haemorrhage	Gastrointestinal disorders	2 (0.00%)
Dupuytren's contracture	Musculoskeletal and connective tissue disorders	2 (0.00%)
Dysacusis	Ear and labyrinth disorders	2 (0.00%)
Dysaesthesia pharynx	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Dysbiosis	Gastrointestinal disorders	2 (0.00%)
Ectopic pregnancy	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Eczema asteatotic	Skin and subcutaneous tissue disorders	2 (0.00%)
Effusion	General disorders and administration site conditions	2 (0.00%)
Electrocardiogram change	Investigations	2 (0.00%)
Electrocardiogram QRS complex prolonged	Investigations	2 (0.00%)
Electrocardiogram ST segment abnormal	Investigations	2 (0.00%)
Electrocardiogram ST-T change	Investigations	2 (0.00%)
Electrocardiogram T wave abnormal	Investigations	2 (0.00%)
Embolism arterial	Vascular disorders	2 (0.00%)
Encephalitis autoimmune	Nervous system disorders	2 (0.00%)
Encephalitis post immunisation	Nervous system disorders	2 (0.00%)
Endolymphatic hydrops	Ear and labyrinth disorders	2 (0.00%)
Eosinophilic oesophagitis	Gastrointestinal disorders	2 (0.00%)
Epididymitis	Infections and infestations	2 (0.00%)
Epinephrine increased	Investigations	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Erection increased	Reproductive system and breast disorders	2 (0.00%)
Erythrospia	Eye disorders	2 (0.00%)
Escherichia test positive	Investigations	2 (0.00%)
Eustachian tube disorder	Ear and labyrinth disorders	2 (0.00%)
Evans syndrome	Blood and lymphatic system disorders	2 (0.00%)
Excessive eye blinking	Eye disorders	2 (0.00%)
External ear inflammation	Ear and labyrinth disorders	2 (0.00%)
Extraocular muscle disorder	Eye disorders	2 (0.00%)
Extremity contracture	Musculoskeletal and connective tissue disorders	2 (0.00%)
Eyelid haematoma	Eye disorders	2 (0.00%)
Eye symptom	Eye disorders	2 (0.00%)
Eye ulcer	Eye disorders	2 (0.00%)
Faecal calprotectin increased	Investigations	2 (0.00%)
Faeces hard	Gastrointestinal disorders	2 (0.00%)
False positive investigation result	Investigations	2 (0.00%)
Fever neonatal	General disorders and administration site conditions	2 (0.00%)
Fibroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Fistula	Musculoskeletal and connective tissue disorders	2 (0.00%)
Flashback	Psychiatric disorders	2 (0.00%)
Foetal hypokinesia	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Forced expiratory volume increased	Investigations	2 (0.00%)
Foreign body aspiration	Injury, poisoning and procedural complications	2 (0.00%)
Full blood count increased	Investigations	2 (0.00%)
Gallbladder oedema	Hepatobiliary disorders	2 (0.00%)
Gastric antral vascular ectasia	Gastrointestinal disorders	2 (0.00%)
Gastrointestinal infection	Infections and infestations	2 (0.00%)
Gastrointestinal inflammation	Gastrointestinal disorders	2 (0.00%)
Gastrointestinal oedema	Gastrointestinal disorders	2 (0.00%)
Gastrointestinal stoma complication	Injury, poisoning and procedural complications	2 (0.00%)
Gastrointestinal tract irritation	Gastrointestinal disorders	2 (0.00%)
Gastrointestinal viral infection	Infections and infestations	2 (0.00%)
Gastrointestinal wall thickening	Gastrointestinal disorders	2 (0.00%)
Genital herpes simplex	Infections and infestations	2 (0.00%)
Genital paraesthesia	Reproductive system and breast disorders	2 (0.00%)
Genital tract inflammation	Reproductive system and breast disorders	2 (0.00%)
Gestational diabetes	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Gingival oedema	Gastrointestinal disorders	2 (0.00%)
Gingivitis ulcerative	Gastrointestinal disorders	2 (0.00%)
Glare	Eye disorders	2 (0.00%)
Glucose tolerance impaired	Metabolism and nutrition disorders	2 (0.00%)
Gonorrhoea	Infections and infestations	2 (0.00%)
Graft versus host disease	Immune system disorders	2 (0.00%)
Granuloma skin	Skin and subcutaneous tissue disorders	2 (0.00%)
Haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Haematology test abnormal	Investigations	2 (0.00%)
Haemoglobinuria	Renal and urinary disorders	2 (0.00%)
Haemoperitoneum	Gastrointestinal disorders	2 (0.00%)
Haemophilia	Congenital, familial and genetic disorders	2 (0.00%)
Haemorrhagic transformation stroke	Nervous system disorders	2 (0.00%)
Hair colour changes	Skin and subcutaneous tissue disorders	2 (0.00%)
Hair growth abnormal	Skin and subcutaneous tissue disorders	2 (0.00%)
Hallucination, tactile	Psychiatric disorders	2 (0.00%)
Hand-arm vibration syndrome	Nervous system disorders	2 (0.00%)
Hand-eye coordination impaired	Nervous system disorders	2 (0.00%)
Haptoglobin increased	Investigations	2 (0.00%)
Heart disease congenital	Congenital, familial and genetic disorders	2 (0.00%)
Heart valve incompetence	Cardiac disorders	2 (0.00%)
Heat illness	Injury, poisoning and procedural complications	2 (0.00%)
Helicobacter infection	Infections and infestations	2 (0.00%)
Hepatic infarction	Hepatobiliary disorders	2 (0.00%)
Hernia	General disorders and administration site conditions	2 (0.00%)
Hernia pain	General disorders and administration site conditions	2 (0.00%)
Herpes zoster meningitis	Infections and infestations	2 (0.00%)
Histamine intolerance	Metabolism and nutrition disorders	2 (0.00%)
HIV antibody positive	Investigations	2 (0.00%)
HIV test positive	Investigations	2 (0.00%)
Humerus fracture	Injury, poisoning and procedural complications	2 (0.00%)
Hydrocephalus	Nervous system disorders	2 (0.00%)
Hydronephrosis	Renal and urinary disorders	2 (0.00%)
Hyperactive pharyngeal reflex	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Hypertensive encephalopathy	Nervous system disorders	2 (0.00%)
Hyperuricaemia	Metabolism and nutrition disorders	2 (0.00%)
Hypnagogic hallucination	Psychiatric disorders	2 (0.00%)
Hypoglycaemic coma	Nervous system disorders	2 (0.00%)
Hyponatraemic syndrome	Metabolism and nutrition disorders	2 (0.00%)
Hypovolaemia	Metabolism and nutrition disorders	2 (0.00%)
Idiopathic angioedema	Skin and subcutaneous tissue disorders	2 (0.00%)
Idiopathic pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
IIIrd nerve paresis	Nervous system disorders	2 (0.00%)
Ileus	Gastrointestinal disorders	2 (0.00%)
Inadequate aseptic technique in use of product	Injury, poisoning and procedural complications	2 (0.00%)
Infrequent bowel movements	Gastrointestinal disorders	2 (0.00%)
Inhibitory drug interaction	General disorders and administration site conditions	2 (0.00%)
Injection site hypoaesthesia	General disorders and administration site conditions	2 (0.00%)
Injection site nodule	General disorders and administration site conditions	2 (0.00%)
Intentional overdose	Injury, poisoning and procedural complications	2 (0.00%)
Intention tremor	Nervous system disorders	2 (0.00%)
Intercepted product preparation error	Injury, poisoning and procedural complications	2 (0.00%)
International normalised ratio fluctuation	Investigations	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Intervertebral disc compression	Musculoskeletal and connective tissue disorders	2 (0.00%)
Intestinal pseudo-obstruction	Gastrointestinal disorders	2 (0.00%)
Ischaemic cardiomyopathy	Cardiac disorders	2 (0.00%)
IVth nerve disorder	Nervous system disorders	2 (0.00%)
Jaundice cholestatic	Hepatobiliary disorders	2 (0.00%)
Jaw fracture	Injury, poisoning and procedural complications	2 (0.00%)
Joint ankylosis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Joint laxity	Musculoskeletal and connective tissue disorders	2 (0.00%)
Keratic precipitates	Eye disorders	2 (0.00%)
Lacrimal disorder	Eye disorders	2 (0.00%)
Lacrimation decreased	Eye disorders	2 (0.00%)
Laryngeal disorder	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Laryngeal inflammation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Latent autoimmune diabetes in adults	Metabolism and nutrition disorders	2 (0.00%)
Lateropulsion	Nervous system disorders	2 (0.00%)
Left ventricular dilatation	Cardiac disorders	2 (0.00%)
Libido decreased	Psychiatric disorders	2 (0.00%)
Ligament disorder	Musculoskeletal and connective tissue disorders	2 (0.00%)
Ligament injury	Injury, poisoning and procedural complications	2 (0.00%)
Ligament rupture	Injury, poisoning and procedural complications	2 (0.00%)
Lipase decreased	Investigations	2 (0.00%)
Lipids increased	Investigations	2 (0.00%)
Liver tenderness	Hepatobiliary disorders	2 (0.00%)
Locked-in syndrome	Nervous system disorders	2 (0.00%)
Loss of bladder sensation	Renal and urinary disorders	2 (0.00%)
Lung hyperinflation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Lymphadenopathy mediastinal	Blood and lymphatic system disorders	2 (0.00%)
Lymphatic disorder	Blood and lymphatic system disorders	2 (0.00%)
Lymph nodes scan abnormal	Investigations	2 (0.00%)
Lymphocyte count abnormal	Investigations	2 (0.00%)
Lymphocyte percentage decreased	Investigations	2 (0.00%)
Macular hole	Eye disorders	2 (0.00%)
Macular rupture	Eye disorders	2 (0.00%)
Mallory-Weiss syndrome	Gastrointestinal disorders	2 (0.00%)
Mastoid disorder	Ear and labyrinth disorders	2 (0.00%)
Mean cell haemoglobin concentration increased	Investigations	2 (0.00%)
Mean platelet volume decreased	Investigations	2 (0.00%)
Melanoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Meningioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Meningitis bacterial	Infections and infestations	2 (0.00%)
Meningitis herpes	Infections and infestations	2 (0.00%)
Meningoencephalitis herpetic	Infections and infestations	2 (0.00%)
Meningoradiculitis	Nervous system disorders	2 (0.00%)
Menopause	Social circumstances	2 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Menstrual discomfort	Reproductive system and breast disorders	2 (0.00%)
Mesenteric artery embolism	Gastrointestinal disorders	2 (0.00%)
Metabolic function test abnormal	Investigations	2 (0.00%)
Metastases to peritoneum	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Metastasis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Microcytic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Microscopic polyangiitis	Vascular disorders	2 (0.00%)
Microvascular coronary artery disease	Cardiac disorders	2 (0.00%)
Middle ear effusion	Ear and labyrinth disorders	2 (0.00%)
Misophonia	Ear and labyrinth disorders	2 (0.00%)
Mitral valve calcification	Cardiac disorders	2 (0.00%)
Mitral valve disease	Cardiac disorders	2 (0.00%)
Mitral valve prolapse	Cardiac disorders	2 (0.00%)
Mucosal discolouration	General disorders and administration site conditions	2 (0.00%)
Multimorbidity	General disorders and administration site conditions	2 (0.00%)
Multiple allergies	Immune system disorders	2 (0.00%)
Multiple fractures	Injury, poisoning and procedural complications	2 (0.00%)
Muscle tone disorder	Nervous system disorders	2 (0.00%)
Myocardial fibrosis	Cardiac disorders	2 (0.00%)
Myocardial oedema	Cardiac disorders	2 (0.00%)
Myoclonic dystonia	Congenital, familial and genetic disorders	2 (0.00%)
Myokymia	Musculoskeletal and connective tissue disorders	2 (0.00%)
Nasal discharge discolouration	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Nasal mucosal disorder	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Nerve conduction studies abnormal	Investigations	2 (0.00%)
Nerve degeneration	Nervous system disorders	2 (0.00%)
Neuritis cranial	Nervous system disorders	2 (0.00%)
Neurogenic bladder	Renal and urinary disorders	2 (0.00%)
Neurological decompensation	Nervous system disorders	2 (0.00%)
Neurosensory hypoacusis	Ear and labyrinth disorders	2 (0.00%)
Neurotoxicity	Nervous system disorders	2 (0.00%)
Neutropenic sepsis	Infections and infestations	2 (0.00%)
Neutrophil percentage increased	Investigations	2 (0.00%)
Nipple exudate bloody	Reproductive system and breast disorders	2 (0.00%)
No reaction on previous exposure to drug	General disorders and administration site conditions	2 (0.00%)
Normocytic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Ocular icterus	Hepatobiliary disorders	2 (0.00%)
Oculofacial paralysis	Nervous system disorders	2 (0.00%)
Oculogyric crisis	Eye disorders	2 (0.00%)
Oedematous pancreatitis	Gastrointestinal disorders	2 (0.00%)
Oesophageal irritation	Gastrointestinal disorders	2 (0.00%)
Oesophageal stenosis	Gastrointestinal disorders	2 (0.00%)
Opisthotonus	Nervous system disorders	2 (0.00%)
Optic nerve disorder	Eye disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Orbital haematoma	Eye disorders	2 (0.00%)
Organ failure	General disorders and administration site conditions	2 (0.00%)
Organic brain syndrome	Psychiatric disorders	2 (0.00%)
Organising pneumonia	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Oscillopsia	Eye disorders	2 (0.00%)
Osteitis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Osteochondritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Osteonecrosis of jaw	Musculoskeletal and connective tissue disorders	2 (0.00%)
Otorrhoea	Ear and labyrinth disorders	2 (0.00%)
Oxygen consumption decreased	Investigations	2 (0.00%)
Oxygen saturation	Investigations	2 (0.00%)
Oxygen saturation increased	Investigations	2 (0.00%)
Paramnesia	Psychiatric disorders	2 (0.00%)
Paratracheal lymphadenopathy	Blood and lymphatic system disorders	2 (0.00%)
Parophthalmia	Eye disorders	2 (0.00%)
Paroxysmal arrhythmia	Cardiac disorders	2 (0.00%)
Patella fracture	Injury, poisoning and procedural complications	2 (0.00%)
Peau d'orange	Skin and subcutaneous tissue disorders	2 (0.00%)
Pelvic discomfort	Reproductive system and breast disorders	2 (0.00%)
Pelvic mass	General disorders and administration site conditions	2 (0.00%)
Penile haemorrhage	Reproductive system and breast disorders	2 (0.00%)
Penile swelling	Reproductive system and breast disorders	2 (0.00%)
Peptic ulcer haemorrhage	Gastrointestinal disorders	2 (0.00%)
Pericardial disease	Cardiac disorders	2 (0.00%)
Peripheral arterial occlusive disease	Vascular disorders	2 (0.00%)
Peripheral artery occlusion	Vascular disorders	2 (0.00%)
Peripheral nerve injury	Injury, poisoning and procedural complications	2 (0.00%)
Peripheral nerve paresthesia	Nervous system disorders	2 (0.00%)
Peripheral paralysis	Nervous system disorders	2 (0.00%)
Peritonsillar abscess	Infections and infestations	2 (0.00%)
Peroneal nerve injury	Injury, poisoning and procedural complications	2 (0.00%)
Persecutory delusion	Psychiatric disorders	2 (0.00%)
Pharyngeal cyst	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pharyngeal stenosis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pharyngotonsillitis	Infections and infestations	2 (0.00%)
Plasma cell myeloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Pleuropericarditis	Cardiac disorders	2 (0.00%)
Polychromasia	Blood and lymphatic system disorders	2 (0.00%)
Polyserositis	General disorders and administration site conditions	2 (0.00%)
Post procedural haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Post thrombotic syndrome	Vascular disorders	2 (0.00%)
Pregnancy with contraceptive device	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premature delivery	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premenstrual pain	Reproductive system and breast disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Preterm premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Prinzmetal angina	Cardiac disorders	2 (0.00%)
Procedural haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Product confusion	Injury, poisoning and procedural complications	2 (0.00%)
Product physical issue	Product issues	2 (0.00%)
Prolapse	General disorders and administration site conditions	2 (0.00%)
Protein total increased	Investigations	2 (0.00%)
Prothrombin time shortened	Investigations	2 (0.00%)
Pseudoallergic reaction	General disorders and administration site conditions	2 (0.00%)
Pseudofolliculitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Pseudomonas infection	Infections and infestations	2 (0.00%)
Psychomotor retardation	Psychiatric disorders	2 (0.00%)
Pulmonary artery dilatation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pulmonary sensitisation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pulse pressure decreased	Investigations	2 (0.00%)
Puncture site bruise	General disorders and administration site conditions	2 (0.00%)
Puncture site induration	General disorders and administration site conditions	2 (0.00%)
Pustular psoriasis	Skin and subcutaneous tissue disorders	2 (0.00%)
Quadrantanopia	Nervous system disorders	2 (0.00%)
Rash rubelliform	Skin and subcutaneous tissue disorders	2 (0.00%)
Recall phenomenon	Injury, poisoning and procedural complications	2 (0.00%)
Red blood cell count abnormal	Investigations	2 (0.00%)
Red blood cell sedimentation rate abnormal	Investigations	2 (0.00%)
Renal atrophy	Renal and urinary disorders	2 (0.00%)
Renal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Renal tubular necrosis	Renal and urinary disorders	2 (0.00%)
Respiratory tract infection bacterial	Infections and infestations	2 (0.00%)
Respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Resting tremor	Nervous system disorders	2 (0.00%)
Resuscitation	Surgical and medical procedures	2 (0.00%)
Retinal exudates	Eye disorders	2 (0.00%)
Retinal fovea disorder	Eye disorders	2 (0.00%)
Retinal injury	Injury, poisoning and procedural complications	2 (0.00%)
Retinitis pigmentosa	Congenital, familial and genetic disorders	2 (0.00%)
Retinopathy	Eye disorders	2 (0.00%)
Retroperitoneal haemorrhage	Gastrointestinal disorders	2 (0.00%)
Reversible cerebral vasoconstriction syndrome	Nervous system disorders	2 (0.00%)
Rheumatoid factor positive	Investigations	2 (0.00%)
Right ventricular dilatation	Cardiac disorders	2 (0.00%)
Right ventricular enlargement	Cardiac disorders	2 (0.00%)
Root canal infection	Infections and infestations	2 (0.00%)
Rubber sensitivity	Immune system disorders	2 (0.00%)
SARS-CoV-2 test	Investigations	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Sciatic nerve neuropathy	Nervous system disorders	2 (0.00%)
Scleroderma	Musculoskeletal and connective tissue disorders	2 (0.00%)
Seborrhoea	Skin and subcutaneous tissue disorders	2 (0.00%)
Septic arthritis staphylococcal	Infections and infestations	2 (0.00%)
Serology negative	Investigations	2 (0.00%)
Seronegative arthritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Serositis	General disorders and administration site conditions	2 (0.00%)
Serotonin syndrome	Nervous system disorders	2 (0.00%)
Serum ferritin abnormal	Investigations	2 (0.00%)
Serum sickness-like reaction	Immune system disorders	2 (0.00%)
Shock haemorrhagic	Vascular disorders	2 (0.00%)
Sinusitis bacterial	Infections and infestations	2 (0.00%)
Skin discharge	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin discomfort	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin hyperpigmentation	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin turgor decreased	Investigations	2 (0.00%)
Skull fracture	Injury, poisoning and procedural complications	2 (0.00%)
SLE arthritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Soft tissue injury	Injury, poisoning and procedural complications	2 (0.00%)
Solar lentigo	Skin and subcutaneous tissue disorders	2 (0.00%)
Soliloquy	Psychiatric disorders	2 (0.00%)
Speech sound disorder	Psychiatric disorders	2 (0.00%)
Spinal column injury	Injury, poisoning and procedural complications	2 (0.00%)
Spinal cord compression	Nervous system disorders	2 (0.00%)
Spinal cord infarction	Nervous system disorders	2 (0.00%)
Spinal cord injury	Injury, poisoning and procedural complications	2 (0.00%)
Spinal fracture	Injury, poisoning and procedural complications	2 (0.00%)
Spleen disorder	Blood and lymphatic system disorders	2 (0.00%)
Splenic vein thrombosis	Blood and lymphatic system disorders	2 (0.00%)
Splinter haemorrhages	Skin and subcutaneous tissue disorders	2 (0.00%)
Sputum abnormal	Investigations	2 (0.00%)
Sputum retention	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Status migrainosus	Nervous system disorders	2 (0.00%)
Steatorrhoea	Gastrointestinal disorders	2 (0.00%)
Stertor	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Stillbirth	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Stoma site haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Superficial injury of eye	Injury, poisoning and procedural complications	2 (0.00%)
Superinfection	Infections and infestations	2 (0.00%)
Temporal lobe epilepsy	Nervous system disorders	2 (0.00%)
Tenosynovitis stenosans	Musculoskeletal and connective tissue disorders	2 (0.00%)
Testis discomfort	Reproductive system and breast disorders	2 (0.00%)
Therapeutic product effect delayed	General disorders and administration site conditions	2 (0.00%)
Thirst decreased	General disorders and administration site conditions	2 (0.00%)
Thoracic outlet syndrome	Nervous system disorders	2 (0.00%)
Thrombosed varicose vein	Vascular disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Thrombosis in device	Product issues	2 (0.00%)
Thrombotic cerebral infarction	Nervous system disorders	2 (0.00%)
Thyroid hormones increased	Investigations	2 (0.00%)
Thyroxine decreased	Investigations	2 (0.00%)
Tongue haemorrhage	Gastrointestinal disorders	2 (0.00%)
Tongue rough	Gastrointestinal disorders	2 (0.00%)
Tonsillar ulcer	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Tooth avulsion	Injury, poisoning and procedural complications	2 (0.00%)
Total lung capacity decreased	Investigations	2 (0.00%)
Toxocariasis	Infections and infestations	2 (0.00%)
Tracheal oedema	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Transplant failure	Injury, poisoning and procedural complications	2 (0.00%)
Traumatic lung injury	Injury, poisoning and procedural complications	2 (0.00%)
Trichodynia	Skin and subcutaneous tissue disorders	2 (0.00%)
Trigeminal palsy	Nervous system disorders	2 (0.00%)
Tryptase decreased	Investigations	2 (0.00%)
Tryptase increased	Investigations	2 (0.00%)
Tubulointerstitial nephritis	Renal and urinary disorders	2 (0.00%)
Tumour marker increased	Investigations	2 (0.00%)
Tympanic membrane hyperaemia	Ear and labyrinth disorders	2 (0.00%)
Type II hypersensitivity	Immune system disorders	2 (0.00%)
Type V hyperlipidaemia	Congenital, familial and genetic disorders	2 (0.00%)
Typical aura without headache	Nervous system disorders	2 (0.00%)
Ulnar nerve palsy	Nervous system disorders	2 (0.00%)
Upper respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Ureteric stenosis	Renal and urinary disorders	2 (0.00%)
Urinary tract disorder	Renal and urinary disorders	2 (0.00%)
Urinary tract pain	Renal and urinary disorders	2 (0.00%)
Urine leukocyte esterase positive	Investigations	2 (0.00%)
Urogenital haemorrhage	Renal and urinary disorders	2 (0.00%)
Urticaria cholinergic	Skin and subcutaneous tissue disorders	2 (0.00%)
Uterine contractions abnormal	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Uterine contractions during pregnancy	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Uterine inflammation	Reproductive system and breast disorders	2 (0.00%)
Uterine spasm	Reproductive system and breast disorders	2 (0.00%)
Vaccination site abscess sterile	General disorders and administration site conditions	2 (0.00%)
Vaccination site atrophy	General disorders and administration site conditions	2 (0.00%)
Vaccination site exfoliation	General disorders and administration site conditions	2 (0.00%)
Vaccination site joint warmth	General disorders and administration site conditions	2 (0.00%)
Vaccination site phlebitis	General disorders and administration site conditions	2 (0.00%)
Vaccination site plaque	General disorders and administration site conditions	2 (0.00%)
Vaccination site recall reaction	General disorders and administration site conditions	2 (0.00%)
Vaccination site ulcer	General disorders and administration site conditions	2 (0.00%)
Vaginal cyst	Reproductive system and breast disorders	2 (0.00%)
Vascular occlusion	Vascular disorders	2 (0.00%)
Vascular rupture	Vascular disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vasoplegia syndrome	Injury, poisoning and procedural complications	2 (0.00%)
Venous oxygen saturation decreased	Investigations	2 (0.00%)
Virologic failure	Infections and infestations	2 (0.00%)
Visual brightness	Eye disorders	2 (0.00%)
Vitamin B12 increased	Investigations	2 (0.00%)
Vitreous degeneration	Eye disorders	2 (0.00%)
Vulval disorder	Reproductive system and breast disorders	2 (0.00%)
Vulval ulceration	Reproductive system and breast disorders	2 (0.00%)
Vulvitis	Infections and infestations	2 (0.00%)
Vulvovaginal rash	Reproductive system and breast disorders	2 (0.00%)
White blood cell disorder	Blood and lymphatic system disorders	2 (0.00%)
White coat hypertension	Vascular disorders	2 (0.00%)
Wrong technique in device usage process	Injury, poisoning and procedural complications	2 (0.00%)
Xanthopsia	Eye disorders	2 (0.00%)
Abdominal abscess	Infections and infestations	1 (0.00%)
Abdominal migraine	Gastrointestinal disorders	1 (0.00%)
Abdominal wall abscess	Infections and infestations	1 (0.00%)
Abdominal wall haematoma	Gastrointestinal disorders	1 (0.00%)
Abnormal withdrawal bleeding	Reproductive system and breast disorders	1 (0.00%)
Aborted pregnancy	Social circumstances	1 (0.00%)
Abscess drainage	Surgical and medical procedures	1 (0.00%)
Abscess jaw	Infections and infestations	1 (0.00%)
Abscess limb	Infections and infestations	1 (0.00%)
Abscess neck	Infections and infestations	1 (0.00%)
Abscess of salivary gland	Infections and infestations	1 (0.00%)
Accident at work	Injury, poisoning and procedural complications	1 (0.00%)
Acetonaemia	Metabolism and nutrition disorders	1 (0.00%)
Achenbach syndrome	Vascular disorders	1 (0.00%)
Achlorhydria	Gastrointestinal disorders	1 (0.00%)
Acidosis hyperchloraemic	Metabolism and nutrition disorders	1 (0.00%)
Acquired macroglossia	Gastrointestinal disorders	1 (0.00%)
Acrochordon	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Activated partial thromboplastin time abnormal	Investigations	1 (0.00%)
Activated partial thromboplastin time ratio increased	Investigations	1 (0.00%)
Acute endocarditis	Infections and infestations	1 (0.00%)
Acute lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Acute phase reaction	General disorders and administration site conditions	1 (0.00%)
Acute polyneuropathy	Nervous system disorders	1 (0.00%)
Acute right ventricular failure	Cardiac disorders	1 (0.00%)
Acute sinusitis	Infections and infestations	1 (0.00%)
Addison's disease	Endocrine disorders	1 (0.00%)
Adenoma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Adhesion	General disorders and administration site conditions	1 (0.00%)
Adjustment disorder with depressed mood	Psychiatric disorders	1 (0.00%)
Administration site bruise	General disorders and administration site conditions	1 (0.00%)
Administration site discomfort	General disorders and administration site conditions	1 (0.00%)
Administration site hypoaesthesia	General disorders and administration site conditions	1 (0.00%)
Administration site induration	General disorders and administration site conditions	1 (0.00%)
Administration site irritation	General disorders and administration site conditions	1 (0.00%)
Administration site joint pain	General disorders and administration site conditions	1 (0.00%)
Administration site paraesthesia	General disorders and administration site conditions	1 (0.00%)
Adrenergic syndrome	Nervous system disorders	1 (0.00%)
Adult failure to thrive	Metabolism and nutrition disorders	1 (0.00%)
Aerococcus urinae infection	Infections and infestations	1 (0.00%)
Agitated depression	Psychiatric disorders	1 (0.00%)
Agnosia	Nervous system disorders	1 (0.00%)
Air embolism	Vascular disorders	1 (0.00%)
Airway secretion clearance therapy	Surgical and medical procedures	1 (0.00%)
Alanine aminotransferase abnormal	Investigations	1 (0.00%)
Albumin globulin ratio decreased	Investigations	1 (0.00%)
Alcoholic hangover	Psychiatric disorders	1 (0.00%)
Alexithymia	Psychiatric disorders	1 (0.00%)
Allergic respiratory disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Allergy test positive	Investigations	1 (0.00%)
Allergy to arthropod bite	Immune system disorders	1 (0.00%)
Alopecia totalis	Skin and subcutaneous tissue disorders	1 (0.00%)
Alopecia universalis	Skin and subcutaneous tissue disorders	1 (0.00%)
Alpha globulin increased	Investigations	1 (0.00%)
Alpha tumour necrosis factor increased	Investigations	1 (0.00%)
Alveolitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Amegakaryocytic thrombocytopenia	Congenital, familial and genetic disorders	1 (0.00%)
Amino acid level decreased	Investigations	1 (0.00%)
Ammonia abnormal	Investigations	1 (0.00%)
Ammonia increased	Investigations	1 (0.00%)
Amniotic cavity infection	Infections and infestations	1 (0.00%)
Amyloidosis	Immune system disorders	1 (0.00%)
Amyotrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Anaemia megaloblastic	Blood and lymphatic system disorders	1 (0.00%)
Anaesthesia dolorosa	Nervous system disorders	1 (0.00%)
Anal erythema	Gastrointestinal disorders	1 (0.00%)
Anal fissure	Gastrointestinal disorders	1 (0.00%)
Analgesic drug level	Investigations	1 (0.00%)
Analgesic drug level above therapeutic	Investigations	1 (0.00%)
Anal infection	Infections and infestations	1 (0.00%)
Anal skin tags	Gastrointestinal disorders	1 (0.00%)
Anal sphincter hypertonia	Gastrointestinal disorders	1 (0.00%)
Anamnestic reaction	Immune system disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Anaphylaxis prophylaxis	Surgical and medical procedures	1 (0.00%)
Anencephaly	Congenital, familial and genetic disorders	1 (0.00%)
Angina bullosa haemorrhagica	Gastrointestinal disorders	1 (0.00%)
Angiokeratoma	Skin and subcutaneous tissue disorders	1 (0.00%)
Angiomyolipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Anhedonia	Psychiatric disorders	1 (0.00%)
Anion gap abnormal	Investigations	1 (0.00%)
Anion gap decreased	Investigations	1 (0.00%)
Anion gap increased	Investigations	1 (0.00%)
Anisomastia	Reproductive system and breast disorders	1 (0.00%)
Anisometropia	Eye disorders	1 (0.00%)
Anomalous pulmonary venous connection	Congenital, familial and genetic disorders	1 (0.00%)
Anorectal disorder	Gastrointestinal disorders	1 (0.00%)
Anorectal swelling	Gastrointestinal disorders	1 (0.00%)
Anorgasmia	Psychiatric disorders	1 (0.00%)
Anovulatory cycle	Endocrine disorders	1 (0.00%)
Anterior chamber cell	Eye disorders	1 (0.00%)
Antibody test normal	Investigations	1 (0.00%)
Antibody test positive	Investigations	1 (0.00%)
Anticholinergic syndrome	Nervous system disorders	1 (0.00%)
Anticoagulation drug level increased	Investigations	1 (0.00%)
Anti-glomerular basement membrane disease	Renal and urinary disorders	1 (0.00%)
Anti Kell antibody test positive	Investigations	1 (0.00%)
Anti-myelin-associated glycoprotein antibodies positive	Investigations	1 (0.00%)
Anti-neutrophil cytoplasmic antibody positive vasculitis	Immune system disorders	1 (0.00%)
Antinuclear antibody increased	Investigations	1 (0.00%)
Antiphospholipid antibodies positive	Investigations	1 (0.00%)
Anti-platelet antibody	Investigations	1 (0.00%)
Antipsychotic drug level increased	Investigations	1 (0.00%)
Anti-thyroid antibody	Investigations	1 (0.00%)
Anxiety disorder due to a general medical condition	Psychiatric disorders	1 (0.00%)
Aortic bruit	Investigations	1 (0.00%)
Aortic dilatation	Vascular disorders	1 (0.00%)
Aortic disorder	Vascular disorders	1 (0.00%)
Aortic valve disease	Cardiac disorders	1 (0.00%)
Aplasia	Congenital, familial and genetic disorders	1 (0.00%)
Aplastic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Apparent death	General disorders and administration site conditions	1 (0.00%)
Appendix disorder	Gastrointestinal disorders	1 (0.00%)
Application site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Application site inflammation	General disorders and administration site conditions	1 (0.00%)
Application site oedema	General disorders and administration site conditions	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Application site paraesthesia	General disorders and administration site conditions	1 (0.00%)
Application site swelling	General disorders and administration site conditions	1 (0.00%)
Application site warmth	General disorders and administration site conditions	1 (0.00%)
Arachnoid cyst	Nervous system disorders	1 (0.00%)
Arterial haemorrhage	Vascular disorders	1 (0.00%)
Arterial stenosis	Vascular disorders	1 (0.00%)
Arteriosclerotic retinopathy	Eye disorders	1 (0.00%)
Arteriovenous fistula	Vascular disorders	1 (0.00%)
Arteriovenous graft thrombosis	Injury, poisoning and procedural complications	1 (0.00%)
Arteritis	Vascular disorders	1 (0.00%)
Arthritis enteropathic	Musculoskeletal and connective tissue disorders	1 (0.00%)
Arthritis infective	Infections and infestations	1 (0.00%)
Arthrodesis	Surgical and medical procedures	1 (0.00%)
Arthropod infestation	Infections and infestations	1 (0.00%)
Aspartate aminotransferase decreased	Investigations	1 (0.00%)
Asterixis	Nervous system disorders	1 (0.00%)
Asthma late onset	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Asthma prophylaxis	Surgical and medical procedures	1 (0.00%)
Asymptomatic bacteriuria	Infections and infestations	1 (0.00%)
Atopy	Immune system disorders	1 (0.00%)
Atrioventricular block second degree	Cardiac disorders	1 (0.00%)
Atrophic glossitis	Gastrointestinal disorders	1 (0.00%)
Atypical femur fracture	Injury, poisoning and procedural complications	1 (0.00%)
Atypical haemolytic uraemic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Audiogram abnormal	Investigations	1 (0.00%)
Auscultation	Investigations	1 (0.00%)
Autism spectrum disorder	Psychiatric disorders	1 (0.00%)
Autoantibody negative	Investigations	1 (0.00%)
Autoimmune anaemia	Blood and lymphatic system disorders	1 (0.00%)
Autoimmune arthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Autoimmune demyelinating disease	Nervous system disorders	1 (0.00%)
Autoimmune hypothyroidism	Endocrine disorders	1 (0.00%)
Autoimmune thyroid disorder	Endocrine disorders	1 (0.00%)
Autoimmune uveitis	Eye disorders	1 (0.00%)
Automatism	Psychiatric disorders	1 (0.00%)
Autonomic neuropathy	Nervous system disorders	1 (0.00%)
Aversion	Psychiatric disorders	1 (0.00%)
Avulsion fracture	Injury, poisoning and procedural complications	1 (0.00%)
Babesiosis	Infections and infestations	1 (0.00%)
Bacterial diarrhoea	Infections and infestations	1 (0.00%)
Bacterial disease carrier	Infections and infestations	1 (0.00%)
Bacterial rhinitis	Infections and infestations	1 (0.00%)
Bacterial test	Investigations	1 (0.00%)
Bacteriuria	Infections and infestations	1 (0.00%)
Band neutrophil count increased	Investigations	1 (0.00%)
Barotrauma	Injury, poisoning and procedural complications	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Barrett's oesophagus	Gastrointestinal disorders	1 (0.00%)
Base excess decreased	Investigations	1 (0.00%)
Basilar migraine	Nervous system disorders	1 (0.00%)
Basophil count abnormal	Investigations	1 (0.00%)
B-cell type acute leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Belligerence	Psychiatric disorders	1 (0.00%)
Benign breast neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Beta 2 microglobulin increased	Investigations	1 (0.00%)
Beta globulin increased	Investigations	1 (0.00%)
Beta haemolytic streptococcal infection	Infections and infestations	1 (0.00%)
Bezold-Jarisch reflex	Cardiac disorders	1 (0.00%)
Bicytopenia	Blood and lymphatic system disorders	1 (0.00%)
Bile duct stone	Hepatobiliary disorders	1 (0.00%)
Biliary cyst	Hepatobiliary disorders	1 (0.00%)
Biliary dilatation	Hepatobiliary disorders	1 (0.00%)
Biliary sepsis	Infections and infestations	1 (0.00%)
Bilirubin conjugated increased	Investigations	1 (0.00%)
Bilirubinuria	Renal and urinary disorders	1 (0.00%)
Bilirubin urine present	Investigations	1 (0.00%)
Binge eating	Psychiatric disorders	1 (0.00%)
Biopsy	Investigations	1 (0.00%)
Bipolar I disorder	Psychiatric disorders	1 (0.00%)
Bite	Injury, poisoning and procedural complications	1 (0.00%)
Bladder cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bladder dilatation	Renal and urinary disorders	1 (0.00%)
Bladder irritation	Renal and urinary disorders	1 (0.00%)
Bladder neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bladder obstruction	Renal and urinary disorders	1 (0.00%)
Blast cell count increased	Investigations	1 (0.00%)
Blast cell crisis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Blastocystis infection	Infections and infestations	1 (0.00%)
Bleeding time abnormal	Investigations	1 (0.00%)
Bleeding varicose vein	Vascular disorders	1 (0.00%)
Blepharochalasis	Eye disorders	1 (0.00%)
Blister rupture	Skin and subcutaneous tissue disorders	1 (0.00%)
Blood alcohol decreased	Investigations	1 (0.00%)
Blood bicarbonate increased	Investigations	1 (0.00%)
Blood bilirubin unconjugated increased	Investigations	1 (0.00%)
Blood cholesterol	Investigations	1 (0.00%)
Blood chromium increased	Investigations	1 (0.00%)
Blood creatine phosphokinase abnormal	Investigations	1 (0.00%)
Blood culture positive	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Blood electrolytes decreased	Investigations	1 (0.00%)
Blood electrolytes increased	Investigations	1 (0.00%)
Blood folate increased	Investigations	1 (0.00%)
Blood follicle stimulating hormone increased	Investigations	1 (0.00%)
Blood heavy metal increased	Investigations	1 (0.00%)
Blood immunoglobulin M abnormal	Investigations	1 (0.00%)
Blood insulin increased	Investigations	1 (0.00%)
Blood ketone body present	Investigations	1 (0.00%)
Blood lactate dehydrogenase abnormal	Investigations	1 (0.00%)
Blood lactic acid decreased	Investigations	1 (0.00%)
Blood loss anaemia	Blood and lymphatic system disorders	1 (0.00%)
Blood luteinising hormone abnormal	Investigations	1 (0.00%)
Blood methaemoglobin present	Investigations	1 (0.00%)
Blood oestrogen increased	Investigations	1 (0.00%)
Blood osmolarity increased	Investigations	1 (0.00%)
Blood parathyroid hormone increased	Investigations	1 (0.00%)
Blood pH decreased	Investigations	1 (0.00%)
Blood potassium abnormal	Investigations	1 (0.00%)
Blood pressure measurement	Investigations	1 (0.00%)
Blood pressure orthostatic abnormal	Investigations	1 (0.00%)
Blood pressure orthostatic decreased	Investigations	1 (0.00%)
Blood pressure orthostatic increased	Investigations	1 (0.00%)
Blood prolactin increased	Investigations	1 (0.00%)
Blood smear test abnormal	Investigations	1 (0.00%)
Blood testosterone decreased	Investigations	1 (0.00%)
Blood testosterone increased	Investigations	1 (0.00%)
Blood thrombin	Investigations	1 (0.00%)
Blood triglycerides abnormal	Investigations	1 (0.00%)
Blood urea abnormal	Investigations	1 (0.00%)
Blood urea decreased	Investigations	1 (0.00%)
Blood uric acid abnormal	Investigations	1 (0.00%)
Blood viscosity increased	Investigations	1 (0.00%)
Body dysmorphic disorder	Psychiatric disorders	1 (0.00%)
Body fat disorder	Metabolism and nutrition disorders	1 (0.00%)
Body tinea	Infections and infestations	1 (0.00%)
Bone abscess	Infections and infestations	1 (0.00%)
Bone cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bone density abnormal	Investigations	1 (0.00%)
Bone density decreased	Investigations	1 (0.00%)
Bone development abnormal	Musculoskeletal and connective tissue disorders	1 (0.00%)
Bone formation increased	Musculoskeletal and connective tissue disorders	1 (0.00%)
Borrelia infection	Infections and infestations	1 (0.00%)
Brain cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Brain herniation	Injury, poisoning and procedural complications	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Breast cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cancer stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cellulitis	Infections and infestations	1 (0.00%)
Breast disorder female	Reproductive system and breast disorders	1 (0.00%)
Breast prosthesis user	Social circumstances	1 (0.00%)
Breathing-related sleep disorder	Psychiatric disorders	1 (0.00%)
Bronchial haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial wall thickening	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchitis chronic	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchopulmonary aspergillosis	Infections and infestations	1 (0.00%)
Brow ptosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Bulbar palsy	Nervous system disorders	1 (0.00%)
Bulimia nervosa	Psychiatric disorders	1 (0.00%)
Burning feet syndrome	Nervous system disorders	1 (0.00%)
Burn of internal organs	Injury, poisoning and procedural complications	1 (0.00%)
Bursal fluid accumulation	Musculoskeletal and connective tissue disorders	1 (0.00%)
Bursal haematoma	Musculoskeletal and connective tissue disorders	1 (0.00%)
Bursitis infective	Infections and infestations	1 (0.00%)
Caffeine consumption	Social circumstances	1 (0.00%)
Calcium ionised increased	Investigations	1 (0.00%)
Calculus urinary	Renal and urinary disorders	1 (0.00%)
Carbon dioxide decreased	Investigations	1 (0.00%)
Carbon monoxide poisoning	Injury, poisoning and procedural complications	1 (0.00%)
Cardiac aneurysm	Cardiac disorders	1 (0.00%)
Cardiac neoplasm unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Cardiac pacemaker insertion	Surgical and medical procedures	1 (0.00%)
Cardiac valve sclerosis	Cardiac disorders	1 (0.00%)
Cardiac valve vegetation	Infections and infestations	1 (0.00%)
Cardiac ventricular thrombosis	Cardiac disorders	1 (0.00%)
Cardiothoracic ratio increased	Investigations	1 (0.00%)
Carotid artery disease	Nervous system disorders	1 (0.00%)
Cataract nuclear	Eye disorders	1 (0.00%)
Catheter site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Cavernous sinus thrombosis	Infections and infestations	1 (0.00%)
Cell marker decreased	Investigations	1 (0.00%)
Cells in urine	Investigations	1 (0.00%)
Cellulitis gangrenous	Infections and infestations	1 (0.00%)
Cellulitis staphylococcal	Infections and infestations	1 (0.00%)
Central cord syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Central nervous system infection	Infections and infestations	1 (0.00%)
Central nervous system inflammation	Nervous system disorders	1 (0.00%)
Central nervous system stimulation	Surgical and medical procedures	1 (0.00%)
Central nervous system vasculitis	Nervous system disorders	1 (0.00%)
Central venous pressure abnormal	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cephalhaematoma	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Cerebellar atrophy	Nervous system disorders	1 (0.00%)
Cerebellar ischaemia	Nervous system disorders	1 (0.00%)
Cerebral arteriosclerosis	Nervous system disorders	1 (0.00%)
Cerebral artery stenosis	Nervous system disorders	1 (0.00%)
Cerebral congestion	Nervous system disorders	1 (0.00%)
Cerebral hyperperfusion syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Cerebral microangiopathy	Nervous system disorders	1 (0.00%)
Cerebral small vessel ischaemic disease	Nervous system disorders	1 (0.00%)
Cerebral ventricular rupture	Nervous system disorders	1 (0.00%)
Cerebrovascular insufficiency	Nervous system disorders	1 (0.00%)
Cervical cord compression	Nervous system disorders	1 (0.00%)
Cervical dysplasia	Reproductive system and breast disorders	1 (0.00%)
Cervical neuritis	Nervous system disorders	1 (0.00%)
Cervix erythema	Reproductive system and breast disorders	1 (0.00%)
Cervix haematoma uterine	Reproductive system and breast disorders	1 (0.00%)
Cervix oedema	Reproductive system and breast disorders	1 (0.00%)
Change in sustained attention	Psychiatric disorders	1 (0.00%)
Charles Bonnet syndrome	Eye disorders	1 (0.00%)
Chest expansion decreased	Investigations	1 (0.00%)
Cheyne-Stokes respiration	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cholecystitis acute	Hepatobiliary disorders	1 (0.00%)
Cholestatic liver injury	Hepatobiliary disorders	1 (0.00%)
Chondrocalcinosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Chorioretinitis	Infections and infestations	1 (0.00%)
Choroiditis	Eye disorders	1 (0.00%)
Chronic myeloid leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Chronic sinusitis	Infections and infestations	1 (0.00%)
Chronic spontaneous urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Ciliary muscle spasm	Eye disorders	1 (0.00%)
Claudication of jaw muscles	Vascular disorders	1 (0.00%)
Claustrophobia	Psychiatric disorders	1 (0.00%)
Clinomania	Psychiatric disorders	1 (0.00%)
Clostridium test positive	Investigations	1 (0.00%)
Clot retraction	Investigations	1 (0.00%)
Coagulation factor increased	Investigations	1 (0.00%)
Coeliac artery stenosis	Gastrointestinal disorders	1 (0.00%)
Cold burn	Injury, poisoning and procedural complications	1 (0.00%)
Colour blindness	Congenital, familial and genetic disorders	1 (0.00%)
Coma hepatic	Nervous system disorders	1 (0.00%)
Coma scale	Investigations	1 (0.00%)
Complement factor C3 decreased	Investigations	1 (0.00%)
Completed suicide	Psychiatric disorders	1 (0.00%)
Compulsions	Psychiatric disorders	1 (0.00%)
Computerised tomogram normal	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Computerised tomogram thorax abnormal	Investigations	1 (0.00%)
Concomitant disease progression	General disorders and administration site conditions	1 (0.00%)
Conduction disorder	Cardiac disorders	1 (0.00%)
Conductive deafness	Ear and labyrinth disorders	1 (0.00%)
Confusional arousal	Psychiatric disorders	1 (0.00%)
Congenital cystic lung	Congenital, familial and genetic disorders	1 (0.00%)
Congenital multiplex arthrogyrosis	Congenital, familial and genetic disorders	1 (0.00%)
Conjunctival disorder	Eye disorders	1 (0.00%)
Conjunctival laceration	Injury, poisoning and procedural complications	1 (0.00%)
Conjunctival pallor	Eye disorders	1 (0.00%)
Connective tissue disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Constricted affect	Psychiatric disorders	1 (0.00%)
Contraceptive diaphragm	Surgical and medical procedures	1 (0.00%)
Contraindicated product prescribed	Injury, poisoning and procedural complications	1 (0.00%)
Contraindication to medical treatment	Social circumstances	1 (0.00%)
Contrast media allergy	Immune system disorders	1 (0.00%)
Contrast media reaction	Immune system disorders	1 (0.00%)
Conus medullaris syndrome	Nervous system disorders	1 (0.00%)
Coombs positive haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Corneal abrasion	Injury, poisoning and procedural complications	1 (0.00%)
Corneal bleeding	Eye disorders	1 (0.00%)
Corneal degeneration	Eye disorders	1 (0.00%)
Corneal dystrophy	Congenital, familial and genetic disorders	1 (0.00%)
Corneal erosion	Eye disorders	1 (0.00%)
Corneal graft rejection	Immune system disorders	1 (0.00%)
Corneal infiltrates	Eye disorders	1 (0.00%)
Corneal oedema	Eye disorders	1 (0.00%)
Coronary artery insufficiency	Cardiac disorders	1 (0.00%)
Cough decreased	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cramp-fasciculation syndrome	Nervous system disorders	1 (0.00%)
Cranial nerve decompression	Surgical and medical procedures	1 (0.00%)
Craniofacial fracture	Injury, poisoning and procedural complications	1 (0.00%)
C-reactive protein decreased	Investigations	1 (0.00%)
Creatinine renal clearance decreased	Investigations	1 (0.00%)
CREST syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Crystal arthropathy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Crystal urine	Investigations	1 (0.00%)
CSF immunoglobulin increased	Investigations	1 (0.00%)
CSF polymorphonuclear cell count increased	Investigations	1 (0.00%)
CSF test abnormal	Investigations	1 (0.00%)
Culture negative	Investigations	1 (0.00%)
Cyanopsia	Eye disorders	1 (0.00%)
Cyanosis central	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cyclic vomiting syndrome	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cyclothymic disorder	Psychiatric disorders	1 (0.00%)
Cystic lung disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cystic lymphangioma	Congenital, familial and genetic disorders	1 (0.00%)
Cystitis bacterial	Infections and infestations	1 (0.00%)
Cystitis escherichia	Infections and infestations	1 (0.00%)
Cystitis klebsiella	Infections and infestations	1 (0.00%)
Cystitis-like symptom	Renal and urinary disorders	1 (0.00%)
Cyst rupture	General disorders and administration site conditions	1 (0.00%)
Cytokine storm	Immune system disorders	1 (0.00%)
Cytomegalovirus infection reactivation	Infections and infestations	1 (0.00%)
Dacryocystitis	Infections and infestations	1 (0.00%)
Dactylitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Dairy intolerance	Metabolism and nutrition disorders	1 (0.00%)
Dandruff	Skin and subcutaneous tissue disorders	1 (0.00%)
Decreased insulin requirement	Metabolism and nutrition disorders	1 (0.00%)
Defect conduction intraventricular	Cardiac disorders	1 (0.00%)
Deficiency anaemia	Blood and lymphatic system disorders	1 (0.00%)
Deficiency of bile secretion	Hepatobiliary disorders	1 (0.00%)
Deformity	General disorders and administration site conditions	1 (0.00%)
Degenerative bone disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Deja vu	Psychiatric disorders	1 (0.00%)
Delusional disorder, unspecified type	Psychiatric disorders	1 (0.00%)
Dementia of the Alzheimer's type, with delirium	Nervous system disorders	1 (0.00%)
Dementia with Lewy bodies	Nervous system disorders	1 (0.00%)
Dependent rubor	Vascular disorders	1 (0.00%)
Dermabrasion	Surgical and medical procedures	1 (0.00%)
Dermal filler injection	Surgical and medical procedures	1 (0.00%)
Dermatochalasis	Eye disorders	1 (0.00%)
Dermatophytosis of nail	Infections and infestations	1 (0.00%)
Dermoid cyst	Congenital, familial and genetic disorders	1 (0.00%)
Device breakage	Product issues	1 (0.00%)
Device infusion issue	Product issues	1 (0.00%)
Device leakage	Product issues	1 (0.00%)
Device pacing issue	Product issues	1 (0.00%)
Device stimulation issue	Product issues	1 (0.00%)
Diabetes insipidus	Endocrine disorders	1 (0.00%)
Diabetic diet	Surgical and medical procedures	1 (0.00%)
Diabetic eye disease	Eye disorders	1 (0.00%)
Diabetic foot infection	Infections and infestations	1 (0.00%)
Diabetic hyperosmolar coma	Nervous system disorders	1 (0.00%)
Diabetic ketosis	Metabolism and nutrition disorders	1 (0.00%)
Diabetic neuropathy	Nervous system disorders	1 (0.00%)
Diabetic wound	Skin and subcutaneous tissue disorders	1 (0.00%)
Diaphragmatic paralysis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Differential white blood cell count abnormal	Investigations	1 (0.00%)
Diffuse alopecia	Skin and subcutaneous tissue disorders	1 (0.00%)
Diffuse large B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Digestive enzyme abnormal	Investigations	1 (0.00%)
Disability	Social circumstances	1 (0.00%)
Disinhibition	Psychiatric disorders	1 (0.00%)
Dissociative amnesia	Psychiatric disorders	1 (0.00%)
Dose calculation error	Injury, poisoning and procedural complications	1 (0.00%)
Drooping shoulder syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Drop attacks	Nervous system disorders	1 (0.00%)
Drug abuse	Psychiatric disorders	1 (0.00%)
Drug administered in wrong device	Injury, poisoning and procedural complications	1 (0.00%)
Drug effective for unapproved indication	General disorders and administration site conditions	1 (0.00%)
Drug exposure before pregnancy	Injury, poisoning and procedural complications	1 (0.00%)
Drug level decreased	Investigations	1 (0.00%)
Drug level fluctuating	Investigations	1 (0.00%)
Drug resistance	General disorders and administration site conditions	1 (0.00%)
Drug screen positive	Investigations	1 (0.00%)
Drug withdrawal syndrome	General disorders and administration site conditions	1 (0.00%)
Dry age-related macular degeneration	Eye disorders	1 (0.00%)
Ductus arteriosus premature closure	Congenital, familial and genetic disorders	1 (0.00%)
Dumping syndrome	Gastrointestinal disorders	1 (0.00%)
Duodenal ulcer	Gastrointestinal disorders	1 (0.00%)
Duodenal ulcer perforation	Gastrointestinal disorders	1 (0.00%)
Duodenitis	Gastrointestinal disorders	1 (0.00%)
Dysdiadochokinesis	Nervous system disorders	1 (0.00%)
Dysfunctional uterine bleeding	Reproductive system and breast disorders	1 (0.00%)
Dysmorphism	Congenital, familial and genetic disorders	1 (0.00%)
Dyspareunia	Reproductive system and breast disorders	1 (0.00%)
Dyspraxia	Nervous system disorders	1 (0.00%)
Dyssomnia	Psychiatric disorders	1 (0.00%)
Ear infection bacterial	Infections and infestations	1 (0.00%)
Ear infection viral	Infections and infestations	1 (0.00%)
Ear injury	Injury, poisoning and procedural complications	1 (0.00%)
Ear neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ear, nose and throat examination abnormal	Investigations	1 (0.00%)
Eastern Cooperative Oncology Group performance status worsened	Investigations	1 (0.00%)
Ebola disease	Infections and infestations	1 (0.00%)
Eczema weeping	Skin and subcutaneous tissue disorders	1 (0.00%)
Ehlers-Danlos syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Ejection fraction abnormal	Investigations	1 (0.00%)
Electrocardiogram normal	Investigations	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Electrocardiogram PR prolongation	Investigations	1 (0.00%)
Electrocardiogram PR shortened	Investigations	1 (0.00%)
Electrocardiogram QT interval abnormal	Investigations	1 (0.00%)
Electrocardiogram ST-T segment abnormal	Investigations	1 (0.00%)
Electrocardiogram T wave peaked	Investigations	1 (0.00%)
Electroencephalogram abnormal	Investigations	1 (0.00%)
Electrolyte depletion	Metabolism and nutrition disorders	1 (0.00%)
Electromyogram abnormal	Investigations	1 (0.00%)
Embedded device	Product issues	1 (0.00%)
Emotional poverty	Psychiatric disorders	1 (0.00%)
Encephalitis enteroviral	Infections and infestations	1 (0.00%)
End stage renal disease	Renal and urinary disorders	1 (0.00%)
Enteritis infectious	Infections and infestations	1 (0.00%)
Enterocolitis haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Eosinophilic bronchitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Ephelides	Skin and subcutaneous tissue disorders	1 (0.00%)
Epidermal necrosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Epileptic aura	Nervous system disorders	1 (0.00%)
Epileptic encephalopathy	Nervous system disorders	1 (0.00%)
Epiphyses premature fusion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Epstein-Barr virus antibody positive	Investigations	1 (0.00%)
Epstein-Barr virus test positive	Investigations	1 (0.00%)
Erosive oesophagitis	Gastrointestinal disorders	1 (0.00%)
Erysipeloid	Infections and infestations	1 (0.00%)
Erythema ab igne	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythema marginatum	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythematotelangiectatic rosacea	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythropenia	Blood and lymphatic system disorders	1 (0.00%)
Erythrosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Eschar	Injury, poisoning and procedural complications	1 (0.00%)
Essential thrombocythaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Exaggerated startle response	Nervous system disorders	1 (0.00%)
Excessive granulation tissue	Skin and subcutaneous tissue disorders	1 (0.00%)
Excessive ocular convergence	Eye disorders	1 (0.00%)
Exercise electrocardiogram abnormal	Investigations	1 (0.00%)
Exercise lack of	Social circumstances	1 (0.00%)
Exploding head syndrome	Psychiatric disorders	1 (0.00%)
Exposure keratitis	Eye disorders	1 (0.00%)
Exposure to contaminated water	Injury, poisoning and procedural complications	1 (0.00%)
Exposure to extreme temperature	Injury, poisoning and procedural complications	1 (0.00%)
External ear cellulitis	Infections and infestations	1 (0.00%)
External ear disorder	Ear and labyrinth disorders	1 (0.00%)
Extradural haematoma	Injury, poisoning and procedural complications	1 (0.00%)
Eye abscess	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Eye complication associated with device	General disorders and administration site conditions	1 (0.00%)
Eyelid bleeding	Eye disorders	1 (0.00%)
Eyelid contusion	Injury, poisoning and procedural complications	1 (0.00%)
Eyelid cyst	Eye disorders	1 (0.00%)
Eyelid exfoliation	Eye disorders	1 (0.00%)
Eyelid infection	Infections and infestations	1 (0.00%)
Eyelid margin crusting	Eye disorders	1 (0.00%)
Eyelid myokymia	Eye disorders	1 (0.00%)
Eyelid retraction	Eye disorders	1 (0.00%)
Eyelid vascular disorder	Eye disorders	1 (0.00%)
Eye opacity	Eye disorders	1 (0.00%)
Face crushing	Injury, poisoning and procedural complications	1 (0.00%)
Facet joint syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Factitious disorder	Psychiatric disorders	1 (0.00%)
Factor II mutation	Congenital, familial and genetic disorders	1 (0.00%)
Factor VIII inhibition	Blood and lymphatic system disorders	1 (0.00%)
Factor V Leiden mutation	Congenital, familial and genetic disorders	1 (0.00%)
Faecal calprotectin	Investigations	1 (0.00%)
Failed in vitro fertilisation	Injury, poisoning and procedural complications	1 (0.00%)
Failure to thrive	Metabolism and nutrition disorders	1 (0.00%)
False negative investigation result	Investigations	1 (0.00%)
Familial hemiplegic migraine	Congenital, familial and genetic disorders	1 (0.00%)
Familial mediterranean fever	Congenital, familial and genetic disorders	1 (0.00%)
Familial periodic paralysis	Congenital, familial and genetic disorders	1 (0.00%)
Fasting	Social circumstances	1 (0.00%)
Fat tissue increased	General disorders and administration site conditions	1 (0.00%)
Febrile neutropenia	Blood and lymphatic system disorders	1 (0.00%)
Female genital tract fistula	Reproductive system and breast disorders	1 (0.00%)
Female sexual dysfunction	Reproductive system and breast disorders	1 (0.00%)
Femoral artery embolism	Vascular disorders	1 (0.00%)
Fibrin degradation products increased	Investigations	1 (0.00%)
Fibrinolysis	Investigations	1 (0.00%)
Fibromuscular dysplasia	Vascular disorders	1 (0.00%)
Fibrosis	General disorders and administration site conditions	1 (0.00%)
Floppy eyelid syndrome	Eye disorders	1 (0.00%)
Foetal cystic hygroma	Congenital, familial and genetic disorders	1 (0.00%)
Foetal heart rate decreased	Investigations	1 (0.00%)
Foetal malformation	Congenital, familial and genetic disorders	1 (0.00%)
Foetal movement disorder	Nervous system disorders	1 (0.00%)
Folate deficiency	Metabolism and nutrition disorders	1 (0.00%)
Foreign body in eye	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in gastrointestinal tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in mouth	Injury, poisoning and procedural complications	1 (0.00%)
Foveal reflex abnormal	Investigations	1 (0.00%)
Fracture blisters	Skin and subcutaneous tissue disorders	1 (0.00%)
Fractured skull depressed	Injury, poisoning and procedural complications	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Fumbling	Nervous system disorders	1 (0.00%)
Fungal peritonitis	Infections and infestations	1 (0.00%)
Galactostasis	Reproductive system and breast disorders	1 (0.00%)
Gallbladder enlargement	Hepatobiliary disorders	1 (0.00%)
Gallbladder polyp	Hepatobiliary disorders	1 (0.00%)
Gastric cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gastric infection	Infections and infestations	1 (0.00%)
Gastric varices haemorrhage	Gastrointestinal disorders	1 (0.00%)
Gastric volvulus	Gastrointestinal disorders	1 (0.00%)
Gastritis bacterial	Infections and infestations	1 (0.00%)
Gastritis erosive	Gastrointestinal disorders	1 (0.00%)
Gastroenteritis bacterial	Infections and infestations	1 (0.00%)
Gastroenteritis norovirus	Infections and infestations	1 (0.00%)
Gastroenteritis rotavirus	Infections and infestations	1 (0.00%)
Gastrointestinal carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gastrointestinal injury	Injury, poisoning and procedural complications	1 (0.00%)
Gastrointestinal mucosal disorder	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal obstruction	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal somatic symptom disorder	Psychiatric disorders	1 (0.00%)
Gastrointestinal surgery	Surgical and medical procedures	1 (0.00%)
Gastroschisis	Congenital, familial and genetic disorders	1 (0.00%)
Generalised onset non-motor seizure	Nervous system disorders	1 (0.00%)
Genital blister	Reproductive system and breast disorders	1 (0.00%)
Genital discomfort	Reproductive system and breast disorders	1 (0.00%)
Genital lesion	Reproductive system and breast disorders	1 (0.00%)
Genital rash	Reproductive system and breast disorders	1 (0.00%)
Genital swelling	Reproductive system and breast disorders	1 (0.00%)
Genitourinary symptom	Renal and urinary disorders	1 (0.00%)
Gianotti-Crosti syndrome	Infections and infestations	1 (0.00%)
Giant papillary conjunctivitis	Eye disorders	1 (0.00%)
Gingival abscess	Infections and infestations	1 (0.00%)
Gingival pruritus	Gastrointestinal disorders	1 (0.00%)
Gingival recession	Gastrointestinal disorders	1 (0.00%)
Gingival ulceration	Gastrointestinal disorders	1 (0.00%)
Glabella reflex abnormal	Nervous system disorders	1 (0.00%)
Gliosis	Nervous system disorders	1 (0.00%)
Glomerular filtration rate abnormal	Investigations	1 (0.00%)
Glomerulonephritis chronic	Renal and urinary disorders	1 (0.00%)
Glomerulonephritis rapidly progressive	Renal and urinary disorders	1 (0.00%)
Glossopharyngeal nerve disorder	Nervous system disorders	1 (0.00%)
Glottal incompetence	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Glucose urine present	Investigations	1 (0.00%)
Glycopenia	Metabolism and nutrition disorders	1 (0.00%)
Glycosylated haemoglobin decreased	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Good syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gouty tophus	Musculoskeletal and connective tissue disorders	1 (0.00%)
Granulocytes abnormal	Investigations	1 (0.00%)
Granuloma annulare	Skin and subcutaneous tissue disorders	1 (0.00%)
Granulomatous liver disease	Hepatobiliary disorders	1 (0.00%)
Grief reaction	Psychiatric disorders	1 (0.00%)
Grip strength	Investigations	1 (0.00%)
Groin abscess	Infections and infestations	1 (0.00%)
Gross motor delay	Nervous system disorders	1 (0.00%)
Growing pains	Musculoskeletal and connective tissue disorders	1 (0.00%)
Gynaecomastia	Reproductive system and breast disorders	1 (0.00%)
Haematoma infection	Infections and infestations	1 (0.00%)
Haematospermia	Reproductive system and breast disorders	1 (0.00%)
Haemochromatosis	Metabolism and nutrition disorders	1 (0.00%)
Haemolytic uraemic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Haemorrhage in pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Haemorrhagic cerebral infarction	Nervous system disorders	1 (0.00%)
Haemorrhagic infarction	Vascular disorders	1 (0.00%)
Haemorrhagic urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Haemorrhagic varicella syndrome	Infections and infestations	1 (0.00%)
Haemorrhoidal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Haemorrhoids thrombosed	Gastrointestinal disorders	1 (0.00%)
Hair disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Hair injury	Injury, poisoning and procedural complications	1 (0.00%)
Halo vision	Eye disorders	1 (0.00%)
Haptoglobin decreased	Investigations	1 (0.00%)
Head deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Hearing disability	Social circumstances	1 (0.00%)
Heart alternation	Cardiac disorders	1 (0.00%)
Hemianopia heteronymous	Nervous system disorders	1 (0.00%)
Hemiapraxia	Nervous system disorders	1 (0.00%)
Heparin-induced thrombocytopenia	Blood and lymphatic system disorders	1 (0.00%)
Hepatic artery embolism	Hepatobiliary disorders	1 (0.00%)
Hepatic cyst infection	Infections and infestations	1 (0.00%)
Hepatic haematoma	Hepatobiliary disorders	1 (0.00%)
Hepatic haemorrhage	Hepatobiliary disorders	1 (0.00%)
Hepatic necrosis	Hepatobiliary disorders	1 (0.00%)
Hepatitis A	Infections and infestations	1 (0.00%)
Hepatitis A antibody positive	Investigations	1 (0.00%)
Hepatitis A virus test positive	Investigations	1 (0.00%)
Hepatitis B	Infections and infestations	1 (0.00%)
Hepatitis B antibody positive	Investigations	1 (0.00%)
Hepatitis B virus test positive	Investigations	1 (0.00%)
Hepatitis C	Infections and infestations	1 (0.00%)
Hepatitis D	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hepatitis infectious mononucleosis	Infections and infestations	1 (0.00%)
Hepatojugular reflux	Cardiac disorders	1 (0.00%)
Hereditary angioedema with normal C1 esterase inhibitor	Congenital, familial and genetic disorders	1 (0.00%)
Hereditary haemorrhagic telangiectasia	Congenital, familial and genetic disorders	1 (0.00%)
Hereditary neuropathy with liability to pressure palsies	Congenital, familial and genetic disorders	1 (0.00%)
Hernia repair	Surgical and medical procedures	1 (0.00%)
Herpangina	Infections and infestations	1 (0.00%)
Herpes pharyngitis	Infections and infestations	1 (0.00%)
Herpes simplex test positive	Investigations	1 (0.00%)
Herpes virus test	Investigations	1 (0.00%)
Heterophoria	Eye disorders	1 (0.00%)
High density lipoprotein decreased	Investigations	1 (0.00%)
High-pitched crying	General disorders and administration site conditions	1 (0.00%)
Hippocampal atrophy	Nervous system disorders	1 (0.00%)
Hirsutism	Skin and subcutaneous tissue disorders	1 (0.00%)
HIV infection	Infections and infestations	1 (0.00%)
HIV test negative	Investigations	1 (0.00%)
Hoffmann's sign	Nervous system disorders	1 (0.00%)
Hostility	Psychiatric disorders	1 (0.00%)
Hydrophobia	Psychiatric disorders	1 (0.00%)
Hydrothorax	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hyperaesthesia eye	Eye disorders	1 (0.00%)
Hyperchloraemia	Metabolism and nutrition disorders	1 (0.00%)
Hypercoagulation	Blood and lymphatic system disorders	1 (0.00%)
Hypercreatininaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperdynamic left ventricle	Cardiac disorders	1 (0.00%)
Hyperferritinaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperfibrinogenaemia	Blood and lymphatic system disorders	1 (0.00%)
Hypergeusia	Nervous system disorders	1 (0.00%)
Hyperglycaemic hyperosmolar nonketotic syndrome	Metabolism and nutrition disorders	1 (0.00%)
Hyperglycinaemia	Congenital, familial and genetic disorders	1 (0.00%)
Hyperintensity in brain deep nuclei	Nervous system disorders	1 (0.00%)
Hyperkinesia	Nervous system disorders	1 (0.00%)
Hyperlipidaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypermetropia	Eye disorders	1 (0.00%)
Hyperoxia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hyperparathyroidism	Endocrine disorders	1 (0.00%)
Hyperparathyroidism primary	Endocrine disorders	1 (0.00%)
Hypersensitivity pneumonitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hypersexuality	Psychiatric disorders	1 (0.00%)
Hypersomnia-bulimia syndrome	Psychiatric disorders	1 (0.00%)
Hypertrichosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Hypertriglyceridaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypervitaminosis B12	Metabolism and nutrition disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hypervolaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyphaema	Injury, poisoning and procedural complications	1 (0.00%)
Hypogammaglobulinaemia	Immune system disorders	1 (0.00%)
Hypoglossal nerve disorder	Nervous system disorders	1 (0.00%)
Hypoglossal nerve paresis	Nervous system disorders	1 (0.00%)
Hypomagnesaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypomania	Psychiatric disorders	1 (0.00%)
Hypophosphataemia	Metabolism and nutrition disorders	1 (0.00%)
Hyposomnia	Psychiatric disorders	1 (0.00%)
Hypotony of eye	Eye disorders	1 (0.00%)
Hypoxic-ischaemic encephalopathy	Nervous system disorders	1 (0.00%)
Hysterectomy	Surgical and medical procedures	1 (0.00%)
Idiopathic urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Idiosyncratic drug reaction	General disorders and administration site conditions	1 (0.00%)
IgA nephropathy	Renal and urinary disorders	1 (0.00%)
Ileectomy	Surgical and medical procedures	1 (0.00%)
Iliotibial band syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Illiteracy	Social circumstances	1 (0.00%)
Illness anxiety disorder	Psychiatric disorders	1 (0.00%)
Immature granulocyte count increased	Investigations	1 (0.00%)
Immediate post-injection reaction	General disorders and administration site conditions	1 (0.00%)
Immobilisation syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Immune-mediated arthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Immune-mediated hepatic disorder	Hepatobiliary disorders	1 (0.00%)
Immune-mediated hepatitis	Hepatobiliary disorders	1 (0.00%)
Immunodeficiency common variable	Immune system disorders	1 (0.00%)
Immunoglobulins decreased	Investigations	1 (0.00%)
Immunology test	Investigations	1 (0.00%)
Immunology test abnormal	Investigations	1 (0.00%)
Immunosuppression	Immune system disorders	1 (0.00%)
Impaired reasoning	Psychiatric disorders	1 (0.00%)
Imperception	Psychiatric disorders	1 (0.00%)
Implant site pain	General disorders and administration site conditions	1 (0.00%)
Impulsive behaviour	Psychiatric disorders	1 (0.00%)
Inability to crawl	Nervous system disorders	1 (0.00%)
Inadequate analgesia	General disorders and administration site conditions	1 (0.00%)
Incision site haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect dose administered by device	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect drug administration rate	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect product administration duration	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect product formulation administered	Injury, poisoning and procedural complications	1 (0.00%)
Increased insulin requirement	Metabolism and nutrition disorders	1 (0.00%)
Infected cyst	Infections and infestations	1 (0.00%)
Infected dermal cyst	Infections and infestations	1 (0.00%)
Infected skin ulcer	Infections and infestations	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Infection parasitic	Infections and infestations	1 (0.00%)
Infection susceptibility increased	Infections and infestations	1 (0.00%)
Infectious pleural effusion	Infections and infestations	1 (0.00%)
Infective exacerbation of bronchiectasis	Infections and infestations	1 (0.00%)
Infective spondylitis	Infections and infestations	1 (0.00%)
Inferior vena caval occlusion	Vascular disorders	1 (0.00%)
Infertility	Reproductive system and breast disorders	1 (0.00%)
Infertility female	Reproductive system and breast disorders	1 (0.00%)
Inflammation of wound	Injury, poisoning and procedural complications	1 (0.00%)
Influenza B virus test positive	Investigations	1 (0.00%)
Infusion site bruising	General disorders and administration site conditions	1 (0.00%)
Infusion site warmth	General disorders and administration site conditions	1 (0.00%)
Ingrowing nail	Skin and subcutaneous tissue disorders	1 (0.00%)
Inguinal mass	Musculoskeletal and connective tissue disorders	1 (0.00%)
Injection	Surgical and medical procedures	1 (0.00%)
Injection site cellulitis	Infections and infestations	1 (0.00%)
Injection site hyperaesthesia	General disorders and administration site conditions	1 (0.00%)
Injection site indentation	General disorders and administration site conditions	1 (0.00%)
Injection site joint movement impairment	General disorders and administration site conditions	1 (0.00%)
Injection site lymphadenopathy	General disorders and administration site conditions	1 (0.00%)
Injection site movement impairment	General disorders and administration site conditions	1 (0.00%)
Injection site papule	General disorders and administration site conditions	1 (0.00%)
Injection site pustule	Infections and infestations	1 (0.00%)
Injection site scar	General disorders and administration site conditions	1 (0.00%)
Injection site vesicles	General disorders and administration site conditions	1 (0.00%)
Injury corneal	Injury, poisoning and procedural complications	1 (0.00%)
Inner ear inflammation	Ear and labyrinth disorders	1 (0.00%)
Inspiratory capacity abnormal	Investigations	1 (0.00%)
Instillation site pain	General disorders and administration site conditions	1 (0.00%)
Insulin-requiring type 2 diabetes mellitus	Metabolism and nutrition disorders	1 (0.00%)
Insulin resistant diabetes	Metabolism and nutrition disorders	1 (0.00%)
Interleukin level increased	Investigations	1 (0.00%)
Internal hernia	Gastrointestinal disorders	1 (0.00%)
Intervertebral disc degeneration	Musculoskeletal and connective tissue disorders	1 (0.00%)
Intervertebral discitis	Infections and infestations	1 (0.00%)
Intestinal dilatation	Gastrointestinal disorders	1 (0.00%)
Intestinal gangrene	Infections and infestations	1 (0.00%)
Intestinal mass	Gastrointestinal disorders	1 (0.00%)
Intra-abdominal haematoma	Gastrointestinal disorders	1 (0.00%)
Intracranial haematoma	Nervous system disorders	1 (0.00%)
Intracranial mass	Nervous system disorders	1 (0.00%)
Intraocular pressure test abnormal	Investigations	1 (0.00%)
Intravascular haemolysis	Blood and lymphatic system disorders	1 (0.00%)
Invasive ductal breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Iodine uptake decreased	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Iodine uptake increased	Investigations	1 (0.00%)
Ischaemic limb pain	Vascular disorders	1 (0.00%)
IVth nerve paresis	Nervous system disorders	1 (0.00%)
Jaw cyst	Musculoskeletal and connective tissue disorders	1 (0.00%)
Job dissatisfaction	Social circumstances	1 (0.00%)
Joint abscess	Infections and infestations	1 (0.00%)
Joint destruction	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint hyperextension	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint microhaemorrhage	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint prosthesis user	Social circumstances	1 (0.00%)
Joint stabilisation	Surgical and medical procedures	1 (0.00%)
Joint vibration	Musculoskeletal and connective tissue disorders	1 (0.00%)
Kaposi's sarcoma AIDS related	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Kaposi's varicelliform eruption	Infections and infestations	1 (0.00%)
Keratoconus	Eye disorders	1 (0.00%)
Kidney fibrosis	Renal and urinary disorders	1 (0.00%)
Kidney small	Renal and urinary disorders	1 (0.00%)
Kidney transplant rejection	Immune system disorders	1 (0.00%)
Labile hypertension	Vascular disorders	1 (0.00%)
Laboratory test normal	Investigations	1 (0.00%)
Lacrimation disorder	Eye disorders	1 (0.00%)
Lactobacillus infection	Infections and infestations	1 (0.00%)
Lactose intolerance	Metabolism and nutrition disorders	1 (0.00%)
Large intestinal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Large intestinal obstruction	Gastrointestinal disorders	1 (0.00%)
Large intestine perforation	Gastrointestinal disorders	1 (0.00%)
Large intestine polyp	Gastrointestinal disorders	1 (0.00%)
Laryngeal erythema	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Laryngeal stenosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Laryngitis allergic	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Laryngitis bacterial	Infections and infestations	1 (0.00%)
Lateral medullary syndrome	Nervous system disorders	1 (0.00%)
Learning disability	Psychiatric disorders	1 (0.00%)
Left atrial dilatation	Cardiac disorders	1 (0.00%)
Left ventricular end-diastolic pressure increased	Investigations	1 (0.00%)
Lennox-Gastaut syndrome	Nervous system disorders	1 (0.00%)
Leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Leukaemoid reaction	Blood and lymphatic system disorders	1 (0.00%)
Leukoplakia	Skin and subcutaneous tissue disorders	1 (0.00%)
Libido increased	Psychiatric disorders	1 (0.00%)
Lid margin discharge	Eye disorders	1 (0.00%)
Ligamentitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ligament pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Limbal swelling	Eye disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Limb crushing injury	Injury, poisoning and procedural complications	1 (0.00%)
Limb deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Limb operation	Surgical and medical procedures	1 (0.00%)
Lip erosion	Gastrointestinal disorders	1 (0.00%)
Lip haematoma	Gastrointestinal disorders	1 (0.00%)
Lipid metabolism disorder	Metabolism and nutrition disorders	1 (0.00%)
Lip infection	Infections and infestations	1 (0.00%)
Lipodystrophy acquired	Skin and subcutaneous tissue disorders	1 (0.00%)
Lip scab	Gastrointestinal disorders	1 (0.00%)
Listeria test positive	Investigations	1 (0.00%)
Listeriosis	Infections and infestations	1 (0.00%)
Lithiasis	General disorders and administration site conditions	1 (0.00%)
Local anaesthesia	Surgical and medical procedures	1 (0.00%)
Long thoracic nerve palsy	Nervous system disorders	1 (0.00%)
Loose body in joint	Musculoskeletal and connective tissue disorders	1 (0.00%)
Loose tooth	Gastrointestinal disorders	1 (0.00%)
Lower gastrointestinal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Lower respiratory tract infection viral	Infections and infestations	1 (0.00%)
Lumbar puncture abnormal	Investigations	1 (0.00%)
Lumbar radiculopathy	Nervous system disorders	1 (0.00%)
Lung abscess	Infections and infestations	1 (0.00%)
Lung carcinoma cell type unspecified stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lung transplant rejection	Immune system disorders	1 (0.00%)
Lupus-like syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Lupus myositis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Lymphadenitis bacterial	Infections and infestations	1 (0.00%)
Lymphangiectasia	Vascular disorders	1 (0.00%)
Lymphangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lymphangiopathy	Vascular disorders	1 (0.00%)
Lymphatic obstruction	Blood and lymphatic system disorders	1 (0.00%)
Lymphocyte percentage increased	Investigations	1 (0.00%)
Lymphocytic infiltration	Blood and lymphatic system disorders	1 (0.00%)
Lymphoproliferative disorder	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
MAGIC syndrome	Vascular disorders	1 (0.00%)
Magnetic resonance imaging abnormal	Investigations	1 (0.00%)
Malignant lymphoid neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Malignant melanoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Malignant pleural effusion	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Mammogram abnormal	Investigations	1 (0.00%)
Mandibular mass	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mass excision	Surgical and medical procedures	1 (0.00%)
Mast cell degranulation present	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Masticatory pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mastocytosis	Blood and lymphatic system disorders	1 (0.00%)
May-Thurner syndrome	Vascular disorders	1 (0.00%)
Mean cell haemoglobin increased	Investigations	1 (0.00%)
Mean platelet volume increased	Investigations	1 (0.00%)
Medial tibial stress syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mediastinal haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Medication overuse headache	Nervous system disorders	1 (0.00%)
Megacolon	Gastrointestinal disorders	1 (0.00%)
Melanocytic naevus	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Meningitis noninfective	Nervous system disorders	1 (0.00%)
Meningitis pneumococcal	Infections and infestations	1 (0.00%)
Meningomyelitis herpes	Infections and infestations	1 (0.00%)
Meningorrhagia	Nervous system disorders	1 (0.00%)
Meniscus injury	Injury, poisoning and procedural complications	1 (0.00%)
Menometrorrhagia	Reproductive system and breast disorders	1 (0.00%)
Meralgia paraesthetica	Nervous system disorders	1 (0.00%)
Mesenteric abscess	Infections and infestations	1 (0.00%)
Mesenteric arterial occlusion	Gastrointestinal disorders	1 (0.00%)
Mesenteric artery aneurysm	Gastrointestinal disorders	1 (0.00%)
Mesenteric panniculitis	Gastrointestinal disorders	1 (0.00%)
Mesenteric vascular insufficiency	Gastrointestinal disorders	1 (0.00%)
Metabolic alkalosis	Metabolism and nutrition disorders	1 (0.00%)
Metabolic encephalopathy	Nervous system disorders	1 (0.00%)
Metabolic syndrome	Metabolism and nutrition disorders	1 (0.00%)
Metamyelocyte count increased	Investigations	1 (0.00%)
Metastases to meninges	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Metastatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Methylenetetrahydrofolate reductase gene mutation	Congenital, familial and genetic disorders	1 (0.00%)
Microangiopathic haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Middle ear inflammation	Ear and labyrinth disorders	1 (0.00%)
Migraine prophylaxis	Surgical and medical procedures	1 (0.00%)
Mini mental status examination abnormal	Investigations	1 (0.00%)
Mitral valve stenosis	Cardiac disorders	1 (0.00%)
Mixed connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Monoclonal immunoglobulin increased	Investigations	1 (0.00%)
Monocyte count abnormal	Investigations	1 (0.00%)
Monocyte percentage increased	Investigations	1 (0.00%)
Mononeuropathy multiplex	Nervous system disorders	1 (0.00%)
Mononucleosis syndrome	Infections and infestations	1 (0.00%)
Mood disorder due to a general medical condition	Psychiatric disorders	1 (0.00%)
Moraxella infection	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Morganella infection	Infections and infestations	1 (0.00%)
Morton's neuralgia	Nervous system disorders	1 (0.00%)
Mucocutaneous disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Mucosal hyperaemia	General disorders and administration site conditions	1 (0.00%)
Mucosal pain	General disorders and administration site conditions	1 (0.00%)
Mucosa vesicle	General disorders and administration site conditions	1 (0.00%)
Multiple injuries	Injury, poisoning and procedural complications	1 (0.00%)
Multiple sclerosis relapse prophylaxis	Surgical and medical procedures	1 (0.00%)
Musculoskeletal deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Myelocyte count increased	Investigations	1 (0.00%)
Myelocytosis	Blood and lymphatic system disorders	1 (0.00%)
Myelofibrosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Myocardial haemorrhage	Cardiac disorders	1 (0.00%)
Myocardial necrosis	Cardiac disorders	1 (0.00%)
Myocardial strain	Investigations	1 (0.00%)
Myocarditis infectious	Infections and infestations	1 (0.00%)
Myocarditis septic	Infections and infestations	1 (0.00%)
Myoclonic epilepsy	Nervous system disorders	1 (0.00%)
Myoglobin blood increased	Investigations	1 (0.00%)
Myoglobinuria	Renal and urinary disorders	1 (0.00%)
Myopathy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Myringitis	Infections and infestations	1 (0.00%)
Nail avulsion	Injury, poisoning and procedural complications	1 (0.00%)
Nail pigmentation	Skin and subcutaneous tissue disorders	1 (0.00%)
Nail ridging	Skin and subcutaneous tissue disorders	1 (0.00%)
Nasal abscess	Infections and infestations	1 (0.00%)
Nasal crusting	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal vestibulitis	Infections and infestations	1 (0.00%)
Natural killer T cell count increased	Investigations	1 (0.00%)
Necrotising colitis	Gastrointestinal disorders	1 (0.00%)
Necrotising retinitis	Eye disorders	1 (0.00%)
Neonatal pneumothorax	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Neonatal respiratory distress	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nephritis	Renal and urinary disorders	1 (0.00%)
Neuroborreliosis	Infections and infestations	1 (0.00%)
Neurological examination abnormal	Investigations	1 (0.00%)
Neurological examination normal	Investigations	1 (0.00%)
Neuronal neuropathy	Nervous system disorders	1 (0.00%)
Neuropsychiatric symptoms	Psychiatric disorders	1 (0.00%)
Neutralising antibodies negative	Investigations	1 (0.00%)
Neutropenia neonatal	Blood and lymphatic system disorders	1 (0.00%)
New daily persistent headache	Nervous system disorders	1 (0.00%)
Night blindness	Eye disorders	1 (0.00%)
NIH stroke scale score decreased	Investigations	1 (0.00%)
Nipple disorder	Reproductive system and breast disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Nipple infection	Infections and infestations	1 (0.00%)
Nodal rhythm	Cardiac disorders	1 (0.00%)
Noninfective chorioretinitis	Eye disorders	1 (0.00%)
Non-tobacco user	Social circumstances	1 (0.00%)
Normal pressure hydrocephalus	Nervous system disorders	1 (0.00%)
Normochromic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Nucleated red cells	Blood and lymphatic system disorders	1 (0.00%)
Numb chin syndrome	Nervous system disorders	1 (0.00%)
Obesity	Metabolism and nutrition disorders	1 (0.00%)
Obliterative bronchiolitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Obsessive-compulsive symptom	Psychiatric disorders	1 (0.00%)
Obsessive thoughts	Psychiatric disorders	1 (0.00%)
Obstruction gastric	Gastrointestinal disorders	1 (0.00%)
Ocular dysmetria	Eye disorders	1 (0.00%)
Ocular hypertension	Eye disorders	1 (0.00%)
Ocular sarcoidosis	Eye disorders	1 (0.00%)
Oedema blister	Skin and subcutaneous tissue disorders	1 (0.00%)
Oedema genital	Reproductive system and breast disorders	1 (0.00%)
Oesophageal achalasia	Gastrointestinal disorders	1 (0.00%)
Oesophageal discomfort	Gastrointestinal disorders	1 (0.00%)
Oesophageal oedema	Gastrointestinal disorders	1 (0.00%)
Oesophageal perforation	Gastrointestinal disorders	1 (0.00%)
Oesophageal rupture	Gastrointestinal disorders	1 (0.00%)
Oesophageal ulcer haemorrhage	Gastrointestinal disorders	1 (0.00%)
Oesophageal varices haemorrhage	Gastrointestinal disorders	1 (0.00%)
Oligoarthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Oligodendroglioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Oligodipsia	Metabolism and nutrition disorders	1 (0.00%)
Oligohydramnios	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Omphalitis	Infections and infestations	1 (0.00%)
On and off phenomenon	Nervous system disorders	1 (0.00%)
Onychalgia	Skin and subcutaneous tissue disorders	1 (0.00%)
Onycholysis	Skin and subcutaneous tissue disorders	1 (0.00%)
Oophoritis	Infections and infestations	1 (0.00%)
Ophthalmic artery thrombosis	Eye disorders	1 (0.00%)
Ophthalmological examination abnormal	Investigations	1 (0.00%)
Ophthalmoplegic migraine	Nervous system disorders	1 (0.00%)
Opiates positive	Investigations	1 (0.00%)
Optic atrophy	Eye disorders	1 (0.00%)
Optic nerve infarction	Eye disorders	1 (0.00%)
Oral administration complication	General disorders and administration site conditions	1 (0.00%)
Oral allergy syndrome	Immune system disorders	1 (0.00%)
Oral bacterial infection	Infections and infestations	1 (0.00%)
Oral discharge	Gastrointestinal disorders	1 (0.00%)
Oral mucosa haematoma	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Oral mucosal discolouration	Gastrointestinal disorders	1 (0.00%)
Oral papule	Gastrointestinal disorders	1 (0.00%)
Oral pigmentation	Gastrointestinal disorders	1 (0.00%)
Oral purpura	Gastrointestinal disorders	1 (0.00%)
Oral pustule	Infections and infestations	1 (0.00%)
Orchitis noninfective	Reproductive system and breast disorders	1 (0.00%)
Oromandibular dystonia	Nervous system disorders	1 (0.00%)
Oropharyngeal candidiasis	Infections and infestations	1 (0.00%)
Oropharyngeal cobble stone mucosa	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Oropharyngeal plaque	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Orthostatic heart rate response increased	Investigations	1 (0.00%)
Orthostatic hypertension	Vascular disorders	1 (0.00%)
Orthostatic tremor	Nervous system disorders	1 (0.00%)
Osmophobia	Psychiatric disorders	1 (0.00%)
Osteoarthropathy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Osteopenia	Musculoskeletal and connective tissue disorders	1 (0.00%)
Otitis media acute	Infections and infestations	1 (0.00%)
Otolithiasis	Ear and labyrinth disorders	1 (0.00%)
Ovarian cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ovarian disorder	Reproductive system and breast disorders	1 (0.00%)
Ovarian enlargement	Reproductive system and breast disorders	1 (0.00%)
Overflow diarrhoea	Gastrointestinal disorders	1 (0.00%)
Ovulation pain	Reproductive system and breast disorders	1 (0.00%)
Oxygen consumption	Investigations	1 (0.00%)
Oxygen consumption increased	Investigations	1 (0.00%)
Oxygen saturation immeasurable	Investigations	1 (0.00%)
Palatal ulcer	Gastrointestinal disorders	1 (0.00%)
Palate injury	Injury, poisoning and procedural complications	1 (0.00%)
Palindromic rheumatism	Musculoskeletal and connective tissue disorders	1 (0.00%)
Palmar-plantar erythrodysesthesia syndrome	Skin and subcutaneous tissue disorders	1 (0.00%)
Palmoplantar pustulosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Pancreatic infarction	Gastrointestinal disorders	1 (0.00%)
Pancreatitis chronic	Gastrointestinal disorders	1 (0.00%)
Pancreatitis necrotising	Gastrointestinal disorders	1 (0.00%)
Pancreatitis relapsing	Gastrointestinal disorders	1 (0.00%)
Parainfluenzae viral laryngotracheobronchitis	Infections and infestations	1 (0.00%)
Paranasal sinus hyposcretion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Paranasal sinus inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Parapharyngeal space infection	Infections and infestations	1 (0.00%)
Parkinsonian rest tremor	Nervous system disorders	1 (0.00%)
Parotid duct obstruction	Gastrointestinal disorders	1 (0.00%)
Parvovirus B19 test positive	Investigations	1 (0.00%)
Parvovirus infection	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Patellofemoral pain syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Paternal exposure before pregnancy	Injury, poisoning and procedural complications	1 (0.00%)
Pathogen resistance	Infections and infestations	1 (0.00%)
Patient uncooperative	Social circumstances	1 (0.00%)
PCO2 abnormal	Investigations	1 (0.00%)
PCO2 decreased	Investigations	1 (0.00%)
Peak expiratory flow rate	Investigations	1 (0.00%)
Peak expiratory flow rate abnormal	Investigations	1 (0.00%)
Pelvic inflammatory disease	Infections and infestations	1 (0.00%)
Penile discomfort	Reproductive system and breast disorders	1 (0.00%)
Penis disorder	Reproductive system and breast disorders	1 (0.00%)
Peptic ulcer	Gastrointestinal disorders	1 (0.00%)
Perichondritis	Infections and infestations	1 (0.00%)
Periodontitis	Infections and infestations	1 (0.00%)
Periorbital abscess	Infections and infestations	1 (0.00%)
Peripheral artery stenosis	Vascular disorders	1 (0.00%)
Peripheral nerve palsy	Nervous system disorders	1 (0.00%)
Peripheral sensorimotor neuropathy	Nervous system disorders	1 (0.00%)
Peripheral vein stenosis	Vascular disorders	1 (0.00%)
Peripheral vein thrombus extension	Vascular disorders	1 (0.00%)
Perivascular dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Persistent generalised lymphadenopathy	Infections and infestations	1 (0.00%)
Personality disorder	Psychiatric disorders	1 (0.00%)
Phaeochromocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Pharyngeal lesion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pharyngeal leukoplakia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pharyngeal pustule	Infections and infestations	1 (0.00%)
Pharyngitis bacterial	Infections and infestations	1 (0.00%)
Phlebitis deep	Vascular disorders	1 (0.00%)
Phobia	Psychiatric disorders	1 (0.00%)
Phrenic nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
pH urine	Investigations	1 (0.00%)
pH urine increased	Investigations	1 (0.00%)
Physical disability	Social circumstances	1 (0.00%)
Physical examination abnormal	Investigations	1 (0.00%)
Pigmentary glaucoma	Eye disorders	1 (0.00%)
Pineal gland cyst	Nervous system disorders	1 (0.00%)
Pituitary apoplexy	Endocrine disorders	1 (0.00%)
Pituitary tumour benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Pityriasis lichenoides et varioliformis acuta	Skin and subcutaneous tissue disorders	1 (0.00%)
Plasma viscosity abnormal	Investigations	1 (0.00%)
Platelet anisocytosis	Blood and lymphatic system disorders	1 (0.00%)
Pneumatosis	General disorders and administration site conditions	1 (0.00%)
Pneumococcal sepsis	Infections and infestations	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Pneumocystis jirovecii pneumonia	Infections and infestations	1 (0.00%)
Pneumonia fungal	Infections and infestations	1 (0.00%)
Pneumonia klebsiella	Infections and infestations	1 (0.00%)
Pneumonia legionella	Infections and infestations	1 (0.00%)
Pneumonia moraxella	Infections and infestations	1 (0.00%)
Pneumonia streptococcal	Infections and infestations	1 (0.00%)
Pneumoperitoneum	Gastrointestinal disorders	1 (0.00%)
Polycythaemia	Blood and lymphatic system disorders	1 (0.00%)
Poor venous access	Vascular disorders	1 (0.00%)
Porphyria	Congenital, familial and genetic disorders	1 (0.00%)
Porphyria acute	Congenital, familial and genetic disorders	1 (0.00%)
Positron emission tomogram	Investigations	1 (0.00%)
Post concussion syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Postictal paralysis	Nervous system disorders	1 (0.00%)
Post laminectomy syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Post lumbar puncture syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Postoperative ileus	Injury, poisoning and procedural complications	1 (0.00%)
Postoperative wound complication	Injury, poisoning and procedural complications	1 (0.00%)
Postoperative wound infection	Infections and infestations	1 (0.00%)
Postpartum haemorrhage	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Postprandial hypoglycaemia	Metabolism and nutrition disorders	1 (0.00%)
Post procedural constipation	Injury, poisoning and procedural complications	1 (0.00%)
Post procedural infection	Infections and infestations	1 (0.00%)
Post procedural oedema	Injury, poisoning and procedural complications	1 (0.00%)
Post stroke epilepsy	Nervous system disorders	1 (0.00%)
Post stroke seizure	Nervous system disorders	1 (0.00%)
Post-traumatic neuralgia	Nervous system disorders	1 (0.00%)
Postural tremor	Nervous system disorders	1 (0.00%)
Posturing	Psychiatric disorders	1 (0.00%)
Pouchitis	Gastrointestinal disorders	1 (0.00%)
Pre-eclampsia	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy test positive	Investigations	1 (0.00%)
Prehypertension	Vascular disorders	1 (0.00%)
Premature menarche	Endocrine disorders	1 (0.00%)
Premature menopause	Reproductive system and breast disorders	1 (0.00%)
Premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Presbycusis	Ear and labyrinth disorders	1 (0.00%)
Prescribed overdose	Injury, poisoning and procedural complications	1 (0.00%)
Priapism	Reproductive system and breast disorders	1 (0.00%)
Primary biliary cholangitis	Hepatobiliary disorders	1 (0.00%)
Primary gastrointestinal follicular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Primary headache associated with sexual activity	Nervous system disorders	1 (0.00%)
Prion disease	Infections and infestations	1 (0.00%)
Procedural site reaction	Injury, poisoning and procedural complications	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Proctitis ulcerative	Gastrointestinal disorders	1 (0.00%)
Product communication issue	Injury, poisoning and procedural complications	1 (0.00%)
Product contamination	Product issues	1 (0.00%)
Product deposit	Product issues	1 (0.00%)
Product dispensing issue	Injury, poisoning and procedural complications	1 (0.00%)
Product formulation issue	Product issues	1 (0.00%)
Product lot number issue	Product issues	1 (0.00%)
Product odour abnormal	Product issues	1 (0.00%)
Product residue present	Investigations	1 (0.00%)
Product taste abnormal	Product issues	1 (0.00%)
Progressive supranuclear palsy	Nervous system disorders	1 (0.00%)
Prohormone brain natriuretic peptide increased	Investigations	1 (0.00%)
Prophylaxis of nausea and vomiting	Surgical and medical procedures	1 (0.00%)
Prostate infection	Infections and infestations	1 (0.00%)
Prostatic abscess	Infections and infestations	1 (0.00%)
Prostatic disorder	Reproductive system and breast disorders	1 (0.00%)
Prostatic pain	Reproductive system and breast disorders	1 (0.00%)
Protein C increased	Investigations	1 (0.00%)
Prothrombin level abnormal	Investigations	1 (0.00%)
Prothrombin level decreased	Investigations	1 (0.00%)
Prothrombin level increased	Investigations	1 (0.00%)
Prothrombin time ratio increased	Investigations	1 (0.00%)
Pseudodementia	Psychiatric disorders	1 (0.00%)
Pseudolymphoma	Blood and lymphatic system disorders	1 (0.00%)
Pseudomonas sepsis	Infections and infestations	1 (0.00%)
Psychological factor affecting medical condition	Psychiatric disorders	1 (0.00%)
Psychotic behaviour	Psychiatric disorders	1 (0.00%)
Psychotic disorder due to a general medical condition	Psychiatric disorders	1 (0.00%)
Pulmonary alveolar haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary arterial pressure abnormal	Investigations	1 (0.00%)
Pulmonary artery occlusion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary calcification	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary function test	Investigations	1 (0.00%)
Pulmonary function test decreased	Investigations	1 (0.00%)
Pulmonary hypertensive crisis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary hypoperfusion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary microemboli	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary necrosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary tuberculosis	Infections and infestations	1 (0.00%)
Pulmonary vasculitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary venous thrombosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulse pressure increased	Investigations	1 (0.00%)
Pulse waveform abnormal	Investigations	1 (0.00%)
Puncture site discharge	General disorders and administration site conditions	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Puncture site haematoma	General disorders and administration site conditions	1 (0.00%)
Puncture site oedema	General disorders and administration site conditions	1 (0.00%)
Puncture site swelling	General disorders and administration site conditions	1 (0.00%)
Pupillary light reflex tests abnormal	Investigations	1 (0.00%)
Purging	Psychiatric disorders	1 (0.00%)
Purple glove syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Putamen haemorrhage	Nervous system disorders	1 (0.00%)
Pylorospasm	Gastrointestinal disorders	1 (0.00%)
Pyramidal tract syndrome	Nervous system disorders	1 (0.00%)
Radial pulse increased	Investigations	1 (0.00%)
Radicular pain	Nervous system disorders	1 (0.00%)
Radioisotope uptake increased	Investigations	1 (0.00%)
Rash maculovesicular	Skin and subcutaneous tissue disorders	1 (0.00%)
Rash neonatal	Skin and subcutaneous tissue disorders	1 (0.00%)
Reaction to colouring	Immune system disorders	1 (0.00%)
Reaction to previous exposure to any vaccine	Injury, poisoning and procedural complications	1 (0.00%)
Reactogenicity event	General disorders and administration site conditions	1 (0.00%)
Rebound effect	General disorders and administration site conditions	1 (0.00%)
Recalled product administered	Injury, poisoning and procedural complications	1 (0.00%)
Rectal abscess	Infections and infestations	1 (0.00%)
Rectal injury	Injury, poisoning and procedural complications	1 (0.00%)
Rectal polyp	Gastrointestinal disorders	1 (0.00%)
Rectal prolapse	Gastrointestinal disorders	1 (0.00%)
Rectal spasm	Gastrointestinal disorders	1 (0.00%)
Rectal ulcer	Gastrointestinal disorders	1 (0.00%)
Red blood cell abnormality	Blood and lymphatic system disorders	1 (0.00%)
Red blood cells urine	Investigations	1 (0.00%)
Red cell distribution width decreased	Investigations	1 (0.00%)
Red ear syndrome	Ear and labyrinth disorders	1 (0.00%)
Red man syndrome	Skin and subcutaneous tissue disorders	1 (0.00%)
Relapsing fever	Infections and infestations	1 (0.00%)
Renal artery stenosis	Renal and urinary disorders	1 (0.00%)
Renal cyst haemorrhage	Renal and urinary disorders	1 (0.00%)
Renal injury	Renal and urinary disorders	1 (0.00%)
Renal transplant failure	Immune system disorders	1 (0.00%)
Renal tubular disorder	Renal and urinary disorders	1 (0.00%)
Renal tubular injury	Renal and urinary disorders	1 (0.00%)
Renal vasculitis	Renal and urinary disorders	1 (0.00%)
Repetitive speech	Nervous system disorders	1 (0.00%)
Respiratory disorder neonatal	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory fume inhalation disorder	Injury, poisoning and procedural complications	1 (0.00%)
Respiratory muscle weakness	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory paralysis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory tract haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Restrictive pulmonary disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Reticulocyte count decreased	Investigations	1 (0.00%)
Reticulocyte count increased	Investigations	1 (0.00%)
Retinal aneurysm	Eye disorders	1 (0.00%)
Retinal artery thrombosis	Eye disorders	1 (0.00%)
Retinal degeneration	Eye disorders	1 (0.00%)
Retinal drusen	Eye disorders	1 (0.00%)
Retinal oedema	Eye disorders	1 (0.00%)
Retinal toxicity	Eye disorders	1 (0.00%)
Retinal vascular occlusion	Eye disorders	1 (0.00%)
Retinal vasculitis	Eye disorders	1 (0.00%)
Retinitis	Infections and infestations	1 (0.00%)
Retinopathy hypertensive	Eye disorders	1 (0.00%)
Reversed hot-cold sensation	Nervous system disorders	1 (0.00%)
Reversible airways obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Rheumatic fever	Musculoskeletal and connective tissue disorders	1 (0.00%)
Rhythm idioventricular	Cardiac disorders	1 (0.00%)
Right ventricular dysfunction	Cardiac disorders	1 (0.00%)
Rinne tuning fork test abnormal	Investigations	1 (0.00%)
Romberg test positive	Investigations	1 (0.00%)
Roseola	Infections and infestations	1 (0.00%)
Saliva discolouration	Gastrointestinal disorders	1 (0.00%)
Salivary duct obstruction	Gastrointestinal disorders	1 (0.00%)
Salmonella test positive	Investigations	1 (0.00%)
Salt craving	Metabolism and nutrition disorders	1 (0.00%)
SAPHO syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
SARS-CoV-1 test positive	Investigations	1 (0.00%)
SARS-CoV-2 sepsis	Infections and infestations	1 (0.00%)
Scalloped tongue	Gastrointestinal disorders	1 (0.00%)
Scapula fracture	Injury, poisoning and procedural complications	1 (0.00%)
Scleral disorder	Eye disorders	1 (0.00%)
Scleral haemorrhage	Eye disorders	1 (0.00%)
Scleral hyperaemia	Eye disorders	1 (0.00%)
Scleroderma associated digital ulcer	Skin and subcutaneous tissue disorders	1 (0.00%)
Scoliosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Scrotal disorder	Reproductive system and breast disorders	1 (0.00%)
Scrotal exfoliation	Reproductive system and breast disorders	1 (0.00%)
Scrotal infection	Infections and infestations	1 (0.00%)
Scrotal inflammation	Reproductive system and breast disorders	1 (0.00%)
Scrotal injury	Injury, poisoning and procedural complications	1 (0.00%)
Seborrhoeic dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Secondary adrenocortical insufficiency	Endocrine disorders	1 (0.00%)
Secondary hypertension	Vascular disorders	1 (0.00%)
Secondary transmission	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Second primary malignancy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Sedation complication	Injury, poisoning and procedural complications	1 (0.00%)
Seizure anoxic	Nervous system disorders	1 (0.00%)
Semen discolouration	Reproductive system and breast disorders	1 (0.00%)
Senile dementia	Nervous system disorders	1 (0.00%)
Sepsis syndrome	Infections and infestations	1 (0.00%)
Septic pulmonary embolism	Infections and infestations	1 (0.00%)
Serratia test positive	Investigations	1 (0.00%)
Shift to the left	Investigations	1 (0.00%)
Sight disability	Social circumstances	1 (0.00%)
Sigmoidoscopy abnormal	Investigations	1 (0.00%)
Silent thyroiditis	Endocrine disorders	1 (0.00%)
Sinus arrhythmia	Cardiac disorders	1 (0.00%)
Sinus node dysfunction	Cardiac disorders	1 (0.00%)
Sinus tarsi syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Sitophobia	Psychiatric disorders	1 (0.00%)
Skin bacterial infection	Infections and infestations	1 (0.00%)
Skin cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Skin lesion removal	Surgical and medical procedures	1 (0.00%)
Skin papilloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Skin wound	Injury, poisoning and procedural complications	1 (0.00%)
Skull fractured base	Injury, poisoning and procedural complications	1 (0.00%)
Sleep disorder due to general medical condition, hypersomnia type	Psychiatric disorders	1 (0.00%)
Sleep inertia	Psychiatric disorders	1 (0.00%)
Small fibre neuropathy	Nervous system disorders	1 (0.00%)
Small for dates baby	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Social avoidant behaviour	Psychiatric disorders	1 (0.00%)
Social fear	Psychiatric disorders	1 (0.00%)
Soft tissue atrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Soft tissue disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Soft tissue haemorrhage	Musculoskeletal and connective tissue disorders	1 (0.00%)
Soft tissue inflammation	General disorders and administration site conditions	1 (0.00%)
Solar dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Somatic dysfunction	Musculoskeletal and connective tissue disorders	1 (0.00%)
Spasmodic dysphonia	Nervous system disorders	1 (0.00%)
Spider vein	Vascular disorders	1 (0.00%)
Spinal epidural haemorrhage	Nervous system disorders	1 (0.00%)
Spinal fusion surgery	Surgical and medical procedures	1 (0.00%)
Spinal meningeal cyst	Nervous system disorders	1 (0.00%)
Spleen atrophy	Blood and lymphatic system disorders	1 (0.00%)
Splenic artery embolisation	Surgical and medical procedures	1 (0.00%)
Splenic haemorrhage	Blood and lymphatic system disorders	1 (0.00%)
Splenic infection	Infections and infestations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Splenitis	Blood and lymphatic system disorders	1 (0.00%)
Splinter	Injury, poisoning and procedural complications	1 (0.00%)
Staphylococcal abscess	Infections and infestations	1 (0.00%)
Staphylococcal skin infection	Infections and infestations	1 (0.00%)
Starvation	Metabolism and nutrition disorders	1 (0.00%)
Stasis dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Status asthmaticus	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Stenotrophomonas test positive	Investigations	1 (0.00%)
Sternal fracture	Injury, poisoning and procedural complications	1 (0.00%)
Sticky skin	Skin and subcutaneous tissue disorders	1 (0.00%)
Stiff leg syndrome	Nervous system disorders	1 (0.00%)
Stiff person syndrome	Nervous system disorders	1 (0.00%)
Still's disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Stoma site discharge	Injury, poisoning and procedural complications	1 (0.00%)
Stoma site extravasation	Injury, poisoning and procedural complications	1 (0.00%)
Stoma site pain	Injury, poisoning and procedural complications	1 (0.00%)
Stoma site pruritus	Injury, poisoning and procedural complications	1 (0.00%)
Strawberry tongue	Gastrointestinal disorders	1 (0.00%)
Streptobacillus infection	Infections and infestations	1 (0.00%)
Streptococcal abscess	Infections and infestations	1 (0.00%)
Streptococcal bacteraemia	Infections and infestations	1 (0.00%)
Stress fracture	Injury, poisoning and procedural complications	1 (0.00%)
Stress urinary incontinence	Renal and urinary disorders	1 (0.00%)
Stroke in evolution	Nervous system disorders	1 (0.00%)
Subacute inflammatory demyelinating polyneuropathy	Nervous system disorders	1 (0.00%)
Subclavian artery thrombosis	Vascular disorders	1 (0.00%)
Subclavian vein stenosis	Vascular disorders	1 (0.00%)
Substance abuse	Psychiatric disorders	1 (0.00%)
Sudden infant death syndrome	General disorders and administration site conditions	1 (0.00%)
Suicidal behaviour	Psychiatric disorders	1 (0.00%)
Superior vena cava syndrome	Vascular disorders	1 (0.00%)
Suprapubic pain	General disorders and administration site conditions	1 (0.00%)
Supraventricular tachyarrhythmia	Cardiac disorders	1 (0.00%)
Suspiciousness	Psychiatric disorders	1 (0.00%)
Suture related complication	Injury, poisoning and procedural complications	1 (0.00%)
Swollen joint count increased	Investigations	1 (0.00%)
Sympathicotonia	Nervous system disorders	1 (0.00%)
Symphysiolysis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Syndactyly	Congenital, familial and genetic disorders	1 (0.00%)
Synovial disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Synovial fluid white blood cells positive	Investigations	1 (0.00%)
Synovial rupture	Injury, poisoning and procedural complications	1 (0.00%)
Syphilis	Infections and infestations	1 (0.00%)
Systemic candida	Infections and infestations	1 (0.00%)
Systemic scleroderma	Musculoskeletal and connective tissue disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Tachycardia foetal	Cardiac disorders	1 (0.00%)
Tachycardia induced cardiomyopathy	Cardiac disorders	1 (0.00%)
Takayasu's arteritis	Vascular disorders	1 (0.00%)
Target skin lesion	Skin and subcutaneous tissue disorders	1 (0.00%)
Teeth brittle	Gastrointestinal disorders	1 (0.00%)
Telangiectasia	Skin and subcutaneous tissue disorders	1 (0.00%)
Temperature perception test increased	Investigations	1 (0.00%)
TEMPI syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Tendon discomfort	Musculoskeletal and connective tissue disorders	1 (0.00%)
Terminal ileitis	Gastrointestinal disorders	1 (0.00%)
Testicular neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Testicular retraction	Reproductive system and breast disorders	1 (0.00%)
Testicular torsion	Reproductive system and breast disorders	1 (0.00%)
Tetanus	Infections and infestations	1 (0.00%)
Thanatophobia	Psychiatric disorders	1 (0.00%)
Therapeutic procedure	Surgical and medical procedures	1 (0.00%)
Therapeutic product effect decreased	General disorders and administration site conditions	1 (0.00%)
Therapeutic product effect incomplete	General disorders and administration site conditions	1 (0.00%)
Therapeutic product effect increased	General disorders and administration site conditions	1 (0.00%)
Therapeutic product effect prolonged	General disorders and administration site conditions	1 (0.00%)
Therapeutic product ineffective	General disorders and administration site conditions	1 (0.00%)
Therapy change	Surgical and medical procedures	1 (0.00%)
Thermohypoaesthesia	Nervous system disorders	1 (0.00%)
Thoracic vertebral fracture	Injury, poisoning and procedural complications	1 (0.00%)
Thought blocking	Psychiatric disorders	1 (0.00%)
Threatened labour	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Thrombectomy	Surgical and medical procedures	1 (0.00%)
Thromboangiitis obliterans	Vascular disorders	1 (0.00%)
Thrombolysis	Surgical and medical procedures	1 (0.00%)
Thyroglobulin increased	Investigations	1 (0.00%)
Thyroglossal cyst	Congenital, familial and genetic disorders	1 (0.00%)
Thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Thyroid cyst	Endocrine disorders	1 (0.00%)
Thyroidectomy	Surgical and medical procedures	1 (0.00%)
Thyroxine free decreased	Investigations	1 (0.00%)
Tidal volume decreased	Investigations	1 (0.00%)
Time perception altered	Psychiatric disorders	1 (0.00%)
Tinea pedis	Infections and infestations	1 (0.00%)
Tinea versicolour	Infections and infestations	1 (0.00%)
Tissue infiltration	General disorders and administration site conditions	1 (0.00%)
T-lymphocyte count increased	Investigations	1 (0.00%)
Tongue cyst	Gastrointestinal disorders	1 (0.00%)
Tongue fungal infection	Infections and infestations	1 (0.00%)
Tongue geographic	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Tonsillar cyst	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tonsillar haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tonsillolith	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tooth discolouration	Gastrointestinal disorders	1 (0.00%)
Tooth erosion	Gastrointestinal disorders	1 (0.00%)
Tooth loss	Gastrointestinal disorders	1 (0.00%)
Torsade de pointes	Cardiac disorders	1 (0.00%)
Tourette's disorder	Congenital, familial and genetic disorders	1 (0.00%)
Toxic neuropathy	Nervous system disorders	1 (0.00%)
Toxoplasma serology positive	Investigations	1 (0.00%)
Toxoplasmosis	Infections and infestations	1 (0.00%)
Tracheal haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Tracheal inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tracheomalacia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Trance	Psychiatric disorders	1 (0.00%)
Transaminases decreased	Investigations	1 (0.00%)
Transcription medication error	Injury, poisoning and procedural complications	1 (0.00%)
Transferrin abnormal	Investigations	1 (0.00%)
Transferrin decreased	Investigations	1 (0.00%)
Transferrin increased	Investigations	1 (0.00%)
Transfusion reaction	Injury, poisoning and procedural complications	1 (0.00%)
Transverse sinus stenosis	Nervous system disorders	1 (0.00%)
Transverse sinus thrombosis	Nervous system disorders	1 (0.00%)
Traumatic fracture	Injury, poisoning and procedural complications	1 (0.00%)
Traumatic haematoma	Injury, poisoning and procedural complications	1 (0.00%)
Traumatic haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Traumatic intracranial haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Treatment failure	General disorders and administration site conditions	1 (0.00%)
Treatment noncompliance	General disorders and administration site conditions	1 (0.00%)
Trigeminal nerve paresis	Nervous system disorders	1 (0.00%)
Tri-iodothyronine	Investigations	1 (0.00%)
Tri-iodothyronine free decreased	Investigations	1 (0.00%)
Tri-iodothyronine free increased	Investigations	1 (0.00%)
Triple negative breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Troponin	Investigations	1 (0.00%)
Truncus coeliacus thrombosis	Gastrointestinal disorders	1 (0.00%)
Tuberculin test positive	Investigations	1 (0.00%)
Tumefactive multiple sclerosis	Nervous system disorders	1 (0.00%)
Tumour marker abnormal	Investigations	1 (0.00%)
Tumour perforation	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Twin pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Tympanic membrane disorder	Ear and labyrinth disorders	1 (0.00%)
Ulcer haemorrhage	General disorders and administration site conditions	1 (0.00%)
Ulnar neuritis	Nervous system disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Umbilical haematoma	Skin and subcutaneous tissue disorders	1 (0.00%)
Undersensing	Product issues	1 (0.00%)
Undifferentiated connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Urethral disorder	Renal and urinary disorders	1 (0.00%)
Urethral haemorrhage	Renal and urinary disorders	1 (0.00%)
Urethral stenosis	Renal and urinary disorders	1 (0.00%)
Urge incontinence	Renal and urinary disorders	1 (0.00%)
Urinary assistance device user	Social circumstances	1 (0.00%)
Urinary bladder haemorrhage	Renal and urinary disorders	1 (0.00%)
Urinary sediment abnormal	Investigations	1 (0.00%)
Urinary sediment present	Investigations	1 (0.00%)
Urinary tract candidiasis	Infections and infestations	1 (0.00%)
Urinary tract discomfort	Renal and urinary disorders	1 (0.00%)
Urinary tract infection enterococcal	Infections and infestations	1 (0.00%)
Urinary tract infection pseudomonal	Infections and infestations	1 (0.00%)
Urine porphobilinogen increased	Investigations	1 (0.00%)
Urobilinogen urine increased	Investigations	1 (0.00%)
Urogenital infection bacterial	Infections and infestations	1 (0.00%)
Urticarial vasculitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticaria pressure	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticaria vesiculosa	Skin and subcutaneous tissue disorders	1 (0.00%)
Uterine disorder	Reproductive system and breast disorders	1 (0.00%)
Vaccination site calcification	General disorders and administration site conditions	1 (0.00%)
Vaccination site cyst	General disorders and administration site conditions	1 (0.00%)
Vaccination site erosion	General disorders and administration site conditions	1 (0.00%)
Vaccination site hypertrophy	General disorders and administration site conditions	1 (0.00%)
Vaccination site ischaemia	General disorders and administration site conditions	1 (0.00%)
Vaccination site streaking	General disorders and administration site conditions	1 (0.00%)
Vaginal lesion	Reproductive system and breast disorders	1 (0.00%)
Vaginal ulceration	Reproductive system and breast disorders	1 (0.00%)
Varicella virus test positive	Investigations	1 (0.00%)
Varicocele	Reproductive system and breast disorders	1 (0.00%)
Vascular stenosis	Vascular disorders	1 (0.00%)
Vascular test abnormal	Investigations	1 (0.00%)
Vasculitis necrotising	Vascular disorders	1 (0.00%)
Vasomotor rhinitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Vena cava embolism	Vascular disorders	1 (0.00%)
Venous haemorrhage	Vascular disorders	1 (0.00%)
Venous occlusion	Vascular disorders	1 (0.00%)
Venous thrombosis in pregnancy	Vascular disorders	1 (0.00%)
Ventricular dysfunction	Cardiac disorders	1 (0.00%)
Ventricular enlargement	Cardiac disorders	1 (0.00%)
Ventricular failure	Cardiac disorders	1 (0.00%)
Vertebral artery stenosis	Nervous system disorders	1 (0.00%)
Vertebral artery thrombosis	Nervous system disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vertebral lesion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Vertebral wedging	Musculoskeletal and connective tissue disorders	1 (0.00%)
Vertebrobasilar stroke	Nervous system disorders	1 (0.00%)
Vessel puncture site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Vessel puncture site injury	General disorders and administration site conditions	1 (0.00%)
Vestibulitis	Infections and infestations	1 (0.00%)
VIIIth nerve lesion	Nervous system disorders	1 (0.00%)
Viral corneal ulcer	Infections and infestations	1 (0.00%)
Viral keratouveitis	Infections and infestations	1 (0.00%)
Viral myocarditis	Infections and infestations	1 (0.00%)
Viral pericarditis	Infections and infestations	1 (0.00%)
Viral sepsis	Infections and infestations	1 (0.00%)
Viral test	Investigations	1 (0.00%)
Viral test positive	Investigations	1 (0.00%)
Viral tonsillitis	Infections and infestations	1 (0.00%)
Visceral pain	General disorders and administration site conditions	1 (0.00%)
Visceral venous thrombosis	Gastrointestinal disorders	1 (0.00%)
Visual acuity reduced transiently	Eye disorders	1 (0.00%)
Visual perseveration	Nervous system disorders	1 (0.00%)
Visual snow syndrome	Eye disorders	1 (0.00%)
Vital capacity	Investigations	1 (0.00%)
Vital functions abnormal	Investigations	1 (0.00%)
Vitamin B12 deficiency	Metabolism and nutrition disorders	1 (0.00%)
Vitamin D	Investigations	1 (0.00%)
VIth nerve disorder	Nervous system disorders	1 (0.00%)
VIth nerve paresis	Nervous system disorders	1 (0.00%)
Vitiligo	Skin and subcutaneous tissue disorders	1 (0.00%)
Vitreoretinal traction syndrome	Eye disorders	1 (0.00%)
Vitritis	Eye disorders	1 (0.00%)
Vocal cord dysfunction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Vomiting psychogenic	Psychiatric disorders	1 (0.00%)
Von Willebrand's disease	Congenital, familial and genetic disorders	1 (0.00%)
Von Willebrand's factor activity decreased	Investigations	1 (0.00%)
Vth nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Vulval abscess	Infections and infestations	1 (0.00%)
Vulval oedema	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal discomfort	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal inflammation	Reproductive system and breast disorders	1 (0.00%)
Wandering pacemaker	Cardiac disorders	1 (0.00%)
Weber tuning fork test abnormal	Investigations	1 (0.00%)
Weight loss diet	Surgical and medical procedures	1 (0.00%)
Weight loss poor	Metabolism and nutrition disorders	1 (0.00%)
Wheat-free diet	Surgical and medical procedures	1 (0.00%)
Winged scapula	Musculoskeletal and connective tissue disorders	1 (0.00%)
Withdrawal bleed	Reproductive system and breast disorders	1 (0.00%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Wound closure	Surgical and medical procedures	1 (0.00%)
Wound necrosis	Injury, poisoning and procedural complications	1 (0.00%)
Writer's cramp	Nervous system disorders	1 (0.00%)
Wrong dose	Injury, poisoning and procedural complications	1 (0.00%)
Wrong patient received product	Injury, poisoning and procedural complications	1 (0.00%)
Xerosis	General disorders and administration site conditions	1 (0.00%)
X-ray abnormal	Investigations	1 (0.00%)

**Appendix 2.2 Interval Summary Tabulation of Case Reports with DME Events from Post-Marketing Data Sources**

BNT162B2 - ALL

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval)

Total Number of Cases with DME 1,226 (Interval)

Total Number of Adverse Events (PT) (DME only) 1,295 (Interval)

MedDRA Version: v.23.1J

SOC and PT	Number of Events	Percentage (%)
<b>Blood and lymphatic system disorders</b>	2	
Agranulocytosis	1	0.0 %
Aplastic anaemia	1	0.0 %
<b>Eye disorders</b>	1	
Angle closure glaucoma	1	0.0 %
<b>Gastrointestinal disorders</b>	43	
Oesophageal ulcer haemorrhage	1	0.0 %
Pancreatitis	6	0.0 %
Pancreatitis acute	12	0.0 %
Tongue oedema	24	0.1 %
<b>General disorders and administration site conditions</b>	51	
Face oedema	51	0.2 %
<b>Hepatobiliary disorders</b>	3	
Acute hepatic failure	1	0.0 %
Hepatic failure	2	0.0 %

<b>Immune system disorders</b>	842	
Anaphylactic reaction	758	2.5 %
Anaphylactic shock	62	0.2 %
Anaphylactoid reaction	10	0.0 %
Anaphylactoid shock	1	0.0 %
Type I hypersensitivity	11	0.0 %
<b>Injury, poisoning and procedural complications</b>	5	
Burn oesophageal	1	0.0 %
Contraindicated product administered	3	0.0 %
Contraindicated product prescribed	1	0.0 %
<b>Metabolism and nutrition disorders</b>	5	
Hyperkalaemia	5	0.0 %
<b>Musculoskeletal and connective tissue disorders</b>	19	
Myopathy	1	0.0 %
Myositis	9	0.0 %
Rhabdomyolysis	9	0.0 %
<b>Psychiatric disorders</b>	20	
Completed suicide	1	0.0 %
Depression suicidal	1	0.0 %
Intentional self-injury	1	0.0 %
Self-injurious ideation	2	0.0 %
Suicidal behaviour	1	0.0 %
Suicidal ideation	12	0.0 %
Suicide attempt	2	0.0 %

<b>Respiratory, thoracic and mediastinal disorders</b>	130	
Laryngeal oedema	27	0.1 %
Oropharyngeal oedema	1	0.0 %
Pharyngeal swelling	102	0.3 %
<b>Skin and subcutaneous tissue disorders</b>	174	
Angioedema	119	0.4 %
Circumoral swelling	2	0.0 %
Dermatitis exfoliative	1	0.0 %
Dermatitis exfoliative generalised	3	0.0 %
Drug reaction with eosinophilia and systemic symptoms	3	0.0 %
Erythema multiforme	12	0.0 %
Skin exfoliation	29	0.1 %
Stevens-Johnson syndrome	4	0.0 %
Toxic epidermal necrolysis	1	0.0 %

### APPENDIX 2.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Case Reports From Post-Marketing Data Sources by Medically Confirmed and Non Medically Confirmed, Region and Country

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

MedDRA Version: v.23.1J

#### Medically Confirmed

Region : European Countries (27 EU)

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
AUSTRIA	154	563					15	105	10	60	129	398
BELGIUM	287	744					200	323	9	75	78	346
BULGARIA	15	124					12	99			3	25
CROATIA	58	253					14	118	2	8	42	127
CYPRUS	15	103					8	62	1	2	6	39
CZECH REPUBLIC	203	780					7	253	3	11	193	516
DENMARK	185	989					63	547	21	68	101	374
ESTONIA	36	115					4	57	3	3	29	55
FINLAND	93	500					16	130	6	42	71	328
FRANCE	1,334	4,489					93	1018	120	431	1121	3040
GERMANY	452	2,002				111	160	633	58	351	234	1018
GREECE	173	1,053					68	546	4	16	101	491
HUNGARY	51	305					25	201	9	22	17	82
IRELAND	101	441					42	98	12	25	47	318
ITALY	1,098	10,183		2	55	107	489	7030	49	109	560	3044
LATVIA	3	125					2	78			1	47
LITHUANIA	6	34					2	10		3	4	21
LUXEMBOURG	53	130					36	43	1	2	16	85
MALTA	12	53					6	27	1	7	5	19
NETHERLANDS	302	595			7	8	83	127	47	169	172	299
POLAND	66	556					22	230	12	36	32	290
PORTUGAL	528	2,032					240	576	10	23	278	1433
ROMANIA	258	723					110	384	95	102	53	237
SLOVAKIA	70	194					51	142		1	19	51

\* I=Interval, C=Cumulative

**Medically Confirmed**

**Region : European Countries (27 EU)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous						
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal		
			I	C	I	C	I	C	I	C	I	C	
SLOVENIA	30	131					8	68	4	12	18	51	
SPAIN	766	2,192			1	1	416	777	31	98	319	1317	
SWEDEN	247	962					8	209	44	153	195	600	
	6,596	30,371			2	63	227	2200	13891	552	1829	3844	14651

**Region : European Economic Area (3 EEA)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
ICELAND	8	110	2	80		12	6	18
LIECHTENSTEIN	1	1	1	1				
NORWAY	127	557	22	164	15	134	90	259
	136	668	25	245	15	146	96	277

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
AFGHANISTAN		1								1
ALBANIA	1	2			1	2				
ANGOLA		2				1				1
AUSTRALIA	291	382			106	128	39	60	146	194
BERMUDA	4	7			2	4			2	3
CANADA	89	524			42	324	2	2	45	198
CAYMAN ISLANDS		1				1				
CHILE	8	50			8	42				8
COLOMBIA	22	52			20	40	1	1	1	11
COSTA RICA	45	117			35	94	1	1	9	22
ECUADOR	11	23			10	19			1	4
FRENCH POLYNESIA		2						1		1
GEORGIA	1	1							1	1

\* I=Interval, C=Cumulative

**Medically Confirmed**

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous							
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal			
			I	C	I	C	I	C	I	C		
HOLY SEE (VATICAN CITY STATE)		2				2						
HONG KONG	76	80			22	22	1	2	53	56		
INDIA	1	1							1	1		
ISRAEL	204	525		1	19	188	6	59	179	278		
JAPAN	1,708	2,439			704	975	18	21	986	1443		
JORDAN		6				5				1		
KOREA, REPUBLIC OF (SOUTH KOREA)	1	1			1	1						
KUWAIT	1	4			1	4						
LEBANON	27	47			6	18	10	11	11	18		
MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	3	10			2	9			1	1		
MALAYSIA	3	9			2	5		1	1	3		
MEXICO	618	1,882			273	588	10	14	335	1280		
NEW ZEALAND	7	10			1	3			6	7		
NORTHERN MARIANA ISLANDS		1				1						
PANAMA	5	22			3	9			2	13		
PERU	1	1			1	1						
PUERTO RICO	2	52			2	49				3		
QATAR	1	8			1	5				3		
SAUDI ARABIA	3	17			2	12			1	5		
SERBIA	4	64			4	46				18		
SINGAPORE	3	15			1	8			2	7		
SWITZERLAND	132	297			7	32	5	22	120	243		
TUNISIA	6	6			6	6						
TURKEY	5	5			5	5						
TURKS AND CAICOS ISLANDS		1										1
UNITED ARAB EMIRATES	2	15			2	10		1		4		
UNITED KINGDOM	3,818	13,466	41	206	2647	7212	38	260	1133	5994		
UNITED STATES	1,291	10,315	3	3	659	7344	23	84	609	2887		
UNITED STATES MINOR OUTLYING ISLANDS		2				2						
	8,394	30,467	44	210	4595	17217	154	540	3645	12710		

\* I=Interval, C=Cumulative

**Non Medically Confirmed**

**Region : European Countries (27 EU)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
AUSTRIA	58	206	8	50	4	4	46	152
BELGIUM	220	661	42	110	5	12	173	539
BULGARIA	47	85	31	59			16	26
CROATIA	19	52	6	27			13	25
CYPRUS	5	19	3	15			2	4
CZECH REPUBLIC	96	219	11	50	6	19	79	150
DENMARK	34	187	16	158	1	1	17	28
ESTONIA	13	47	5	33		1	8	13
FINLAND	28	101		25	2	5	26	71
FRANCE	300	938	36	258	15	40	249	640
GERMANY	598	1,879	403	1232	42	125	153	522
GREECE	55	117	25	53	2	7	28	57
HUNGARY	54	168	29	119	2	3	23	46
IRELAND	46	139	35	45	1	1	10	93
ITALY	187	875	78	565	9	13	100	297
LATVIA	5	87		59			5	28
LITHUANIA	16	49	2	13		1	14	35
LUXEMBOURG		2		1				1
MALTA	12	37	7	26			5	11
NETHERLANDS	815	1,683	544	1201	27	61	244	421
POLAND	65	205	14	98	14	23	37	84
PORTUGAL	54	290	19	76	1	4	34	210
ROMANIA	115	238	20	61	1	1	94	176
SLOVAKIA	31	92	20	70		1	11	21
SLOVENIA	3	14	1	10			2	4
SPAIN	92	266	45	103	3	9	44	154
SWEDEN	88	460	26	264	5	13	57	183
	3,056	9,116	1426	4781	140	344	1490	3991

**Region : European Economic Area (3 EEA)**

Interval Total #	Cumulative Total #	Spontaneous		
		Nonserious	Serious Fatal	Serious Non Fatal

\* I=Interval, C=Cumulative



**Non Medically Confirmed**

**Region : European Economic Area (3 EEA)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
ICELAND	3	12		6		2	3	4
NORWAY	23	88	4	44	2	3	17	41
	26	100	4	50	2	5	20	45

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
ALBANIA		1					1					
AMERICAN SAMOA		1					1					
ANDORRA		1					1					
ARGENTINA	1	4					3			1	1	
AUSTRALIA	3	8					2	6	1	1	1	
BAHRAIN	1	5					4			1	1	
BERMUDA		1					1					
BOSNIA AND HERZEGOVINA	1	1					1	1				
BRAZIL	1	1					1	1				
CANADA	101	206					28	107	1	3	72	96
CHILE	53	78					41	59			12	19
COLOMBIA	4	9					4	7				2
COSTA RICA	24	56					17	42	5	6	2	8
ECUADOR	3	5					1	1			2	4
EGYPT	1	1									1	1
FRENCH SOUTHERN TERRITORIES	1	1							1	1		
GEORGIA	1	1									1	1
GUINEA	1	1									1	1
HONG KONG	20	26					6	7			14	19
INDIA	1	2						1			1	1
IRAQ	2	2					2	2				
ISRAEL	99	627					50	432		12	49	183
JAPAN	27	37					14	20			13	17

\* I=Interval, C=Cumulative

**Non Medically Confirmed**

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
JORDAN	1	9						2			1	7
KUWAIT	1	3					1	3				
LEBANON	3	7					2	3			1	4
MACAO		1										1
MALAYSIA	1	2					1	1		1		
MEXICO	90	182					70	138	2	3	18	41
MONACO		1										1
NORTHERN MARIANA ISLANDS		3						3				
OMAN		3						3				
PANAMA	4	5					4	5				
PERU	11	12					9	10			2	2
PUERTO RICO	6	27					3	22	1	1	2	4
QATAR	6	13					1	5			5	8
SAUDI ARABIA	6	20					4	15		1	2	4
SERBIA	15	49					9	33			6	16
SINGAPORE	79	90					17	27	1	1	61	62
SWAZILAND		1								1		
SWITZERLAND	17	29					3	10	1	2	13	17
TURKEY	16	16					12	12			4	4
TURKS AND CAICOS ISLANDS	1	1									1	1
UKRAINE	1	1					1	1				
UNITED ARAB EMIRATES	14	43					7	23		1	7	19
UNITED KINGDOM	5,935	19,756				1	1213	3111	25	119	4697	16526
UNITED STATES	5,872	17,163	1	1	11	15	3497	12030	65	164	2310	4969
URUGUAY	1	1					1	1				
	12,425	38,513	1	1	11	16	5022	16155	102	317	7301	22041

\* I=Interval, C=Cumulative

### Appendix 2.4: Cumulative and Interval Summary Tabulation of Fatal Case Reports From Post-Marketing Data Sources by Country

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 966 (Interval) / 3,185 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous			
			Serious Fatal		Nonserious		Serious Fatal	
			I	C	I	C	I	C
AUSTRALIA	39	61					39	61
AUSTRIA	14	64					14	64
BELGIUM	14	87					14	87
CANADA	3	5					3	5
COLOMBIA	1	1					1	1
COSTA RICA	6	7					6	7
CROATIA	2	8					2	8
CYPRUS	1	2					1	2
CZECH REPUBLIC	9	30					9	30
DENMARK	22	69					22	69
ESTONIA	3	4					3	4
FINLAND	8	47					8	47
FRANCE	135	471					135	471
FRENCH POLYNESIA		1						1
FRENCH SOUTHERN TERRITORIES	1	1					1	1
GERMANY	100	476					100	476
GREECE	6	23					6	23
HONG KONG	1	2					1	2
HUNGARY	11	25					11	25
ICELAND		14						14
IRELAND	13	26					13	26
ISRAEL	6	71					6	71
ITALY	58	122		2			58	122
JAPAN	18	21					18	21
LEBANON	10	11					10	11

\* I=Interval, C=Cumulative

Country Where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous			
			Serious Fatal		Nonserious		Serious Fatal	
			I	C	I	C	I	C
LITHUANIA		4						4
LUXEMBOURG	1	2					1	2
MALAYSIA		2						2
MALTA	1	7					1	7
MEXICO	12	17					12	17
NETHERLANDS	74	230					74	230
NORWAY	17	137					17	137
POLAND	26	59					26	59
PORTUGAL	11	27					11	27
PUERTO RICO	1	1					1	1
ROMANIA	96	103					96	103
SAUDI ARABIA		1						1
SINGAPORE	1	1					1	1
SLOVAKIA		2						2
SLOVENIA	4	12					4	12
SPAIN	34	107					34	107
SWAZILAND		1						1
SWEDEN	49	166					49	166
SWITZERLAND	6	24					6	24
UNITED ARAB EMIRATES		2						2
UNITED KINGDOM	63	379					63	379
UNITED STATES	88	249	1	1		1	88	248
	965	3,182	1	3		1	965	3181

\* I=Interval, C=Cumulative

### APPENDIX 2.5: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

Total Number of Adverse Events (PT): 112,695 (Interval) / 414,597 (Cumulative)

MedDRA Version: v.23.1J

*System Organ Class*

**Blood and lymphatic system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal lymphadenopathy	1	2					1	2
Abnormal clotting factor	1	2					1	2
Acquired haemophilia	2	4					2	4
Agranulocytosis	1	4					1	4
Anaemia	32	76			8	22	24	54
Anaemia macrocytic	2	2					2	2
Anaemia megaloblastic	1	1					1	1
Anaemia vitamin B12 deficiency	2	3			2	2		1
Anisocytosis		2						2
Antiphospholipid syndrome	1	3					1	3
Aplastic anaemia	1	1					1	1
Atypical haemolytic uraemic syndrome	1	1					1	1
Autoimmune anaemia	1	1					1	1
Autoimmune haemolytic anaemia	4	9					4	9
Autoimmune neutropenia	2	2					2	2
Bicytopenia	1	1					1	1
Blood disorder	4	9			4	6		3
Blood loss anaemia	1	1					1	1
Bone marrow oedema	1	2					1	2
Coagulopathy	22	44			3	9	19	35
Coombs negative haemolytic anaemia	1	2					1	2
Coombs positive haemolytic anaemia	1	1					1	1
Deficiency anaemia	1	1			1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Disseminated intravascular coagulation	6	8
Eosinophilia	5	11
Erythropeia		1
Evans syndrome	1	2
Factor VIII inhibition		1
Febrile neutropenia		1
Granulomatous lymphadenitis		3
Haemolysis	2	4
Haemolytic anaemia	7	14
Haemolytic uraemic syndrome		1
Haemorrhagic diathesis	4	6
Haemorrhagic disorder	10	11
Heparin-induced thrombocytopenia		1
Hypercoagulation	1	1
Hyperbrinogenemia		1
Hyperleukocytosis	7	18
Immune thrombocytopenia	42	94
Increased tendency to bruise	4	13
Intravascular haemolysis		1
Iron deficiency anaemia	1	4
Leukaemoid reaction		1
Leukocytosis	9	34
Leukopenia	15	30
Lymphadenitis	66	207
Lymphadenopathy	1,543	5,621
Lymphadenopathy mediastinal	1	2
Lymphatic disorder	1	2
Lymphatic obstruction	1	1
Lymph node pain	266	939
Lymphocytic infiltration		1
Lymphocytosis	3	9
Lymphopenia	12	44

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	8
			3	5	8
					1
				1	2
					1
					1
					3
				2	4
				7	14
					1
				4	6
				10	11
					1
				1	1
					1
				7	18
1	1			42	94
			7	4	6
					1
		1	1		3
					1
	1	5	13	4	21
	1	1	1	14	29
		32	102	34	105
12	20	765	3225	778	2396
		1	2		
			1	1	1
				1	1
5	6	100	496	166	443
					1
		1	5	2	4
		6	18	6	26

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Mast cell activation syndrome		4						4
Mastocytosis		1						1
Microangiopathic haemolytic anaemia	1	1					1	1
Microcytic anaemia		2						2
Monocytosis	3	6			1	3	2	3
Myelocytosis		1						1
Myelosuppression		4						4
Neutropenia	14	48		1			14	48
Neutropenia neonatal		1						1
Neutrophilia	5	11			1	4	4	7
Normochromic anaemia	1	1					1	1
Normochromic normocytic anaemia	1	3			1	3		
Normocytic anaemia		2				1		1
Nucleated red cells		1				1		
Pancytopenia	12	23					12	23
Paratracheal lymphadenopathy	1	2					1	2
Platelet anisocytosis		1						1
Platelet disorder	4	6			1	2	3	4
Polychromasia	1	2					1	2
Polycythaemia		1				1		
Pseudolymphoma		1						1
Red blood cell abnormality	1	1					1	1
Sickle cell anaemia with crisis	3	3					3	3
Spleen atrophy		1						1
Spleen disorder	2	2					2	2
Splenic haemorrhage	1	1					1	1
Splenic infarction	4	5					4	5
Splenic vein thrombosis	1	2					1	2
Splenitis	1	1					1	1
Splenomegaly	3	11			1	3	2	8
Spontaneous haematoma	2	3					2	3
Thrombocytopenia	126	207		1	1	1	125	206

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Thrombocytopenic purpura	4	6			1	2	3	4
Thrombocytosis	2	5			1	2	1	3
Thrombotic microangiopathy	2	4					2	4
Thrombotic thrombocytopenic purpura	4	6					4	6
White blood cell disorder	2	2					2	2
	2,292	7,643	18	31	938	3937	1354	3706

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute cardiac event	1	5					1	5
Acute coronary syndrome	22	50					22	50
Acute left ventricular failure	1	2					1	2
Acute myocardial infarction	48	121					48	121
Acute right ventricular failure	1	1					1	1
Angina pectoris	64	167				1	64	166
Angina unstable	1	6					1	6
Aortic valve calcification	2	2					2	2
Aortic valve disease		1						1
Aortic valve incompetence	3	4					3	4
Aortic valve stenosis	1	3					1	3
Arrhythmia	130	369		1	1	1	129	368
Arrhythmia supraventricular	2	13				1	2	12
Arteriosclerosis coronary artery	2	7			1	1	1	6
Arteriospasm coronary	1	5					1	5
Atrial fibrillation	179	500	2	2		1	179	499
Atrial flutter	15	33			3	6	12	27
Atrial tachycardia	1	8				3	1	5
Atrial thrombosis	1	2					1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Atrioventricular block	7	12
Atrioventricular block complete	6	19
Atrioventricular block first degree	1	4
Atrioventricular block second degree	1	1
Bezold-Jarisch reflex		1
Bradyarrhythmia	1	2
Bradycardia	47	206
Bundle branch block	1	2
Bundle branch block left	4	11
Bundle branch block right	4	19
Cardiac aneurysm		1
Cardiac arrest	98	273
Cardiac asthma	5	6
Cardiac discomfort	7	16
Cardiac disorder	39	91
Cardiac failure	99	281
Cardiac failure acute	11	25
Cardiac failure chronic	2	5
Cardiac failure congestive	12	33
Cardiac fibrillation	4	12
Cardiac flutter	34	93
Cardiac hypertrophy	1	2
Cardiac tamponade	3	5
Cardiac valve disease		4
Cardiac valve sclerosis		1
Cardiac ventricular thrombosis		1
Cardiogenic shock	7	30
Cardiomegaly	5	8
Cardiomyopathy	3	11
Cardiopulmonary failure	6	14
Cardio-respiratory arrest	33	90
Cardio-respiratory distress	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	7	11
				6	19
		1	3		1
			1	1	1
				1	2
	1			47	206
				1	2
		1	1	3	10
		1	6	3	13
					1
		1	1	97	272
				5	6
		3	8	4	8
		19	38	20	53
				99	281
				11	25
				2	5
				12	33
				4	12
				34	93
				1	2
				3	5
			1		3
					1
					1
				7	30
		1	3	4	5
				3	11
				6	14
				33	90
				1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiovascular disorder	39	134
Cardiovascular insufficiency	3	7
Conduction disorder		1
Congestive cardiomyopathy		4
Coronary artery disease	7	15
Coronary artery dissection	2	2
Coronary artery insufficiency	1	1
Coronary artery occlusion	3	6
Coronary artery stenosis	4	10
Coronary artery thrombosis	5	8
Cor pulmonale		2
Cor pulmonale acute	1	2
Defect conduction intraventricular	1	1
Dilatation atrial	2	3
Dilatation ventricular	1	2
Extrasystoles	33	111
Heart alternation	1	1
Heart valve incompetence	2	2
Hepatojugular reflux	1	1
Hyperdynamic left ventricle		1
Hypertensive heart disease	4	8
Intracardiac thrombus	2	5
Ischaemic cardiomyopathy	1	2
Left atrial dilatation	1	1
Left ventricular dilatation	1	2
Left ventricular dysfunction	4	6
Left ventricular failure	2	12
Left ventricular hypertrophy	2	6
Microvascular coronary artery disease	1	2
Mitral valve calcification	1	2
Mitral valve disease	1	2
Mitral valve incompetence	6	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		18	53	21	81
				3	7
					1
					4
				7	15
				2	2
				1	1
				3	6
				4	10
				5	8
					2
				1	2
				1	1
				2	3
				1	2
		11	46	22	65
		1	1		
		1	1	1	1
		1	1		
					1
				4	8
				2	5
				1	2
				1	1
		1	2		
		1	1	3	5
				2	12
				2	6
				1	2
				1	2
				1	2
				6	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mitral valve prolapse		2
Mitral valve stenosis	1	1
Myocardial fibrosis		2
Myocardial haemorrhage		1
Myocardial hypoxia		2
Myocardial infarction	120	317
Myocardial ischaemia	4	27
Myocardial necrosis		1
Myocardial oedema		2
Myocardial rupture	1	3
Myocarditis	83	157
Nodal rhythm		1
Palpitations	535	1,866
Paroxysmal arrhythmia		2
Pericardial disease	1	2
Pericardial effusion	22	49
Pericardial haemorrhage	3	6
Pericarditis	62	146
Pleuropericarditis	1	2
Postural orthostatic tachycardia syndrome	4	17
Prinzmetal angina	1	2
Pulseless electrical activity	1	6
Rhythm idioventricular		1
Right ventricular dilatation	2	2
Right ventricular dysfunction		1
Right ventricular enlargement		2
Right ventricular failure	3	5
Sinus arrest	2	4
Sinus arrhythmia		1
Sinus bradycardia	2	11
Sinus node dysfunction		1
Sinus tachycardia	27	115

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
					2
					1
					2
		1	1	119	316
				4	27
					1
					2
				1	3
				83	157
			1		
	5	254	877	281	989
					2
		1	1		1
				22	49
				3	6
				62	146
				1	2
1	1	1	3	3	14
				1	2
				1	6
					1
		1	1	1	1
					1
			2		
				3	5
				2	4
					1
		1	5	1	6
					1
1	1	9	37	18	78

\* I=Interval, C=Cumulative  
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System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Stress cardiomyopathy	4	9				1	4	8
Supraventricular extrasystoles	6	19			1	5	5	14
Supraventricular tachyarrhythmia		1						1
Supraventricular tachycardia	13	55			2	10	11	45
Tachyarrhythmia	3	22			1	7	2	15
Tachycardia	470	2,369	2	12	229	1145	241	1224
Tachycardia foetal		1						1
Tachycardia induced cardiomyopathy		1						1
Tachycardia paroxysmal	2	9		1		3	2	6
Torsade de pointes		1						1
Tricuspid valve incompetence	5	6					5	6
Ventricular arrhythmia	1	7					1	7
Ventricular dysfunction	1	1					1	1
Ventricular enlargement	1	1					1	1
Ventricular extrasystoles	17	69			8	27	9	42
Ventricular failure	1	1					1	1
Ventricular fibrillation	11	33					11	33
Ventricular hypertrophy	1	3					1	3
Ventricular hypokinesia	4	4					4	4
Ventricular tachycardia	8	26					8	26
Wandering pacemaker		1						1
	2,472	8,348	6	24	575	2308	1897	6040

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amegakaryocytic thrombocytopenia		1				1
Anencephaly	1	1			1	1
Anomalous pulmonary venous connection		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aplasia		1				1
Atrial septal defect		1				1
Cerebral palsy	3	3			3	3
Colour blindness		1		1		
Congenital cystic lung		1				1
Congenital multiplex arthrogyposis	1	1			1	1
Corneal dystrophy	1	1			1	1
Cystic lymphangioma		1				1
Dermoid cyst		1				1
Ductus arteriosus premature closure		1				1
Dysmorphism		1				1
Ehlers-Danlos syndrome		1				1
Factor II mutation	1	1	1	1		
Factor V Leiden mutation	1	1			1	1
Familial hemiplegic migraine		1				1
Familial mediterranean fever		1				1
Familial periodic paralysis		1				1
Foetal cystic hygroma		1				1
Foetal malformation	1	1			1	1
Gastroschisis	1	1			1	1
Haemophilia		2				2
Heart disease congenital		2				2
Hereditary angioedema with normal C1 esterase inhibitor		1				1
Hereditary haemorrhagic telangiectasia		1		1		
Hereditary neuropathy with liability to pressure palsies	1	1			1	1
Huntington's disease	1	5	1	1		4
Hyperglycinaemia		1				1
Hypertrophic cardiomyopathy	1	5			1	5
Macroglossia	3	8			3	8

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
		3	3
	1		
			1
		1	1
		1	1
			1
			1
			1
			1
1	1		
		1	1
			1
			1
			1
		1	1
		1	1
			2
			2
			1
			1
1	1		4
			1
		1	5
		3	8

\* I=Interval, C=Cumulative  
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System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Methylenetetrahydrofolate reductase gene mutation	1	1	1	1		
Myoclonic dystonia		2				2
Porphyria	1	1			1	1
Porphyria acute		1				1
Retinitis pigmentosa		2				2
Syndactyly		1				1
Thyroglossal cyst	1	1			1	1
Tourette's disorder	1	1			1	1
Type V hyperlipidaemia	1	2			1	2
Von Willebrand's disease		1				1
	21	64	3	5	18	59

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute vestibular syndrome	2	8				2	2	6
Auditory disorder	3	9			1	2	2	7
Auricular swelling	1	9				4	1	5
Autophony	1	2			1	1		1
Cerumen impaction	1	2			1	2		
Conductive deafness		1						1
Deafness	88	197			1	2	87	195
Deafness bilateral	2	7					2	7
Deafness neurosensory	15	36					15	36
Deafness transitory	4	9					4	9
Deafness unilateral	41	98				1	41	97
Dysacusis	1	2				1	1	1
Ear canal erythema	1	3			1	2		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ear congestion	5	13
Ear discomfort	58	207
Ear disorder	11	37
Ear haemorrhage	4	6
Ear pain	161	583
Ear pruritus	10	42
Ear swelling	16	47
Endolymphatic hydrops		2
Eustachian tube disorder		2
Eustachian tube dysfunction	1	4
Excessive cerumen production	5	8
External ear disorder		1
External ear inflammation		2
External ear pain	3	7
Hyperacusis	22	62
Hypoacusis	63	187
Inner ear disorder	3	9
Inner ear inflammation		1
Mastoid disorder	1	2
Meniere's disease	12	24
Middle ear effusion		2
Middle ear inflammation		1
Misophonia	1	2
Motion sickness	14	38
Neurosensory hypoacusis	1	2
Otolithiasis		1
Otorrhoea		2
Paraesthesia ear	3	7
Presbycusis		1
Red ear syndrome		1
Sudden hearing loss	33	68
Tinnitus	384	908

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7	2	6
		41	146	17	61
		9	27	2	10
		2	3	2	3
		82	304	79	279
		7	31	3	11
		4	23	12	24
					2
			1		1
		1	1		3
		3	6	2	2
			1		
			1		1
		2	5	1	2
		11	32	11	30
		32	101	31	86
		1	3	2	6
					1
		1	1		1
				12	24
			1		1
				1	2
		5	20	9	18
				1	2
					1
			2		
		1	4	2	3
					1
			1		
				33	68
1	1	172	415	212	493

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Tympanic membrane disorder		1				1			
Tympanic membrane hyperaemia	1	2				1		1	1
Vertigo	374	1,406	2	4	149	708	225	698	
Vertigo labyrinthine	1	3					1		3
Vertigo positional	20	57		1	5	11	15		46
Vestibular disorder	4	14			2	7	2		7
	1,371	4,145	3	6	538	1881	833		2264

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Addison's disease		1				1	
Adrenal disorder	1	4	1	2			2
Adrenal insufficiency	1	4			1		4
Adrenal mass	1	2	1	2			
Adrenocortical insufficiency acute	4	13			4		13
Adrenomegaly	1	3	1	3			
Anovulatory cycle		1					1
Autoimmune hypothyroidism	1	1			1		1
Autoimmune thyroid disorder	1	1			1		1
Autoimmune thyroiditis	7	20			7		20
Basedow's disease	6	10			6		10
Diabetes insipidus		1					1
Goitre	6	19	2	9	4		10
Hyperparathyroidism		1		1			
Hyperparathyroidism primary		1		1			
Hyperthyroidism	11	22			11		22
Hypothyroidism	10	22		1	10		21
Pituitary apoplexy		1					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Premature menarche	1	1	1	1		
Secondary adrenocortical insufficiency	1	1			1	1
Silent thyroiditis	1	1			1	1
Thyroid cyst		1				1
Thyroid disorder	6	12	4	10	2	2
Thyroiditis	2	6	1	4	1	2
Thyroiditis acute		3				3
Thyroiditis subacute	3	9	2	8	1	1
Thyroid mass	3	6	1	3	2	3
Thyroid pain	2	7	2	4		3
Thyrotoxic crisis	3	3			3	3
	72	177	16	49	56	128

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal sensation in eye	11	29			8	19	3	10
Accommodation disorder	1	5			1	3		2
Acute macular outer retinopathy	1	2					1	2
Age-related macular degeneration	2	3					2	3
Altered visual depth perception	2	2			2	2		
Amaurosis	1	2					1	2
Amaurosis fugax	5	9			1	1	4	8
Amblyopia	1	2				1	1	1
Angle closure glaucoma	1	3					1	3
Anisometropia	1	1			1	1		
Anterior chamber cell		1						1
Arteriosclerotic retinopathy	1	1					1	1
Asthenopia	33	121			17	57	16	64

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\* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Autoimmune uveitis		1
Binocular eye movement disorder	2	3
Blepharitis	3	14
Blepharochalasis		1
Blepharospasm	15	44
Blindness	43	103
Blindness transient	6	26
Blindness unilateral	18	32
Cataract	7	10
Cataract nuclear		1
Central vision loss	1	2
Chalazion	1	3
Charles Bonnet syndrome		1
Chorioretinopathy	1	2
Choroidal neovascularisation		3
Choroiditis		1
Chromatopsia	2	5
Ciliary muscle spasm		1
Conjunctival disorder		1
Conjunctival haemorrhage	29	80
Conjunctival hyperaemia	20	41
Conjunctival irritation		7
Conjunctival oedema	2	5
Conjunctival pallor		1
Conjunctivitis allergic	1	7
Corneal bleeding		1
Corneal degeneration		1
Corneal disorder		2
Corneal erosion		1
Corneal infiltrates		1
Corneal oedema		1
Corneal opacity		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	3
		2	9	1	5
			1		
		8	21	7	23
1	1			43	103
				6	26
				18	32
			1	7	9
					1
				1	2
			1	1	2
					1
				1	2
					3
					1
		1	4	1	1
			1		
					1
	2			29	80
		9	20	11	21
			4		3
		1	2	1	3
					1
		1	6		1
					1
					1
					2
					1
			1		1
					2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cyanopsia		1
Dark circles under eyes	2	4
Dermatochalasis	1	1
Diabetic eye disease		1
Diplopia	100	194
Dry age-related macular degeneration	1	1
Dry eye	24	95
Dyschromatopsia	2	4
Eczema eyelids	1	3
Endocrine ophthalmopathy	5	6
Episcleritis	1	11
Erythema of eyelid	6	24
Erythroptosis		2
Excessive eye blinking		2
Excessive ocular convergence	1	1
Exophthalmos	3	6
Exposure keratitis		1
Extraocular muscle disorder	2	2
Extraocular muscle paresis	2	5
Eye allergy	1	7
Eye colour change	1	4
Eye discharge	10	29
Eye disorder	37	106
Eye haematoma	1	5
Eye haemorrhage	39	80
Eye inflammation	5	25
Eye irritation	39	195
Eyelid bleeding	1	1
Eyelid cyst		1
Eyelid disorder	4	14
Eyelid exfoliation		1
Eyelid function disorder	4	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2	1	2
		1	1		
			1		
		59	91	41	103
				1	1
		14	58	10	37
		1	3	1	1
		1	3		
				5	6
			4	1	7
		3	13	3	11
			1		1
					2
				1	1
				3	6
			1		
		1	1	1	1
				2	5
		1	6		1
			1	1	3
		7	18	3	11
		25	67	12	39
				1	5
				39	80
		3	13	2	12
	1	24	132	15	63
				1	1
					1
		3	10	1	4
					1
			4	4	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid haematoma		2
Eyelid irritation	3	10
Eyelid margin crusting		1
Eyelid myoclonus	1	3
Eyelid myokymia		1
Eyelid oedema	33	121
Eyelid pain	5	23
Eyelid ptosis	20	63
Eyelid rash	2	7
Eyelid retraction		1
Eyelid sensory disorder	1	5
Eyelids pruritus	6	23
Eyelid vascular disorder	1	1
Eye movement disorder	13	41
Eye oedema	4	31
Eye opacity		1
Eye pain	175	707
Eye paraesthesia		8
Eye pruritus	57	235
Eye swelling	98	370
Eye symptom	2	2
Eye ulcer	1	2
Floppy eyelid syndrome		1
Foreign body sensation in eyes	8	25
Gaze palsy	5	12
Giant papillary conjunctivitis		1
Glare		2
Glaucoma	5	13
Halo vision		1
Heterophoria	1	1
Hyperaesthesia eye		1
Hypermetropia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	5	2	5
			1		
				1	3
					1
	1	14	52	19	69
		5	16		7
		10	31	10	32
		2	4		3
					1
		1	5		
		3	12	3	11
		1	1		
		5	13	8	28
		3	20	1	11
			1		
	1	92	355	83	352
			5		3
	2	35	140	22	95
	2	57	187	41	183
		1	1	1	1
		1	2		
					1
		6	14	2	11
				5	12
					1
			2		
				5	13
					1
				1	1
			1		
			1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia eye	5	19
Hypotony of eye	1	1
Iridocyclitis	10	19
Iritis	2	7
Keratic precipitates		2
Keratitis	3	8
Keratoconus	1	1
Lacrimonal disorder		2
Lacrimation decreased		2
Lacrimation disorder	1	1
Lacrimation increased	48	239
Lagophthalmos	4	7
Lid margin discharge	1	1
Limbal swelling	1	1
Macular degeneration	1	8
Macular hole	1	2
Macular oedema	3	7
Macular rupture	1	2
Maculopathy	3	5
Metamorphopsia	4	15
Miosis	1	9
Mydriasis	11	25
Myopia	1	3
Necrotising retinitis	1	1
Night blindness		1
Noninfective chorioretinitis		1
Ocular discomfort	36	98
Ocular dysmetria	1	1
Ocular hyperaemia	72	262
Ocular hypertension		1
Ocular myasthenia	2	3
Ocular sarcoidosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	3	9
				1	1
				10	19
		1	4	1	3
					2
			3	3	5
				1	1
			1		1
					2
				1	1
		32	148	16	91
		3	4	1	3
		1	1		
				1	1
				1	8
				1	2
				3	7
				1	2
				3	5
			3	4	12
		1	3		6
		9	15	2	10
			1	1	2
				1	1
			1		
					1
		30	77	6	21
		1	1		
		47	160	25	102
					1
				2	3
					1

\* I=Interval, C=Cumulative  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ocular vascular disorder	6	6
Oculogyric crisis		2
Ophthalmic artery thrombosis	1	1
Ophthalmic vein thrombosis	6	6
Ophthalmoplegia	1	3
Optic atrophy	1	1
Optic ischaemic neuropathy	7	8
Optic nerve disorder	1	2
Optic nerve infarction	1	1
Optic neuropathy		3
Orbital haematoma		2
Orbital oedema	3	6
Oscillopsia	1	2
Papilloedema	1	6
Parophthalmia	2	2
Periorbital discomfort	1	4
Periorbital disorder	1	3
Periorbital oedema	6	36
Periorbital pain	3	13
Periorbital swelling	30	120
Photophobia	62	307
Photopsia	26	89
Pigmentary glaucoma	1	1
Pupil fixed	3	8
Pupillary disorder	2	5
Pupillary reflex impaired	1	3
Pupils unequal	4	10
Retinal aneurysm	1	1
Retinal artery occlusion	14	19
Retinal artery thrombosis		1
Retinal degeneration		1
Retinal detachment	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	4	4
					2
				1	1
				6	6
				1	3
				1	1
				7	8
				1	2
				1	1
					3
					2
				3	6
		1	2		
				1	6
				2	2
		1	2		2
			2	1	1
		3	17	3	19
		1	7	2	6
		13	62	17	58
		25	138	37	169
		14	39	12	50
				1	1
				3	8
		2	4		1
		1	1		2
		2	3	2	7
				1	1
				14	19
					1
					1
				4	7

\* I=Interval, C=Cumulative

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retinal disorder	1	4
Retinal drusen	1	1
Retinal exudates	2	2
Retinal fovea disorder	2	2
Retinal haemorrhage	5	8
Retinal oedema	1	1
Retinal tear	4	8
Retinal toxicity		1
Retinal vascular occlusion	1	1
Retinal vascular thrombosis	5	5
Retinal vasculitis	1	1
Retinal vein occlusion	19	27
Retinal vein thrombosis	8	8
Retinopathy	1	2
Retinopathy hypertensive		1
Scintillating scotoma	1	3
Scleral discolouration		7
Scleral disorder	1	1
Scleral haemorrhage	1	1
Scleral hyperaemia		1
Scleritis	4	9
Strabismus	3	9
Sudden visual loss	5	8
Swelling of eyelid	45	149
Ulcerative keratitis		5
Uveitis	5	30
Vision blurred	230	772
Visual acuity reduced	11	30
Visual acuity reduced transiently	1	1
Visual brightness		2
Visual impairment	153	429
Visual snow syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		2
				1	1
				2	2
				2	2
				5	8
				1	1
				4	8
					1
				1	1
	1	1	1	4	4
				1	1
				19	27
				8	8
				1	2
					1
			2	1	1
			3		4
				1	1
				1	1
			1		
				4	9
		1	3	2	6
				5	8
		23	83	22	66
					5
				5	30
		100	375	130	397
	1	5	11	6	19
				1	1
			1		1
	2	63	182	90	247
				1	1

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vitreoretinal traction syndrome		1							1
Vitreous degeneration		2							2
Vitreous detachment	7	21		1			7		21
Vitreous disorder		4				1			3
Vitreous floaters	9	36			2	13	7		23
Vitreous haemorrhage	5	5					5		5
Vitritis		1							1
Xanthopsia		2				1			1
Xerophthalmia	2	3					2		3
	1,885	6,188	1	15	821	2846	1064		3342

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal adhesions	1	2					1		2
Abdominal discomfort	170	585	1	3	118	367	52		218
Abdominal distension	69	222			39	127	30		95
Abdominal mass	3	3			2	2	1		1
Abdominal migraine	1	1					1		1
Abdominal pain	396	1,522		3	196	865	200		657
Abdominal pain lower	28	98			14	49	14		49
Abdominal pain upper	343	1,324	2	3	187	674	156		650
Abdominal rigidity	3	18			3	11			7
Abdominal symptom	2	9			1	5	1		4
Abdominal tenderness	6	12			3	5	3		7
Abdominal wall haematoma		1							1
Abdominal wall haemorrhage	1	3					1		3
Abnormal faeces	8	41			5	30	3		11
Achlorhydria	1	1			1	1			

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Acquired macroglossia		1
Acute abdomen	5	11
Aerophagia	1	3
Anaesthesia oral		13
Anal erythema		1
Anal fissure		1
Anal haemorrhage	6	14
Anal incontinence	12	34
Anal pruritus	2	3
Anal skin tags		1
Anal sphincter atony		5
Anal sphincter hypertonia		1
Angina bullosa haemorrhagica	1	1
Angular cheilitis	1	4
Anorectal discomfort	2	6
Anorectal disorder	1	1
Anorectal swelling		1
Aphthous ulcer	18	72
Appendix disorder	1	1
Aptyalism	1	4
Ascites	1	7
Atrophic glossitis		1
Barrett's oesophagus	1	1
Bowel movement irregularity	5	21
Breath odour	4	17
Burning mouth syndrome	1	3
Cardiospasm	4	4
Change of bowel habit	2	3
Chapped lips	4	14
Cheilitis	6	22
Chronic gastritis	1	3
Coeliac artery stenosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				5	11
			1	1	2
			8		5
					1
					1
		3	6	3	8
	1	8	18	4	16
		1	2	1	1
			1		
					5
			1		
				1	1
			3	1	1
		2	5		1
				1	1
					1
1	1	10	42	8	30
				1	1
		1	4		
				1	7
					1
				1	1
		5	19		2
		2	8	2	9
			2	1	1
		3	3	1	1
		1	2	1	1
		3	9	1	5
		6	13		9
			1	1	2
					1

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Coeliac disease	1	6
Colitis	21	35
Colitis ischaemic	5	6
Colitis microscopic	1	3
Colitis ulcerative	17	35
Constipation	62	184
Crohn's disease	8	26
Cyclic vomiting syndrome		1
Defaecation disorder	1	2
Defaecation urgency	5	21
Dental caries	2	3
Dental discomfort	1	11
Dental paraesthesia	1	3
Diarrhoea	1,154	4,641
Diarrhoea haemorrhagic	14	41
Discoloured vomit	1	5
Diverticulum	1	4
Diverticulum intestinal	4	5
Dry mouth	112	520
Dumping syndrome	1	1
Duodenal ulcer		1
Duodenal ulcer haemorrhage	1	2
Duodenal ulcer perforation		1
Duodenitis		1
Duodenogastric reflux	2	4
Dysbiosis		2
Dyschezia	2	4
Dyspepsia	77	257
Dysphagia	163	660
Enlarged uvula	9	26
Enteritis	4	11
Enterocolitis	3	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
		10	16	11	19
				5	6
				1	3
1	1			17	35
		34	104	28	80
			1	8	25
					1
		1	1		1
		3	12	2	9
		1	2	1	1
		1	10		1
		1	3		
4	21	701	2666	453	1975
				14	41
			2	1	3
			3	1	1
		1	1	3	4
	2	68	296	44	224
		1	1		
					1
				1	2
					1
		2	3		1
					2
		1	2	1	2
		42	156	35	101
1	4	76	296	87	364
		4	10	5	16
		1	3	3	8
				3	6

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Enterocolitis haemorrhagic	1	1
Eosinophilic oesophagitis	1	2
Epigastric discomfort	6	17
Erosive oesophagitis		1
Eructation	9	50
Faecaloma	2	5
Faecal vomiting	1	3
Faeces discoloured	14	46
Faeces hard	2	2
Faeces pale	1	6
Faeces soft	10	26
Flatulence	47	154
Food poisoning	3	7
Frequent bowel movements	6	37
Functional gastrointestinal disorder	7	18
Gastric antral vascular ectasia	1	2
Gastric dilatation	3	7
Gastric disorder	17	50
Gastric haemorrhage	4	9
Gastric ulcer	6	9
Gastric varices haemorrhage		1
Gastric volvulus		1
Gastritis	12	37
Gastritis erosive	1	1
Gastrointestinal disorder	45	143
Gastrointestinal haemorrhage	16	38
Gastrointestinal hypermotility	2	9
Gastrointestinal hypomotility	2	3
Gastrointestinal inflammation		2
Gastrointestinal motility disorder	4	13
Gastrointestinal mucosal disorder	1	1
Gastrointestinal necrosis	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2		
		3	7	3	10
					1
		3	25	6	25
				2	5
				1	3
		11	31	3	15
				2	2
		1	3		3
		6	16	4	10
	1	29	91	18	63
		2	4	1	3
		3	20	3	17
		4	8	3	10
				1	2
		2	3	1	4
		11	33	6	17
				4	9
				6	9
					1
					1
		6	18	6	19
				1	1
1	1	33	107	12	36
				16	38
		1	3	1	6
		2	2		1
			1		1
		4	11		2
				1	1
				3	8

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gastrointestinal obstruction		1
Gastrointestinal oedema	1	2
Gastrointestinal pain	34	101
Gastrointestinal sounds abnormal	6	24
Gastrointestinal tract irritation	2	2
Gastrointestinal wall thickening	1	2
Gastrooesophageal reflux disease	25	97
Gingival bleeding	17	34
Gingival blister	1	4
Gingival discolouration	1	3
Gingival discomfort	4	8
Gingival disorder	1	6
Gingival erythema		5
Gingival oedema		2
Gingival pain	12	56
Gingival pruritus	1	1
Gingival recession		1
Gingival swelling	9	31
Gingival ulceration		1
Gingivitis ulcerative		2
Glossitis	3	26
Glossodynia	43	140
Haematemesis	18	61
Haematochezia	41	115
Haemoperitoneum	1	2
Haemorrhoidal haemorrhage		1
Haemorrhoids	6	21
Haemorrhoids thrombosed		1
Hiatus hernia	3	6
Hyperaesthesia teeth	2	13
Hyperchlorhydria		8
Hypertrophy of tongue papillae		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
	1	19	47	15	54
		4	14	2	10
		2	2		
		1	2		
		14	51	11	46
		7	17	10	17
		1	3		1
			1	1	2
	1	3	4	1	4
		1	4		2
			4		1
			1		1
		6	23	6	33
				1	1
			1		
		5	21	4	10
			1		
					2
		1	17	2	9
		26	82	17	58
				18	61
		1	1	40	114
				1	2
			1		
		3	8	3	13
					1
		1	3	2	3
		2	9		4
			2		6
			2		1

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoaesthesia oral	128	658
Hypoaesthesia teeth		5
Ileus		2
Ileus paralytic	3	7
Impaired gastric emptying	4	6
Infantile vomiting		4
Inflammatory bowel disease	2	4
Infrequent bowel movements		2
Internal hernia	1	1
Intestinal dilatation		1
Intestinal haemorrhage	6	9
Intestinal infarction	1	3
Intestinal ischaemia	15	27
Intestinal mass		1
Intestinal obstruction	7	18
Intestinal perforation	1	3
Intestinal pseudo-obstruction		2
Intra-abdominal haematoma		1
Intussusception	9	13
Irritable bowel syndrome	10	43
Large intestinal haemorrhage		1
Large intestinal obstruction		1
Large intestine perforation	1	1
Large intestine polyp		1
Lip blister	6	27
Lip discolouration		4
Lip disorder	6	25
Lip dry	11	34
Lip erosion		1
Lip erythema	2	16
Lip exfoliation		4
Lip haematoma	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		92	393	36	265
			5		
					2
				3	7
				4	6
			3		1
				2	4
			2		
				1	1
					1
				6	9
				1	3
				15	27
					1
				7	18
				1	3
					2
					1
				9	13
		6	14	4	29
					1
					1
				1	1
			1		
		4	13	2	14
			1		3
		5	20	1	5
		5	17	6	17
					1
		1	9	1	7
			2		2
				1	1

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lip haemorrhage	2	4
Lip oedema	22	161
Lip pain	14	48
Lip pruritus	6	59
Lip scab		1
Lip swelling	146	614
Lip ulceration	3	6
Loose tooth	1	1
Lower gastrointestinal haemorrhage		1
Mallory-Weiss syndrome		2
Megacolon		1
Melaena	8	24
Mesenteric arterial occlusion		1
Mesenteric artery aneurysm	1	1
Mesenteric artery embolism		2
Mesenteric artery thrombosis	2	3
Mesenteric panniculitis		1
Mesenteric vascular insufficiency		1
Mesenteric vein thrombosis	7	10
Mouth cyst	1	3
Mouth haemorrhage	11	21
Mouth swelling	22	107
Mouth ulceration	41	135
Mucous stools	4	11
Nausea	3,172	12,762
Necrotising colitis	1	1
Noninfective gingivitis	3	15
Noninfective sialoadenitis	1	3
Obstruction gastric		1
Obstructive pancreatitis	2	3
Odynophagia	44	172
Oedema mouth	4	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	3
1	1	11	69	11	92
		5	28	9	20
		3	30	3	29
					1
	2	85	281	61	333
		3	4		2
				1	1
					1
					2
					1
				8	24
					1
				1	1
					2
				2	3
					1
					1
				7	10
			2	1	1
		4	11	7	10
		11	45	11	62
		17	54	24	81
		1	7	3	4
5	68	1936	7343	1236	5419
				1	1
		1	8	2	7
			1	1	2
					1
				2	3
1	2	33	107	11	65
1	1	1	8	3	17

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oedematous pancreatitis		2
Oesophageal achalasia	1	1
Oesophageal discomfort		1
Oesophageal disorder		4
Oesophageal irritation		2
Oesophageal oedema		1
Oesophageal pain	1	10
Oesophageal perforation		1
Oesophageal spasm		6
Oesophageal stenosis	1	2
Oesophageal ulcer haemorrhage	1	1
Oesophageal varices haemorrhage		1
Oesophagitis	3	3
Oral blood blister	3	8
Oral discharge		1
Oral discomfort	33	129
Oral disorder	10	34
Oral dysaesthesia	2	12
Oral lichen planus	3	3
Oral mucosa erosion	2	4
Oral mucosa haematoma	1	1
Oral mucosal blistering	10	39
Oral mucosal discolouration		1
Oral mucosal eruption	4	13
Oral mucosal erythema	3	14
Oral mucosal exfoliation	3	7
Oral mucosal roughening	2	3
Oral pain	30	115
Oral papule		1
Oral pigmentation	1	1
Oral pruritus	18	83
Oral purpura	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
			1		
			1		3
			1		1
					1
			5	1	5
					1
			2		4
				1	2
				1	1
					1
		2	2	1	1
		1	3	2	5
			1		
	1	26	87	7	42
		4	21	6	13
		1	8	1	4
		1	1	2	2
		2	4		
		1	1		
		7	29	3	10
					1
		3	10	1	3
		1	7	2	7
		1	4	2	3
		1	1	1	2
		22	65	8	50
					1
		1	1		
		11	39	7	44
				1	1

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Overflow diarrhoea		1
Palatal disorder	1	4
Palatal oedema	5	45
Palatal swelling	6	26
Palatal ulcer		1
Pancreatic disorder	2	4
Pancreatic infarction		1
Pancreatitis	6	27
Pancreatitis acute	12	26
Pancreatitis chronic	1	1
Pancreatitis necrotising		1
Pancreatitis relapsing		1
Paraesthesia oral	243	1,268
Parotid duct obstruction		1
Parotid gland enlargement	4	10
Peptic ulcer		1
Peptic ulcer haemorrhage	1	2
Plicated tongue		5
Pneumoperitoneum		1
Pouchitis		1
Proctalgia	2	9
Proctitis	2	3
Proctitis ulcerative		1
Pylorospasm		1
Rectal discharge		3
Rectal haemorrhage	27	72
Rectal polyp		1
Rectal prolapse		1
Rectal spasm		1
Rectal tenesmus	1	3
Rectal ulcer		1
Reflux gastritis	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	2
		2	14	3	31
		3	12	3	14
					1
		1	1	1	3
					1
				6	27
				12	26
				1	1
					1
					1
2	4	163	746	80	522
					1
		2	6	2	4
					1
				1	2
			3		2
					1
					1
		1	6	1	3
		2	2		1
					1
			1		
			2		1
				27	72
			1		
					1
			1		
			1	1	2
					1
			2	1	1

\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Regurgitation		3
Retching	35	174
Retroperitoneal haemorrhage	1	2
Saliva discolouration		1
Salivary duct obstruction		1
Salivary gland disorder	2	5
Salivary gland enlargement	3	12
Salivary gland pain	3	10
Salivary hypersecretion	16	61
Scalloped tongue	1	1
Small intestinal haemorrhage	1	5
Small intestinal obstruction	2	6
Steatorrhoea	1	2
Stiff tongue	2	6
Stomatitis	25	84
Strawberry tongue		1
Subileus	1	4
Submaxillary gland enlargement	2	4
Swollen tongue	131	573
Teeth brittle	1	1
Teething	1	5
Terminal ileitis		1
Thrombosis mesenteric vessel	1	3
Tongue blistering	7	16
Tongue coated	3	15
Tongue cyst	1	1
Tongue discolouration	10	22
Tongue discomfort	18	82
Tongue disorder	15	78
Tongue dry	3	23
Tongue eruption	3	15
Tongue erythema	4	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
1	1	23	102	12	72
				1	2
					1
		1	3	1	2
			6	3	6
		1	5	2	5
		9	32	7	29
				1	1
				1	5
				2	6
		1	1		1
		2	2		4
	1	15	52	10	32
			1		
		1	1		3
		2	4		
1	1	59	218	72	355
		1	1		
			2	1	3
					1
				1	3
		3	9	4	7
	1	2	9	1	6
				1	1
		5	12	5	10
		10	51	8	31
		9	42	6	36
		2	14	1	9
		3	7		8
		2	10	2	5

\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Tongue geographic		1				1			
Tongue haematoma		3				3			
Tongue haemorrhage	1	2			1	2			
Tongue movement disturbance	5	12			2	4	3	8	
Tongue oedema	23	123	1	1	8	29	15	94	
Tongue pruritus	8	51			4	24	4	27	
Tongue rough	1	2			1	2			
Tongue spasm	1	4					1	4	
Tongue ulceration	7	26			3	15	4	11	
Toothache	46	128			30	86	16	42	
Tooth discolouration	1	1			1	1			
Tooth disorder	4	13			4	11		2	
Tooth erosion	1	1			1	1			
Tooth loss		1							1
Trichoglossia		3				3			
Truncus coeliacus thrombosis		1							1
Upper gastrointestinal haemorrhage	3	10					3	10	
Uvulitis	2	6			1	3	1	3	
Visceral venous thrombosis		1							1
Volvulus		3							3
Vomiting	1,144	4,289	4	21	590	2144	554	2145	
Vomiting projectile	13	46			8	21	5	25	
	8,976	35,250	28	148	5070	19088	3906	16162	

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Acute phase reaction	1	1			1	1			
Adhesion		1							1

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Administration site bruise		1
Administration site discomfort	1	1
Administration site erythema		3
Administration site hypoaesthesia	1	1
Administration site induration		1
Administration site irritation	1	1
Administration site joint movement impairment		2
Administration site joint pain		1
Administration site movement impairment	2	2
Administration site oedema		14
Administration site pain	3	50
Administration site paraesthesia		1
Administration site pruritus		2
Administration site reaction	4	6
Administration site swelling	1	3
Adverse drug reaction	9	35
Adverse event	10	20
Adverse reaction	1	3
Alcohol interaction		2
Apparent death		1
Application site coldness		2
Application site erythema	2	3
Application site haemorrhage		1
Application site inflammation		1
Application site oedema		1
Application site pain		5
Application site paraesthesia		1
Application site swelling	1	1
Application site vesicles	1	2
Application site warmth		1
Asthenia	1,489	6,581
Atrophy	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			3		
		1	1		
			1		
		1	1		
					2
			1		
		1	1	1	1
			14		
		3	49		1
			1		
			2		
		4	5		1
		1	3		
		3	22	6	13
		9	19	1	1
	1	1	3		
					2
					1
			1		1
		2	2		1
					1
			1		
			5		
			1		
		1	1		
				1	2
			1		
4	12	939	4286	550	2295
		1	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Axillary pain	391	1,117
Brain death	3	8
Breakthrough pain		2
Cardiac death	4	9
Catheter site haemorrhage		1
Chest discomfort	369	1,409
Chest pain	582	1,988
Chills	2,999	13,227
Chronic fatigue syndrome	19	34
Complication associated with device		3
Concomitant disease aggravated	2	10
Concomitant disease progression		1
Condition aggravated	277	852
Crepitations	1	6
Crying	27	118
Cyst	3	7
Cyst rupture		1
Death	208	852
Decreased activity	3	10
Deformity		1
Discharge		4
Discomfort	167	578
Disease progression	4	13
Disease recurrence	166	540
Drowning	2	5
Drug effective for unapproved indication	1	1
Drug ineffective	966	3,555
Drug interaction	24	58
Drug resistance		1
Drug withdrawal syndrome		1
Effusion	1	2
Enanthema		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
3	5	134	563	257	554
				3	8
			1		1
				4	9
			1		
	3	200	670	169	739
	4	227	797	355	1191
7	53	1990	8795	1009	4432
1	1	1	2	18	32
			1		2
				2	10
					1
1	1	112	364	165	488
		1	3		3
		18	75	9	43
		2	5	1	2
			1		
1	1			208	852
		2	8	1	2
			1		
			2		2
	4	99	359	68	219
		1	3	3	10
1	2	21	119	145	421
				2	5
		1	1		
5	8	1	5	965	3550
		9	31	15	27
					1
					1
				1	2
			1		2

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Energy increased	9	19
Exercise tolerance decreased	9	21
Extensive swelling of vaccinated limb	129	358
Eye complication associated with device		1
Face oedema	51	208
Facial discomfort	6	27
Facial pain	59	247
Fatigue	4,737	18,374
Fat tissue increased		1
Feeling abnormal	701	2,197
Feeling cold	294	1,355
Feeling drunk	20	92
Feeling hot	400	1,726
Feeling jittery	11	59
Feeling of body temperature change	88	320
Feeling of relaxation	2	3
Fever neonatal	2	2
Fibrosis	1	1
Foaming at mouth	5	13
Gait disturbance	239	747
Gait inability	66	224
Generalised oedema	5	14
General physical health deterioration	109	404
General symptom	1	3
Glassy eyes	1	8
Hangover	7	45
Hernia		1
Hernia pain		1
High-pitched crying		1
Hunger	4	22
Hyperpyrexia	73	336
Hyperthermia	28	150

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	15	3	4
	1	4	9	5	12
		116	319	13	39
					1
		17	55	34	153
		6	20		7
		29	131	30	116
21	144	2917	10965	1820	7409
			1		
1	3	454	1432	247	765
1	5	152	764	142	591
		11	50	9	42
		258	1087	142	639
	1	7	38	4	21
		44	166	44	154
		1	1	1	2
				2	2
		1	1		
		2	4	3	9
	1	89	358	150	389
	1	19	79	47	145
		3	6	2	8
		31	97	78	307
				1	3
			6	1	2
		4	23	3	22
					1
			1		
			1		
		4	19		3
	3	2	2	71	334
		16	77	12	73

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypothermia	31	129
Idiosyncratic drug reaction		1
Ill-defined disorder	3	6
Illness	406	1,179
Immediate post-injection reaction		1
Impaired healing	3	7
Impaired self-care	1	3
Implant site pain		1
Inadequate analgesia	1	1
Induration	65	196
Inflammation	143	441
Inflammatory pain	2	8
Influenza like illness	664	2,514
Infusion site pain		3
Infusion site warmth	1	1
Inhibitory drug interaction		2
Injected limb mobility decreased	24	97
Injection site bruising	2	9
Injection site discolouration		3
Injection site discomfort	2	16
Injection site erythema	25	130
Injection site extravasation	1	5
Injection site haematoma		7
Injection site haemorrhage	1	8
Injection site hyperaesthesia		1
Injection site hypersensitivity		4
Injection site hypoaesthesia	1	2
Injection site indentation		1
Injection site induration		15
Injection site inflammation	5	14
Injection site joint movement impairment		1
Injection site joint pain		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				31	129
			1		
		1	3	2	3
2	3	246	638	160	541
			1		
		1	3	2	4
			1	1	2
					1
				1	1
		57	176	8	20
		96	289	47	152
		1	4	1	4
1	5	334	1206	330	1308
			3		
		1	1		
			1		1
	1	14	60	10	37
		2	9		
			3		
		2	16		
		22	126	3	4
		1	5		
			6		1
		1	8		
			1		
			3		1
		1	2		
			1		
			15		
		5	14		
					1
			3		

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Injection site lymphadenopathy		1
Injection site mass	2	9
Injection site movement impairment		1
Injection site muscle weakness	2	4
Injection site nodule	1	2
Injection site oedema	1	150
Injection site pain	87	1,329
Injection site papule		1
Injection site paraesthesia		14
Injection site pruritus	12	51
Injection site rash	1	17
Injection site reaction	7	32
Injection site scar		1
Injection site swelling	22	100
Injection site urticaria	3	28
Injection site vesicles	1	1
Injection site warmth	8	32
Injury associated with device	1	3
Instillation site pain		1
Irritability postvaccinal		6
Lithiasis		1
Localised oedema	16	81
Local reaction	36	122
Loss of control of legs	4	19
Malaise	2,130	7,931
Mass	20	68
Moaning	3	9
Mucosal discolouration	2	2
Mucosal disorder	1	10
Mucosal dryness	3	12
Mucosal haemorrhage	1	3
Mucosal hyperaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			7	2	2
					1
		1	3	1	1
		1	2		
		1	150		
		81	1303	6	26
			1		
			14		
		11	50	1	1
		1	15		2
		4	24	3	8
			1		
		20	98	2	2
		3	26		2
				1	1
		7	30	1	2
		1	3		
			1		
			5		1
			1		
	1	9	42	7	39
		31	96	5	26
				4	19
3	62	1352	4644	778	3287
		12	43	8	25
		2	3	1	6
		1	1	1	1
		1	8		2
		3	8		4
		1	1		2
					1

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mucosal inflammation	1	3
Mucosal pain		1
Mucosa vesicle		1
Multimorbidity	1	2
Multi-organ disorder	2	4
Multiple organ dysfunction syndrome	10	43
Necrosis	2	5
No adverse event	44	125
Nodule	83	221
Non-cardiac chest pain	3	7
Non-pitting oedema	1	3
No reaction on previous exposure to drug	2	2
Obstruction		3
Oedema	82	342
Oedema mucosal	2	9
Oedema peripheral	90	268
Oral administration complication		1
Organ failure	1	2
Pain	2,255	8,638
Pelvic mass	2	2
Performance status decreased	2	8
Peripheral swelling	587	1,793
Physical deconditioning	5	13
Pneumatosis	1	1
Polyp	2	3
Polyserositis	1	2
Potentiating drug interaction	4	13
Pre-existing condition improved	3	9
Prolapse	1	2
Pseudoallergic reaction	2	2
Puncture site bruise	1	2
Puncture site discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
			1		
					1
				1	2
		1	1	1	3
	1			10	43
				2	5
		44	125		
		68	193	15	28
		2	3	1	4
			1	1	2
		2	2		
			1		2
		52	252	30	90
			2	2	7
2	2	39	119	51	149
			1		
				1	2
4	12	1458	5923	797	2715
				2	2
		1	4	1	4
2	4	281	928	306	865
		2	7	3	6
				1	1
		1	2	1	1
				1	2
		3	12	1	1
		2	8	1	1
			1	1	1
		1	1	1	1
				1	2
					1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Puncture site haematoma		1
Puncture site induration		2
Puncture site oedema		1
Puncture site pain	2	5
Puncture site swelling	1	1
Pyrexia	4,289	19,293
Reactogenicity event	1	1
Rebound effect		1
Screaming	7	13
Secretion discharge	13	31
Sensation of blood flow	1	6
Sensation of foreign body	47	189
Sense of oppression	5	19
Sensitivity to weather change	2	6
Serositis	1	2
Shoulder injury related to vaccine administration	3	9
Sluggishness	17	48
Soft tissue inflammation	1	1
Stenosis	3	4
Sudden cardiac death	7	17
Sudden death	52	215
Sudden infant death syndrome	1	1
Suprapubic pain		1
Swelling	474	1,362
Swelling face	246	921
Symptom recurrence	2	3
Systemic inflammatory response syndrome	5	24
Temperature intolerance	13	30
Temperature regulation disorder	8	46
Tenderness	99	266
Terminal state	1	3
Therapeutic product effect decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		
			1		
		2	5		
		1	1		
23	86	2765	11893	1524	7400
				1	1
					1
		5	9	2	4
		11	21	2	10
			1	1	5
		18	74	29	115
		2	5	3	14
		1	4	1	2
				1	2
		2	4	1	5
		11	35	6	13
		1	1		
		1	1	2	3
				7	17
	1			52	215
				1	1
			1		
		249	785	225	577
	5	134	441	112	480
			1	2	2
				5	24
		5	15	8	15
		5	25	3	21
	3	71	188	28	78
				1	3
		1	1		

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Therapeutic product effect delayed	2	2
Therapeutic product effect incomplete		1
Therapeutic product effect increased		1
Therapeutic product effect prolonged		1
Therapeutic product ineffective		1
Therapeutic response unexpected	59	135
Thirst	69	231
Thirst decreased		2
Tissue infiltration		1
Treatment noncompliance		1
Ulcer	1	11
Ulcer haemorrhage		1
Vaccination site abscess sterile		2
Vaccination site anaesthesia		3
Vaccination site atrophy		2
Vaccination site bruising	68	235
Vaccination site calcification	1	1
Vaccination site coldness	3	13
Vaccination site cyst		1
Vaccination site dermatitis		4
Vaccination site discharge	1	8
Vaccination site discolouration	10	51
Vaccination site discomfort	53	194
Vaccination site dryness	1	3
Vaccination site dysaesthesia	1	4
Vaccination site eczema	1	5
Vaccination site erosion		1
Vaccination site erythema	565	2,278
Vaccination site exfoliation	1	2
Vaccination site extravasation	7	21
Vaccination site granuloma	3	3
Vaccination site haematoma	38	130

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
					1
			1		1
					1
		54	125	5	10
	1	39	124	30	107
			1		1
			1		
					1
			6	1	5
					1
					2
					3
			1		1
		52	169	16	66
				1	1
		2	11	1	2
					1
			3		1
		1	6		2
		10	37		14
		42	148	11	46
		1	2		1
			2	1	2
		1	3		2
			1		
	1	452	1716	113	562
		1	1		1
		7	19		2
		2	2	1	1
		33	101	5	29

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site haemorrhage	27	99
Vaccination site hyperaesthesia	4	26
Vaccination site hypersensitivity	16	76
Vaccination site hypertrophy		1
Vaccination site hypoaesthesia	21	100
Vaccination site induration	86	320
Vaccination site inflammation	149	432
Vaccination site injury		5
Vaccination site irritation	8	23
Vaccination site ischaemia		1
Vaccination site joint discomfort	2	3
Vaccination site joint erythema	8	24
Vaccination site joint inflammation	2	5
Vaccination site joint movement impairment	8	61
Vaccination site joint pain	6	46
Vaccination site joint swelling	5	19
Vaccination site joint warmth	1	2
Vaccination site lymphadenopathy	25	121
Vaccination site macule	2	11
Vaccination site mass	100	384
Vaccination site movement impairment	70	283
Vaccination site necrosis	3	6
Vaccination site nodule	7	45
Vaccination site oedema	79	367
Vaccination site pain	2,695	11,834
Vaccination site pallor	1	3
Vaccination site papule	3	10
Vaccination site paraesthesia	18	146
Vaccination site phlebitis	1	2
Vaccination site plaque		2
Vaccination site pruritus	240	889
Vaccination site rash	91	323

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		22	75	5	24
		3	15	1	11
		16	70		6
					1
		13	70	8	30
		73	248	13	72
	1	134	357	15	75
			4		1
		6	15	2	8
					1
		2	3		
		6	15	2	9
		1	1	1	4
		4	37	4	24
		4	33	2	13
		5	17		2
		1	2		
		15	75	10	46
		2	11		
	1	62	235	38	149
		40	193	30	90
				3	6
		6	39	1	6
1	1	46	236	33	131
4	69	2102	9104	593	2730
			2	1	1
		3	8		2
		14	105	4	41
		1	2		
			1		1
		209	692	31	197
		67	223	24	100

\* I=Interval, C=Cumulative  
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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site reaction	188	580			105	271	83	309
Vaccination site recall reaction	1	2			1	2		
Vaccination site scab		8				5		3
Vaccination site scar	1	4			1	3		1
Vaccination site streaking	1	1			1	1		
Vaccination site swelling	555	2,178	1	14	444	1613	111	565
Vaccination site thrombosis	1	4					1	4
Vaccination site ulcer		2				1		1
Vaccination site urticaria	20	126			13	95	7	31
Vaccination site vesicles	6	32			4	22	2	10
Vaccination site warmth	259	1,112	1	2	223	864	36	248
Vascular stent thrombosis	3	3					3	3
Vessel puncture site haemorrhage		1				1		
Vessel puncture site injury		1				1		
Visceral pain		1				1		
Withdrawal syndrome	1	3			1	2		1
Xerosis		1						1
	32,639	130,132	90	530	19899	79498	12740	50634

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure	1	3			1	3
Autoimmune hepatitis	2	3			2	3
Bile duct stone		1				1
Biliary colic	3	7			3	7
Biliary cyst	1	1	1	1		
Biliary dilatation	1	1			1	1
Biliary tract disorder	2	4	1	1	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholangitis	2	3			2	3
Cholecystitis	3	9			3	9
Cholecystitis acute	1	1			1	1
Cholelithiasis	4	9		2	4	7
Cholestasis	6	14			6	14
Cholestatic liver injury		1				1
Congestive hepatopathy		2				2
Deficiency of bile secretion		1				1
Drug-induced liver injury	3	5			3	5
Gal bladder disorder	4	12	1	5	3	7
Gal bladder enlargement		1				1
Gal bladder oedema	1	2			1	2
Gal bladder polyp		1		1		
Granulomatous liver disease		1				1
Hepatic artery embolism		1				1
Hepatic cirrhosis	1	4			1	4
Hepatic cyst	3	5	1	3	2	2
Hepatic failure	2	10			2	10
Hepatic function abnormal	11	15	4	5	7	10
Hepatic haematoma		1				1
Hepatic haemorrhage	1	1			1	1
Hepatic infarction	1	2			1	2
Hepatic lesion		3		1		2
Hepatic necrosis		1				1
Hepatic pain	4	19	1	8	3	11
Hepatic steatosis	3	5	1	3	2	2
Hepatitis	10	23			10	23
Hepatitis acute	5	14			5	14
Hepatitis cholestatic	2	6			2	6
Hepatocellular injury	8	19			8	19
Hepatomegaly	3	7	1	2	2	5
Hyperbilirubinaemia	4	8			4	8

\* I=Interval, C=Cumulative  
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System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertransaminasaemia		6		1		5
Immune-mediated hepatic disorder	1	1			1	1
Immune-mediated hepatitis	1	1			1	1
Jaundice	14	41	3	10	11	31
Jaundice cholestatic	1	2			1	2
Liver disorder	7	14	3	6	4	8
Liver injury	5	13			5	13
Liver tenderness	1	2		1	1	1
Ocular icterus	1	2	1	2		
Portal vein thrombosis	9	9			9	9
Primary biliary cholangitis		1				1
	132	318	18	52	114	266

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic oedema	4	12			2	3	2	9
Allergic reaction to excipient	3	12			1	5	2	7
Allergy to arthropod bite	1	1			1	1		
Allergy to arthropod sting	2	3			1	2	1	1
Allergy to chemicals	1	2			1	2		
Allergy to vaccine	37	212		1	21	109	16	103
Amyloidosis		1						1
Anamnestic reaction	1	1					1	1
Anaphylactic reaction	757	1,961	1	3	3	4	754	1957
Anaphylactic shock	62	233		2			62	233
Anaphylactoid reaction	10	52					10	52
Anaphylactoid shock	1	3					1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Anti-neutrophil cytoplasmic antibody positive vasculitis		1
Atopy		1
Autoimmune disorder	20	47
Bacille Calmette-Guerin scar reactivation	2	9
Contrast media allergy		1
Contrast media reaction		1
Corneal graft rejection		1
Cytokine storm		1
Decreased immune responsiveness		3
Drug hypersensitivity	24	97
Food allergy	6	16
Graft versus host disease	1	2
Haemophagocytic lymphohistiocytosis	5	8
Hypersensitivity	381	1,393
Hypogammaglobulinaemia	1	1
Immune-mediated adverse reaction	1	4
Immune system disorder	15	47
Immunisation reaction	2	6
Immunodeficiency	3	11
Immunodeficiency common variable	1	1
Immunosuppression		1
Kidney transplant rejection	1	1
Lung transplant rejection		1
Multiple allergies	1	2
Oral allergy syndrome		1
Reaction to colouring	1	1
Reaction to excipient	5	23
Reaction to preservatives	2	5
Renal transplant failure	1	1
Rubber sensitivity		2
Sarcoidosis	6	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				20	47
			5	2	4
			1		
					1
					1
					3
		11	53	13	44
		2	5	4	11
				1	2
				5	8
	7	204	596	177	797
				1	1
			1	1	3
		8	22	7	25
			2	2	4
				3	11
				1	1
					1
				1	1
					1
		1	1		1
					1
					1
		2	10	3	13
		2	2		3
				1	1
			1		1
				6	13

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Seasonal allergy	14	30			11	22	3	8
Sensitisation	1	7				5	1	2
Serum sickness	2	6			1	1	1	5
Serum sickness-like reaction		2						2
Systemic immune activation	3	5					3	5
Type I hypersensitivity	11	48					11	48
Type II hypersensitivity	1	2					1	2
Type III immune complex mediated reaction	3	4					3	4
Type IV hypersensitivity reaction	5	20			2	10	3	10
	1,398	4,319	1	13	274	863	1124	3456

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal infection	4	6					4	6
Abdominal wall abscess		1						1
Abscess	12	21			6	9	6	12
Abscess jaw		1						1
Abscess limb	1	1					1	1
Abscess neck	1	1					1	1
Abscess of salivary gland		1						1
Abscess oral	1	3			1	1		2
Acarodermatitis	1	3				1	1	2
Acne pustular		2				1		1
Acute endocarditis	1	1					1	1
Acute sinusitis	1	1			1	1		
Adenopathy syphilitic	1	2					1	2
Aerococcus urinae infection		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
African trypanosomiasis	1	2
Amniotic cavity infection	1	1
Anal infection		1
Appendicitis	31	70
Appendicitis perforated	9	10
Arthritis bacterial		2
Arthritis infective	1	1
Arthritis viral	1	2
Arthropod infestation		1
Asymptomatic bacteriuria		1
Asymptomatic COVID-19	102	249
Atypical pneumonia	1	5
Babesiosis		1
Bacteraemia	1	4
Bacterial diarrhoea		1
Bacterial disease carrier		1
Bacterial infection	5	11
Bacterial pyelonephritis	1	2
Bacterial rhinitis		1
Bacterial sepsis	3	5
Bacterial vaginosis	2	2
Bacteriuria		1
Beta haemolytic streptococcal infection		1
Biliary sepsis		1
Blastocystis infection		1
Blister infected		3
Body tinea		1
Bone abscess		1
Borrelia infection		1
Breast abscess		3
Breast cellulitis	1	1
Bronchiolitis	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	1
			1		
	1			31	70
				9	10
					2
				1	1
			1	1	1
					1
					1
		8	31	94	218
				1	5
					1
				1	4
					1
					1
		2	3	3	8
				1	2
					1
				3	5
		2	2		
					1
					1
					1
			3		
			1		
					1
					1
					3
				1	1
				1	3

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bronchitis	18	65
Bronchitis bacterial		3
Bronchopulmonary aspergillosis		1
Bursitis infective		1
Candida infection	4	13
Cardiac valve vegetation		1
Cavernous sinus thrombosis	1	1
Cellulitis	79	206
Cellulitis gangrenous		1
Cellulitis staphylococcal		1
Central nervous system infection		1
Cholecystitis infective	1	2
Chorioretinitis		1
Chronic sinusitis	1	1
Citrobacter infection	1	2
Clostridium difficile colitis	2	4
Clostridium difficile infection	1	3
Coccidioidomycosis		2
Complicated appendicitis	1	2
Conjunctivitis	16	93
Conjunctivitis bacterial	1	4
Conjunctivitis viral	1	2
Corneal infection	1	2
Coronavirus infection	10	27
COVID-19	1,806	5,100
COVID-19 pneumonia	47	174
Creutzfeldt-Jakob disease	3	4
Cystitis	23	57
Cystitis bacterial	1	1
Cystitis escherichia	1	1
Cystitis klebsiella		1
Cytomegalovirus infection	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	30	8	35
					3
					1
					1
		1	7	3	6
					1
				1	1
				79	206
					1
					1
					1
				1	2
					1
		1	1		
				1	2
				2	4
				1	3
					2
				1	2
		14	59	2	34
				1	4
		1	2		
				1	2
		7	12	3	15
6	12	480	1187	1326	3913
1	2			47	174
				3	4
		10	27	13	30
		1	1		
				1	1
					1
				1	2

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cytomegalovirus infection reactivation		1
Dacryocystitis	1	1
Dermatitis infected	1	4
Dermatophytosis of nail	1	1
Dermo-hypodermatitis	4	8
Device related infection	1	2
Diabetic foot infection		1
Diarrhoea infectious	2	2
Disseminated Bacillus Calmette-Guerin infection	7	12
Disseminated varicella zoster virus infection	3	5
Diverticulitis	19	41
Dysentery	15	182
Ear infection	29	70
Ear infection bacterial		1
Ear infection viral	1	1
Ebola disease		1
Eczema herpeticum	1	4
Encephalitis	12	33
Encephalitis enteroviral		1
Encephalitis viral	2	3
Endocarditis		4
Enteritis infectious	1	1
Enterococcal infection	2	3
Epididymitis		2
Epiglottitis	2	3
Epstein-Barr virus infection		3
Epstein-Barr virus infection reactivation		6
Erysipelas	20	41
Erysipeloid		1
Escherichia bacteraemia	2	3
Escherichia infection	2	7
Escherichia sepsis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		1	2		2
		1	1		
		1	1	3	7
				1	2
			1		
				2	2
				7	12
				3	5
				19	41
5	6			15	182
		13	36	16	34
					1
		1	1		
					1
				1	4
				12	33
					1
				2	3
					4
				1	1
				2	3
					2
				2	3
					3
					6
				20	41
					1
				2	3
				2	7
					2

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Escherichia urinary tract infection	4	7
External ear cellulitis		1
Eye abscess		1
Eye infection	5	19
Eyelid infection		1
Febrile infection		3
Folliculitis	1	8
Fungal infection	3	9
Fungal peritonitis	1	1
Fungal skin infection	1	4
Furuncle	3	17
Gangrene	2	3
Gastric infection		1
Gastritis bacterial		1
Gastroenteritis	11	40
Gastroenteritis bacterial	1	1
Gastroenteritis norovirus	1	1
Gastroenteritis rotavirus	1	1
Gastroenteritis viral	7	21
Gastrointestinal infection	1	2
Gastrointestinal viral infection	1	2
Genital herpes	8	16
Genital herpes simplex		2
Genital herpes zoster	1	3
Gianotti-Crosti syndrome		1
Gingival abscess		1
Gingivitis	6	16
Gonorrhoea		2
Groin abscess		1
Haematoma infection		1
Haemorrhagic varicella syndrome		1
Helicobacter infection		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	7
					1
					1
			8	5	11
			1		
					3
		1	6		2
		2	7	1	2
				1	1
		1	2		2
			5	3	12
				2	3
					1
					1
		6	15	5	25
				1	1
				1	1
		4	12	3	9
			1	1	1
			1	1	1
		2	8	6	8
			2		
				1	3
			1		
					1
		3	12	3	4
					2
					1
					1
					2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hepatic cyst infection		1
Hepatitis A	1	1
Hepatitis B	1	1
Hepatitis C		1
Hepatitis D	1	1
Hepatitis infectious mononucleosis		1
Hepatitis viral	2	4
Herpangina	1	1
Herpes dermatitis	1	3
Herpes ophthalmic	7	25
Herpes pharyngitis	1	1
Herpes simplex	10	45
Herpes simplex encephalitis	1	4
Herpes simplex reactivation	3	6
Herpes virus infection	10	39
Herpes zoster	261	997
Herpes zoster cutaneous disseminated	2	5
Herpes zoster infection neurological		3
Herpes zoster meningitis	1	2
Herpes zoster meningoencephalitis	3	3
Herpes zoster oticus	7	17
Herpes zoster reactivation	2	15
HIV infection		1
Hordeolum	4	16
Impetigo	1	3
Infected cyst		1
Infected dermal cyst		1
Infected skin ulcer		1
Infection	66	173
Infection parasitic		1
Infection susceptibility increased		1
Infectious mononucleosis	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	1
					1
				1	1
					1
				2	4
		1	1		
			1	1	2
				7	25
				1	1
		5	28	5	17
				1	4
		3	5		1
		7	27	3	12
2	2	92	490	169	507
				2	5
					3
				1	2
				3	3
				7	17
			4	2	11
					1
		2	9	2	7
			1	1	2
					1
					1
	1	28	65	38	108
			1		
					1
		2	3	2	6

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Infectious pleural effusion		1
Infective exacerbation of bronchiectasis	1	1
Infective exacerbation of chronic obstructive airways disease		3
Infective spondylitis	1	1
Influenza	243	789
Injection site cellulitis	1	1
Injection site infection		9
Injection site pustule	1	1
Intervertebral discitis		1
Intestinal gangrene		1
Joint abscess	1	1
Kaposi's varicelliform eruption	1	1
Kidney infection	12	26
Klebsiella infection		3
Labyrinthitis	15	48
Lactobacillus infection		1
Large intestine infection	3	4
Laryngitis	3	19
Laryngitis bacterial		1
Lip infection		1
Listeriosis		1
Localised infection	8	32
Lower respiratory tract infection	32	105
Lower respiratory tract infection viral		1
Lung abscess		1
Lyme disease	2	6
Lymphadenitis bacterial		1
Lymphangitis	10	28
Lymph gland infection	4	8
Lymph node abscess	9	11
Mastitis	15	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					3
				1	1
1	4	109	324	134	465
				1	1
			9		
				1	1
					1
					1
				1	1
				1	1
				12	26
					3
		3	7	12	41
					1
				3	4
		2	10	1	9
					1
			1		
					1
		2	14	6	18
				32	105
					1
					1
				2	6
					1
				10	28
		1	4	3	4
				9	11
				15	33

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Measles	5	5
Meningitis	9	18
Meningitis aseptic	3	14
Meningitis bacterial		2
Meningitis herpes	1	2
Meningitis pneumococcal		1
Meningitis viral	2	11
Meningoencephalitis herpetic	2	2
Meningomyelitis herpes		1
Mononucleosis syndrome		1
Moraxella infection		1
Morganella infection	1	1
Mumps	1	3
Myelitis	5	18
Myocarditis infectious		1
Myocarditis septic		1
Myringitis	1	1
Nasal abscess	1	1
Nasal herpes	2	6
Nasal vestibulitis		1
Nasopharyngitis	227	742
Necrotising fasciitis	1	3
Neuroborreliosis		1
Neutropenic sepsis		2
Nipple infection	1	1
Omphalitis	1	1
Oophoritis	1	1
Ophthalmic herpes simplex		4
Ophthalmic herpes zoster	18	46
Oral bacterial infection		1
Oral candidiasis	10	33
Oral fungal infection	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	5
				9	18
				3	14
					2
				1	2
					1
				2	11
				2	2
					1
					1
					1
				1	1
				1	3
				5	18
					1
					1
				1	1
		2	4		2
	2	158	507	69	235
				1	3
					1
					2
		1	1		
				1	1
				1	1
					4
				18	46
					1
		5	19	5	14
		2	5		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oral herpes	57	227
Oral pustule		1
Oral viral infection		3
Orchitis	1	6
Oropharyngeal candidiasis	1	1
Osteomyelitis		4
Otitis externa	1	6
Otitis media	3	6
Otitis media acute		1
Parainfluenzae viral laryngotracheobronchitis	1	1
Parapharyngeal space infection		1
Parotitis	3	15
Parvovirus infection	1	1
Pathogen resistance		1
Pelvic inflammatory disease		1
Perichondritis		1
Periodontitis		1
Periorbital abscess		1
Periorbital cellulitis	1	3
Peritonitis	1	4
Peritonsillar abscess	1	2
Persistent generalised lymphadenopathy	1	1
Pertussis		3
Pharyngeal pustule	1	1
Pharyngitis	11	41
Pharyngitis bacterial	1	1
Pharyngitis streptococcal	1	10
Pharyngotonsillitis	1	2
Pneumococcal sepsis		1
Pneumocystis jirovecii pneumonia		1
Pneumonia	144	462
Pneumonia bacterial	6	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	34	143	23	84
			1		
			2		1
			1	1	5
				1	1
					4
		1	4		2
		3	5		1
			1		
				1	1
					1
		1	8	2	7
		1	1		
					1
					1
			1		
			1		
					1
				1	3
				1	4
				1	2
				1	1
					3
		1	1		
1	1	7	25	4	16
				1	1
			6	1	4
				1	2
					1
					1
			1	144	461
				6	18

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pneumonia fungal		1
Pneumonia klebsiella		1
Pneumonia legionella		1
Pneumonia moraxella		1
Pneumonia pneumococcal		3
Pneumonia staphylococcal	1	3
Pneumonia streptococcal		1
Pneumonia viral	5	8
Postoperative wound infection		1
Post procedural infection		1
Post viral fatigue syndrome	16	39
Prion disease		1
Prostate infection		1
Prostatic abscess	1	1
Pseudomonal sepsis	1	1
Pseudomonas infection	2	2
Pulmonary sepsis	1	7
Pulmonary tuberculosis	1	1
Pulpitis dental	1	6
Pustule	5	25
Pyelonephritis	8	16
Q fever	3	16
Rash pustular	3	15
Rectal abscess	1	1
Relapsing fever	1	1
Respiratory tract infection	14	46
Respiratory tract infection bacterial	1	2
Respiratory tract infection viral	2	3
Retinitis		1
Rhinitis	23	97
Rhinovirus infection	1	4
Root canal infection	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					1
					3
				1	3
					1
				5	8
					1
					1
1	1	1	3	15	36
					1
					1
				1	1
				1	1
				2	2
				1	7
				1	1
			3	1	3
	1	4	13	1	12
				8	16
				3	16
		1	8	2	7
				1	1
				1	1
				14	46
				1	2
		1	2	1	1
					1
		17	65	6	32
		1	3		1
		1	2		

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Roseola		1
SARS-CoV-2 sepsis		1
Scarlet fever	1	2
Scrotal infection		1
Secondary transmission	1	1
Sepsis	34	104
Sepsis syndrome		1
Septic arthritis staphylococcal	2	2
Septic pulmonary embolism		1
Septic shock	10	29
Severe acute respiratory syndrome	3	6
Sialoadenitis	5	15
Sinusitis	43	121
Sinusitis bacterial		2
Skin bacterial infection	1	1
Skin infection	8	11
Soft tissue infection		4
Splenic infection		1
Sputum purulent	3	6
Staphylococcal abscess	1	1
Staphylococcal bacteraemia	2	3
Staphylococcal infection	5	11
Staphylococcal sepsis	3	6
Staphylococcal skin infection		1
Streptobacillus infection		1
Streptococcal abscess	1	1
Streptococcal bacteraemia		1
Streptococcal infection	1	5
Subcutaneous abscess	2	9
Superinfection	2	2
Superinfection bacterial	4	7
Suspected COVID-19	132	549

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
1	1			1	2
					1
				1	1
				34	104
					1
				2	2
					1
				10	29
				3	6
				5	15
		28	82	15	39
					2
				1	1
		4	6	4	5
					4
					1
				3	6
		1	1		
				2	3
				5	11
				3	6
					1
					1
				1	1
					1
			2	1	3
			2	2	7
				2	2
				4	7
		57	193	75	356

\* I=Interval, C=Cumulative  
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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sweating fever	12	58
Syphilis		1
Systemic candida		1
Tetanus	1	1
Tinea pedis	1	1
Tinea versicolour		1
Tongue fungal infection	1	1
Tonsillitis	11	35
Tonsillitis bacterial	1	7
Tooth abscess	4	8
Tooth infection	5	14
Toxocariasis	2	2
Toxoplasmosis	1	1
Tracheitis	3	7
Tuberculosis		3
Upper respiratory tract infection	9	29
Urinary tract candidiasis		1
Urinary tract infection	73	244
Urinary tract infection bacterial	3	12
Urinary tract infection enterococcal		1
Urinary tract infection pseudomonal	1	1
Urogenital infection bacterial	1	1
Urosepsis	6	21
Vaccination site abscess	3	13
Vaccination site cellulitis	14	74
Vaccination site infection	8	36
Vaccination site pustule	3	5
Vaccine breakthrough infection	19	19
Vaginal infection	1	6
Varicella	5	12
Varicella zoster virus infection	1	4
Vestibular neuronitis	12	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				12	58
					1
					1
				1	1
		1	1		
			1		
		1	1		
1	1	3	11	8	24
				1	7
		4	5		3
		3	11	2	3
				2	2
		1	1		
		2	4	1	3
					3
		6	16	3	13
					1
1	1	30	98	43	146
				3	12
					1
				1	1
				6	21
		3	7		6
		9	27	5	47
		3	16	5	20
		2	4	1	1
				19	19
		1	5		1
		2	7	3	5
			2	1	2
		2	4	10	31

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vestibulitis		1						1
Viral corneal ulcer		1						1
Viral infection	16	43			4	20	12	23
Viral keratouveitis	1	1					1	1
Viral labyrinthitis	2	5				3	2	2
Viral myocarditis		1						1
Viral pericarditis		1						1
Viral pharyngitis		4						4
Viral rash	3	17			2	8	1	9
Viral sepsis	1	1					1	1
Viral tonsillitis		1						1
Viral upper respiratory tract infection		3				1		2
Virologic failure	1	2			1	1		1
Vulval abscess		1						1
Vulvitis	1	2				1	1	1
Vulvovaginal candidiasis	4	12			1	4	3	8
Vulvovaginal mycotic infection	2	4			1	3	1	1
Wound infection	3	4					3	4
	4,264	13,113	20	37	1252	3893	3012	9220

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accident	5	8			1	3	4	5
Accidental exposure to product	6	50			6	49		1
Accidental overdose	5	86			5	79		7
Accidental underdose		4				4		
Adverse event following immunisation	3	4			1	2	2	2
Airway burns		3						3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alcohol poisoning		2
Animal bite	1	2
Ankle fracture	5	5
Arteriovenous fistula thrombosis	2	3
Arteriovenous graft thrombosis	1	1
Arthropod bite	4	11
Arthropod sting	4	6
Atypical femur fracture		1
Avulsion fracture	1	1
Back injury	4	8
Barotrauma		1
Bite		1
Bone contusion		2
Booster dose missed		5
Brachial plexus injury	2	4
Brain contusion	1	2
Brain herniation	1	1
Burn oesophageal	1	2
Burn of internal organs		1
Burn oral cavity	2	6
Burns second degree	1	3
Carbon monoxide poisoning	1	1
Cartilage injury		3
Central cord syndrome		1
Cerebral hyperperfusion syndrome		1
Cerebral ventricle collapse	1	2
Chest crushing	2	3
Chest injury	5	10
Chillblains	35	53
Circumstance or information capable of leading to device use error		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	2		
				5	5
				2	3
				1	1
		4	10		1
		4	5		1
					1
		1	1		
		2	5	2	3
			1		
					1
			1		1
			5		
				2	4
				1	2
				1	1
		1	1		1
					1
				2	6
		1	2		1
				1	1
			1		2
					1
					1
				1	2
				2	3
				5	10
		30	40	5	13
			4		

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Circumstance or information capable of leading to medication error	64	433
Clavicle fracture	1	2
Cold burn		1
Concussion	8	21
Conjunctival laceration		1
Contraindicated product administered	3	9
Contraindicated product prescribed	1	1
Contusion	185	429
Corneal abrasion		1
Counterfeit product administered	4	4
Craniofacial injury	5	9
Craniofacial fracture		1
Decreased embryo viability	2	2
Delayed recovery from anaesthesia	2	2
Dental restoration failure		2
Dose calculation error		1
Drug administered in wrong device		1
Drug exposure before pregnancy		1
Ear injury	1	1
Electric shock	1	6
Epicondylitis	2	7
Eschar		1
Expired product administered	22	52
Exposure during pregnancy	48	152
Exposure to contaminated water	1	1
Exposure to extreme temperature	1	1
Exposure to SARS-CoV-2	44	111
Exposure via breast milk	65	288
Exposure via eye contact	1	3
Exposure via skin contact	5	39
Extra dose administered		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		64	433		
				1	2
			1		
		2	7	6	14
			1		
		1	6	2	3
		1	1		
	2	93	236	92	193
					1
		4	4		
				5	9
					1
		1	1	1	1
		1	1	1	1
			2		
			1		
			1		
			1		
		1	1		
			2	1	4
		1	4	1	3
					1
		20	49	2	3
1	1	35	129	13	23
		1	1		
				1	1
	1	42	92	2	19
		46	252	19	36
		1	3		
		5	39		
			3		

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Extradural haematoma		1
Eye contusion	5	22
Eye injury	5	24
Eyelid contusion	1	1
Face crushing		1
Face injury	8	21
Facial bones fracture	9	13
Failed in vitro fertilisation	1	1
Fall	257	702
Femoral neck fracture	2	9
Femur fracture	5	13
Foetal exposure during pregnancy	2	4
Foot fracture	3	3
Foreign body aspiration		2
Foreign body in eye		1
Foreign body in gastrointestinal tract	1	1
Foreign body in mouth	1	1
Foreign body in throat	2	9
Fracture	2	9
Fractured skull depressed		1
Frostbite		3
Gastrointestinal injury	1	1
Gastrointestinal stoma complication		2
Hair injury		1
Hand fracture		6
Head injury	43	122
Heart injury	5	13
Heat illness	1	2
Heat oedema	1	4
Heat stroke		7
Hip fracture	7	19
Humerus fracture	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	4	16	1	6
		1	14	4	10
				1	1
		1	6	7	15
				9	13
				1	1
1	1	83	241	174	461
				2	9
				5	13
		1	1	1	3
		1	1	2	2
					2
			1		
				1	1
				1	1
				2	9
		1	1	1	8
					1
			2		1
		1	1		
			1		1
			1		
					6
		14	36	29	86
				5	13
		1	1		1
			1	1	3
			4		3
				7	19
				2	2

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyphaema		1
Iliotibial band syndrome		1
Inadequate aseptic technique in use of product	2	2
Inappropriate schedule of product administration	604	1,488
Incision site haemorrhage		1
Incision site pain	1	3
Incomplete course of vaccination	6	30
Incorrect dosage administered	1	4
Incorrect dose administered	27	97
Incorrect dose administered by device	1	1
Incorrect drug administration rate		1
Incorrect product administration duration	1	1
Incorrect product formulation administered	1	1
Incorrect route of product administration	130	541
Inflammation of wound	1	1
Infusion related reaction	1	3
Injection related reaction	5	21
Injury	17	28
Injury corneal		1
Intentional dose omission		3
Intentional overdose		2
Intentional product misuse	4	8
Intentional product use issue	2	4
Intercepted medication error		3
Intercepted product preparation error		2
Jaw fracture		2
Joint dislocation	2	11
Joint injury	13	28
Ligament injury		2
Ligament rupture	1	2
Ligament sprain	6	18
Limb crushing injury	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		2	2		
1	1	587	1466	17	22
					1
				1	3
		6	30		
		1	4		
		26	93	1	4
		1	1		
			1		
		1	1		
		1	1		
		127	527	3	14
		1	1		
				1	3
		1	6	4	15
		7	11	10	17
					1
			3		
			1		1
		4	8		
		2	4		
			3		
			2		
					2
			1	2	10
		7	16	6	12
			2		
			1	1	1
		5	11	1	7
				1	1

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Limb injury	21	60
Lip injury	5	7
Lower limb fracture	3	6
Maternal exposure before pregnancy	4	8
Maternal exposure during breast feeding	9	19
Maternal exposure during pregnancy	81	365
Maternal exposure timing unspecified	3	17
Medication error	3	19
Meniscus injury		1
Mouth injury	2	5
Multiple fractures		2
Multiple injuries		1
Muscle injury	1	7
Muscle rupture	1	4
Muscle strain	20	51
Nail avulsion		1
Nasal injury	1	5
Neck injury	2	5
Nerve injury	18	41
Occupational exposure to product	6	17
Occupational exposure to SARS-CoV-2		8
Off label use	617	1,921
Overdose	145	380
Palate injury		1
Patella fracture	2	2
Paternal exposure before pregnancy	1	1
Pelvic fracture	2	6
Periorbital haematoma	1	3
Peripheral nerve injury		2
Peroneal nerve injury		2
Phrenic nerve injury		1
Poisoning	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	39	12	21
		4	5	1	2
				3	6
		2	5	2	3
		3	10	6	9
3	3	62	316	19	49
		3	17		
		2	16	1	3
			1		
		2	4		1
					2
					1
		1	4		3
				1	4
	1	7	25	13	26
			1		
		1	4		1
		1	3	1	2
		11	20	7	21
		6	17		
			7		1
1	1	590	1861	27	60
		141	369	4	11
			1		
				2	2
				1	1
				2	6
				1	3
					2
					2
					1
				4	7

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Poor quality product administered	112	871
Post concussion syndrome		1
Post laminectomy syndrome		1
Post lumbar puncture syndrome		1
Postoperative ileus		1
Postoperative wound complication		1
Post procedural complication		4
Post procedural constipation	1	1
Post procedural haemorrhage	1	2
Post procedural oedema		1
Post-traumatic neck syndrome		3
Prescribed overdose		1
Procedural dizziness	2	4
Procedural haemorrhage		2
Procedural nausea		4
Procedural pain	1	3
Procedural site reaction		1
Product administered at inappropriate site	39	150
Product administered to patient of inappropriate age	16	54
Product administration error	4	35
Product communication issue		1
Product confusion		2
Product dispensing issue	1	1
Product dose omission in error	1	3
Product dose omission issue	38	71
Product label confusion	1	6
Product preparation error	33	282
Product preparation issue	108	287
Product prescribing error		3
Product storage error	24	45
Product use in unapproved indication	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		112	869		2
			1		
					1
					1
					1
	1				4
		1	1		
				1	2
			1		
					3
			1		
		1	1	1	3
					2
					4
			1	1	2
					1
		36	140	3	10
		16	52		2
		2	30	2	5
			1		
			2		
		1	1		
		1	3		
		38	69		2
		1	6		
		33	280		2
		108	283		4
			3		
		24	45		
		1	3		

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product use issue	101	1,072
Reaction to previous exposure to any vaccine		1
Recalled product administered	1	1
Recall phenomenon	2	2
Rectal injury	1	1
Respiratory fume inhalation disorder	1	1
Retinal injury	2	2
Rib fracture	7	14
Road traffic accident	12	21
Scapula fracture	1	1
Scar	7	15
Scratch	8	28
Scrotal injury		1
Sedation complication	1	1
Skeletal injury	1	3
Skin abrasion	5	14
Skin injury	1	6
Skin laceration	9	27
Skin wound	1	1
Skull fracture	1	2
Skull fractured base		1
Soft tissue injury	1	2
Spinal column injury	1	2
Spinal compression fracture	1	3
Spinal cord injury		2
Spinal fracture	2	2
Splenic rupture	3	3
Splinter	1	1
Sternal fracture	1	1
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		92	1031	9	41
					1
		1	1		
		2	2		
				1	1
				1	1
				2	2
			1	7	13
		4	6	8	15
				1	1
		5	7	2	8
		7	19	1	9
			1		
				1	1
		1	2		1
		2	6	3	8
		1	6		
		5	14	4	13
				1	1
				1	2
					1
			1	1	1
				1	3
					2
				2	2
				3	3
		1	1		
				1	1
					1
			1		
				1	1
					2

\* I=Interval, C=Cumulative  
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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stoma site pain		1
Stoma site pruritus		1
Subcutaneous haematoma	3	4
Subdural haematoma	11	14
Subdural haemorrhage	3	4
Sunburn	3	12
Superficial injury of eye		2
Suture related complication		1
Synovial rupture		1
Tendon injury	1	5
Tendon rupture	3	3
Thermal burn	6	12
Thermal burns of eye	2	9
Thoracic vertebral fracture		1
Tongue injury		3
Tooth avulsion		2
Tooth fracture	4	5
Tooth injury	2	4
Toxicity to various agents	4	11
Tracheal haemorrhage		1
Tracheal obstruction	2	3
Transcription medication error		1
Transfusion reaction	1	1
Transplant failure		2
Traumatic fracture		1
Traumatic haematoma	1	1
Traumatic haemorrhage		1
Traumatic intracranial haemorrhage		1
Traumatic lung injury		2
Ulnar nerve injury		4
Underdose	41	336
Upper limb fracture	7	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		1	1	2	3
				11	14
				3	4
		3	8		4
			1		1
					1
			1		
				1	5
				3	3
		2	4	4	8
				2	9
					1
			2		1
					2
		3	3	1	2
		2	3		1
	1			4	11
					1
				2	3
			1		
		1	1		
					2
					1
				1	1
					1
			2		
					4
		41	334		2
		1	2	6	14

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination complication	18	140
Vaccination error	3	7
Vaccination failure	409	642
Vascular injury	3	4
Vasoplegia syndrome	2	2
Venous injury	3	3
Vth nerve injury		1
Wound	11	30
Wound complication	1	4
Wound haemorrhage	5	11
Wound necrosis		1
Wound secretion	1	3
Wrist fracture		3
Wrong dose		1
Wrong patient received product		1
Wrong product administered	19	58
Wrong schedule		3
Wrong technique in device usage process		2
Wrong technique in product usage process	69	270
	3,895	12,926

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	3	7	85	11	55
		3	7		
2	3	1	1	408	641
		1	1	2	3
				2	2
				3	3
					1
		4	17	7	13
		1	3		1
		4	6	1	5
					1
				1	3
					3
			1		
			1		
		18	57	1	1
			3		
			2		
		68	266	1	4
10	20	2766	10443	1129	2483

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Activated partial thromboplastin time abnormal	1	1
Activated partial thromboplastin time prolonged	7	11
Activated partial thromboplastin time ratio increased		1
Activated partial thromboplastin time shortened	5	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2	7	9
			1		
		1	2	4	4

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alanine aminotransferase abnormal		1
Alanine aminotransferase decreased		2
Alanine aminotransferase increased	15	48
A bumin globulin ratio decreased		1
Allergy test positive		1
Alpha globulin increased		1
Alpha tumour necrosis factor increased	1	1
Amino acid level decreased		1
Ammonia abnormal		1
Ammonia increased		1
Amylase increased	2	5
Analgesic drug level		1
Analgesic drug level above therapeutic		1
Anion gap abnormal		1
Anion gap decreased		1
Anion gap increased		1
Antibody test abnormal	3	30
Antibody test negative	2	9
Antibody test normal	1	1
Antibody test positive		1
Anticoagulation drug level below therapeutic	3	3
Anticoagulation drug level increased		1
Anti Kell antibody test positive	1	1
Anti-myelin-associated glycoprotein ant bodies positive		1
Antinuclear antibody increased	1	1
Antinuclear antibody positive	1	5
Antiphospholipid antibodies positive	1	1
Anti-platelet antibody	1	1
Antipsychotic drug level increased		1
Anti-thyroid antibody	1	1
Anti-thyroid antibody positive	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
		6	25	9	23
			1		
			1		
			1	1	1
			1		
			1		
					1
		2	2		3
					1
					1
			1		
			1		
			1		
		3	30		
		2	9		
		1	1		
			1		
		1	1	2	2
					1
		1	1		
					1
		1	1		
		1	3		2
				1	1
				1	1
					1
		1	1		
			1	1	2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aortic bruit		1
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased	9	26
Audiogram abnormal	1	1
Auscultation		1
Autoantibody negative		1
Bacterial test	1	1
Bacterial test positive	5	9
Band neutrophil count increased		1
Base excess decreased	1	1
Basophil count abnormal		1
Basophil count decreased	1	2
Basophil count increased		2
Beta 2 microglobulin increased		1
Beta globulin increased		1
Bilirubin conjugated increased		1
Bilirubin urine present		1
Biopsy	1	1
Blast cell count increased		1
Bleeding time abnormal		1
Blood albumin decreased	1	6
Blood alcohol decreased	1	1
Blood alkaline phosphatase increased	6	16
Blood bicarbonate decreased	2	4
Blood bicarbonate increased	1	1
Blood bilirubin abnormal	2	2
Blood bilirubin decreased		2
Blood bilirubin increased	5	16
Blood bilirubin unconjugated increased		1
Blood calcium decreased	4	9
Blood calcium increased		3
Blood chloride decreased		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		6	17	3	9
		1	1		
			1		
					1
				1	1
		1	4	4	5
					1
		1	1		
			1		
		1	2		
			2		
			1		
			1		
			1		
		1	1		
					1
					1
		1	5		1
		1	1		
		4	9	2	7
		1	2	1	2
		1	1		
		1	1	1	1
			2		
		3	9	2	7
			1		
		3	8	1	1
			2		1
			3		1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood chloride increased		7
Blood cholesterol	1	1
Blood cholesterol abnormal	3	3
Blood cholesterol increased	5	15
Blood chromium increased	1	1
Blood copper increased	1	2
Blood count abnormal	5	11
Blood creatine increased	1	4
Blood creatine phosphokinase abnormal	1	1
Blood creatine phosphokinase increased	8	30
Blood creatine phosphokinase MB increased		2
Blood creatinine abnormal	2	3
Blood creatinine decreased		3
Blood creatinine increased	9	25
Blood culture positive	1	1
Blood electrolytes decreased	1	1
Blood electrolytes increased		1
Blood fibrinogen decreased	3	4
Blood fibrinogen increased	3	4
Blood folate decreased	2	3
Blood folate increased	1	1
Blood follicle stimulating hormone increased	1	1
Blood gases abnormal	2	2
Blood glucose	1	2
Blood glucose abnormal	2	17
Blood glucose decreased	23	72
Blood glucose fluctuation	4	29
Blood glucose increased	48	206
Blood growth hormone abnormal	1	2
Blood heavy metal increased		1
Blood immunoglobulin E increased	1	2
Blood immunoglobulin G decreased		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6		1
		1	1		
		3	3		
		3	11	2	4
				1	1
		1	2		
		1	6	4	5
			2	1	2
		1	1		
		2	13	6	17
			1		1
		1	1	1	2
			2		1
		7	17	2	8
				1	1
				1	1
			1		
		1	1	2	3
		3	4		
		1	2	1	1
		1	1		
				1	1
				2	2
				1	2
			10	2	7
		8	34	15	38
		2	16	2	13
		24	120	24	86
		1	2		
			1		
				1	2
			3		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood immunoglobulin G increased		2
Blood immunoglobulin M abnormal	1	1
Blood immunoglobulin M increased		3
Blood insulin increased	1	1
Blood iron decreased	3	10
Blood iron increased	2	3
Blood ketone body increased		2
Blood ketone body present		1
Blood lactate dehydrogenase abnormal		1
Blood lactate dehydrogenase increased	6	13
Blood lactic acid decreased		1
Blood lactic acid increased	3	15
Blood luteinising hormone abnormal		1
Blood magnesium decreased		4
Blood methaemoglobin present		1
Blood oestrogen increased		1
Blood osmolarity increased		1
Blood parathyroid hormone increased	1	1
Blood pH	1	2
Blood pH decreased	1	1
Blood pH increased	1	4
Blood phosphorus decreased	2	5
Blood potassium abnormal		1
Blood potassium decreased	9	33
Blood potassium increased	5	9
Blood pressure abnormal	23	67
Blood pressure ambulatory increased	2	2
Blood pressure decreased	110	332
Blood pressure diastolic decreased	3	15
Blood pressure diastolic increased	4	22
Blood pressure immeasurable	1	3
Blood pressure increased	346	1,191

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
				1	1
			3		
		1	1		
		1	6	2	4
		1	2	1	1
					2
					1
			1		
		3	5	3	8
			1		
		1	6	2	9
			1		
			2		2
			1		
					1
			1		
		1	1		
				1	2
				1	1
		1	2		2
			2	2	3
					1
		6	18	3	15
		2	4	3	5
		15	37	8	30
		1	1	1	1
	2	39	123	71	209
		2	12	1	3
		1	9	3	13
		1	1		2
	2	158	569	188	622

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure measurement	1	1
Blood pressure orthostatic abnormal		1
Blood pressure orthostatic decreased		1
Blood pressure orthostatic increased	1	1
Blood pressure systolic		2
Blood pressure systolic abnormal	2	2
Blood pressure systolic decreased	3	9
Blood pressure systolic increased	22	74
Blood prolactin increased		1
Blood smear test abnormal		1
Blood sodium decreased	9	20
Blood sodium increased	1	3
Blood test abnormal	14	21
Blood testosterone decreased		1
Blood testosterone increased		1
Blood thrombin	1	1
Blood thyroid stimulating hormone decreased	1	4
Blood thyroid stimulating hormone increased	5	16
Blood triglycerides abnormal	1	1
Blood triglycerides increased	2	5
Blood urea abnormal	1	1
Blood urea decreased		1
Blood urea increased	3	12
Blood uric acid abnormal		1
Blood uric acid increased	1	5
Blood urine		3
Blood urine present	21	56
Blood viscosity increased		1
Body height decreased	5	29
Body temperature	18	28
Body temperature abnormal	23	99
Body temperature decreased	23	91

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
		1	1		
			1		1
				2	2
		1	2	2	7
		5	30	17	44
			1		
			1		
		6	12	3	8
			1	1	2
		6	10	8	11
			1		
			1		
				1	1
		1	2		2
		3	11	2	5
		1	1		
		1	2	1	3
		1	1		
					1
		2	10	1	2
			1		
		1	3		2
			1		2
		13	33	8	23
			1		
		5	28		1
		14	19	4	9
		9	50	14	49
		15	49	8	42

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature fluctuation	16	45
Body temperature increased	252	977
Bone density abnormal	1	1
Bone density decreased	1	1
Brain natriuretic peptide increased	3	5
Brain scan abnormal		2
Breath sounds		3
Breath sounds abnormal	9	23
Calcium ionised increased		1
Capillary nail refill test abnormal	1	4
Carbohydrate antigen 125 increased		2
Carbon dioxide decreased	1	1
Carbon dioxide increased	1	2
Carcinoembryonic antigen increased		2
Cardiac murmur	4	8
Cardiothoracic ratio increased	1	1
Carotid bruit		2
Cell marker decreased	1	1
Cells in urine	1	1
Central venous pressure abnormal	1	1
Chest expansion decreased		1
Chest X-ray abnormal	2	6
Clostridium test positive	1	1
Clot retraction		1
Coagulation factor increased	1	1
Coagulation time prolonged		5
Coma scale		1
Coma scale abnormal	1	8
Complement factor C3 decreased		1
Complement factor C3 increased	1	2
Computerised tomogram normal		1
Computerised tomogram thorax abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	20	7	25
1	3	188	740	64	237
		1	1		
		1	1		
		2	2	1	3
					2
			2		1
		5	7	4	16
			1		
		1	3		1
			2		
				1	1
			1	1	1
					2
			1	4	7
				1	1
					2
				1	1
		1	1		
			1		
			1	2	5
				1	1
					1
				1	1
			2		3
					1
				1	8
			1		
			1	1	1
			1		
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Corneal reflex decreased	2	6
Coronavirus test positive	1	5
Cortisol decreased		2
C-reactive protein abnormal	2	4
C-reactive protein decreased		1
C-reactive protein increased	79	246
Creatinine renal clearance decreased		1
Crystal urine		1
CSF immunoglobulin increased	1	1
CSF polymorphonuclear cell count increased	1	1
CSF protein increased	1	3
CSF test abnormal		1
Culture negative		1
Culture urine positive	1	2
Cytomegalovirus test positive	1	2
Differential white blood cell count abnormal		1
Digestive enzyme abnormal	1	1
Drug level decreased		1
Drug level fluctuating	1	1
Drug level increased	2	2
Drug screen positive	1	1
Ear, nose and throat examination abnormal	1	1
Eastern Cooperative Oncology Group performance status worsened	1	1
Ejection fraction abnormal		1
Ejection fraction decreased	1	5
Electrocardiogram abnormal	11	27
Electrocardiogram change		2
Electrocardiogram normal	1	1
Electrocardiogram PR prolongation		1
Electrocardiogram PR shortened	1	1
Electrocardiogram QRS complex prolonged	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	4
			2	1	3
					2
			2	2	2
			1		
		37	111	42	135
					1
			1		
				1	1
				1	1
				1	3
					1
					1
		1	2		
			1	1	1
					1
		1	1		
				1	1
		1	1	1	1
		1	1		
		1	1		
			1		
				1	5
		7	14	4	13
			1		1
				1	1
					1
				1	1
				1	2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Electrocardiogram QRS complex shortened	1	3
Electrocardiogram QT interval abnormal		1
Electrocardiogram QT prolonged		5
Electrocardiogram repolarisation abnormality	1	4
Electrocardiogram ST segment abnormal		2
Electrocardiogram ST segment depression	2	5
Electrocardiogram ST segment elevation	5	9
Electrocardiogram ST-T change	1	2
Electrocardiogram ST-T segment abnormal		1
Electrocardiogram T wave abnormal	1	2
Electrocardiogram T wave inversion	2	7
Electrocardiogram T wave peaked		1
Electroencephalogram abnormal		1
Electromyogram abnormal	1	1
Eosinophil count decreased	1	6
Eosinophil count increased	2	13
Epinephrine increased		2
Epstein-Barr virus antibody positive	1	1
Epstein-Barr virus test positive		1
Escherichia test positive	1	2
Exercise electrocardiogram abnormal	1	1
Faecal calprotectin		1
Faecal calprotectin increased	2	2
False negative investigation result	1	1
False positive investigation result	1	2
Fibrin D dimer increased	40	71
Fibrin degradation products increased	1	1
Fibrinolysis	1	1
Foetal heart rate abnormal		3
Foetal heart rate decreased	1	1
Forced expiratory volume increased		2
Foveal reflex abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
					5
				1	4
					2
				2	5
				5	9
				1	2
					1
		1	2		
	1			2	7
			1		
					1
		1	1		
		1	4		2
		1	5	1	8
			1		1
			1	1	1
		1	2		
				1	1
					1
				2	2
				1	1
			1	1	1
		15	27	25	44
				1	1
				1	1
					3
				1	1
					2
				1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Full blood count abnormal	1	5
Full blood count increased	1	2
Gamma-glutamyltransferase increased	11	22
Gastric pH decreased	1	3
General physical condition abnormal	2	13
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	9	25
Glucose urine present		1
Glycosylated haemoglobin decreased		1
Glycosylated haemoglobin increased	2	5
Granulocytes abnormal	1	1
Grip strength		1
Grip strength decreased	21	47
Haematocrit decreased	6	16
Haematocrit increased	1	4
Haematology test abnormal	1	2
Haemoglobin abnormal	1	2
Haemoglobin decreased	21	74
Haemoglobin increased	2	5
Haptoglobin decreased		1
Haptoglobin increased	1	2
Heart rate	6	12
Heart rate abnormal	23	69
Heart rate decreased	36	123
Heart rate increased	313	1,355
Heart rate irregular	40	126
Heart sounds abnormal	1	5
Hepatic enzyme abnormal	3	4
Hepatic enzyme increased	22	38
Hepatitis A antibody positive		1
Hepatitis A virus test positive	1	1
Hepatitis B antibody positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	3
		1	1		1
		8	14	3	8
		1	3		
			2	2	11
			1		
		6	16	3	9
					1
			1		
		1	2	1	3
		1	1		
					1
		13	25	8	22
		5	14	1	2
			2	1	2
			1	1	1
		1	1		1
		9	33	12	41
		1	2	1	3
					1
		1	1		1
		2	3	4	9
	1	12	39	11	30
		13	47	23	76
		176	769	137	586
		17	56	23	70
			1	1	4
				3	4
	1	14	21	8	17
			1		
		1	1		
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatitis B virus test positive	1	1
Herpes simplex test positive	1	1
Herpes virus test	1	1
High density lipoprotein decreased	1	1
Histamine level increased		4
HIV antibody positive	1	2
HIV test false positive	2	3
HIV test negative	1	1
HIV test positive	2	2
Hormone level abnormal	1	6
Immature granulocyte count increased		1
Immunoglobulins decreased		1
Immunoglobulins increased	2	3
Immunology test	1	1
Immunology test abnormal	1	1
Inflammatory marker increased	1	15
Influenza B virus test positive		1
Inspiratory capacity abnormal		1
Inspiratory capacity decreased		3
Interleukin level increased		1
International normalised ratio abnormal	2	6
International normalised ratio decreased	12	25
International normalised ratio fluctuation	1	2
International normalised ratio increased	14	62
Intraocular pressure increased	2	9
Intraocular pressure test abnormal		1
Iodine uptake decreased		1
Iodine uptake increased		1
Laboratory test abnormal	5	9
Laboratory test normal		1
Left ventricular end-diastolic pressure increased		1
Lipase decreased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		1	1		
		1	1		
			3		1
		1	2		
		2	3		
				1	1
		1	1	1	1
			2	1	4
			1		
			1		
		1	2	1	1
		1	1		
		1	1		
			3	1	12
			1		
			1		
			1		2
					1
		1	2	1	4
		3	8	9	17
				1	2
		1	16	13	46
		2	5		4
			1		
			1		
					1
		4	6	1	3
			1		
					1
		1	2		

\* I=Interval, C=Cumulative  
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lipase increased	1	10
Lipids increased		2
Listeria test positive	1	1
Liver function test abnormal	5	18
Liver function test increased	7	19
Low density lipoprotein increased	1	4
Lumbar puncture abnormal		1
Lymph node palpable	3	15
Lymph nodes scan abnormal		2
Lymphocyte count abnormal		2
Lymphocyte count decreased	6	17
Lymphocyte count increased	1	5
Lymphocyte percentage decreased		2
Lymphocyte percentage increased		1
Magnetic resonance imaging abnormal	1	1
Magnetic resonance imaging brain abnormal	2	3
Mammogram abnormal	1	1
Mast cell degranulation present		1
Mean cell haemoglobin concentration decreased	2	4
Mean cell haemoglobin concentration increased		2
Mean cell haemoglobin decreased	1	5
Mean cell haemoglobin increased		1
Mean cell volume decreased	2	5
Mean cell volume increased	1	3
Mean platelet volume decreased	1	2
Mean platelet volume increased		1
Metabolic function test abnormal		2
Metamyelocyte count increased		1
Mini mental status examination abnormal		1
Monoclonal immunoglobulin increased		1
Monocyte count abnormal		1
Monocyte count decreased		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5	1	5
			2		
		1	1		
		1	4	4	14
		2	6	5	13
		1	3		1
					1
		3	12		3
					2
			1		1
		3	13	3	4
		1	2		3
			2		
			1		
				1	1
			1	2	2
		1	1		
			1		
		2	4		
			2		
		1	4		1
			1		
		1	3	1	2
		1	3		
		1	2		
			1		
			2		
					1
					1
			1		1
			3		1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Monocyte count increased	2	11
Monocyte percentage increased		1
Muscle strength abnormal	1	3
Myelocyte count increased		1
Myocardial necrosis marker increased	2	9
Myocardial strain	1	1
Myoglobin blood increased		1
Natural killer T cell count increased		1
Nerve conduction studies abnormal	1	2
Neurological examination abnormal		1
Neurological examination normal		1
Neutralising ant bodies negative		1
Neutrophil count abnormal	1	4
Neutrophil count decreased	5	15
Neutrophil count increased	10	27
Neutrophil percentage increased		2
NIH stroke scale score decreased	1	1
Nitrite urine present	2	3
N-terminal prohormone brain natriuretic peptide increased	4	9
Ophthalmological examination abnormal	1	1
Opiates positive		1
Orthostatic heart rate response increased		1
Oxygen consumption		1
Oxygen consumption decreased	1	2
Oxygen consumption increased		1
Oxygen saturation	1	2
Oxygen saturation abnormal	9	26
Oxygen saturation decreased	128	584
Oxygen saturation immeasurable		1
Oxygen saturation increased	2	2
Parvovirus B19 test positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10		1
			1		
		1	2		1
					1
				2	9
				1	1
					1
			1		
		1	1		1
					1
			1		
			1		
				1	4
		3	8	2	7
		10	22		5
			1		1
				1	1
		2	3		
			1	4	8
		1	1		
					1
			1		
			1		
		1	1		1
			1		
				1	2
1	1	4	15	5	11
	1	31	117	97	467
					1
				2	2
			1		

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System Organ Class

Investigations

	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Preferred Term		
PCO2 abnormal	1	1
PCO2 decreased	1	1
Peak expiratory flow rate	1	1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased	3	7
pH urine		1
pH urine increased		1
Physical examination abnormal		1
Plasma viscosity abnormal	1	1
Platelet count abnormal	3	3
Platelet count decreased	63	112
Platelet count increased	9	23
PO2 decreased	6	8
Polymerase chain reaction positive	1	4
Positron emission tomogram	1	1
Pregnancy test positive	1	1
Procalcitonin increased	3	3
Product residue present	1	1
Prohormone brain natriuretic peptide increased	1	1
Prostatic specific antigen increased		3
Protein C increased	1	1
Protein total decreased	1	4
Protein total increased		2
Protein urine present	3	6
Prothrombin level abnormal	1	1
Prothrombin level decreased	1	1
Prothrombin level increased		1
Prothrombin time prolonged	4	8
Prothrombin time ratio increased	1	1
Prothrombin time shortened	2	2
Pulmonary arterial pressure abnormal		1
Pulmonary arterial pressure increased	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				1	1
					1
				3	7
					1
					1
					1
				1	1
		1	1	2	2
		19	36	44	76
		6	15	3	8
		3	4	3	4
		1	3		1
				1	1
		1	1		
		1	1	2	2
				1	1
				1	1
			2		1
				1	1
		1	4		
			2		
		3	6		
				1	1
				1	1
					1
		2	5	2	3
		1	1		
		1	1	1	1
					1
		1	1	3	4

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary function test	1	1
Pulmonary function test decreased	1	1
Pulse abnormal	11	45
Pulse absent	4	9
Pulse pressure decreased	1	2
Pulse pressure increased		1
Pulse volume decreased	1	7
Pulse waveform abnormal		1
Pupillary light reflex tests abnormal	1	1
Quality of life decreased	3	11
Radial pulse abnormal	3	5
Radial pulse increased		1
Radioisotope uptake increased		1
Red blood cell count abnormal	1	2
Red blood cell count decreased	6	16
Red blood cell count increased	1	3
Red blood cell sedimentation rate abnormal	1	2
Red blood cell sedimentation rate increased	8	36
Red blood cells urine	1	1
Red blood cells urine positive	2	4
Red cell distribution width decreased		1
Red cell distribution width increased		3
Respiratory rate decreased	12	26
Respiratory rate increased	21	95
Reticulocyte count decreased	1	1
Reticulocyte count increased		1
Rheumatoid factor increased	2	4
Rheumatoid factor positive		2
Rinne tuning fork test abnormal		1
Romberg test positive		1
Salmonella test positive	1	1
SARS-CoV-1 test positive	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
		4	18	7	27
		1	2	3	7
			1	1	1
			1		
		1	6		1
			1		
				1	1
			4	3	7
		1	1	2	4
					1
					1
		1	2		
		4	11	2	5
		1	3		
			1	1	1
		3	19	5	17
				1	1
		1	2	1	2
			1		
			2		1
		6	11	6	15
		5	28	16	67
				1	1
			1		
				2	4
			2		
			1		
			1		
				1	1
		1	1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 ant body test	3	4
SARS-CoV-2 ant body test negative	25	153
SARS-CoV-2 ant body test positive	11	92
SARS-CoV-2 test		2
SARS-CoV-2 test false positive	3	11
SARS-CoV-2 test negative	4	9
SARS-CoV-2 test positive	111	542
Sensory level abnormal	3	8
Serology negative	1	2
Serratia test positive		1
Serum ferritin abnormal	1	2
Serum ferritin decreased	1	4
Serum ferritin increased	1	5
Shift to the left		1
Sigmoidoscopy abnormal	1	1
Sinus rhythm	2	4
Skin temperature	4	7
Skin turgor decreased	1	2
Sputum abnormal		2
Stenotrophomonas test positive		1
Streptococcus test positive		3
Swollen joint count increased		1
Synovial fluid white blood cells positive		1
Temperature difference of extremities	1	4
Temperature perception test increased		1
Thyroglobulin increased		1
Thyroid function test abnormal	1	5
Thyroid hormones increased	1	2
Thyroxine decreased		2
Thyroxine free decreased	1	1
Thyroxine free increased	2	3
Tidal volume decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	2	2
		20	133	5	20
		10	84	1	8
					2
		2	10	1	1
		1	5	3	4
		38	144	73	398
		1	5	2	3
		1	2		
					1
			1	1	1
			1	1	3
		1	4		1
					1
				1	1
			2	2	2
		2	2	2	5
				1	2
					2
					1
			1		2
					1
					1
				1	4
					1
					1
		1	5		
		1	1		1
			2		
		1	1		
			1	2	2
				1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
T-lymphocyte count increased		1
Total lung capacity decreased	2	2
Toxoplasma serology positive	1	1
Transaminases decreased	1	1
Transaminases increased	5	20
Transferrin abnormal		1
Transferrin decreased	1	1
Transferrin increased		1
Tri-iodothyronine		1
Tri-iodothyronine decreased		3
Tri-iodothyronine free decreased	1	1
Tri-iodothyronine free increased		1
Troponin	1	1
Troponin I increased	4	8
Troponin increased	24	59
Troponin T increased	5	9
Tryptase decreased		2
Tryptase increased		2
Tuberculin test positive		1
Tumour marker abnormal		1
Tumour marker increased	2	2
Urinary sediment abnormal		1
Urinary sediment present		1
Urine analysis abnormal	3	11
Urine ketone body present	3	3
Urine leukocyte esterase positive	1	2
Urine output	1	3
Urine output decreased	7	16
Urine output increased		5
Urine porphobilinogen increased	1	1
Urobilinogen urine increased		1
Varicella virus test positive	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1	1	1
		1	1		
			1	1	1
		2	7	3	13
			1		
		1	1		
			1		
			1		
			1		2
		1	1		
			1		
				1	1
		1	2	3	6
		6	11	18	48
				5	9
			2		
			1		1
			1		
					1
		2	2		
			1		
			1		
		3	8		3
		2	2	1	1
		1	2		
		1	1		2
		5	8	2	8
			4		1
				1	1
			1		
				1	1

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vascular test abnormal		1				1			
Venous oxygen saturation decreased	1	2					1	2	
Viral test		1						1	
Viral test positive	1	1			1	1			
Vital capacity		1						1	
Vital functions abnormal		1						1	
Vitamin B12 decreased	3	5				1	3	4	
Vitamin B12 increased	2	2			1	1	1	1	
Vitamin D	1	1					1	1	
Vitamin D decreased	4	8			3	7	1	1	
Von Willebrand's factor activity decreased		1						1	
Weber tuning fork test abnormal		1				1			
Weight decreased	62	186			24	100	38	86	
Weight increased	17	35			14	26	3	9	
White blood cell count abnormal	3	3			2	2	1	1	
White blood cell count decreased	17	39			9	23	8	16	
White blood cell count increased	25	83			15	44	10	39	
White blood cells urine	1	3				1	1	2	
White blood cells urine positive	3	5			2	4	1	1	
X-ray abnormal	1	1					1	1	
	2,750	9,473	2	12	1336	4783	1414	4690	

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abnormal loss of weight	1	3			1	1		2	
Abnormal weight gain		3						3	
Acetonaemia		1				1			
Acidosis	4	8			1	2	3	6	

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System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Acidosis hyperchloraemic		1
Adult failure to thrive		1
Alcohol intolerance	2	3
Appetite disorder	2	14
Body fat disorder	1	1
Cachexia	2	12
Cell death	5	5
Dairy intolerance	1	1
Decreased appetite	420	1,666
Decreased insulin requirement	1	1
Dehydration	86	277
Diabetes mellitus	23	57
Diabetes mellitus inadequate control	15	35
Diabetic complication	1	3
Diabetic ketoacidosis	2	18
Diabetic ketosis		1
Diabetic metabolic decompensation		5
Diet refusal		7
Dyslipidaemia	1	4
Eating disorder symptom	1	3
Electrolyte depletion		1
Electrolyte imbalance	1	8
Failure to thrive		1
Feeding disorder	34	124
Fluid imbalance	2	3
Fluid intake reduced	3	16
Fluid overload	2	4
Fluid retention	14	37
Folate deficiency		1
Food aversion	4	12
Food craving	1	5
Food intolerance	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1	2	2
			7	2	7
		1	1		
				2	12
				5	5
				1	1
1	5	234	912	186	754
				1	1
		31	117	55	160
				23	57
				15	35
				1	3
				2	18
					1
					5
					7
		1	4		
		1	1		2
			1		
			1	1	7
					1
		19	73	15	51
		1	1	1	2
		1	7	2	9
				2	4
		8	17	6	20
			1		
		1	5	3	7
			2	1	3
		2	2	2	3

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System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Food refusal	2	12
Glucose tolerance impaired		2
Glycopenia	1	1
Gout	13	55
Haemochromatosis		1
Histamine intolerance		2
Hypercalcaemia	1	4
Hyperchloraemia	1	1
Hypercholesterolaemia	1	3
Hypercreatininaemia	1	1
Hyperferritinaemia	1	1
Hyperglycaemia	32	103
Hyperglycaemic hyperosmolar nonketotic syndrome		1
Hyperkalaemia	5	15
Hyperlactacidaemia	3	3
Hyperlipidaemia		1
Hypernatraemia	3	18
Hyperphagia		3
Hypertriglyceridaemia	1	1
Hyperuricaemia	2	2
Hypervitaminosis B12		1
Hypervolaemia		1
Hypoalbuminaemia	1	3
Hypocalcaemia	2	8
Hypoglycaemia	15	105
Hypokalaemia	12	42
Hypokalaemic syndrome	1	3
Hypomagnesaemia		1
Hyponatraemia	12	27
Hyponatraemic syndrome	2	2
Hypophagia	13	45

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	9
			2		
		1	1		
		4	21	9	34
			1		
					2
		1	1		3
				1	1
		1	3		
				1	1
				1	1
		8	21	24	82
					1
				5	15
				3	3
					1
		1	4	2	14
			2		1
				1	1
		2	2		
					1
			2	1	1
			1	2	7
		4	30	11	75
				12	42
		1	1		2
					1
		2	7	10	20
		1	1	1	1
		2	10	11	35

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System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypophosphataemia		1
Hypovitaminosis	2	3
Hypovolaemia		2
Increased appetite	2	8
Increased insulin requirement		1
Insulin-requiring type 2 diabetes mellitus		1
Insulin resistance	1	7
Insulin resistant diabetes	1	1
Iron deficiency	3	5
Ketoacidosis		7
Lactic acidosis	1	6
Lactose intolerance		1
Latent autoimmune diabetes in adults		2
Lipid metabolism disorder		1
Malnutrition	1	6
Marasmus	1	4
Metabolic acidosis	2	13
Metabolic alkalosis		1
Metabolic disorder	1	3
Metabolic syndrome		1
Obesity		1
Oligodipsia		1
Overweight		5
Polydipsia	3	16
Poor feeding infant	2	3
Postprandial hypoglycaemia		1
Salt craving		1
Starvation	1	1
Tetany	4	11
Type 1 diabetes mellitus	8	16
Type 2 diabetes mellitus	4	8
Underweight	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1	1	2
					2
		2	7		1
					1
					1
		1	3		4
				1	1
		1	2	2	3
					7
				1	6
			1		
					2
			1		
			3	1	3
				1	4
			2	2	11
			1		
		1	1		2
					1
			1		
					1
			3		2
			7	3	9
		1	2	1	1
					1
					1
				1	1
		2	3	2	8
				8	16
				4	8
			1	2	2

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vitamin B12 deficiency		1							1
Vitamin D deficiency	4	12			2	6	2	6	
Weight fluctuation	3	6			3	6			
Weight loss poor	1	1					1	1	
	805	2,976	1	5	345	1322	460	1654	

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Amyotrophy	1	1					1	1	
Ankylosing spondylitis	3	14					3	14	
Antisynthetase syndrome		2				1		1	
Arthralgia	2,411	9,676	9	55	1424	5822	987	3854	
Arthritis	59	195			24	86	35	109	
Arthritis allergic		2				1		1	
Arthritis enteropathic		1						1	
Arthritis reactive	10	30		1			10	30	
Arthropathy	14	52			11	38	3	14	
Autoimmune arthritis	1	1					1	1	
Axillary mass	45	120			16	56	29	64	
Back disorder	3	14			3	13		1	
Back pain	550	2,060		5	311	1155	239	905	
Bone development abnormal	1	1			1	1			
Bone disorder	3	9			1	7	2	2	
Bone formation increased		1				1			
Bone pain	138	565	2	3	84	342	54	223	
Bone swelling	3	19			1	13	2	6	
Bursal fluid accumulation		1				1			
Bursal haematoma		1						1	

\* I=Interval, C=Cumulative

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bursitis	17	39
Cervical spinal stenosis		2
Chondritis		2
Chondrocalcinosis	1	1
Coccydynia	3	4
Connective tissue disorder		1
Costochondritis	7	23
CREST syndrome		1
Crystal arthropathy		1
Dactylitis	1	1
Decreased nasolabial fold		2
Degenerative bone disease		1
Drooping shoulder syndrome		1
Dupuytren's contracture	1	2
Enthesopathy	2	3
Epiphyses premature fusion		1
Extremity contracture		2
Facet joint syndrome		1
Facial asymmetry	7	13
Fasciitis		3
Fibromyalgia	15	52
Finger deformity	1	3
Fistula		2
Flank pain	12	54
Foot deformity	2	4
Gouty tophus	1	1
Groin pain	24	79
Growing pains		1
Haemarthrosis	7	8
Haematoma muscle	4	5
Hand deformity	2	5
Head deformity	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	5	13	12	26
					2
			1		1
				1	1
		3	4		
					1
			3	7	20
					1
					1
				1	1
			1		1
			1		
			1		
				1	2
				2	3
					1
			2		
			1		
		1	4	6	9
			1		2
		6	18	9	34
		1	3		
			1		1
		7	33	5	21
		1	3	1	1
				1	1
2	2	11	37	13	42
			1		
				7	8
				4	5
			1	2	4
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Immobilisation syndrome	1	1
Immune-mediated arthritis		1
Inguinal mass		1
Intervertebral disc compression	1	2
Intervertebral disc degeneration	1	1
Intervertebral disc disorder	1	2
Intervertebral disc protrusion	6	13
Jaw clicking	1	6
Jaw cyst		1
Jaw disorder	5	13
Joint ankylosis		2
Joint contracture		3
Joint destruction		1
Joint effusion	6	29
Joint hyperextension		1
Joint instability		5
Joint laxity	1	2
Joint lock	6	16
Joint microhaemorrhage		1
Joint noise	4	11
Joint range of motion decreased	77	239
Joint stiffness	44	182
Joint swelling	130	387
Joint vibration		1
Joint warmth	4	14
Ligament disorder	1	2
Ligamentitis	1	1
Ligament pain	1	1
Limb deformity		1
Limb discomfort	275	978
Limb mass	9	38
Loose body in joint	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
				1	2
		1	1		
		1	2		
		4	8	2	5
		1	4		2
			1		
1	1	4	9	1	4
					2
			3		
					1
		1	11	5	18
			1		
			1		4
				1	2
		5	9	1	7
					1
		1	5	3	6
	1	32	115	45	124
		19	72	25	110
		60	187	70	200
					1
		1	7	3	7
			1	1	1
				1	1
		1	1		
			1		
1	4	163	576	112	402
		6	23	3	15
				1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lupus-like syndrome		1
Lupus myositis	1	1
Mandibular mass		1
Mastication disorder	6	19
Masticatory pain		1
Medial tibial stress syndrome		1
Mixed connective tissue disease		1
Mobility decreased	109	412
Muscle atrophy	6	11
Muscle contracture	3	31
Muscle discomfort	5	26
Muscle disorder	11	29
Muscle fatigue	58	178
Muscle mass	2	3
Muscle oedema		3
Muscle rigidity	6	42
Muscle spasms	215	774
Muscle swelling	8	26
Muscle tightness	38	174
Muscle twitching	48	215
Muscular weakness	319	1,105
Musculoskeletal chest pain	46	198
Musculoskeletal deformity		1
Musculoskeletal discomfort	41	151
Musculoskeletal disorder	18	53
Musculoskeletal pain	52	366
Musculoskeletal stiffness	316	1,108
Myalgia	3,084	13,010
Myalgia intercostal	2	6
Myofascial pain syndrome		5
Myokymia		2
Myopathy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		
		4	12	2	7
			1		
					1
					1
		52	206	57	206
		2	5	4	6
1	1	1	21	2	10
		5	23		3
		9	21	2	8
		30	68	28	110
		1	2	1	1
			1		2
	1	3	21	3	21
2	2	108	426	107	348
		5	15	3	11
	1	24	120	14	54
		32	122	16	93
		126	493	193	612
		22	95	24	103
					1
		27	98	14	53
		7	21	11	32
	1	36	242	16	124
	2	183	576	133	532
16	76	1987	7995	1097	5015
		1	2	1	4
			2		3
			1		1
		1	1		

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myosclerosis		5
Myositis	9	32
Neck mass	5	33
Neck pain	437	1,658
Nuchal rigidity	4	33
Oligoarthritis		1
Osteitis	1	2
Osteoarthritis	10	29
Osteoarthropathy	1	1
Osteochondritis	1	2
Osteonecrosis of jaw	2	2
Osteopenia		1
Osteoporosis	1	3
Pain in extremity	2,787	10,300
Pain in jaw	72	272
Palindromic rheumatism	1	1
Patellofemoral pain syndrome	1	1
Periarthritis	10	41
Plantar fasciitis	3	8
Polyarthritis	11	25
Polychondritis	2	4
Polymyalgia rheumatica	19	41
Polymyositis		3
Posture abnormal	3	6
Psoriatic arthropathy	12	25
Purple glove syndrome	1	1
Rhabdomyolysis	9	24
Rheumatic disorder	4	9
Rheumatic fever	1	1
Rheumatoid arthritis	62	138
Rotator cuff syndrome	7	14
Sacroiliitis	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
	1	2	9	7	23
		3	23	2	10
2	4	230	931	207	727
		3	15	1	18
					1
				1	2
		5	14	5	15
		1	1		
		1	2		
				2	2
			1		
		1	2		1
8	45	1824	6788	963	3512
1	1	37	143	35	129
				1	1
				1	1
	1	1	9	9	32
		2	3	1	5
				11	25
				2	4
				19	41
					3
		3	5		1
				12	25
				1	1
				9	24
		2	5	2	4
				1	1
2	3		1	62	137
			3	7	11
		2	3	2	4

\* I=Interval, C=Cumulative  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SAPHO syndrome		1
Scleroderma	2	2
Scoliosis	1	1
Seronegative arthritis		2
Sinus tarsi syndrome		1
Sjogren's syndrome	6	13
SLE arthritis		2
Soft tissue atrophy	1	1
Soft tissue disorder		1
Soft tissue haemorrhage		1
Soft tissue swelling	7	9
Somatic dysfunction		1
Spinal disorder	2	8
Spinal osteoarthritis	2	7
Spinal pain	25	121
Spinal stenosis	1	3
Spondylitis	2	4
Still's disease	1	1
Symphysiolysis		1
Synovial cyst	7	23
Synovial disorder		1
Synovitis		6
Systemic lupus erythematosus	14	31
Systemic scleroderma		1
Temporomandibular joint syndrome	3	15
Tendon discomfort		1
Tendon disorder		5
Tendonitis	14	38
Tendon pain	7	20
Tenosynovitis	3	11
Tenosynovitis stenosans	1	2
Torticollis	1	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	2
				1	1
			1		2
				6	13
					2
				1	1
			1		
			1		
		4	5	3	4
					1
			3	2	5
		1	5	1	2
		10	71	15	50
			2	1	1
				2	4
				1	1
					1
		3	6	4	17
			1		
			2		4
	1	1	1	13	30
					1
		1	10	2	5
			1		
			2		3
		5	15	9	23
		3	11	4	9
		1	6	2	5
				1	2
		1	10		3

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\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Trigger finger	7	11			6	8	1	3
Trismus	10	26			4	13	6	13
Undifferentiated connective tissue disease		1						1
Vertebral lesion	1	1					1	1
Vertebral wedging		1						1
Weight bearing difficulty	5	13			3	5	2	8
Winged scapula		1				1		
	11,924	46,120	47	213	7038	27435	4886	18685

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acoustic neuroma	3	4			3	4
Acrochordon		1				1
Acute leukaemia		3				3
Acute lymphocytic leukaemia	1	1			1	1
Acute myeloid leukaemia	2	7			2	7
Adenoma benign		1		1		
Angiomyolipoma		1				1
Basal cell carcinoma	1	3			1	3
B-cell lymphoma	1	3			1	3
B-cell type acute leukaemia		1				1
Benign breast neoplasm		1		1		
Bladder cancer		1				1
Bladder neoplasm	1	1			1	1
Blast cell crisis		1				1
Bone neoplasm	2	4	1	2	1	2
Brain cancer metastatic	1	1			1	1
Brain neoplasm	2	5			2	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast cancer	7	13			7	13
Breast cancer metastatic		1				1
Breast cancer stage III	1	1			1	1
Cardiac neoplasm unspecified		1				1
Chronic lymphocytic leukaemia	4	5			4	5
Chronic myeloid leukaemia recurrent		1				1
Colon cancer	1	2			1	2
Diffuse large B-cell lymphoma	1	1			1	1
Ear neoplasm		1		1		
Essential thrombocythaemia		1				1
Fibroma		2		2		
Gastric cancer		1				1
Gastrointestinal carcinoma	1	1			1	1
Good syndrome		1				1
Haemangioma		2		1		1
Invasive ductal breast carcinoma	1	1			1	1
Kaposi's sarcoma AIDS related		1				1
Leukaemia	4	10		1	4	9
Leukaemia recurrent	1	1			1	1
Lipoma	3	6	2	3	1	3
Lung carcinoma cell type unspecified stage I		1				1
Lung neoplasm malignant	3	7			3	7
Lymphangioma		1				1
Lymphoma	6	18			6	18
Lymphoproliferative disorder	1	1			1	1
Malignant lymphoid neoplasm		1				1
Malignant melanoma		1				1
Malignant pleural effusion	1	1			1	1
Melanocytic naevus		1				1
Melanoma recurrent	2	2			2	2
Meningioma	1	1			1	1
Metastases to lymph nodes		7				7

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Metastases to meninges		1					1
Metastases to peritoneum		2					2
Metastasis	1	2			1		2
Metastatic neoplasm	1	1			1		1
Monoclonal gammopathy	3	3	1	1	2		2
Myelodysplastic syndrome	1	3			1		3
Myelof brosis		1					1
Neoplasm	11	15	6	9	5		6
Neoplasm malignant	7	16			7		16
Neoplasm progression	1	5		1	1		4
Neoplasm skin	1	4	1	3			1
Non-Hodgkin's lymphoma	1	4			1		4
Oligodendroglioma	1	1			1		1
Ovarian cancer		1					1
Pancreatic carcinoma	2	3			2		3
Phaeochromocytoma		1					1
Pituitary tumour benign		1					1
Plasma cell myeloma		2					2
Primary gastrointestinal follicular lymphoma		1					1
Prostate cancer	3	6			3		6
Renal cancer	1	2			1		2
Sarcoma		1					1
Second primary malignancy		1					1
Skin cancer		1					1
Skin papilloma		1					1
TEMPI syndrome		1					1
Testicular neoplasm	1	1			1		1
Thyroid cancer	1	1			1		1
Triple negative breast cancer	1	1			1		1
Tumour perforation		1					1
	89	218	11	26	78		192

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acoustic neuritis		3				1		2
Acute disseminated encephalomyelitis	3	8					3	8
Acute motor axonal neuropathy	1	2					1	2
Acute polyneuropathy		1						1
Adrenergic syndrome		1				1		
Ageusia	122	481	2	3	85	323	37	158
Agnosia	1	1					1	1
Akathisia	1	4			1	3		1
Akinesia	2	3					2	3
Alexia		2				1		1
Allodynia	5	17			2	9	3	8
Altered state of consciousness	25	81		1			25	81
Amnesia	56	143			18	52	38	91
Amnesic disorder	1	3					1	3
Anaesthesia	5	42			4	35	1	7
Anaesthesia dolorosa	1	1					1	1
Anosmia	90	385	2	2	60	271	30	114
Anterograde amnesia	1	3					1	3
Anticholinergic syndrome		1						1
Apallic syndrome	1	3					1	3
Aphasia	89	206	1	1	16	53	73	153
Apraxia	1	3				1	1	2
Arachnoid cyst		1						1
Areflexia	2	7			1	1	1	6
Asterixis	1	1					1	1
Ataxia	16	36			6	10	10	26
Atonic seizures	1	4					1	4
Aura	6	21			2	11	4	10
Autoimmune demyelinating disease		1						1
Autonomic nervous system imbalance	5	16			3	5	2	11
Autonomic neuropathy	1	1					1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Axonal neuropathy	1	4
Balance disorder	158	492
Band sensation		6
Basal ganglia haemorrhage	1	5
Basal ganglia infarction	1	2
Basal ganglia stroke	2	4
Basilar artery occlusion	1	2
Basilar artery thrombosis	4	7
Basilar migraine	1	1
Brachial plexopathy		3
Bradykinesia	7	20
Brain compression	1	2
Brain hypoxia	1	3
Brain injury	3	12
Brain oedema	3	15
Brain stem haemorrhage	1	4
Brain stem infarction	3	3
Brain stem ischaemia	1	2
Brain stem stroke	4	6
Brain stem syndrome		6
Bulbar palsy	1	1
Burning feet syndrome		1
Burning sensation	191	623
Burning sensation mucosal		5
Carotid arteriosclerosis	1	2
Carotid artery disease	1	1
Carotid artery dissection	1	4
Carotid artery occlusion	7	8
Carotid artery stenosis	1	2
Carotid artery thrombosis	4	5
Carpal tunnel syndrome	8	12
Cataplexy	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		3
2	3	59	204	99	288
			4		2
				1	5
				1	2
				2	4
				1	2
				4	7
				1	1
			1		2
		4	10	3	10
				1	2
				1	3
				3	12
				3	15
				1	4
				3	3
				1	2
				4	6
					6
				1	1
					1
		117	367	74	256
			4		1
			1	1	1
				1	1
				1	4
				7	8
				1	2
				4	5
		3	5	5	7
				1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Central nervous system inflammation	1	1
Central nervous system lesion	2	6
Central nervous system vasculitis	1	1
Central pain syndrome		2
Cerebellar ataxia	2	4
Cerebellar atrophy		1
Cerebellar haematoma	2	2
Cerebellar haemorrhage	2	4
Cerebellar infarction	3	7
Cerebellar ischaemia	1	1
Cerebellar stroke	3	8
Cerebellar syndrome	1	7
Cerebral amyloid angiopathy	1	2
Cerebral arteriosclerosis	1	1
Cerebral artery embolism	4	5
Cerebral artery occlusion	6	6
Cerebral artery stenosis		1
Cerebral artery thrombosis	7	7
Cerebral atrophy	1	6
Cerebral congestion	1	1
Cerebral disorder	2	13
Cerebral haematoma	5	15
Cerebral haemorrhage	69	132
Cerebral infarction	68	118
Cerebral ischaemia	20	31
Cerebral microangiopathy	1	1
Cerebral small vessel ischaemic disease		1
Cerebral thrombosis	31	44
Cerebral venous sinus thrombosis	27	35
Cerebral venous thrombosis	9	11
Cerebrospinal fluid leakage	1	2
Cerebrovascular accident	305	684

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2	1	4
				1	1
			1		1
		1	2	1	2
					1
				2	2
				2	4
				3	7
				1	1
				3	8
				1	7
				1	2
				1	1
				4	5
				6	6
					1
				7	7
				1	6
				1	1
		2	9		4
				5	15
				69	132
				68	118
				20	31
				1	1
					1
				31	44
				27	35
				9	11
				1	2
2	2			305	684

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cerebrovascular disorder	3	7
Cerebrovascular insufficiency	1	1
Cervical cord compression	1	1
Cervical neuritis		1
Cervical radiculopathy	4	10
Cervicobrachial syndrome	2	15
Cervicogenic headache	1	2
Cholinergic syndrome	2	6
Chorea		5
Chronic inflammatory demyelinating polyradiculoneuropathy	1	4
Circadian rhythm sleep disorder	4	5
Clonic convulsion		4
Clonus	3	12
Clumsiness	4	12
Cluster headache	24	77
Cognitive disorder	20	95
Cold-stimulus headache	3	5
Coma	11	40
Coma hepatic		1
Complex regional pain syndrome	4	10
Consciousness fluctuating	1	7
Conus medullaris syndrome	1	1
Convulsions local	1	3
Coordination abnormal	24	70
Cramp-fasciculation syndrome	1	1
Cranial nerve disorder		9
Cranial nerve palsies multiple	2	2
Cranial nerve paralysis		2
Decreased vibratory sense	2	3
Dementia	12	47
Dementia Alzheimer's type	2	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	7
				1	1
				1	1
			1		
		1	5	3	5
		1	7	1	8
		1	1		1
				2	6
			1		4
				1	4
		3	4	1	1
					4
		1	4	2	8
		1	5	3	7
		9	25	15	52
1	1	5	30	15	65
		1	1	2	4
				11	40
					1
		1	4	3	6
				1	7
				1	1
				1	3
1	1	8	18	16	52
				1	1
			4		5
				2	2
					2
				2	3
				12	47
				2	11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dementia of the Alzheimer's type, with delirium		1
Dementia with Lewy bodies		1
Demyelinating polyneuropathy	2	7
Demyelination	6	14
Depressed level of consciousness	54	243
Diabetic coma	2	3
Diabetic hyperosmolar coma	1	1
Diabetic neuropathy		1
Diplegia	5	17
Disturbance in attention	117	413
Dizziness	2,249	8,639
Dizziness exertional	9	27
Dizziness postural	93	330
Dreamy state	1	3
Drop attacks	9	24
Drop attacks		1
Dropped head syndrome		2
Dysaesthesia	20	90
Dysarthria	81	235
Dysdiadochokinesis	1	1
Dysgeusia	223	1,002
Dysgraphia	6	13
Dyskinesia	48	111
Dyslalia	2	4
Dyslexia	2	4
Dysmetria	3	4
Dyspraxia	1	1
Dysstasia	66	206
Dystonia	11	21
Embolic cerebral infarction	3	4
Embolic stroke	11	16
Encephalitis autoimmune	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				2	7
				6	14
	1	1	1	53	242
				2	3
			1		1
				5	17
1	2	45	191	72	222
1	59	1307	4910	942	3729
		1	5	8	22
	1	42	120	51	210
		1	2		1
		3	13	6	11
					1
					2
		10	49	10	41
1	1	20	61	61	174
				1	1
3	4	163	697	60	305
		2	6	4	7
		19	55	29	56
		1	1	1	3
			1	2	3
				3	4
				1	1
		26	91	40	115
		1	1	10	20
				3	4
				11	16
				2	2

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Encephalitis post immunisation		2
Encephalopathy	2	14
Epilepsy	80	234
Epileptic aura		1
Epileptic encephalopathy		1
Essential tremor	1	4
Exaggerated startle response	1	1
Exertional headache	1	4
Extensor plantar response	1	4
Extrapyramidal disorder	4	8
Facial nerve disorder	3	23
Facial neuralgia	4	18
Facial paralysis	410	1,274
Facial paresis	72	248
Facial spasm	6	23
Febrile convulsion	21	73
Fine motor skill dysfunction	4	13
Focal dyscognitive seizures	3	4
Foetal movement disorder		1
Formication	14	60
Freezing phenomenon	2	5
Fumbling		1
Generalised onset non-motor seizure		1
Generalised tonic-clonic seizure	29	106
Glabellar reflex abnormal		1
Gliosis		1
Glossopharyngeal nerve disorder	1	1
Gross motor delay		1
Guillain-Barre syndrome	51	109
Haemorrhage intracranial	4	11
Haemorrhagic cerebral infarction		1
Haemorrhagic stroke	16	37

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				2	14
				80	234
					1
					1
		1	1		3
		1	1		
		1	2		2
		1	2		2
		1	2	3	6
		2	15	1	8
		4	8		10
2	4	2	5	408	1269
		26	81	46	167
		4	12	2	11
		15	38	6	35
		2	6	2	7
				3	4
					1
		8	29	6	31
		1	2	1	3
					1
					1
				29	106
			1		
					1
				1	1
					1
			1	51	108
				4	11
					1
				16	37

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemorrhagic transformation stroke	1	2
Hand-arm vibration syndrome		2
Hand-eye coordination impaired		2
Headache	6,217	25,397
Head discomfort	128	397
Head titubation	3	6
Hemianaesthesia	3	36
Hemianopia	3	6
Hemianopia heteronymous		1
Hemianopia homonymous	4	6
Hemiapraxia	1	1
Hemidysaesthesia		8
Hemihyperaesthesia	1	3
Hemiparaesthesia	14	62
Hemiparesis	68	172
Hemiplegia	39	84
Hemiplegic migraine	2	5
Hippocampal atrophy		1
Hoffmann's sign		1
Horner's syndrome	1	4
Hydrocephalus	2	2
Hyperaesthesia	47	167
Hypergeusia		1
Hyperintensity in brain deep nuclei	1	1
Hyperkinesia		1
Hyperreflexia	1	6
Hypersomnia	77	294
Hypertensive encephalopathy	1	2
Hypertonia	3	15
Hypoaesthesia	715	2,471
Hypogeusia	1	18
Hypoglossal nerve disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					2
					2
14	118	3935	15686	2282	9711
		68	244	60	153
		1	4	2	2
				3	36
				3	6
					1
				4	6
				1	1
					8
				1	3
				14	62
		1	1	67	171
				39	84
				2	5
					1
			1		
				1	4
				2	2
		26	102	21	65
					1
				1	1
			1		
		1	3		3
		44	176	33	118
				1	2
		2	7	1	8
1	8	396	1409	319	1062
			15	1	3
					1

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoglossal nerve paresis	1	1
Hypoglycaemic coma		2
Hypokinesia	53	118
Hyporeflexia	2	15
Hyporesponsive to stimuli		11
Hyposmia	4	23
Hypotonia	23	69
Hypotonic-hyporesponsive episode	3	29
Hypoxic-ischaemic encephalopathy		1
Idiopathic intracranial hypertension	4	6
IIIrd nerve disorder	2	3
IIIrd nerve paralysis	5	13
IIIrd nerve paresis	1	2
Inability to crawl	1	1
Incoherent	14	28
Infant irritability	2	8
Intention tremor	1	2
Intercostal neuralgia	1	4
Intracranial aneurysm	4	7
Intracranial haematoma		1
Intracranial mass	1	1
Intracranial pressure increased	5	8
Intraventricular haemorrhage	2	3
Irregular sleep wake rhythm disorder	1	3
Ischaemic cerebral infarction	19	36
Ischaemic stroke	89	186
IVth nerve disorder	1	2
IVth nerve paralysis	1	6
IVth nerve paresis		1
Lacunar infarction	2	6
Lacunar stroke	5	7
Language disorder	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
		20	60	33	58
			5	2	10
			3		8
		4	17		6
		12	34	11	35
			5	3	24
					1
				4	6
				2	3
				5	13
				1	2
				1	1
		5	11	9	17
		1	5	1	3
				1	2
		1	1		3
				4	7
					1
				1	1
				5	8
				2	3
		1	3		
				19	36
				89	186
				1	2
				1	6
					1
				2	6
				5	7
		1	1	3	8

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lateral medullary syndrome	1	1
Lateropulsion	1	2
Lennox-Gastaut syndrome		1
Lethargy	359	1,228
Leukoencephalopathy	3	7
Lhermitte's sign	2	3
Locked-in syndrome	1	2
Long thoracic nerve palsy		1
Loss of consciousness	383	1,119
Loss of proprioception		3
Lumbar radiculopathy		1
Medication overuse headache		1
Memory impairment	65	185
Meningeal disorder		3
Meningism	2	9
Meningitis noninfective		1
Meningoradiculitis	2	2
Meningorrhagia	1	1
Mental impairment	25	90
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Migraine	390	1,495
Migraine with aura	36	107
Migraine without aura	5	6
Mononeuropathy		5
Mononeuropathy multiplex	1	1
Monoparesis	22	58
Monoplegia	17	73
Morton's neuralgia		1
Motor dysfunction	26	68
Movement disorder	77	263
Multiple sclerosis	13	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
					1
1	6	198	599	161	629
				3	7
		1	2	1	1
				1	2
			1		
		2	5	381	1114
					3
			1		
					1
		37	93	28	92
			1		2
		1	4	1	5
					1
				2	2
				1	1
	1			25	90
					1
					1
5	7	140	666	250	829
	1	13	42	23	65
		1	1	4	5
					5
				1	1
		2	11	20	47
				17	73
					1
		3	21	23	47
		37	143	40	120
				13	47

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Multiple sclerosis relapse	15	41
Muscle contractions involuntary	11	58
Muscle spasticity	3	14
Muscle tone disorder		2
Myasthenia gravis	6	17
Myasthenia gravis crisis	4	6
Myelitis transverse	9	34
Myelopathy	1	3
Myoclonic epilepsy	1	1
Myoclonus	7	34
Narcolepsy	6	12
Nerve compression	13	37
Nerve degeneration		2
Nervous system disorder	33	96
Neuralgia	106	357
Neuralgic amyotrophy	7	19
Neuritis	7	36
Neuritis cranial		2
Neurological decompensation	1	2
Neurological symptom	13	41
Neurologic neglect syndrome	2	4
Neuromuscular pain	1	3
Neuromyelitis optica spectrum disorder	2	3
Neuromyopathy		3
Neuronal neuropathy	1	1
Neuropathy peripheral	87	204
Neurotoxicity		2
New daily persistent headache		1
Noninfective encephalitis		6
Normal pressure hydrocephalus	1	1
Numb chin syndrome		1
Nystagmus	9	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				15	41
		7	33	4	25
		1	3	2	11
					2
				6	17
				4	6
				9	34
				1	3
				1	1
		1	7	6	27
				6	12
		8	26	5	11
					2
		11	30	22	66
	1	42	162	64	195
	1		5	7	14
		5	23	2	13
					2
		1	1		1
	1	3	11	10	30
				2	4
			1	1	2
				2	3
					3
				1	1
		2	4	85	200
					2
			1		
					6
				1	1
					1
		2	10	7	23

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Occipital neuralgia	5	15
Oculofacial paralysis	2	2
On and off phenomenon		1
Ophthalmoplegic migraine	1	1
Opisthotonus	1	2
Optic neuritis	11	32
Oromandibular dystonia		1
Orthostatic intolerance	3	5
Orthostatic tremor	1	1
Paraesthesia	861	3,704
Paraesthesia mucosal	1	7
Paralysis	50	149
Paraparesis	6	16
Paraplegia	2	4
Paresis	12	37
Paresis cranial nerve		3
Parkinsonian rest tremor		1
Parkinsonism	4	9
Parkinson's disease	8	21
Parosmia	50	159
Partial seizures	5	22
Patient elopement	1	4
Peripheral motor neuropathy	1	3
Peripheral nerve palsy	1	1
Peripheral nerve paresis	1	2
Peripheral paralysis	1	2
Peripheral sensorimotor neuropathy		1
Peripheral sensory neuropathy	3	15
Peroneal nerve palsy	4	16
Persistent postural-perceptual dizziness	1	4
Petit mal epilepsy	10	41
Phantom limb syndrome		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6	3	9
				2	2
			1		
		1	1		
				1	2
				11	32
			1		
		2	2	1	3
		1	1		
1	9	480	2116	381	1588
			2	1	5
	1			50	149
				6	16
				2	4
		4	10	8	27
			1		2
			1		
		1	2	3	7
				8	21
		24	98	26	61
				5	22
			2	1	2
				1	3
				1	1
				1	2
				1	2
					1
		1	5	2	10
		2	6	2	10
			1	1	3
				10	41
			1		2

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pineal gland cyst	1	1
Pleocytosis	1	4
Polyneuropathy	9	22
Poor quality sleep	37	171
Posterior reversible encephalopathy syndrome	2	3
Post herpetic neuralgia	2	10
Postictal paralysis	1	1
Postictal state		6
Post stroke epilepsy	1	1
Post stroke seizure		1
Post-traumatic neuralgia		1
Postural tremor		1
Presyncope	226	875
Primary cough headache		3
Primary headache associated with sexual activity		1
Progressive supranuclear palsy	1	1
Psychogenic seizure	1	5
Psychomotor hyperactivity	10	31
Psychomotor skills impaired	2	5
Pyramidal tract syndrome		1
Quadrantanopia	1	2
Quadriparesis	1	6
Quadriplegia	2	3
Radial nerve palsy	3	3
Radicular pain		1
Radiculitis brachial	1	10
Radiculopathy	2	14
Reduced facial expression	6	14
Reflexes abnormal	2	3
Repetitive speech		1
Resting tremor		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1	1	3
				9	22
	1	21	102	16	69
			4	2	3
				1	1
			3		3
				1	1
					1
			1		
			1		
	2	136	438	90	437
			1		2
					1
				1	1
			1	1	4
		4	13	6	18
			2	2	3
					1
				1	2
				1	6
				2	3
		1	1	2	2
			1		
		1	6		4
			5	2	9
		2	7	4	7
		1	1	1	2
					1
			1		1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restless legs syndrome	14	49
Retinal migraine	2	9
Retrograde amnesia	2	5
Reversed hot-cold sensation		1
Reversible cerebral vasoconstriction syndrome		2
Ruptured cerebral aneurysm		5
Sciatica	12	63
Sciatic nerve neuropathy		2
Sedation	3	21
Seizure	227	648
Seizure anoxic		1
Seizure cluster		4
Seizure like phenomena	2	8
Senile dementia		1
Sensorimotor disorder	1	6
Sensory disturbance	45	146
Sensory loss	37	111
Serotonin syndrome		2
Sinus headache	52	147
Sleep deficit	4	13
Sleep paralysis	1	8
Slow response to stimuli	2	7
Slow speech	7	15
Small fiber neuropathy		1
Somnolence	328	1,406
Spasmodic dysphonia		1
Speech disorder	94	295
Spinal cord compression	1	2
Spinal cord disorder		4
Spinal cord infarction	2	2
Spinal cord ischaemia	3	3
Spinal epidural haemorrhage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	21	8	28
			2	2	7
		1	2	1	3
					1
					2
					5
		9	31	3	32
					2
		1	12	2	9
		1	1	226	647
					1
					4
				2	8
					1
		1	1		5
		27	90	18	56
		16	50	21	61
					2
	1	30	73	22	74
		3	7	1	6
		1	6		2
		1	4	1	3
		4	6	3	9
					1
1	3	190	848	138	558
			1		
1	2	32	133	62	162
				1	2
					4
				2	2
				3	3
				1	1

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Spinal meningeal cyst	1	1
Status epilepticus	18	47
Status migrainosus		2
Stiff leg syndrome		1
Stiff person syndrome	1	1
Stroke in evolution		1
Stupor	3	16
Subacute inflammatory demyelinating polyneuropathy	1	1
Subarachnoid haemorrhage	19	37
Sudden onset of sleep	2	6
Superior sagittal sinus thrombosis	2	4
Sympathicotonia		1
Syncope	542	1,780
Tardive dyskinesia	2	3
Taste disorder	74	261
Temporal lobe epilepsy	1	2
Tension headache	66	206
Thalamic infarction	2	4
Thermohypoaesthesia		1
Thoracic outlet syndrome		2
Thrombotic cerebral infarction	2	2
Thrombotic stroke	4	6
Thunderclap headache		5
Tongue biting	4	9
Tongue paralysis	5	8
Tonic clonic movements	3	17
Tonic convulsion	4	17
Toxic neuropathy	1	1
Transient aphasia	3	4
Transient global amnesia	3	11
Transient ischaemic attack	156	262

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				18	47
					2
					1
				1	1
					1
			4	3	12
				1	1
				19	37
				2	6
				2	4
					1
2	7	2	6	540	1774
				2	3
		47	167	27	94
				1	2
	2	30	82	36	124
			1	2	4
			1		
			1		1
				2	2
				4	6
					5
		2	2	2	7
				5	8
				3	17
				4	17
				1	1
				3	4
		1	3	2	8
1	1	1	1	155	261

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Transverse sinus stenosis	1	1
Transverse sinus thrombosis	1	1
Tremor	405	1,701
Trigeminal nerve disorder	5	19
Trigeminal nerve paresis	1	1
Trigeminal neuralgia	14	47
Trigeminal neuritis		3
Trigeminal palsy	1	2
Tumefactive multiple sclerosis	1	1
Tunnel vision	8	30
Typical aura without headache	1	2
Ulnar nerve palsy	1	2
Ulnar neuritis	1	1
Unresponsive to stimuli	33	129
Vagus nerve disorder	1	3
Vascular dementia	1	7
Vascular encephalopathy	1	4
Vascular headache	1	7
Vertebral artery dissection	3	4
Vertebral artery stenosis	1	1
Vertebral artery thrombosis		1
Vertebrobasilar stroke	1	1
Vestibular migraine	5	10
VIIIth nerve lesion		1
Visual field defect	13	45
Visual perseveration	1	1
VIth nerve disorder		1
VIth nerve paralysis	10	20
VIth nerve paresis	1	1
Vocal cord paralysis		3
White matter lesion	2	7
Writer's cramp		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
	6	229	801	176	900
		2	8	3	11
		6	18	8	29
			1		2
				1	2
				1	1
				8	30
				1	2
			1	1	1
				1	1
				33	129
				1	3
				1	7
				1	4
		1	3		4
				3	4
				1	1
					1
				1	1
		1	2	4	8
					1
		4	19	9	26
				1	1
					1
				10	20
		1	1		
					3
		1	4	1	3
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	18,308	67,004	46	265	8501	32869	9807	34135

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion	3	4			3	4
Abortion missed	6	12			6	12
Abortion spontaneous	59	134			59	134
Anembryonic gestation	2	2			2	2
Cephalhaematoma	1	1			1	1
Ectopic pregnancy		2				2
Foetal death	5	10			5	10
Foetal growth restriction	1	4			1	4
Foetal hypokinesia	2	2			2	2
Gestational diabetes	1	2			1	2
Haemorrhage in pregnancy	1	1			1	1
Morning sickness	1	10		1	1	9
Oligohydramnios		1				1
Postpartum haemorrhage		1		1		
Pregnancy	1	4		3	1	1
Pregnancy with contraceptive device	2	2			2	2
Premature baby	5	10			5	10
Premature delivery		2				2
Premature labour	2	3			2	3
Premature rupture of membranes		1				1
Preterm premature rupture of membranes		2				2
Small for dates baby	1	1			1	1
Stillbirth	2	2			2	2
Threatened labour		1		1		

\* I=Interval, C=Cumulative  
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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Twin pregnancy		1		1		
Uterine contractions abnormal		2		1		1
Uterine contractions during pregnancy		2		1		1
	95	219		9	95	210

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device breakage		1				1
Device infusion issue		1				1
Device leakage	1	1	1	1		
Device pacing issue	1	1			1	1
Device stimulation issue		1		1		
Embedded device	1	1			1	1
Liquid product physical issue	2	38	2	38		
Needle issue	4	19	4	17		2
Oversensing	3	8	1	2	2	6
Product colour issue	3	42	3	42		
Product complaint	10	35	9	33	1	2
Product container issue		3		3		
Product contamination		1		1		
Product contamination physical	1	3	1	3		
Product deposit		1		1		
Product formulation issue		1				1
Product leakage	1	16	1	16		
Product lot number issue		1		1		
Product odour abnormal		1		1		
Product packaging quantity issue		22		22		
Product physical issue		2		2		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product quality issue	9	24	9	24		
Product supply issue	12	28	12	28		
Product taste abnormal		1		1		
Product temperature excursion issue	63	468	63	466		2
Suspected counterfeit product	4	7	4	7		
Suspected product quality issue		5		5		
Syringe issue	1	9	1	9		
Thrombosis in device	1	2			1	2
Undersensing	1	1			1	1
	118	744	111	724	7	20

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour	12	27			5	13	7	14
Abnormal dreams	29	100			22	70	7	30
Acute psychosis	3	3					3	3
Acute stress disorder	1	3					1	3
Adjustment disorder with depressed mood	1	1					1	1
Affective disorder	3	5			2	4	1	1
Affect lability	5	9			2	4	3	5
Aggression	15	33			5	11	10	22
Agitated depression		1						1
Agitation	35	154		1	16	74	19	80
Alcoholic hangover		1						1
Alexithymia		1				1		
Anger	2	15			1	10	1	5
Anhedonia	1	1			1	1		
Anorgasmia		1						1

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Anxiety	192	722
Anxiety disorder	1	3
Anxiety disorder due to a general medical condition		1
Apathy	16	61
Attention deficit hyperactivity disorder	3	3
Autism spectrum disorder	1	1
Automatism		1
Autoscopy	6	10
Aversion	1	1
Behaviour disorder	5	14
Belligerence		1
Binge eating		1
Bipolar disorder	1	3
Bipolar I disorder	1	1
Body dysmorphic disorder		1
Bradyphrenia	15	43
Breathing-related sleep disorder	1	1
Bruxism	2	6
Bulimia nervosa		1
Catatonia		4
Change in sustained attention	1	1
Claustrophobia		1
Clinomania	1	1
Communication disorder	3	19
Completed suicide	1	1
Compulsions		1
Confusional arousal		1
Confusional state	252	847
Constricted affect		1
Conversion disorder	3	5
Cyclothymic disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		116	424	76	298
		1	2		1
			1		
		8	26	8	35
		1	1	2	2
				1	1
					1
		2	4	4	6
		1	1		
			1	5	13
					1
					1
				1	3
				1	1
					1
		7	17	8	26
		1	1		
			2	2	4
					1
			2		2
		1	1		
			1		
		1	1		
		1	9	2	10
				1	1
					1
					1
4	7	79	292	173	555
					1
		2	3	1	2
					1

\* I=Interval, C=Cumulative  
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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Daydreaming	4	8
Decreased interest	3	11
Deja vu	1	1
Delirium	61	168
Delirium febrile	1	3
Delusion	8	22
Delusional disorder, unspecified type		1
Delusional perception	1	4
Depersonalisation/derealisation disorder	2	7
Depressed mood	41	150
Depression	39	127
Depression suicidal	1	2
Derealisation	2	14
Discouragement	1	2
Disinhibition		1
Disorganised speech	4	12
Disorientation	98	305
Dissociation	5	25
Dissociative amnesia	1	1
Dissociative disorder		2
Distractibility		2
Disturbance in social behaviour		2
Drug abuse	1	1
Dysphemia	8	20
Dysphoria	8	13
Dyssomnia	1	1
Eating disorder	30	88
Emotional disorder	13	40
Emotional distress	11	29
Emotional poverty	1	1
Enuresis	3	8
Euphoric mood	12	30

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	2	4
		1	5	2	6
				1	1
				61	168
				1	3
		1	9	7	13
					1
		1	2		2
		1	5	1	2
	1	21	65	20	85
		15	45	24	82
				1	2
			8	2	6
		1	2		
					1
			3	4	9
	2	36	112	62	193
		2	14	3	11
		1	1		
			1		1
			2		
			2		
				1	1
		2	7	6	13
		3	4	5	9
		1	1		
		16	53	14	35
		9	23	4	17
		6	12	5	17
				1	1
			2	3	6
		9	19	3	11

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Exploding head syndrome		1
Factitious disorder	1	1
Fear	17	62
Fear of death	4	7
Fear of falling	1	3
Fear of injection	1	4
Feeling of despair	4	10
Flashback	1	2
Flat affect	1	4
Frustration tolerance decreased	3	12
Gastrointestinal somatic symptom disorder	1	1
Generalised anxiety disorder	1	3
Grief reaction	1	1
Habit cough	3	3
Hallucination	53	189
Hallucination, auditory	8	30
Hallucination, olfactory	2	8
Hallucinations, mixed	3	9
Hallucination, tactile		2
Hallucination, visual	22	54
Head banging	2	5
Helplessness	1	3
Hostility	1	1
Hydrophobia		1
Hypersexuality		1
Hypersomnia-bulimia syndrome		1
Hypervigilance	1	3
Hypnagogic hallucination		2
Hypomania		1
Hyposomnia		1
Illness anxiety disorder		1
Illusion	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		9	43	8	19
		2	4	2	3
			1	1	2
		1	4		
		1	4	3	6
				1	2
		1	2		2
		3	11		1
		1	1		
		1	2		1
				1	1
		1	1	2	2
				53	189
				8	30
				2	8
				3	9
					2
				22	54
		1	3	1	2
			1	1	2
				1	1
			1		
					1
					1
		1	2		1
					2
					1
			1		1
			3	1	3

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Immunisation anxiety related reaction	2	14
Impaired reasoning		1
Imperception	1	1
Impulsive behaviour		1
Inappropriate affect	2	3
Indifference	1	4
Initial insomnia	6	33
Insomnia	384	1,480
Intentional self-injury	1	3
Intrusive thoughts	2	3
Irritability	67	212
Lack of spontaneous speech	4	8
Laziness	1	7
Learning disability		1
L bido decreased		2
L bido increased		1
Listless	11	23
Logorrhoea	1	5
Loss of libido	3	6
Major depression	5	7
Mania	2	9
Mental disorder	13	40
Mental fatigue	18	76
Mental status changes	5	9
Middle insomnia	22	116
Mood altered	6	26
Mood disorder due to a general medical condition		1
Mood swings	2	15
Morose		3
Mutism	4	12
Near death experience	14	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			10	2	4
				1	1
			1		
		1	1	1	2
			1	1	3
		4	23	2	10
		215	884	169	596
				1	3
		1	2	1	1
		44	146	23	66
			1	4	7
		1	6		1
					1
			1		1
			1		
		8	12	3	11
			1	1	4
		2	3	1	3
				5	7
		1	2	1	7
		8	27	5	13
		5	16	13	60
		3	5	2	4
		10	78	12	38
		3	14	3	12
					1
		1	5	1	10
			2		1
		2	6	2	6
		1	1	13	31

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Negative thoughts	1	3
Nervousness	70	264
Neuropsychiatric symptoms		1
Nightmare	26	106
Obsessive-compulsive symptom		1
Obsessive thoughts		1
Organic brain syndrome		2
Osmophobia		1
Panic attack	34	95
Panic disorder	5	11
Panic reaction	11	42
Paramnesia	1	2
Paranoia	3	18
Persecutory delusion	1	2
Persistent depressive disorder		3
Personality change	3	20
Personality disorder		1
Phobia	1	1
Phonophobia		5
Post-traumatic stress disorder	1	4
Posturing		1
Pressure of speech		3
Pseudodementia		1
Psychiatric symptom	2	7
Psychological factor affecting medical condition		1
Psychomotor retardation	1	2
Psychotic behaviour		1
Psychotic disorder	8	18
Psychotic disorder due to a general medical condition		1
Psychotic symptom		4
Purging	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
		48	159	22	105
			1		
		14	63	12	43
					1
					1
					2
					1
		19	47	15	48
		5	8		3
		8	26	3	16
				1	2
		2	9	1	9
			1	1	1
			1		2
		1	5	2	15
			1		
				1	1
			2		3
			2	1	2
					1
			1		2
					1
		1	3	1	4
					1
				1	2
					1
		2	3	6	15
					1
					4
				1	1

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Reading disorder		3
Restlessness	57	212
Schizophrenia	2	3
Self-injurious ideation	2	4
Sense of a foreshortened future		4
Sitophobia		1
Sleep attacks	1	4
Sleep disorder	123	378
Sleep disorder due to a general medical condition	3	23
Sleep disorder due to general medical condition, hypersomnia type		1
Sleep disorder due to general medical condition, insomnia type	10	35
Sleep inertia		1
Sleep talking	2	6
Sleep terror	3	8
Social avoidant behaviour		1
Social fear		1
Soliloquy	1	2
Somatic symptom disorder	2	9
Somnambulism	1	3
Sopor	5	14
Speech sound disorder	2	2
Staring	3	9
Stereotypy		3
Stress	28	93
Substance abuse		1
Suicidal behaviour	1	1
Suicidal ideation	12	30
Suicide attempt	2	6
Suspiciousness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		24	114	33	98
				2	3
		1	1	1	3
			2		2
			1		
		1	2		2
		76	229	47	149
		3	17		6
			1		
		2	16	8	19
					1
		2	5		1
			3	3	5
					1
					1
		1	2		
		2	4		5
		1	3		
1	2		4	5	10
		2	2		
			1	3	8
					3
		17	68	11	25
					1
				1	1
				12	30
				2	6
			1		

\* I=Interval, C=Cumulative  
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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Tachyphrenia		8				6			2
Tearfulness	9	24			3	8	6		16
Tension	5	29			3	22	2		7
Terminal insomnia	2	11			1	8	1		3
Thanatophobia		1				1			
Thinking abnormal	15	57			10	40	5		17
Thought blocking		1							1
Tic	2	10				4	2		6
Time perception altered	1	1			1	1			
Trance	1	1			1	1			
Vomiting psychogenic		1							1
	2,148	7,426	5	13	986	3610	1162		3816

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Acute kidney injury	38	124					38		124
A buminuria	1	2		1			1		2
Anti-glomerular basement membrane disease	1	1					1		1
Anuria	5	20					5		20
Azotaemia		3							3
Bilirubinuria	1	1					1		1
Bladder dilatation	1	1					1		1
Bladder discomfort	2	7			1	6	1		1
Bladder disorder	4	13			2	6	2		7
Bladder dysfunction	2	4				1	2		3
Bladder irritation		1							1
Bladder obstruction		1							1
Bladder pain	1	10				3	1		7

\* I=Interval, C=Cumulative  
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System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Bladder spasm		4
Bladder sphincter atony		2
Calculus urinary		1
Choluria	1	2
Chromaturia	14	51
Chronic kidney disease	8	18
Costovertebral angle tenderness		4
Cystitis haemorrhagic	2	6
Cystitis interstitial	1	2
Cystitis-like symptom		1
Cystitis noninfective	1	2
Dysuria	34	89
End stage renal disease	1	1
Genitourinary symptom		1
Glomerulonephritis		3
Glomerulonephritis chronic		1
Glomerulonephritis minimal lesion	3	9
Glomerulonephritis rapidly progressive		1
Haematuria	20	56
Haemoglobinuria	1	2
Haemorrhage urinary tract	7	19
Hydronephrosis		2
Hypertonic bladder		3
IgA nephropathy	1	1
Incontinence	13	37
Kidney fibrosis		1
Kidney small		1
Leukocyturia	2	6
Loss of bladder sensation		2
Micturition disorder	1	8
Micturition urgency	12	29
Myoglobinuria	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		2
			1		2
				1	2
		9	35	5	16
				8	18
			3		1
				2	6
				1	2
					1
			1	1	1
		11	40	23	49
				1	1
					1
					3
					1
				3	9
					1
		3	15	17	41
				1	2
			1	7	18
					2
			3		
				1	1
		3	9	10	28
					1
					1
		2	5		1
					2
		1	4		4
		4	12	8	17
				1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nephritis		1
Nephrolithiasis	16	30
Nephropathy	4	6
Nephrotic syndrome	5	16
Neurogenic bladder		2
Nocturia	2	5
Oliguria	4	12
Pollakiuria	26	81
Polyuria	8	25
Prerenal failure	2	3
Proteinuria	3	12
Renal artery stenosis		1
Renal atrophy	1	2
Renal colic	3	5
Renal cyst	4	7
Renal cyst haemorrhage		1
Renal disorder	9	30
Renal failure	31	88
Renal haemorrhage	2	3
Renal impairment	18	40
Renal infarct	3	4
Renal injury	1	1
Renal pain	34	147
Renal tubular disorder	1	1
Renal tubular injury		1
Renal tubular necrosis	1	2
Renal vasculitis		1
Stress urinary incontinence	1	1
Tubulointerstitial nephritis		2
Ureteric stenosis		2
Urethral disorder		1
Urethral haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				16	30
			1	4	5
				5	16
					2
		2	4		1
		1	5	3	7
		16	53	10	28
		3	15	5	10
				2	3
		1	5	2	7
					1
				1	2
		1	2	2	3
		1	3	3	4
					1
		3	12	6	18
				31	88
				2	3
				18	40
				3	4
				1	1
		13	65	21	82
				1	1
					1
				1	2
					1
		1	1		
					2
					2
			1		
					1

\* I=Interval, C=Cumulative  
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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urethral stenosis		1						1
Urge incontinence		1			1			
Urinary bladder haemorrhage	1	1					1	1
Urinary incontinence	32	103			13	38	19	65
Urinary retention	14	62					14	62
Urinary tract discomfort	1	1			1	1		
Urinary tract disorder		2				1		1
Urinary tract inflammation	1	5			1	1		4
Urinary tract pain		2				1		1
Urine abnormality	5	8			3	6	2	2
Urine flow decreased	2	5			1	2	1	3
Urine odour abnormal	5	15			4	10	1	5
Urogenital haemorrhage	1	2					1	2
	420	1,296		1	101	375	319	921

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal withdrawal bleeding		1				1		
Adnexa uteri pain	1	13			1	7		6
Amenorrhoea	11	23			3	8	8	15
Anisomastia		1				1		
Benign prostatic hyperplasia	2	2			1	1	1	1
Breast cyst	1	4			1	2		2
Breast discharge		4				4		
Breast discomfort	4	14			2	8	2	6
Breast disorder	3	5			2	4	1	1
Breast disorder female		1				1		
Breast engorgement	2	3			1	2	1	1

\* I=Interval, C=Cumulative  
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System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast enlargement	1	6
Breast haematoma	2	2
Breast induration	1	3
Breast inflammation	4	6
Breast mass	17	32
Breast milk discolouration		2
Breast oedema	2	7
Breast pain	91	241
Breast swelling	29	67
Breast tenderness	12	29
Cervical dysplasia	1	1
Cervix erythema		1
Cervix haematoma uterine	1	1
Cervix oedema		1
Dysfunctional uterine bleeding		1
Dysmenorrhoea	18	46
Dyspareunia		1
Endometriosis	4	6
Erectile dysfunction	12	36
Erection increased	1	2
Female genital tract fistula		1
Female sexual dysfunction	1	1
Galactorrhoea	2	4
Galactostasis	1	1
Genital blister		1
Genital discomfort		1
Genital haemorrhage	2	4
Genital lesion		1
Genital pain		3
Genital paraesthesia	1	2
Genital rash		1
Genital swelling	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	3
				2	2
			2	1	1
			2	4	4
		5	12	12	20
			2		
			4	2	3
	1	34	109	57	132
		12	31	17	36
		6	14	6	15
				1	1
					1
				1	1
			1		
					1
		9	27	9	19
			1		
		1	1	3	5
				12	36
				1	2
					1
		1	1		
				2	4
		1	1		
			1		
					1
				2	4
			1		
			1		2
		1	2		
			1		
		1	1		

\* I=Interval, C=Cumulative  
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System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Genital tract inflammation		2
Genital ulceration		3
Gynaecomastia	1	1
Haematospermia	1	1
Hypomenorrhoea	3	9
Infertility		1
Infertility female	1	1
Lactation disorder	2	3
Menometrorrhagia		1
Menopausal symptoms	2	5
Menorrhagia	63	122
Menstrual discomfort	2	2
Menstrual disorder	20	61
Menstruation delayed	16	53
Menstruation irregular	33	67
Metrorrhagia	14	50
Nipple disorder	1	1
Nipple exudate bloody	1	2
Nipple pain	6	20
Nipple swelling	3	8
Oedema genital	1	1
Oligomenorrhoea	4	6
Orchitis noninfective		1
Ovarian cyst	2	3
Ovarian disorder	1	1
Ovarian enlargement	1	1
Ovulation pain		1
Pelvic discomfort	1	2
Pelvic haemorrhage		3
Pelvic pain	15	47
Penile discomfort		1
Penile haemorrhage	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		2
				1	1
				1	1
		2	6	1	3
					1
				1	1
		1	1	1	2
					1
			3	2	2
1	1	34	59	29	63
		1	1	1	1
1	1	13	46	7	15
		6	20	10	33
1	1	17	44	16	23
		7	23	7	27
		1	1		
			1	1	1
		3	13	3	7
		1	6	2	2
				1	1
		1	2	3	4
			1		
		1	1	1	2
				1	1
		1	1		
					1
				1	2
					3
		7	24	8	23
			1		
				1	2

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System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Penile swelling		2
Penis disorder		1
Perineal pain	2	3
Polymenorrhoea	6	19
Postmenopausal haemorrhage	12	18
Premature menopause		1
Premenstrual pain		2
Premenstrual syndrome	2	7
Priapism		1
Prostatic disorder	1	1
Prostatic pain	1	1
Prostatitis	5	8
Prostatomegaly	2	4
Pruritus genital		4
Scrotal disorder		1
Scrotal erythema	1	3
Scrotal exfoliation		1
Scrotal inflammation		1
Scrotal pain	2	6
Scrotal swelling		3
Semen discolouration	1	1
Suppressed lactation	1	8
Testicular pain	8	16
Testicular retraction		1
Testicular swelling	3	8
Testicular torsion		1
Testis discomfort	1	2
Uterine disorder		1
Uterine haemorrhage	4	8
Uterine inflammation		2
Uterine pain	1	4
Uterine spasm		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
		2	2		1
		4	14	2	5
				12	18
					1
			2		
		1	6	1	1
					1
		1	1		
				1	1
		2	2	3	6
			2	2	2
			3		1
			1		
			1	1	2
					1
			1		
		2	4		2
					3
				1	1
			4	1	4
		5	10	3	6
					1
		3	5		3
					1
		1	1		1
			1		
				4	8
			1		1
			1	1	3
			1		1

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 \* AE=Adverse Event  
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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaginal cyst	1	2					1	2
Vaginal discharge		9				8		1
Vaginal disorder	1	3				2	1	1
Vaginal haemorrhage	38	106			14	41	24	65
Vaginal lesion		1				1		
Vaginal ulceration	1	1					1	1
Varicocele	1	1			1	1		
Vulval disorder		2				1		1
Vulval haemorrhage	2	4					2	4
Vulval oedema		1				1		
Vulval ulceration	1	2			1	1		1
Vulvovaginal burning sensation	3	6			2	4	1	2
Vulvovaginal discomfort	1	1					1	1
Vulvovaginal inflammation		1						1
Vulvovaginal pain	5	10			2	5	3	5
Vulvovaginal pruritus		3				2		1
Vulvovaginal rash		2				1		1
Vulvovaginal swelling	1	5			1	2		3
Vulvovaginal ulceration	2	3					2	3
Withdrawal bleed		1				1		
	533	1,370	3	4	220	648	313	722

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute pulmonary oedema	10	35					10	35
Acute respiratory distress syndrome	13	36					13	36
Acute respiratory failure	14	58					14	58
Allergic cough	3	8			1	2	2	6

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergic respiratory disease		1
Allergic respiratory symptom		3
Allergic sinusitis		2
Alveolitis	1	1
Aphonia	23	86
Apnoea	9	27
Apnoeic attack		2
Asphyxia	3	16
Aspiration	5	24
Asthma	106	379
Asthma exercise induced		3
Asthma late onset		1
Asthmatic crisis	5	28
Atelectasis	3	15
Bradypnoea	1	2
Bronchial disorder	1	7
Bronchial haemorrhage		1
Bronchial hyperreactivity	1	3
Bronchial obstruction	2	5
Bronchial oedema	1	2
Bronchial secretion retention	1	2
Bronchial wall thickening		1
Bronchiectasis	3	8
Bronchitis chronic	1	1
Bronchopneumopathy	1	4
Bronchospasm	46	211
Bronchostenosis	3	5
Catarrh	6	16
Cheyne-Stokes respiration		1
Choking	17	50
Choking sensation	11	40
Chronic obstructive pulmonary disease	23	84

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					3
			1		1
				1	1
1	1	15	36	8	50
				9	27
					2
				3	16
				5	24
		40	131	66	248
			1		2
					1
2	3			5	28
		2	3	1	12
				1	2
		1	4		3
					1
				1	3
				2	5
				1	2
		1	2		
					1
				3	8
		1	1		
		1	1		3
	1	19	69	27	142
				3	5
		4	9	2	7
					1
1	1			17	50
		4	12	7	28
1	1	3	10	20	74

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chronic respiratory failure		4
Cough	806	2,842
Cough decreased		1
Cyanosis central		1
Cystic lung disease		1
Diaphragmalgia	4	10
Diaphragmatic disorder	2	3
Diaphragmatic paralysis		1
Diaphragmatic spasm		3
Dry throat	44	149
Dysaesthesia pharynx		2
Dysphonia	108	399
Dyspnoea	1,431	5,169
Dyspnoea at rest	10	33
Dyspnoea exertional	50	197
Emphysema	5	13
Eosinophilic bronchitis	1	1
Epiglottic oedema		5
Epistaxis	180	441
Glottal incompetence		1
Grunting	3	11
Haemoptysis	30	69
Haemothorax		3
Hiccups	1	12
Hydrothorax		1
Hyperactive pharyngeal reflex		2
Hypercapnia	2	6
Hyperoxia	1	1
Hypersensitivity pneumonitis		1
Hyperventilation	37	125
Hypopnoea	20	59
Hypoventilation	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
2	6	476	1638	330	1204
			1		
			1		1
		1	5	3	5
		1	2	1	1
					1
			1		2
1	2	35	88	9	61
			2		
	1	51	200	57	199
5	13	561	2018	870	3151
				10	33
		13	77	37	120
		2	4	3	9
				1	1
					5
	1	76	208	104	233
					1
		2	7	1	4
		10	24	20	45
					3
		1	9		3
					1
			1		1
				2	6
				1	1
					1
	1	20	54	17	71
		4	12	16	47
				3	8

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 \* AE=Adverse Event  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoxia	31	118
Idiopathic pulmonary fibrosis	1	2
Increased bronchial secretion	2	10
Increased upper airway secretion	2	26
Increased viscosity of bronchial secretion		4
Increased viscosity of upper respiratory secretion	5	10
Interstitial lung disease	9	20
Intranasal hypoesthesia		4
Intranasal paraesthesia	1	10
Irregular breathing	3	17
Laryngeal discomfort	6	15
Laryngeal disorder		2
Laryngeal dyspnoea	1	6
Laryngeal erythema		1
Laryngeal inflammation		2
Laryngeal obstruction	1	6
Laryngeal oedema	27	156
Laryngeal pain	2	11
Laryngeal stenosis		1
Laryngitis allergic		1
Laryngospasm	7	47
Larynx irritation	2	7
Lower respiratory tract congestion	3	10
Lung consolidation	2	3
Lung disorder	36	92
Lung hyperinflation	1	2
Lung infiltration	8	19
Lung opacity	4	9
Mediastinal haemorrhage		1
Mouth breathing		3
Nasal congestion	136	533

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				31	118
				1	2
			2	2	8
			12	2	14
			1		3
		3	4	2	6
				9	20
			3		1
		1	10		
		2	5	1	12
		2	6	4	9
					2
				1	6
					1
			1		1
				1	6
				27	156
		2	5		6
					1
					1
		1	8	6	39
		1	2	1	5
		1	4	2	6
				2	3
	1	16	31	20	61
		1	2		
		2	5	6	14
		2	2	2	7
					1
					3
	1	103	411	33	122

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal crusting		1
Nasal discharge discolouration		2
Nasal discomfort	13	56
Nasal disorder	5	10
Nasal dryness	7	17
Nasal mucosal disorder		2
Nasal obstruction	4	16
Nasal odour	1	3
Nasal oedema	7	32
Nasal pruritus	5	21
Neonatal pneumothorax		1
Neonatal respiratory distress		1
Nocturnal dyspnoea	2	4
Obliterative bronchiolitis		1
Obstructive airways disorder	8	32
Organising pneumonia		2
Oropharyngeal blistering	2	16
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	154	369
Oropharyngeal oedema	1	12
Oropharyngeal pain	535	2,137
Oropharyngeal plaque		1
Oropharyngeal spasm		6
Oropharyngeal swelling	2	7
Orthopnoea	3	13
Painful respiration	20	67
Paranasal sinus discomfort	9	48
Paranasal sinus hypersecretion	1	8
Paranasal sinus hyposecretion		1
Paranasal sinus inflammation		1
Pharyngeal cyst	2	2
Pharyngeal disorder	4	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
		6	34	7	22
		3	8	2	2
		4	10	3	7
			1		1
		2	9	2	7
			1	1	2
		6	18	1	14
		3	11	2	10
					1
					1
		1	1	1	3
			4	8	28
					2
				2	16
			1		
		87	192	67	177
			2	1	10
1	6	365	1401	170	736
					1
					6
			2	2	5
			1	3	12
		7	28	13	39
		8	40	1	8
			7	1	1
			1		
					1
				2	2
		2	10	2	6

\* I=Interval, C=Cumulative  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal enanthema		3
Pharyngeal erythema	13	39
Pharyngeal haemorrhage	2	3
Pharyngeal hypoaesthesia	10	49
Pharyngeal inflammation	3	21
Pharyngeal lesion	1	1
Pharyngeal leukoplakia		1
Pharyngeal mass	4	10
Pharyngeal oedema	11	56
Pharyngeal paraesthesia	27	124
Pharyngeal stenosis	2	2
Pharyngeal swelling	102	425
Pharyngeal ulceration	2	9
Pleural effusion	31	69
Pleurisy	3	25
Pleuritic pain	8	28
Pneumonia aspiration	21	78
Pneumonitis	11	39
Pneumothorax	10	12
Pneumothorax spontaneous	2	3
Productive cough	54	180
Prolonged expiration		3
Pulmonary alveolar haemorrhage	1	1
Pulmonary arterial hypertension	2	4
Pulmonary artery dilatation	1	2
Pulmonary artery occlusion	1	1
Pulmonary artery thrombosis	1	5
Pulmonary calcification	1	1
Pulmonary congestion	14	32
Pulmonary embolism	436	683
Pulmonary fibrosis	6	12
Pulmonary haemorrhage	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
		10	24	3	15
				2	3
		7	25	3	24
		2	9	1	12
		1	1		
			1		
		3	7	1	3
	1	4	12	7	44
		16	56	11	68
				2	2
	1	40	158	62	267
		1	3	1	6
		4	10	27	59
		1	2	2	23
		5	12	3	16
				21	78
			4	11	35
				10	12
				2	3
		26	85	28	95
			2		1
				1	1
				2	4
				1	2
				1	1
				1	5
		1	1		
				14	32
2	2			436	683
				6	12
				4	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary hypertension	6	9
Pulmonary hypertensive crisis	1	1
Pulmonary hypoperfusion		1
Pulmonary infarction	14	25
Pulmonary mass	5	8
Pulmonary microemboli	1	1
Pulmonary necrosis		1
Pulmonary oedema	33	94
Pulmonary pain	23	96
Pulmonary sarcoidosis	1	3
Pulmonary sensitisation		2
Pulmonary thrombosis	35	57
Pulmonary vasculitis		1
Pulmonary venous thrombosis	1	1
Rales	9	36
Respiration abnormal	10	52
Respiratory acidosis	6	11
Respiratory alkalosis	2	5
Respiratory arrest	14	56
Respiratory depression		10
Respiratory disorder	59	180
Respiratory disorder neonatal	1	1
Respiratory distress	165	892
Respiratory failure	47	149
Respiratory fatigue		9
Respiratory muscle weakness		1
Respiratory paralysis		1
Respiratory symptom	6	16
Respiratory tract congestion	12	40
Respiratory tract haemorrhage		1
Respiratory tract inflammation	1	2
Respiratory tract irritation	5	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	9
				1	1
					1
				14	25
		2	3	3	5
				1	1
					1
				33	94
		8	42	15	54
			1	1	2
			1		1
	1			35	57
					1
				1	1
		1	5	8	31
		6	19	4	33
			1	6	10
		1	1	1	4
	1			14	56
					10
		13	48	46	132
				1	1
	1		2	165	890
				47	149
			1		8
					1
					1
	1	2	6	4	10
		8	32	4	8
					1
		1	1		1
		3	7	2	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract oedema	2	20
Restrictive pulmonary disease		1
Reversible airways obstruction		1
Rhinalgia	11	34
Rhinitis allergic	2	13
Rhinorrhoea	282	1,072
Rhonchi		7
Sinonasal obstruction	1	5
Sinus congestion	13	57
Sinus disorder	18	62
Sinus pain	23	79
Sleep apnoea syndrome	4	8
Sneezing	65	267
Snoring	4	13
Sputum discoloured	10	17
Sputum increased	3	6
Sputum retention	1	2
Status asthmaticus		1
Stertor		2
Stridor	11	51
Suffocation feeling	6	36
Tachypnoea	29	166
Throat clearing	2	15
Throat irritation	139	578
Throat tightness	144	644
Tonsillar cyst	1	1
Tonsillar disorder	1	5
Tonsillar erythema	1	4
Tonsillar haemorrhage		1
Tonsillar hypertrophy	11	41
Tonsillar inflammation	3	7
Tonsillar ulcer		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	20
					1
					1
		8	25	3	9
		2	9		4
2	5	220	822	62	250
			2		5
		1	2		3
		7	41	6	16
		15	50	3	12
		10	35	13	44
			1	4	7
	1	46	189	19	78
		2	8	2	5
		4	8	6	9
		2	4	1	2
		1	1		1
					1
					2
		3	8	8	43
		1	13	5	23
		13	68	16	98
		1	7	1	8
	1	96	351	43	227
	2	73	255	71	389
		1	1		
		1	3		2
		1	3		1
					1
		10	27	1	14
		3	5		2
			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Tonsillolith		1				1			
Tracheal inflammation		1				1			
Tracheal oedema		2							2
Tracheal pain		3				2			1
Tracheal stenosis	3	3					3		3
Tracheomalacia		1							1
Upper-airway cough syndrome	7	32			6	25	1		7
Upper airway obstruction	2	10					2		10
Upper respiratory tract congestion	9	46			5	39	4		7
Upper respiratory tract inflammation		2				1			1
Use of accessory respiratory muscles		14				7			7
Vasomotor rhinitis		1				1			
Vocal cord disorder	2	5					2		5
Vocal cord dysfunction		1							1
Wheezing	127	429			54	161	73		268
Yawning	7	17			3	7	4		10
	6,311	22,281	18	56	2731	9702	3580		12579

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Acne	23	47			17	36	6		11
Acute febrile neutrophilic dermatosis	2	7					2		7
Acute generalised exanthematous pustulosis	2	3					2		3
Alopecia	32	76			15	39	17		37
Alopecia areata	2	5				3	2		2
Alopecia totalis	1	1					1		1
Alopecia universalis		1				1			
Androgenetic alopecia	2	2					2		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Angioedema	119	485
Angiokeratoma	1	1
Blister	73	234
Blister rupture		1
Blood blister	8	17
Brow ptosis		1
Butterfly rash	1	7
Capillaritis	1	2
Chronic spontaneous urticaria		1
Circumoral oedema	2	10
Circumoral swelling	2	7
Cold sweat	154	577
Cold urticaria	2	3
Cutaneous lupus erythematosus	1	2
Cutaneous sarcoidosis	1	2
Cutaneous symptom		6
Cutaneous vasculitis	2	6
Dandruff		1
Decubitus ulcer	4	8
Dermal cyst	1	5
Dermatitis	27	76
Dermatitis acneiform		6
Dermatitis allergic	37	138
Dermatitis atopic	6	16
Dermatitis bullous	9	32
Dermatitis contact	3	8
Dermatitis diaper	1	2
Dermatitis exfoliative	1	5
Dermatitis exfoliative generalised	3	6
Dermatitis herpetiformis		4
Dermatomyositis	3	9
Dermatosis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	117	482
		1	1		
		33	121	40	113
			1		
		2	2	6	15
			1		
			3	1	4
		1	2		
					1
		2	7		3
		2	5		2
		78	280	76	297
		2	3		
				1	2
				1	2
			2		4
		1	2	1	4
			1		
		1	3	3	5
		1	3		2
		12	44	15	32
			5		1
		17	52	20	86
		3	7	3	9
1	1			9	32
		1	5	2	3
		1	1		1
				1	5
				3	6
			2		2
				3	9
			3		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diabetic wound		1
Diffuse alopecia	1	1
Drug eruption	13	35
Drug reaction with eosinophilia and systemic symptoms	3	3
Dry skin	42	108
Dyshidrotic eczema		6
Ecchymosis	14	20
Eczema	33	104
Eczema asteatotic	1	2
Eczema nummular	1	3
Eczema weeping		1
Ephelides	1	1
Epidermal necrosis		1
Erythema	775	2,800
Erythema ab igne	1	1
Erythema annulare	2	3
Erythema marginatum		1
Erythema multiforme	12	45
Erythema nodosum	14	23
Erythematotelangiectatic rosacea		1
Erythrodermia		1
Excessive granulation tissue		1
Exfoliative rash	2	7
Fixed eruption		3
Fracture blisters		1
Granuloma annulare	1	1
Granuloma skin	1	2
Guttate psoriasis	2	4
Haemorrhage subcutaneous	13	21
Haemorrhagic urticaria	1	1
Hair colour changes		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		7	16	6	19
				3	3
		22	60	20	48
			2		4
		7	10	7	10
	1	17	50	16	54
			1	1	1
			2	1	1
			1		
		1	1		
					1
1	5	523	1780	252	1020
		1	1		
				2	3
			1		
				12	45
		4	7	10	16
			1		
			1		
					1
				2	7
			3		
			1		
		1	1		
		1	1		1
			1	2	3
				13	21
				1	1
			2		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hair disorder	1	1
Hair growth abnormal	1	2
Hair texture abnormal	4	4
Hand dermatitis	2	5
Henoch-Schonlein purpura	2	4
Hidradenitis		4
Hirsutism		1
Hyperhidrosis	519	2,121
Hypersensitivity vasculitis	14	21
Hypertrichosis		1
Idiopathic angioedema		2
Idiopathic urticaria		1
Ingrowing nail		1
Itching scar	1	6
Leukoplakia		1
Lichenoid keratosis	2	4
Lichen planus		3
Lipodystrophy acquired		1
Livedo reticularis	11	47
Lividity	1	8
Macule	2	11
Madarosis	1	4
Mechanical urticaria		14
Miliaria	14	37
Mucocutaneous disorder	1	1
Nail discolouration	3	12
Nail pigmentation	1	1
Nail ridging	1	1
Neurodermatitis	1	5
Neutrophilic dermatosis	1	3
Night sweats	92	406
Oculomucocutaneous syndrome	7	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	2		
		2	2	2	2
		2	5		
		1	2	1	2
			2		2
			1		
	3	280	1169	239	952
				14	21
			1		
					2
			1		
			1		
		1	4		2
			1		
		1	1	1	3
			1		2
					1
	1	8	20	3	27
			1	1	7
		1	7	1	4
			1	1	3
	2		10		4
		8	18	6	19
		1	1		
		3	7		5
				1	1
				1	1
		1	5		
			1	1	2
	3	53	245	39	161
				7	8

\* I=Interval, C=Cumulative  
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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema blister	1	1
Onychalgia		1
Onychoclasis	3	5
Onycholysis		1
Pain of skin	67	228
Palmar erythema	1	14
Palmar-plantar erythrodysesthesia syndrome		1
Palmoplantar pustulosis		1
Palpable purpura	1	3
Panniculitis	1	3
Papule	8	34
Peau d'orange		2
Pemphigoid	4	18
Pemphigus	2	7
Perioral dermatitis	1	3
Perivascular dermatitis		1
Pernio-like erythema		4
Petechiae	58	144
Photosensitivity reaction	13	56
Pigmentation disorder	3	9
Piloerection	6	25
Pityriasis	1	6
Pityriasis lichenoides et varioliformis acuta	1	1
Pityriasis rosea	9	25
Plantar erythema	1	3
Prurigo	1	5
Pruritus	1,074	3,839
Pruritus allergic		6
Pseudofolliculitis		2
Psoriasis	22	53
Purpura	22	52
Pustular psoriasis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		2	4	1	1
			1		
		33	110	34	118
			10	1	4
					1
			1		
			2	1	1
				1	3
		4	18	4	16
			2		
				4	18
				2	7
		1	3		
			1		
			3		1
	1	27	68	31	76
		4	26	9	30
		1	6	2	3
		3	8	3	17
		1	4		2
		1	1		
		4	12	5	13
			2	1	1
			4	1	1
1	5	681	2374	393	1465
			2		4
			1		1
		5	22	17	31
	1	11	19	11	33
				1	2

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash	1,090	3,659
Rash erythematous	180	704
Rash macular	103	388
Rash maculo-papular	24	109
Rash maculovesicular		1
Rash morbilliform	8	25
Rash neonatal	1	1
Rash papular	57	196
Rash pruritic	182	682
Rash rubelliform		2
Rash vesicular	19	75
Red man syndrome		1
Rosacea	1	8
Scab	9	21
Scar pain	1	4
Scleroderma associated digital ulcer		1
Seborrhoea	1	2
Seborrhoeic dermatitis		1
Sensitive skin	241	684
Skin burning sensation	45	172
Skin depigmentation	1	5
Skin discharge	1	2
Skin discolouration	59	172
Skin discomfort		2
Skin disorder	33	109
Skin erosion	3	9
Skin exfoliation	29	81
Skin fissures	6	9
Skin haemorrhage	14	20
Skin hyperpigmentation	1	2
Skin hypertrophy	2	5
Skin indentation	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	8	691	2194	399	1465
1	3	102	377	78	327
		58	232	45	156
		11	59	13	50
			1		
		5	13	3	12
		1	1		
		30	116	27	80
		95	361	87	321
					2
		8	44	11	31
					1
			4	1	4
		6	15	3	6
			3	1	1
					1
			1	1	1
			1		
		190	570	51	114
	2	25	99	20	73
		1	3		2
				1	2
		36	102	23	70
			2		
		15	53	18	56
		2	3	1	6
		19	44	10	37
		4	5	2	4
		8	12	6	8
			1	1	1
			3	2	2
		1	3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin induration	3	6
Skin irritation	22	68
Skin laxity		3
Skin lesion	16	79
Skin mass	9	27
Skin necrosis	3	5
Skin odour abnormal	1	6
Skin oedema		3
Skin plaque	3	8
Skin reaction	28	87
Skin sensitisation	11	20
Skin striae	2	3
Skin swelling	16	50
Skin tightness	10	41
Skin ulcer	8	22
Skin warm	25	121
Skin weeping	2	5
Skin wrinkling	4	5
Solar dermatitis	1	1
Solar lentigo	1	2
Splinter haemorrhages		2
Stasis dermatitis	1	1
Stevens-Johnson syndrome	4	13
Sticky skin	1	1
Systemic lupus erythematosus rash	3	6
Target skin lesion		1
Telangiectasia	1	1
Toxic epidermal necrolysis	1	5
Toxic skin eruption	8	12
Trichodynia		2
Umbilical haematoma	1	1
Urticaria	607	2,140

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	2	3
		11	35	11	33
			2		1
		12	48	4	31
		8	18	1	9
				3	5
		1	5		1
			3		
		1	4	2	4
		15	50	13	37
		5	10	6	10
		1	2	1	1
		11	33	5	17
		4	17	6	24
		3	9	5	13
	1	12	54	13	67
				2	5
		3	3	1	2
				1	1
				1	2
			1		1
		1	1		
		1	2	2	4
					1
				1	1
				1	5
				8	12
			1		1
				1	1
	1	395	1276	212	864

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Urticaria cholinergic		2				2			
Urticaria chronic	4	6			1	1	3	5	
Urticarial vasculitis		1						1	
Urticaria papular	2	6			2	4		2	
Urticaria pressure		1						1	
Urticaria thermal	2	4			2	4			
Urticaria vesiculosa	1	1			1	1			
Vascular purpura	3	11			1	4	2	7	
Vasculitic rash	3	10			2	4	1	6	
Vitiligo	1	1					1	1	
Yellow skin	3	17			1	10	2	7	
	6,365	22,286	4	38	3722	12726	2643	9560	

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Aborted pregnancy		1				1	
Bedridden	21	72	11	34	10	38	
Breast prosthesis user	1	1	1	1			
Caffeine consumption	1	1	1	1			
Contraindication to medical treatment		1		1			
Contraindication to vaccination		3		3			
Disability		1				1	
Exercise lack of		1		1			
Fasting	1	1	1	1			
Hearing disability		1		1			
Illiteracy		1				1	
Immobile	6	16			6	16	
Impaired driving ability	10	39	5	20	5	19	

\* I=Interval, C=Cumulative  
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System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired quality of life	7	11	4	6	3	5
Impaired work ability	28	117	8	37	20	80
Job dissatisfaction	1	1	1	1		
Joint prosthesis user		1				1
Loss of personal independence in daily activities	109	307	48	165	61	142
Menopause	2	2	1	1	1	1
Non-tobacco user	1	1	1	1		
Patient uncooperative	1	1	1	1		
Physical disability		1				1
Sight disability		1				1
Sitting disability	3	11	3	6		5
Urinary assistance device user		1		1		
Walking aid user	5	6	4	5	1	1
Walking disability	3	9	1	3	2	6
Water pollution	2	3		1	2	2
	202	612	91	291	111	321

System Organ Class

**SOC Not Yet Coded**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
	7	31	7	31
	7	31	7	31

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion induced	1	3	1	1		2
Abscess drainage		1				1
Airway secretion clearance therapy		1				1
Anaphylaxis prophylaxis	1	1			1	1
Arthrodesis	1	1	1	1		
Asthma prophylaxis		1				1
Axillary lymphadenectomy	3	3			3	3
Bed rest	4	4	2	2	2	2
Cardiac pacemaker insertion		1		1		
Central nervous system stimulation		1				1
Contraceptive diaphragm	1	1	1	1		
COVID-19 immunisation	3	5		2	3	3
Cranial nerve decompression		1				1
Dermabrasion		1		1		
Dermal filler injection	1	1	1	1		
Diabetic diet		1				1
Drainage	1	2	1	2		
Gastrointestinal surgery	1	1			1	1
Hernia repair	1	1	1	1		
Hysterectomy	1	1			1	1
Ileectomy	1	1			1	1
Immunisation	2	7	1	5	1	2
Injection		1		1		
Joint stabilisation		1		1		
Limb immobilisation	1	8		6	1	2
Limb operation	1	1			1	1
Local anaesthesia		1		1		
Mass excision		1		1		
Migraine prophylaxis	1	1			1	1
Multiple sclerosis relapse prophylaxis	1	1			1	1
Prophylaxis of nausea and vomiting		1				1
Resuscitation	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion removal		1		1		
Spinal fusion surgery		1				1
Splenic artery embolisation	1	1			1	1
Therapeutic procedure	1	1	1	1		
Therapy change		1		1		
Thrombectomy	1	1			1	1
Thrombolysis	1	1			1	1
Thyroidectomy	1	1	1	1		
Tooth extraction	3	3	2	2	1	1
Weight loss diet		1				1
Wheat-free diet	1	1			1	1
Wound closure		1		1		
	36	72	13	35	23	37

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Achenbach syndrome		1				1			
Air embolism	1	1					1	1	
Aneurysm	3	5					3	5	
Aneurysm ruptured		4							4
Angiopathy	2	8				5	2	3	
Aortic aneurysm	3	7					3	7	
Aortic aneurysm rupture		3							3
Aortic arteriosclerosis	2	7			1	3	1	4	
Aortic dilatation	1	1			1	1			
Aortic disorder	1	1					1	1	
Aortic dissection	5	10					5	10	
Aortic embolus	3	3					3	3	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Aortic stenosis	2	5
Aortitis	1	2
Arterial disorder	2	2
Arterial haemorrhage		1
Arterial occlusive disease	3	5
Arterial rupture		1
Arterial stenosis		1
Arterial thrombosis	5	11
Arteriosclerosis	3	17
Arteriovenous fistula	1	1
Arteritis		1
Axillary vein thrombosis	1	2
Behcet's syndrome	2	5
Bleeding varicose vein	1	1
Blood pressure fluctuation	21	79
Blood pressure inadequately controlled		3
Bloody discharge	3	4
Blue toe syndrome	5	9
Capillary disorder	1	2
Capillary fragility	1	3
Circulatory collapse	54	184
Claudication of jaw muscles	1	1
CT hypotension complex		2
Cyanosis	36	124
Deep vein thrombosis	278	402
Dependent rubor	1	1
Diastolic hypertension		4
Diastolic hypotension		2
Embolism	43	57
Embolism arterial	1	2
Embolism venous	3	5
Essential hypertension	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
				1	2
				2	2
					1
				3	5
					1
					1
				5	11
		2	3	1	14
				1	1
					1
		1	1		1
				2	5
				1	1
		12	43	9	36
			2		1
		1	1	2	3
		1	3	4	6
		1	2		
		1	2		1
	1			54	184
				1	1
					2
		19	46	17	78
1	2	1	1	277	401
				1	1
			1		3
					2
				43	57
				1	2
				3	5
		1	1	2	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Extremity necrosis	3	3
Femoral artery embolism		1
Fibromuscular dysplasia	1	1
Flushing	164	871
Giant cell arteritis	11	19
Haematoma	48	115
Haemodynamic instability	4	6
Haemorrhage	98	195
Hot flush	210	766
Hyperaemia	5	23
Hypertension	563	1,891
Hypertensive crisis	96	405
Hypertensive emergency	4	13
Hypertensive urgency	3	7
Hypoperfusion	1	6
Hypotension	208	894
Hypotensive crisis	2	8
Hypovolaemic shock	23	39
Infarction	8	15
Inferior vena caval occlusion	1	1
Internal haemorrhage	20	22
Ischaemia	7	12
Ischaemic limb pain	1	1
Jugular vein distension		3
Jugular vein thrombosis	3	5
Labile blood pressure		3
Labile hypertension		1
Lymphangiectasia	1	1
Lymphangiopathy	1	1
Lymphoedema	23	85
MAGIC syndrome		1
Malignant hypertension	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
					1
				1	1
	1	107	530	57	341
				11	19
		21	53	27	62
		1	2	3	4
1	2		3	98	192
		125	443	85	323
		4	16	1	7
1	5	148	578	415	1313
	2			96	405
				4	13
				3	7
			1	1	5
2	4	72	278	136	616
				2	8
				23	39
				8	15
				1	1
				20	22
		1	1	6	11
				1	1
			1		2
		1	1	2	4
					3
			1		
				1	1
				1	1
	1	4	41	19	44
					1
				2	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
May-Thurner syndrome		1
Microembolism	1	5
Microscopic polyangiitis	1	2
Neurogenic shock		18
Orthostatic hypertension		1
Orthostatic hypotension	8	34
Pallor	85	419
Pelvic venous thrombosis	2	5
Peripheral arterial occlusive disease	1	2
Peripheral artery occlusion	2	2
Peripheral artery stenosis	1	1
Peripheral artery thrombosis	6	8
Peripheral circulatory failure	8	14
Peripheral coldness	115	397
Peripheral embolism	8	10
Peripheral ischaemia	14	22
Peripheral vascular disorder	8	39
Peripheral vein stenosis	1	1
Peripheral vein thrombus extension	1	1
Peripheral venous disease	9	11
Phlebitis	30	47
Phlebitis deep	1	1
Phlebitis superficial	7	8
Poor peripheral circulation	6	15
Poor venous access	1	1
Post thrombotic syndrome	2	2
Prehypertension	1	1
Raynaud's phenomenon	17	49
Secondary hypertension	1	1
Shock	13	59
Shock haemorrhagic	2	2
Shock symptom	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	5
				1	2
					18
					1
		5	14	3	20
	1	39	179	46	240
				2	5
		1	1		1
				2	2
				1	1
		1	1	5	7
		4	4	4	10
	2	68	224	47	173
			1	8	9
		2	3	12	19
	1	6	16	2	23
				1	1
				1	1
		4	6	5	5
		19	23	11	24
				1	1
		6	6	1	2
		5	12	1	3
		1	1		
				2	2
		1	1		
		9	24	8	25
		1	1		
		1	1	12	58
				2	2
				1	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Spider vein		1
Subclavian artery thrombosis		1
Subclavian vein stenosis	1	1
Subclavian vein thrombosis	3	7
Superficial vein prominence	3	5
Superior vena cava syndrome		1
Systolic hypertension		6
Takayasu's arteritis		1
Thromboangiitis obliterans	1	1
Thrombophlebitis	51	60
Thrombophlebitis superficial	48	62
Thrombosed varicose vein	2	2
Thrombosis	276	421
Varicose vein	6	14
Vascular occlusion	2	2
Vascular pain	5	9
Vascular rupture	1	2
Vascular stenosis	1	1
Vasculitis	34	64
Vasculitis necrotising	1	1
Vasoconstriction	4	13
Vasodilatation	8	20
Vasospasm	1	3
Vein discolouration	2	5
Vein disorder	5	13
Vein rupture	2	5
Vena cava embolism		1
Vena cava thrombosis	2	4
Venous haemorrhage		1
Venous occlusion	1	1
Venous thrombosis	15	23
Venous thrombosis in pregnancy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				1	1
				3	7
		1	3	2	2
					1
					6
					1
				1	1
		24	25	27	35
1	1	17	20	31	42
				2	2
1	2	2	3	274	418
		3	9	3	5
				2	2
		2	4	3	5
		1	1		1
				1	1
		18	26	16	38
				1	1
		2	4	2	9
		5	10	3	10
			1	1	2
		2	5		
		2	7	3	6
				2	5
					1
				2	4
					1
				1	1
		1	1	14	22
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Venous thrombosis limb	23	29		1	2	3	21	26
White coat hypertension	1	2			1	2		
Withdrawal hypertension		3				2		1
	2,857	8,389	7	26	783	2711	2074	5678

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

**APPENDIX 2.5.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term per Country**

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

Total Number of Adverse Events (PT): 112,695 (Interval) / 414,597 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Feeling of body temperature change		1		1
Swelling face		1		1
		3		3

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle tightness		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis		1				1
Paraesthesia		1		1		
		2		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Erythema		1		1
Pruritus		1		1
Rash		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ALBANIA**

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
		2		2

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Off label use	1	1	1	1
Product use issue	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AMERICAN SAMOA**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ANDORRA**

*System Organ Class*

**Injury, poisoning and procedural complications**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous	
Nonserious	
I	C
	1

Product administered to patient of inappropriate age

1

1

1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ANGOLA**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Swollen tongue		1		1
Vomiting		1		1
		2		2

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pyrexia		1		1
		1		1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nasopharyngitis		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**ARGENTINA**

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error		1		1
Intentional product misuse	1	1	1	1
	1	2	1	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
SARS-CoV-2 antibody test negative		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diabetes mellitus	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pain in extremity		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRALIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood disorder	1	1	1	1		
Lymphadenopathy	8	8	7	7	1	1
	9	9	8	8	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Arrhythmia	2	2			2	2
Bradycardia	2	4			2	4
Cardiac arrest	3	5			3	5
Myocardial infarction	1	1			1	1
Palpitations	4	6	4	6		
Tachycardia	9	11	8	8	1	3
	21	30	12	14	9	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	3	3			3	3
Deafness unilateral	2	2			2	2
Ear pain	1	1	1	1		
Paraesthesia ear	1	1	1	1		
Tinnitus	2	2	2	2		
Vertigo	1	1	1	1		
Vertigo positional		1				1
	10	11	5	5	5	6

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenocortical insufficiency acute	1	1	1	1
Hyperthyroidism	2	2	2	2
	3	3	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage	2	2			2	2
Eye discharge		1		1		
Eye pain	2	3	2	3		
Eye pruritus	2	2	2	2		
Iridocyclitis	1	1			1	1
Mydriasis		2				2
Ocular discomfort	1	1	1	1		
Ocular hyperaemia	2	3	2	3		
Photophobia	2	2	2	2		
Pupil fixed	1	3			1	3
Pupils unequal		1				1
Retinal artery occlusion	1	1			1	1
Vision blurred	1	1	1	1		
Visual impairment	3	3	3	3		
	18	26	13	16	5	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	8	8	7	7	1	1
Abdominal tenderness	1	1	1	1		
Anal haemorrhage	1	1	1	1		
Diarrhoea	10	10	10	10		
Dysphagia	2	4	2	2		2
Gastrointestinal haemorrhage		1				1
Haematemesis	1	1			1	1
Hypoaesthesia oral		1				1
Lip swelling	3	3	3	3		
Nausea	26	35	26	33		2
Odynophagia	1	1	1	1		
Pancreatitis	1	1			1	1
Paraesthesia oral	8	8	7	7	1	1
Rectal haemorrhage	3	3			3	3
Retching	1	1	1	1		
Swollen tongue	3	4	2	3	1	1
Vomiting	18	23	12	13	6	10
	88	107	74	83	14	24

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	3	3	3		
Chest discomfort	13	13	12	12	1	1
Chest pain	2	2	2	2		
Chills	17	18	17	17		1
Concomitant disease aggravated	1	1			1	1
Condition aggravated		3				3
Crying		1		1		
Death	3	6			3	6
Disease progression	1	1			1	1
Drug ineffective	1	1			1	1
Extensive swelling of vaccinated limb	2	2	1	1	1	1
Face oedema	1	1	1	1		
Facial pain	1	1	1	1		
Fatigue	26	31	25	30	1	1
Feeling abnormal	1	4	1	3		1
Feeling hot	5	7	5	6		1
Feeling jittery		1		1		
Feeling of body temperature change	2	2	2	2		
Foaming at mouth		1				1
Gait disturbance	2	3	2	3		
General physical health deterioration	2	4			2	4
Illness	1	1	1	1		
Inflammation	1	1	1	1		
Influenza like illness	3	3	3	3		
Injected limb mobility decreased	1	1	1	1		
Localised oedema	1	1	1	1		
Malaise	11	14	7	8	4	6
Multiple organ dysfunction syndrome		1				1
Oedema peripheral		1				1
Pain	2	3	2	3		
Peripheral swelling		1		1		
Pyrexia	36	41	33	36	3	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body	1	1	1	1		
Soft tissue inflammation	1	1	1	1		
Swelling face	2	2	2	2		
Vaccination site bruising	1	2	1	2		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	4	2	3		1
Vaccination site pain	12	17	12	16		1
Vaccination site reaction	18	18	18	18		
Vaccination site swelling	3	6	3	5		1
Vaccination site warmth	1	1	1	1		
	181	227	163	188	18	39

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Liver injury	1	1	1	1
	1	1	1	1

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	33	54			33	54
Hypersensitivity	1	1	1	1		
	34	55	1	1	33	54

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis	1	1			1	1
Cellulitis	2	2			2	2
COVID-19	1	2		1	1	1
Herpes zoster	2	2	2	2		
Nasopharyngitis	1	1	1	1		
Oral herpes	1	1	1	1		
Pneumonia	6	11			6	11
Pneumonia viral		1				1
Pulmonary sepsis		1				1
Respiratory tract infection	1	1			1	1
Rhinovirus infection	1	1	1	1		
Sepsis	1	3			1	3
Septic shock		1				1
Urosepsis		2				2
Vaccination site cellulitis	1	1	1	1		
	18	31	6	7	12	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		2		2		
Adverse event following immunisation	2	2			2	2
Circumstance or information capable of leading to medication error	1	1	1	1		
Contusion	5	6	5	5		1
Exposure via breast milk	1	1	1	1		
Fall	2	5	1	2	1	3
Inadequate aseptic technique in use of product	1	1	1	1		
Nerve injury	1	1	1	1		
Off label use	2	2	2	2		
Pelvic fracture		1				1
Poor quality product administered	1	1	1	1		
Product preparation error		2		2		
Product use issue	2	3	2	3		
Scar	1	1	1	1		
	19	29	16	22	3	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased	1	1			1	1
Blood pressure decreased	2	2	2	2		
Blood pressure increased	3	6	3	4		2
Body temperature increased		1		1		
Coma scale abnormal		1				1
Heart rate increased	3	4	3	3		1
Heart rate irregular		1				1
Liver function test increased	1	1	1	1		
Neutrophil count decreased	1	1	1	1		
Oxygen saturation decreased	2	6	1	2	1	4
Respiratory rate increased	1	3		1	1	2
Weight decreased		1				1
White blood cell count decreased	1	1	1	1		
	15	29	12	16	3	13

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	5	1	3	1	2
Diabetes mellitus	1	1			1	1
Diabetic ketoacidosis		1				1
Food refusal		1		1		
Hyperglycaemia		1				1
Hyperglycaemic hyperosmolar nonketotic syndrome		1				1
Hypophagia		1				1
	3	11	1	4	2	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	15	17	15	17		
Back pain	1	1	1	1		
Joint stiffness	1	1	1	1		
Limb discomfort	1	1	1	1		
Mobility decreased	1	1	1	1		
Muscle spasms	1	2	1	2		
Muscle tightness	2	2	2	2		
Muscle twitching	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	26	30	26	29		1
Neck pain	3	3	3	3		
Pain in extremity	5	6	5	6		
Spinal pain	1	1	1	1		
	59	68	59	67		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness		1				1
Aphasia		1				1
Areflexia	1	1			1	1
Balance disorder	1	2	1	1		1
Burning sensation	1	1	1	1		
Cerebral haemorrhage		1				1
Cerebrovascular accident	4	7			4	7
Cognitive disorder		1				1
Consciousness fluctuating		1				1
Demyelination	1	1			1	1
Depressed level of consciousness	3	5			3	5
Dizziness	21	30	21	24		6
Drooling	1	1			1	1
Dysarthria	1	3			1	3
Dysgeusia	2	2	2	2		
Dyskinesia		1		1		
Facial paralysis	7	9			7	9
Facial paresis	3	5		1	3	4
Headache	54	60	53	58	1	2
Head discomfort	1	1	1	1		
Hemiparesis	1	1			1	1
Hypoaesthesia	6	7	6	7		
Hyporesponsive to stimuli		1				1
Ischaemic stroke	1	2			1	2
Lethargy	25	28	23	26	2	2
Loss of consciousness	5	9			5	9
Migraine	2	3	2	3		
Migraine with aura	1	1	1	1		
Monoplegia	1	2			1	2
Multiple sclerosis	2	2			2	2
Multiple sclerosis relapse	1	1			1	1
Neuropathy peripheral	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Occipital neuralgia	1	1	1	1		
Orthostatic tremor	1	1	1	1		
Paraesthesia	13	14	13	14		
Presyncope	9	10	7	8	2	2
Seizure	8	10			8	10
Sensory disturbance		1		1		
Sensory loss	1	1	1	1		
Somnolence	1	6		4	1	2
Speech disorder	1	1	1	1		
Syncope	32	39			32	39
Transient ischaemic attack	2	2			2	2
Tremor	4	8	4	8		
Trigeminal neuralgia	1	1	1	1		
Unresponsive to stimuli	7	9			7	9
	228	296	140	166	88	130

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	2	6	1	1	1	5
Confusional state	2	4	2	3		1
Delirium	1	2			1	2
Depressed mood		1		1		
Disorientation	2	2	2	2		
Hallucination	2	2			2	2
Hallucination, tactile		1				1
Insomnia	2	2	2	2		
Nervousness		2		1		1
Panic reaction	1	1	1	1		
Somatic symptom disorder		1				1
	12	24	8	11	4	13

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	2			1	2
Incontinence	1	1	1	1		
Urinary incontinence		1				1
	2	4	1	1	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute pulmonary oedema		1				1	
Apnoea	1	1			1	1	
Aspiration		1				1	
Cough	23	30	22	28	1	2	
Dry throat	2	2	2	2			
Dysphonia		1		1			
Dyspnoea	20	24	11	12	9	12	
Hypopnoea	1	2	1	2			
Hypoxia	1	3			1	3	
Nasal congestion	3	3	3	3			
Oropharyngeal pain	10	12	10	12			
Pharyngeal swelling	1	2			1	2	
Pleuritic pain	1	1	1	1			
Pneumonia aspiration	2	3			2	3	
Pulmonary congestion	1	1			1	1	
Pulmonary embolism	5	5			5	5	
Pulmonary oedema	1	1			1	1	
Rales		1				1	
Respiratory distress	2	2			2	2	
Respiratory failure	2	3			2	3	
Rhinorrhoea	7	11	7	11			
Sinus pain	1	1	1	1			
Tachypnoea	2	3	2	2		1	
Throat irritation	6	6	6	6			
Throat tightness	5	6	3	4	2	2	
Wheezing	4	7	4	6		1	
	101	133	73	91	28	42	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	3	3			3	3
Cold sweat	5	9	5	6		3
Erythema	4	7	4	7		
Hyperhidrosis	7	9	6	8	1	1
Pruritus	10	13	10	13		
Rash	22	24	20	22	2	2
Rash macular		1				1
Rash pruritic	2	3	2	3		
Sensitive skin	1	1	1	1		
Skin sensitisation	1	1	1	1		
Urticaria	9	11	9	11		
	64	82	58	72	6	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse		1				1
Cyanosis	2	2	1	1	1	1
Deep vein thrombosis	2	3			2	3
Flushing	9	11	9	11		
Hot flush	1	3	1	3		
Hypertension	13	13	12	12	1	1
Hypotension	8	12	8	9		3
Pallor	1	2	1	1		1
Peripheral circulatory failure	1	1			1	1
Peripheral coldness	1	1	1	1		
Thrombophlebitis	2	2	2	2		
Vasoconstriction	1	1	1	1		
Venous thrombosis	1	1	1	1		
	42	53	37	42	5	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agranulocytosis		1				1
Anaemia	1	1			1	1
Antiphospholipid syndrome		1				1
Autoimmune haemolytic anaemia		1				1
Bone marrow oedema		1				1
Coagulopathy	1	1			1	1
Immune thrombocytopenia		1				1
Leukocytosis		2				2
Leukopenia	1	4			1	4
Lymphadenopathy	3	32	1	15	2	17
Lymph node pain	1	7		5	1	2
Lymphocytosis		1				1
Lymphopenia		1		1		
Neutropenia		1				1
Pancytopenia	1	1			1	1
Splenic vein thrombosis	1	1			1	1
Spontaneous haematoma	1	1			1	1
Thrombocytopenia	2	4			2	4
	12	62	1	21	11	41

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	2			1	2
Acute left ventricular failure	1	1			1	1
Acute myocardial infarction		1				1
Angina pectoris	3	5			3	5
Arrhythmia	3	7			3	7
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	2	7			2	7
Bradycardia		4				4
Bundle branch block left	1	1			1	1
Bundle branch block right		1				1
Cardiac arrest	3	4			3	4
Cardiac failure	2	8			2	8
Cardiac hypertrophy		1				1
Cardiomegaly		1		1		
Cardiomyopathy		1				1
Cardiopulmonary failure	1	2			1	2
Cardio-respiratory arrest		2				2
Cardiovascular disorder	2	11	1	9	1	2
Extrasystoles	1	3		1	1	2
Left ventricular failure		2				2
Myocardial infarction	2	4			2	4
Myocarditis		3				3
Palpitations	6	21	3	7	3	14
Pericardial effusion	2	2			2	2
Pericarditis		1				1
Sinus tachycardia	1	3			1	3
Supraventricular tachycardia	1	1			1	1
Tachycardia	4	16		2	4	14
Tachycardia paroxysmal		1				1
Ventricular extrasystoles		1				1
Ventricular fibrillation		1				1
	36	119	4	20	32	99

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hereditary angioedema with normal C1 esterase inhibitor		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear discomfort		2		2		
Ear pain		2		2		
External ear pain	1	1			1	1
Hypoacusis	1	1			1	1
Sudden hearing loss	2	2			2	2
Tinnitus	2	4	2	3		1
Vertigo	6	24	1	11	5	13
	12	36	3	18	9	18

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune thyroiditis		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute macular outer retinopathy	1	1			1	1
Altered visual depth perception	1	1	1	1		
Blepharospasm		1				1
Conjunctival haemorrhage	2	2			2	2
Diplopia		2		1		1
Endocrine ophthalmopathy	1	1			1	1
Eye haemorrhage		1				1
Eye irritation		1				1
Eyelid oedema		1				1
Eyelid ptosis		1				1
Eye movement disorder		1				1
Eye pain	1	3		2	1	1
Eye pruritus		2		2		
Eye swelling		1		1		
Lacrimation increased		1		1		
Ocular hyperaemia		2		2		
Periorbital swelling		1				1
Photophobia	1	4	1	4		
Pupillary reflex impaired		1				1
Pupils unequal		1				1
Retinal artery occlusion	1	1			1	1
Retinal tear	1	1			1	1
Strabismus		1		1		
Swelling of eyelid		1				1
Vision blurred	1	6	1	4		2
Visual impairment	5	9		1	5	8
Vitreous haemorrhage	2	2			2	2
	17	50	3	20	14	30

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain	1	4		1	1	3
Abdominal pain lower	1	2			1	2
Abdominal pain upper	1	4	1	2		2
Chapped lips		1				1
Colitis		1				1
Defaecation urgency		1		1		
Diarrhoea	5	26	5	19		7
Diarrhoea haemorrhagic	1	3			1	3
Dry mouth	1	8	1	6		2
Dysphagia	3	10		3	3	7
Flatulence	1	1	1	1		
Gastrointestinal disorder		2		2		
Gastrointestinal hypermotility		1		1		
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain		1				1
Glossodynia		1				1
Haematemesis		2				2
Hypoaesthesia oral	1	9	1	4		5
Lip dry		2		1		1
Lip erythema		1				1
Lip pruritus		1				1
Lip swelling	1	6			1	6
Mouth swelling		2				2
Nausea	19	80	16	50	3	30
Oral discomfort		2				2
Oral disorder	1	1	1	1		
Oral mucosa erosion	1	1	1	1		
Oral mucosal erythema		1				1
Oral pruritus		2				2
Palatal swelling		1				1
Paraesthesia oral		5		1		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retching	1	2	1	2		
Stomatitis	1	1	1	1		
Swollen tongue		10		2		8
Thrombosis mesenteric vessel		1				1
Tongue discomfort		4		1		3
Toothache	1	1			1	1
Trichoglossia		1		1		
Vomiting	12	29	10	19	2	10
	53	233	40	122	13	111

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site hypoaesthesia	1	1	1	1		
Administration site joint pain		1		1		
Application site pain		1		1		
Asthenia	10	33	6	25	4	8
Axillary pain	1	2		1	1	1
Cardiac death		1				1
Chest discomfort	3	10		2	3	8
Chest pain	5	14	2	5	3	9
Chills	17	89	17	56		33
Complication associated with device		1		1		
Concomitant disease aggravated		2				2
Concomitant disease progression		1				1
Condition aggravated	2	3	1	1	1	2
Death	4	18			4	18
Discomfort		1		1		
Disease progression		1				1
Disease recurrence	1	2			1	2
Drug ineffective	3	31			3	31
Exercise tolerance decreased		1		1		
Face oedema		4		1		3
Fatigue	20	129	17	98	3	31
Feeling abnormal	2	7	2	5		2
Feeling cold		6		1		5
Feeling drunk		2		2		
Feeling hot	1	9		4	1	5
Feeling jittery		1		1		
Feeling of body temperature change		2		2		
Gait disturbance	2	8	1	5	1	3
Generalised oedema		1		1		
General physical health deterioration	4	13		2	4	11
Hangover		1		1		
Illness		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Inflammation		1					1
Influenza like illness	4	11	4	9			2
Injected limb mobility decreased	1	1			1		1
Injection site bruising		1		1			
Injection site pain		2		2			
Injection site paraesthesia		1		1			
Localised oedema		1					1
Malaise	2	14	1	8	1		6
Multiple organ dysfunction syndrome	1	3			1		3
Oedema		1					1
Oedema mucosal		1		1			
Oedema peripheral	1	2			1		2
Pain	4	18	2	11	2		7
Performance status decreased	1	3	1	2			1
Peripheral swelling	2	10	1	4	1		6
Pyrexia	30	143	20	87	10		56
Sensation of foreign body		6					6
Sense of oppression	1	1			1		1
Swelling		8		5			3
Swelling face		8		2			6
Systemic inflammatory response syndrome		1					1
Therapeutic response unexpected		1		1			
Thirst	1	1	1	1			
Vaccination site anaesthesia		1					1
Vaccination site discolouration		2					2
Vaccination site dysaesthesia		1					1
Vaccination site erythema	4	15	2	9	2		6
Vaccination site haemorrhage		1		1			
Vaccination site hypoaesthesia		7		4			3
Vaccination site induration		4		2			2
Vaccination site inflammation	1	1			1		1
Vaccination site joint pain	1	2		1	1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site lymphadenopathy	1	8	1	5		3
Vaccination site movement impairment	1	6	1	5		1
Vaccination site pain	14	95	11	78	3	17
Vaccination site paraesthesia	1	2	1	1		1
Vaccination site pruritus		5		2		3
Vaccination site rash		4		3		1
Vaccination site reaction	1	5	1	5		
Vaccination site swelling	3	20	1	13	2	7
Vaccination site urticaria	1	2		1	1	1
Vaccination site warmth	1	6		4	1	2
	153	823	95	488	58	335

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic	1	1			1	1
Cholestasis		1				1
Congestive hepatopathy		1				1
Hepatic pain	1	2		1	1	1
Hepatic steatosis		1		1		
	2	6		2	2	4

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	8			2	8
Anaphylactic shock		6				6
Anaphylactoid reaction		2				2
Autoimmune disorder		1				1
Hypersensitivity	3	16		1	3	15
Type I hypersensitivity	1	1			1	1
	6	34		1	6	33

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	9	9			9	9
Bacterial sepsis		1				1
Bronchiolitis		1				1
Bronchitis	1	1			1	1
Central nervous system infection		1				1
Conjunctivitis		1				1
Coronavirus infection		1				1
COVID-19	9	47	1	5	8	42
COVID-19 pneumonia		4				4
Disseminated varicella zoster virus infection	1	1			1	1
Ear infection		1				1
Erysipelas		1				1
Escherichia sepsis		1				1
Gastroenteritis		1		1		
Gingivitis	1	1	1	1		
Helicobacter infection		1				1
Herpes simplex encephalitis	1	1			1	1
Herpes zoster	2	9		5	2	4
Herpes zoster cutaneous disseminated		1				1
Infection	1	1			1	1
Influenza		1		1		
Meningitis bacterial		1				1
Nasopharyngitis		1		1		
Oral pustule		1		1		
Pneumonia	3	10			3	10
Pneumonia bacterial		2				2
Pustule		1		1		
Rash pustular		3		1		2
Rhinitis	1	2	1	2		
Sepsis	1	2			1	2
Septic shock		1				1
Suspected COVID-19	1	2			1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonsillitis bacterial		1				1
Urinary tract infection	1	1			1	1
Vaccination site pustule		1		1		
Vestibular neuronitis	1	1			1	1
Viral infection		1		1		
Viral rash		1				1
	33	118	3	21	30	97

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Concussion	1	1			1	1
Contusion	1	1			1	1
Craniocerebral injury	1	1			1	1
Eye contusion	1	1			1	1
Eyelid contusion	1	1			1	1
Facial bones fracture	1	1			1	1
Fall	5	8		1	5	7
Foreign body aspiration		1				1
Head injury		1				1
Inappropriate schedule of product administration		3		3		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	1	10	1	10		
Injury	1	1			1	1
Intentional overdose		1				1
Maternal exposure during pregnancy	1	1	1	1		
Off label use	1	9	1	9		
Poor quality product administered		1		1		
Product administered at inappropriate site		1		1		
Product preparation error		1		1		
Product use issue	1	6	1	6		
Rib fracture	1	1			1	1
Road traffic accident	1	1			1	1
Subcutaneous haematoma	1	1			1	1
Subdural haemorrhage	1	1			1	1
Toxicity to various agents		1				1
Underdose		1		1		
Vaccination complication		1				1
Vaccination failure	15	17			15	17
Wound haemorrhage	1	1			1	1
Wrong technique in product usage process		3		3		
	37	79	5	38	32	41

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged	1	1			1	1
Alanine aminotransferase increased		1		1		
Analgesic drug level above therapeutic		1				1
Antibody test abnormal		2		2		
Anti-platelet antibody	1	1			1	1
Aspartate aminotransferase increased		1		1		
Beta globulin increased		1		1		
Blood albumin decreased		1		1		
Blood creatine phosphokinase increased	1	3		1	1	2
Blood creatine phosphokinase MB increased		1				1
Blood glucose fluctuation		1				1
Blood glucose increased	1	1			1	1
Blood lactate dehydrogenase increased		1		1		
Blood pressure abnormal	2	3			2	3
Blood pressure decreased		3		1		2
Blood pressure immeasurable		1				1
Blood pressure increased	1	11	1	5		6
Blood pressure systolic increased		1				1
Blood urea increased		1		1		
Body temperature abnormal		1		1		
Body temperature increased	3	15	3	13		2
Brain natriuretic peptide increased		1				1
Breath sounds		1		1		
Breath sounds abnormal	1	1			1	1
C-reactive protein increased		4		2		2
Electrocardiogram abnormal		1		1		
Electrocardiogram change		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram ST-T change	1	1			1	1
Faecal calprotectin increased	1	1			1	1
Fibrin D dimer increased		2		1		1
Heart rate decreased		2				2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	4	1	2		2
Interleukin level increased		1				1
Intraocular pressure increased		1				1
Lymph node palpable		1		1		
Lymphocyte count increased		1				1
Nerve conduction studies abnormal		1				1
Neutralising antibodies negative		1		1		
Opiates positive		1				1
Oxygen saturation		1				1
Oxygen saturation decreased	3	7		2	3	5
Oxygen saturation immeasurable		1				1
Platelet count increased		1		1		
Pulmonary function test decreased	1	1	1	1		
Red blood cell sedimentation rate increased		1		1		
Respiratory rate decreased		1				1
SARS-CoV-2 antibody test negative	1	4		1	1	3
SARS-CoV-2 test positive	2	5			2	5
Sensory level abnormal	2	2			2	2
Serum ferritin decreased		1		1		
Serum ferritin increased		1		1		
Shift to the left		1				1
Transaminases increased	1	2		1	1	1
Transferrin increased		1		1		
Troponin I increased		1				1
Troponin increased		1				1
Troponin T increased	1	3			1	3
Urine ketone body present	1	1	1	1		
White blood cell count increased		1		1		
White blood cells urine		1				1
	27	117	7	50	20	67

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis	1	1	1	1		
Cachexia	1	2			1	2
Decreased appetite	2	6	1	5	1	1
Dehydration	1	1			1	1
Histamine intolerance		1				1
Hyperglycaemia		2				2
Hypernatraemia		1				1
Hypoglycaemia		1				1
Hypokalaemia	1	1			1	1
Hypophagia		1				1
Marasmus		1				1
	6	18	2	6	4	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	11	57	5	32	6	25
Arthritis		1		1		
Back pain	4	11	1	4	3	7
Bone pain		1		1		
Bursitis		2		1		1
Facial asymmetry	1	1			1	1
Flank pain	1	1			1	1
Groin pain		1		1		
Intervertebral disc protrusion	1	1			1	1
Joint range of motion decreased		1				1
Joint swelling	3	6	1	2	2	4
Limb discomfort		1				1
Muscle disorder	1	1			1	1
Muscle spasms	2	9	1	5	1	4
Muscle twitching		1		1		
Muscular weakness	3	10		2	3	8
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal disorder	2	2			2	2
Myalgia	6	54	6	35		19
Neck pain		6		5		1
Nuchal rigidity		2		1		1
Pain in extremity	16	71	10	50	6	21
Rhabdomyolysis	1	1			1	1
Rheumatoid arthritis		1				1
Spinal pain	1	4		2	1	2
Tendon disorder		1		1		
Weight bearing difficulty	1	1	1	1		
	55	249	25	145	30	104

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasm malignant		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute disseminated encephalomyelitis	1	3			1	3
Ageusia	1	3	1	3		
Allodynia	1	1	1	1		
Amnesia	1	1	1	1		
Anosmia		1		1		
Aphasia	3	4		1	3	3
Balance disorder	1	4	1	2		2
Basal ganglia stroke	1	1			1	1
Basilar migraine	1	1			1	1
Bradykinesia		2		1		1
Burning sensation	1	3	1	2		1
Cerebellar stroke	1	1			1	1
Cerebral artery occlusion	1	1			1	1
Cerebral haemorrhage	2	3			2	3
Cerebral infarction	3	3			3	3
Cerebral ischaemia		1				1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	3	7			3	7
Clonus		1				1
Depressed level of consciousness		1				1
Disturbance in attention	3	7	2	3	1	4
Dizziness	18	70	14	45	4	25
Dizziness postural		1		1		
Dysaesthesia	4	7	1	2	3	5
Dysarthria	1	2			1	2
Dysgeusia	2	8	1	4	1	4
Dysgraphia		1		1		
Dyskinesia	1	1			1	1
Dysstasia		2		1		1
Epilepsy	2	4			2	4
Facial paralysis	4	8	1	1	3	7
Facial paresis	5	11			5	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Facial spasm		1					1
Febrile convulsion		1		1			
Formication		1		1			
Generalised tonic-clonic seizure		3					3
Glossopharyngeal nerve disorder	1	1			1		1
Headache	26	164	17	114	9		50
Head discomfort		2		1			1
Hemianaesthesia		2					2
Hemidysaesthesia		2					2
Hemiparaesthesia	1	2			1		2
Hemiparesis	2	3			2		3
Hemiplegia	1	1			1		1
Hyperaesthesia		1					1
Hyperreflexia		1					1
Hypersomnia		2		2			
Hypertonia		1					1
Hypoaesthesia	4	24	2	10	2		14
Hypogeusia		2		1			1
Hypoglossal nerve paresis	1	1			1		1
Hypokinesia		1		1			
Hyposmia		1					1
Hypotonia		4		3			1
Ischaemic cerebral infarction	1	1			1		1
Ischaemic stroke	1	1			1		1
Language disorder	1	1	1	1			
Leukoencephalopathy	1	1			1		1
Locked-in syndrome	1	1			1		1
Loss of consciousness	2	8			2		8
Memory impairment	2	5	1	2	1		3
Meningism		1					1
Migraine	2	6	1	5	1		1
Monoparesis		2					2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monoplegia	1	2			1	2
Movement disorder		3		2		1
Multiple sclerosis		2				2
Muscle contractions involuntary	1	3		1	1	2
Muscle spasticity		1				1
Myoclonus	1	1			1	1
Narcolepsy		1				1
Nervous system disorder		1				1
Neuralgia		3		1		2
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neurological symptom		1				1
Neuropathy peripheral		1				1
Occipital neuralgia		1		1		
Paraesthesia	11	42	1	16	10	26
Paresis		1				1
Parosmia		2		2		
Peroneal nerve palsy	1	1			1	1
Petit mal epilepsy		1				1
Post herpetic neuralgia	1	1			1	1
Presyncope	4	20		4	4	16
Radial nerve palsy	1	1			1	1
Radiculopathy		1				1
Reduced facial expression		1		1		
Ruptured cerebral aneurysm		1				1
Seizure	2	5			2	5
Sensory disturbance	1	2			1	2
Somnolence	5	27	4	18	1	9
Speech disorder	2	5		1	2	4
Status epilepticus		1				1
Subarachnoid haemorrhage		2				2
Syncope	2	23			2	23

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		3		2		1
Tension headache		2		1		1
Thalamic infarction	1	1			1	1
Transient ischaemic attack	1	1			1	1
Tremor	1	4		2	1	2
Trigeminal neuralgia	1	2			1	2
Tunnel vision		2				2
Unresponsive to stimuli		4				4
Vascular encephalopathy	1	1			1	1
Visual field defect	1	2			1	2
	148	594	51	264	97	330

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Syringe issue		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		2		2		
Anxiety	1	4		2	1	2
Apathy		2		2		
Confusional state	4	7	1	1	3	6
Daydreaming		1				1
Delirium	1	1			1	1
Disorganised speech		1		1		
Disorientation		3		2		1
Hallucination		1				1
Head banging		1				1
Insomnia		6		4		2
Lack of spontaneous speech	1	1			1	1
Mania		1				1
Panic attack		1				1
Panic reaction		1		1		
Personality change		1				1
Psychotic disorder		1				1
Restlessness		5		4		1
Sleep attacks		1		1		
Sleep disorder		1				1
Sleep disorder due to general medical condition, hypersomnia type		1		1		
Somatic symptom disorder		1				1
Sopor	1	1			1	1
Tension		1		1		
Thinking abnormal		1				1
	8	47	1	22	7	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Dysuria		1		1		
Haematuria	1	2			1	2
Incontinence	1	1			1	1
Pollakiuria	1	1	1	1		
Renal disorder		1		1		
Renal failure	1	2			1	2
Renal pain	1	3			1	3
Urinary retention		1				1
	6	13	1	3	5	10

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		1				1
Breast pain		1		1		
Menorrhagia	1	1			1	1
Menstruation irregular	1	1			1	1
Metrorrhagia		1				1
Vaginal discharge		1		1		
Vaginal haemorrhage	1	2			1	2
	3	8		2	3	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1				1
Apnoea	1	1			1	1
Asthma		2				2
Atelectasis		1				1
Bronchial obstruction	1	1			1	1
Choking		1				1
Chronic obstructive pulmonary disease	1	2	1	1		1
Cough	2	13	2	10		3
Dry throat		1		1		
Dyspnoea	15	46	3	7	12	39
Dyspnoea exertional	1	9		2	1	7
Emphysema		2		1		1
Epistaxis	1	3	1	2		1
Grunting		1		1		
Hyperventilation	2	3	1	1	1	2
Hypopnoea	1	1			1	1
Laryngeal oedema		1				1
Laryngeal pain		1				1
Laryngospasm		1				1
Lung disorder		1		1		
Lung infiltration		1				1
Obstructive airways disorder		1		1		
Oropharyngeal pain	3	10	3	7		3
Painful respiration	1	1	1	1		
Pharyngeal lesion	1	1	1	1		
Pharyngeal swelling	1	7		2	1	5
Pleural effusion	1	3			1	3
Pleurisy		1				1
Pneumonia aspiration		4				4
Pneumothorax spontaneous	1	1			1	1
Productive cough		1		1		
Pulmonary congestion		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	12	23			12	23
Pulmonary hypertensive crisis	1	1			1	1
Pulmonary infarction		2				2
Pulmonary oedema		3				3
Rales		2		1		1
Respiratory depression		1				1
Respiratory disorder		1		1		
Respiratory distress		1				1
Respiratory failure		2				2
Rhinitis allergic		1				1
Sinus congestion		1		1		
Tachypnoea		1		1		
Throat irritation	1	6	1	3		3
Throat tightness		4				4
Use of accessory respiratory muscles		1		1		
	47	174	14	48	33	126

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Alopecia		2		2			
Angioedema	2	2			2	2	
Blister		1				1	
Cold sweat		1				1	
Dermatitis allergic		2				2	
Dermatitis bullous	1	1			1	1	
Drug eruption		2				2	
Eczema		3		1		2	
Erythema	3	15	2	9	1	6	
Hand dermatitis	1	1	1	1			
Hirsutism		1		1			
Hyperhidrosis	4	5	4	4		1	
Idiopathic angioedema		1				1	
Lividity		1		1			
Night sweats		2		1		1	
Onychoclasia		1		1			
Pain of skin		2		1		1	
Palmar erythema		1				1	
Pemphigus		1				1	
Petechiae		3		1		2	
Prurigo	1	1			1	1	
Pruritus	4	32		7	4	25	
Pruritus allergic		1				1	
Psoriasis	1	1			1	1	
Rash	6	32	3	7	3	25	
Rash macular		5		1		4	
Rash morbilliform		1				1	
Rash pruritic	2	7	1	2	1	5	
Skin burning sensation		1				1	
Skin discolouration		1				1	
Skin exfoliation	1	2	1	1		1	
Skin indentation		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion		1				1
Skin reaction		1		1		
Skin striae		1		1		
Skin tightness		1				1
Skin wrinkling	1	1	1	1		
Urticaria	3	17	1	2	2	15
Urticaria pressure		1				1
	30	156	14	47	16	109

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	1	1	1		
Impaired driving ability		1				1
Impaired quality of life	1	1			1	1
Impaired work ability	2	12	1	5	1	7
Loss of personal independence in daily activities	1	2			1	2
	5	17	2	6	3	11

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm ruptured		1				1
Arterial occlusive disease	1	1			1	1
Arteriosclerosis		1				1
Circulatory collapse	9	24			9	24
Deep vein thrombosis	4	8			4	8
Flushing		11		1		10
Haematoma	2	2			2	2
Haemorrhage		1				1
Hot flush	1	5		2	1	3
Hypertension	2	12		1	2	11
Hypertensive crisis	2	10			2	10
Hypertensive emergency		1				1
Hypotension	1	12		3	1	9
Pallor	1	7		2	1	5
Peripheral coldness	1	3	1	2		1
Peripheral vascular disorder	1	1	1	1		
Poor peripheral circulation		1		1		
Shock		1				1
Thrombophlebitis	2	2	1	1	1	1
Thrombosed varicose vein	1	1			1	1
Thrombosis	4	4			4	4
Vasculitis		1				1
Venous thrombosis limb	3	5		1	3	4
	35	115	3	15	32	100

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**BAHRAIN**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	1	1			1	1
Chills	1	3		2	1	1
Pain	1	2		1	1	1
Pyrexia	1	3		2	1	1
Swelling	1	1			1	1
Vaccination site pain		1		1		
	5	11		6	5	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart rate increased	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	1	1			1	1
Myalgia		2		2		
Neck pain		1		1		
	1	4		3	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache		1		1		
Paraesthesia	1	1			1	1
	1	2		1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	1			1	1
Pruritus		1		1		
	1	2		1	1	1

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hot flush		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BELGIUM**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathy	9	17		3	9	14
Leukocytosis		1				1
Lymphadenitis	1	2	1	1		1
Lymphadenopathy	15	35	5	6	10	29
Lymph node pain	4	8			4	8
Neutropenia		1				1
Neutrophilia		1				1
Thrombocytopenia		2				2
	29	67	6	10	23	57

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		3				3
Arrhythmia	2	4			2	4
Atrial fibrillation		3				3
Atrioventricular block complete		2				2
Bradycardia	1	10			1	10
Bundle branch block left		1				1
Cardiac arrest	2	9	1	1	1	8
Cardiac disorder		2				2
Cardiac failure	1	4			1	4
Cardiogenic shock	1	2			1	2
Cardiomegaly	1	1			1	1
Cardio-respiratory arrest		3				3
Cardiovascular disorder	17	57	4	8	13	49
Coronary artery thrombosis		1				1
Myocardial infarction		1				1
Palpitations	4	14	3	5	1	9
Pericardial effusion		1				1
Pericarditis	1	1			1	1
Rhythm idioventricular		1				1
Sinus tachycardia		1				1
Stress cardiomyopathy		1		1		
Supraventricular tachycardia	1	1			1	1
Tachyarrhythmia		1				1
Tachycardia	9	29		2	9	27
Ventricular tachycardia		1				1
	40	154	8	17	32	137

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	2			1	2
Deafness unilateral		1				1
Dysacusis	1	1			1	1
Ear discomfort	1	2	1	2		
Ear pain	3	6	1	1	2	5
Endolymphatic hydrops		2				2
Hyperacusis		2				2
Hypoacusis		1				1
Sudden hearing loss		1				1
Tinnitus	2	7	1	1	1	6
Vertigo	9	28	4	6	5	22
Vertigo positional		1		1		
	17	54	7	11	10	43

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute macular outer retinopathy		1				1	
Angle closure glaucoma		1				1	
Asthenopia	1	2	1	2			
Blindness	1	3			1	3	
Diplopia		1				1	
Endocrine ophthalmopathy	1	1			1	1	
Eye irritation	1	1			1	1	
Eye movement disorder		1				1	
Eye pain	2	7	2	4		3	
Eye swelling		3				3	
Glaucoma		1				1	
Lacrimation increased	1	2		1	1	1	
Mydriasis	1	1	1	1			
Ocular discomfort	2	2	2	2			
Ocular hyperaemia		1		1			
Photophobia	1	3			1	3	
Photopsia		1				1	
Scleral discolouration		1				1	
Swelling of eyelid		1				1	
Vision blurred	5	10	3	5	2	5	
Visual impairment	3	6	2	2	1	4	
	19	50	11	18	8	32	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	4	2	2		2
Abdominal distension		2		1		1
Abdominal pain	1	10		1	1	9
Abdominal pain upper	4	8	1	2	3	6
Abdominal symptom		1		1		
Anal incontinence	1	1	1	1		
Aphthous ulcer	1	3			1	3
Breath odour		2				2
Constipation	1	1			1	1
Diarrhoea	11	30	3	7	8	23
Diarrhoea haemorrhagic	1	1			1	1
Dry mouth	1	3			1	3
Dyspepsia	1	1			1	1
Dysphagia	1	5	1	2		3
Faecal vomiting	1	1			1	1
Faeces discoloured		1				1
Flatulence	2	2	2	2		
Gastric dilatation	2	2	1	1	1	1
Gastric disorder		1				1
Gastrointestinal disorder	1	2			1	2
Gastrointestinal pain		3				3
Gastrooesophageal reflux disease	1	1			1	1
Gingival pain		1				1
Hyperaesthesia teeth		1				1
Hypoaesthesia oral	1	1	1	1		
Intestinal dilatation		1				1
Intestinal ischaemia		2				2
Intestinal obstruction	1	1			1	1
Lip swelling		5		1		4
Nausea	89	311	19	34	70	277
Noninfective gingivitis		1				1
Odynophagia		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pruritus		1				1
Paraesthesia oral	1	6	1	1		5
Retching	1	4			1	4
Salivary hypersecretion		2		1		1
Stomatitis		1				1
Swollen tongue	1	8		1	1	7
Tongue discomfort		1				1
Vomiting	11	44	3	4	8	40
	137	477	35	64	102	413

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	13	36	6	9	7	27
Axillary pain	3	8		2	3	6
Chest discomfort	1	13	1	2		11
Chest pain	10	24	3	6	7	18
Chills	136	385	26	36	110	349
Condition aggravated	1	2	1	1		1
Crying		2				2
Death	2	4			2	4
Discomfort	3	4		1	3	3
Disease recurrence		2				2
Drug ineffective	15	68			15	68
Drug resistance		1				1
Exercise tolerance decreased		3				3
Extensive swelling of vaccinated limb	8	9	1	1	7	8
Face oedema	1	3	1	2		1
Facial pain	2	2	1	1	1	1
Fatigue	167	487	38	73	129	414
Feeling abnormal	5	11	2	4	3	7
Feeling cold	2	10		3	2	7
Feeling drunk		1		1		
Feeling hot	1	7		4	1	3
Feeling of body temperature change	2	6			2	6
Gait disturbance		3				3
General physical health deterioration	2	17		1	2	16
Hyperthermia	2	2	2	2		
Hypothermia	2	4			2	4
Illness	1	5		4	1	1
Inflammation	1	3	1	1		2
Influenza like illness	27	75	7	14	20	61
Injection site discomfort	1	1	1	1		
Injection site erythema	1	1			1	1
Injection site haematoma		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site hypersensitivity		1				1
Injection site pain	2	3	2	3		
Injection site reaction	5	9	2	3	3	6
Malaise	91	289	16	29	75	260
Multiple organ dysfunction syndrome		2				2
Oedema peripheral	1	1			1	1
Pain	11	20	4	6	7	14
Peripheral swelling	12	42	5	7	7	35
Pyrexia	152	405	47	71	105	334
Sensation of foreign body		2		1		1
Sense of oppression	2	6	1	3	1	3
Sudden death	3	16			3	16
Swelling		2				2
Swelling face	1	5	1	1		4
Therapeutic response unexpected	1	1	1	1		
Thirst		2		1		1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	20	35	19	25	1	10
Vaccination site haematoma	1	5	1	3		2
Vaccination site hypersensitivity		1				1
Vaccination site hypertrophy		1				1
Vaccination site induration	5	11	5	7		4
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy	1	2			1	2
Vaccination site movement impairment		4		1		3
Vaccination site pain	32	85	20	32	12	53
Vaccination site pruritus		3		1		2
Vaccination site rash		1		1		
Vaccination site reaction	88	220	22	29	66	191
Vaccination site swelling	9	22	7	11	2	11
Vaccination site warmth	2	9	1	3	1	6
	849	2,407	246	411	603	1996

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic		1				1
Hepatic failure		1				1
Hepatitis	1	2			1	2
Liver disorder	3	4	2	2	1	2
	4	8	2	2	2	6

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient	1	1			1	1
Allergy to vaccine		1				1
Anaphylactic reaction	5	33			5	33
Anaphylactic shock	1	5			1	5
Anaphylactoid reaction		1				1
Autoimmune disorder	5	6			5	6
Food allergy	1	1			1	1
Hypersensitivity	7	21	1	3	6	18
	20	69	1	3	19	66

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis		2				2
Asymptomatic COVID-19	3	25			3	25
COVID-19	23	91	6	17	17	74
COVID-19 pneumonia	1	3			1	3
Dermo-hypodermatitis		1				1
Erysipelas		1				1
Herpes ophthalmic		3				3
Herpes simplex		1				1
Herpes virus infection	1	1			1	1
Herpes zoster		5		4		1
Infection	1	3	1	2		1
Influenza	2	5	1	3	1	2
Laryngitis		1				1
Localised infection		1				1
Nasopharyngitis	1	2			1	2
Oral herpes	1	5		1	1	4
Parapharyngeal space infection		1				1
Pneumonia		3				3
Pneumonia bacterial		1				1
Pyelonephritis	1	2			1	2
Respiratory tract infection	1	3			1	3
Rhinitis		1				1
Scarlet fever		1				1
Sepsis		2				2
Septic shock	1	2			1	2
Sinusitis		1				1
Suspected COVID-19	1	1			1	1
Tonsillitis		2		1		1
Urinary tract infection		1		1		
Urosepsis		1				1
Vestibular neuronitis		1				1
	37	173	8	29	29	144

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Chillblains		1				1	
Concussion		1				1	
Contusion	2	3	1	1	1	2	
Drug administered in wrong device		1		1			
Eschar		1				1	
Expired product administered		2		1		1	
Exposure during pregnancy		1		1			
Exposure via breast milk	1	2	1	2			
Exposure via skin contact		1		1			
Facial bones fracture		1					1
Fall	3	11		2	3	9	
Inappropriate schedule of product administration	1	1	1	1			
Incorrect dose administered	1	1	1	1			
Incorrect route of product administration	34	128	34	128			
Maternal exposure during pregnancy		1		1			
Muscle strain	7	11	1	2	6	9	
Occupational exposure to product		1		1			
Off label use	2	4	2	4			
Procedural pain	1	1			1	1	
Product administered at inappropriate site	1	1			1	1	
Product preparation issue		1		1			
Product use issue	2	4	2	4			
Underdose		1		1			
Vaccination failure	2	17			2	17	
Wrong product administered	1	2	1	2			
Wrong technique in product usage process	34	112	34	112			
	92	311	78	267	14	44	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased	1	1	1	1		
Aspartate aminotransferase increased	1	1	1	1		
Blood glucose decreased		1		1		
Blood glucose increased		1		1		
Blood lactic acid increased		2				2
Blood pressure abnormal	1	3	1	1		2
Blood pressure decreased	5	10		1	5	9
Blood pressure increased	2	8	1	1	1	7
Blood pressure systolic increased		1		1		
Blood test abnormal	1	1			1	1
Blood urine present		1				1
Body temperature decreased		1				1
Body temperature fluctuation		1				1
Body temperature increased	7	13	4	6	3	7
C-reactive protein increased	1	4	1	2		2
Fibrin D dimer increased	1	3			1	3
Gamma-glutamyltransferase increased	1	1	1	1		
Heart rate decreased		2				2
Heart rate increased	1	11		3	1	8
Heart rate irregular		1		1		
Hepatic enzyme increased	1	1	1	1		
Liver function test abnormal		3				3
N-terminal prohormone brain natriuretic peptide increased		1				1
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	3	25	1	1	2	24
Prohormone brain natriuretic peptide increased	1	1			1	1
Red blood cell sedimentation rate increased		1		1		
Respiratory rate increased		1				1
SARS-CoV-2 antibody test positive		1		1		
SARS-CoV-2 test positive		1				1
Serum ferritin increased	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Troponin increased		3				3
Troponin T increased	1	1			1	1
Weight decreased		1				1
White blood cell count decreased		1		1		
	29	110	13	27	16	83

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	5	14	2	4	3	10
Dehydration		1				1
Diabetic complication		1				1
Hypoglycaemia		5				5
Hypokalaemia		1				1
Hyponatraemia		1				1
Ketoacidosis		3				3
Lactic acidosis	1	2			1	2
Metabolic acidosis		1				1
Tetany		1				1
Vitamin D deficiency		1				1
	6	31	2	4	4	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	59	176	9	15	50	161
Arthritis	1	4		1	1	3
Axillary mass		1				1
Back pain	1	8		2	1	6
Bone pain		5				5
Facial asymmetry	1	1			1	1
Jaw disorder	1	1	1	1		
Joint range of motion decreased	2	2			2	2
Joint stiffness		1				1
Joint swelling		1				1
Limb discomfort	2	7		2	2	5
Mobility decreased	2	4		1	2	3
Muscle contracture		1				1
Muscle fatigue	2	2	1	1	1	1
Muscle spasms	1	3		1	1	2
Muscle tightness		1				1
Muscular weakness	1	5		1	1	4
Musculoskeletal chest pain		3		2		1
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness	23	54	18	31	5	23
Myalgia	124	389	28	51	96	338
Myosclerosis		1				1
Neck pain	5	14	1	2	4	12
Pain in extremity	26	59	20	32	6	27
Pain in jaw		1				1
Posture abnormal	1	1	1	1		
SAPHO syndrome		1				1
Spinal pain		2		2		
	252	749	79	146	173	603

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Allodynia		1				1
Altered state of consciousness		5				5
Amnesia		1				1
Anosmia		1				1
Aphasia	1	2			1	2
Balance disorder	3	8			3	8
Brain injury	1	1			1	1
Burning sensation	4	6	1	2	3	4
Cerebral haemorrhage	1	1			1	1
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis	1	2			1	2
Cerebrovascular accident	5	11			5	11
Coma		1				1
Decreased vibratory sense		1				1
Depressed level of consciousness		10				10
Disturbance in attention	2	2	1	1	1	1
Dizziness	18	55	3	11	15	44
Dizziness postural		1				1
Dysaesthesia		1				1
Dysgeusia	2	10	2	3		7
Dyspraxia	1	1			1	1
Dysstasia	1	2			1	2
Dystonia		1				1
Epilepsy	1	10			1	10
Facial paralysis	3	13			3	13
Facial paresis	1	6			1	6
Facial spasm	2	2	2	2		
Formication		1				1
Generalised tonic-clonic seizure	1	3			1	3
Haemorrhage intracranial		1				1
Haemorrhagic stroke		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	169	514	37	78	132	436
Head discomfort		1				1
Hemianaesthesia		1				1
Hemiparaesthesia		1				1
Hemiparesis		2				2
Hemiplegia	1	3			1	3
Hyperaesthesia	1	1			1	1
Hypersomnia		2				2
Hypoaesthesia	4	10	2	3	2	7
Hyporeflexia		1				1
Hyporesponsive to stimuli		1				1
Lethargy		2				2
Loss of consciousness	1	9			1	9
Memory impairment	1	2		1	1	1
Migraine	3	15			3	15
Migraine with aura		2				2
Muscle contractions involuntary	1	1			1	1
Nervous system disorder	12	38	3	6	9	32
Neuralgia	1	3		1	1	2
Neuritis		1				1
Neuropathy peripheral		1				1
Orthostatic intolerance		1				1
Paraesthesia	8	21	4	10	4	11
Paralysis		1				1
Paresis		1				1
Parkinson's disease		2				2
Parosmia	1	2	1	1		1
Patient elopement		1				1
Peripheral motor neuropathy	1	1			1	1
Polyneuropathy		1				1
Poor quality sleep		4		2		2
Presyncope	3	12	2	2	1	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restless legs syndrome		1		1		
Sedation		2				2
Seizure	3	12			3	12
Sensory disturbance		2		2		
Sensory loss		1				1
Sinus headache		1				1
Sleep deficit		1				1
Somnolence	2	11		2	2	9
Speech disorder	1	3	1	3		
Syncope	4	30			4	30
Taste disorder		1		1		
Thoracic outlet syndrome		1				1
Transient ischaemic attack	1	1			1	1
Tremor	3	13	1	2	2	11
Unresponsive to stimuli		3				3
Visual field defect		2				2
	271	906	61	135	210	771

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Syringe issue		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		1				1
Acute psychosis	1	1			1	1
Agitation	1	6	1	1		5
Anxiety	1	8	1	1		7
Apathy	1	3		1	1	2
Confusional state	2	5	2	2		3
Delirium		1				1
Disorientation		2				2
Hallucination	1	4			1	4
Hallucination, visual		1				1
Illusion		1				1
Insomnia	6	21	2	6	4	15
Irritability		1				1
Nightmare	1	1			1	1
Restlessness	1	3		1	1	2
Sleep disorder	2	6	2	2		4
Sleep disorder due to a general medical condition		1		1		
Staring		1				1
Thinking abnormal		1				1
	17	68	8	15	9	53

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	3			1	3
Leukocyturia		1		1		
Renal disorder	2	5			2	5
Renal failure		3				3
Renal pain		3				3
Urinary retention		1				1
	3	16		1	3	15

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain	3	3	1	1	2	2
Suppressed lactation	1	1			1	1
Vaginal haemorrhage		1				1
	4	5	1	1	3	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		1				1
Acute respiratory failure		4				4
Aphonia		1		1		
Asthma		2				2
Asthma exercise induced		1				1
Bradypnoea		1				1
Bronchial disorder		1				1
Bronchospasm		3				3
Cheyne-Stokes respiration		1				1
Cough	6	17	2	4	4	13
Diaphragmalgia	1	1			1	1
Dry throat		2		1		1
Dysphonia		3		1		2
Dyspnoea	17	54	2	4	15	50
Dyspnoea exertional	3	5			3	5
Epistaxis	1	2			1	2
Hyperventilation	1	4		1	1	3
Hypoxia		1				1
Laryngeal oedema		1				1
Laryngospasm		1				1
Lower respiratory tract congestion		1				1
Lung disorder	1	1			1	1
Lung infiltration		1				1
Nasal congestion		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	3	13	3	6		7
Painful respiration	1	3			1	3
Pharyngeal erythema		1				1
Pharyngeal swelling	1	6			1	6
Pleural effusion		2				2
Pneumonia aspiration		1				1
Pneumonitis	1	3			1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Productive cough		1					1
Pulmonary arterial hypertension	1	1			1		1
Pulmonary embolism	4	9			4		9
Pulmonary infarction		1					1
Pulmonary oedema	1	3			1		3
Rales	1	2			1		2
Respiration abnormal		2					2
Respiratory acidosis	1	1			1		1
Respiratory arrest		1					1
Respiratory disorder	24	56	1	3	23		53
Respiratory distress		4					4
Respiratory failure		1					1
Rhinorrhoea	1	7		3	1		4
Sinus pain		1					1
Sneezing	2	4	1	2	1		2
Suffocation feeling		1					1
Tachypnoea		2					2
Throat tightness	1	3			1		3
Tonsillar inflammation		1					1
Upper airway obstruction		1					1
Wheezing	1	3			1		3
	73	245	9	28	64		217

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		4				4
Cold sweat		2				2
Dry skin		1				1
Eczema	1	1	1	1		
Erythema	6	21	5	6	1	15
Hyperhidrosis	4	14	1	4	3	10
Hypersensitivity vasculitis	1	1			1	1
Livedo reticularis		1				1
Night sweats		2				2
Pain of skin	2	4		1	2	3
Palmoplantar pustulosis		1		1		
Papule	2	2	1	1	1	1
Pruritus	9	24	5	8	4	16
Pruritus allergic		1				1
Rash	4	11	4	5		6
Rash erythematous	3	4	3	3		1
Rash macular	1	2			1	2
Rash maculo-papular		1				1
Rash pruritic		1				1
Sensitive skin	3	4	1	1	2	3
Skin burning sensation		1				1
Skin disorder	13	37	4	5	9	32
Skin mass	1	1			1	1
Skin sensitisation		1				1
Urticaria	1	6			1	6
Yellow skin		1				1
	51	149	25	36	26	113

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immobile		1				1
Impaired work ability	1	1	1	1		
Loss of personal independence in daily activities	1	1	1	1		
	2	3	2	2		1

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis	1	3			1	3
Deep vein thrombosis	4	5			4	5
Flushing		1				1
Haematoma	1	2	1	1		1
Haemorrhage		1				1
Hot flush	2	12	1	3	1	9
Hypertension	11	36	2	3	9	33
Hypertensive crisis		1				1
Hypotension	2	18	1	2	1	16
Hypovolaemic shock		1				1
Lymphoedema		1				1
Neurogenic shock		2				2
Orthostatic hypotension		1		1		
Pallor		3				3
Peripheral coldness		1				1
Phlebitis		1				1
Thrombophlebitis		1				1
Thrombosis	1	2			1	2
Vasculitis		2		1		1
	22	94	5	11	17	83

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BERMUDA**

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Ear congestion	1	1	1	1
Ear discomfort	1	1	1	1
	2	2	2	2

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Sudden visual loss		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Feeling cold		1		1		
Pain	1	1			1	1
Peripheral swelling	1	1			1	1
Pyrexia		1		1		
	2	5		3	2	2

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Balance disorder		1		1
Dizziness		1		1
Paraesthesia		1		1
		3		3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1			1	1
Night sweats		1		1		
Rash	1	1	1	1		
	2	3	1	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**BOSNIA AND HERZEGOVINA**

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BRAZIL**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pain	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BULGARIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenia	1	1			1	1
Lymphadenopathy	2	16	2	15		1
Lymph node pain	2	4	2	4		
	5	21	4	19	1	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Arrhythmia	1	1			1	1
Extrasystoles		2		2		
Heart alternation	1	1	1	1		
Palpitations	2	4	1	3	1	1
Tachycardia	2	3	1	1	1	2
Ventricular extrasystoles		1				1
	6	13	3	7	3	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral		1				1
Tinnitus	1	2	1	2		
Vertigo	3	12	2	8	1	4
	4	15	3	10	1	5

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Conjunctivitis allergic		1		1
Eye pain		2		2
Lacrimation increased	1	2	1	2
Photophobia		1		1
	1	6	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		1		1
Abdominal pain upper		1				1
Dental discomfort		1		1		
Diarrhoea		2		2		
Dry mouth		2		2		
Epigastric discomfort		1		1		
Gastrointestinal disorder		1		1		
Lip swelling		1				1
Nausea	4	15	4	14		1
Paraesthesia oral		1		1		
Swollen tongue		1				1
Vomiting		5		4		1
	4	34	4	28		6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	18	2	16		2
Axillary pain	1	1	1	1		
Chest pain		1		1		
Chills	8	28	8	25		3
Condition aggravated	1	1	1	1		
Discomfort		2		2		
Drug ineffective	4	11			4	11
Fatigue	11	28	11	28		
Feeling cold		1		1		
Feeling hot	1	1	1	1		
Gait disturbance	1	3		2	1	1
Hypothermia		1				1
Influenza like illness	1	2	1	2		
Injection site erythema		2		2		
Injection site oedema		1		1		
Injection site pain		6		6		
Injection site swelling		3		3		
Malaise	4	12	4	12		
Oedema peripheral	1	2	1	2		
Pain	2	5	2	5		
Peripheral swelling		2		2		
Pyrexia	10	32	10	30		2
Swelling	1	3	1	3		
Swelling face		1		1		
Thirst		1		1		
Vaccination site erythema	1	17		14	1	3
Vaccination site extravasation		1		1		
Vaccination site induration	1	2		1	1	1
Vaccination site oedema		1		1		
Vaccination site pain	12	58	12	57		1
Vaccination site paraesthesia		1		1		
Vaccination site reaction		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		19		17		2
	62	269	55	241	7	28

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Anaphylactoid reaction		1				1
Hypersensitivity		1		1		
	1	3	1	2		1

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis	1	1	1	1		
COVID-19	5	15	1	4	4	11
COVID-19 pneumonia		2				2
Groin abscess		1				1
Herpes simplex		1		1		
Nasopharyngitis	3	3	3	3		
Pneumonia	1	1			1	1
Sinusitis	1	1	1	1		
Sweating fever		1				1
Tracheitis	1	1	1	1		
	12	27	7	11	5	16

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial bones fracture	1	1			1	1
Inappropriate schedule of product administration		1		1		
Joint injury	1	1			1	1
Off label use		1		1		
Overdose	2	2	2	2		
	4	6	2	4	2	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Antibody test abnormal	1	1	1	1		
Anti-thyroid antibody positive		1				1
Blood glucose increased	2	2	1	1	1	1
Blood pressure ambulatory increased	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood pressure diastolic decreased		1		1		
Blood pressure increased	3	7	2	5	1	2
Body temperature abnormal		1		1		
Body temperature increased	1	31	1	29		2
C-reactive protein increased	1	1			1	1
Heart rate increased		1		1		
Heart rate irregular	1	1	1	1		
HIV test positive	1	1	1	1		
Lymphocyte count decreased		1		1		
Rheumatoid factor increased		1				1
Rheumatoid factor positive		1		1		
SARS-CoV-2 test positive		1				1
	12	54	7	43	5	11

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		3		2		1
		3		2		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	7	28	7	28		
Arthritis		1		1		
Back pain	1	5	1	5		
Bone pain	1	1	1	1		
Limb discomfort	1	2	1	2		
Mastication disorder		1		1		
Mobility decreased		1		1		
Muscle spasms		1		1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness		2		1		1
Myalgia	6	37	6	37		
Neck pain		1		1		
Pain in extremity	8	12	8	12		
Rheumatoid arthritis		1				1
Spinal pain		1		1		
Trismus		1		1		
	25	96	25	94		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		2		2		
Disturbance in attention		1		1		
Dizziness	3	15	3	14		1
Dizziness postural		1		1		
Facial paralysis	1	3			1	3
Headache	11	47	11	43		4
Head discomfort		2		1		1
Hypoaesthesia	1	1	1	1		
Lethargy	1	1	1	1		
Meningism		1		1		
Movement disorder	1	2	1	1		1
Myelitis transverse		1				1
Neuralgia		1		1		
Neuromyelitis optica spectrum disorder		1				1
Paraesthesia	4	9	4	8		1
Peripheral sensory neuropathy		1		1		
Presyncope	1	1	1	1		
Seizure		1				1
Syncope	2	2			2	2
Tremor	1	5		4	1	1
	26	99	22	82	4	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Agitation		2		2
Communication disorder		1		1
Insomnia		2		2
		5		5

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Renal pain		1		1
		1		1

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
			Breast pain	1	1	1
Erectile dysfunction		1				1
	1	2	1	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	2	5	2	5		
Dysphonia	1	1	1	1		
Dyspnoea	3	6	3	4		2
Epistaxis	1	1	1	1		
Interstitial lung disease		1				1
Oropharyngeal pain	2	5	2	5		
Painful respiration		1		1		
Paranasal sinus discomfort	1	1	1	1		
Productive cough	1	1	1	1		
Rhinorrhoea	1	2	1	2		
Throat irritation	1	1	1	1		
	13	25	13	22		3

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Drug eruption		1		1		
Erythema	2	5	2	5		
Hyperhidrosis		6		4		2
Pruritus	3	3	2	2	1	1
Rash	2	4	2	4		
Rash erythematous		1		1		
Rash macular	1	1			1	1
Rash pruritic		1		1		
Urticaria		3		2		1
	8	26	6	21	2	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Circulatory collapse	1	1			1	1
Haematoma	1	1			1	1
Hot flush		1		1		
Hypertension	2	3	1	2	1	1
Jugular vein distension		1				1
Pallor		1		1		
Peripheral coldness		1		1		
Vasodilatation	1	1	1	1		
Vasospasm		1				1
	5	13	2	8	3	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CANADA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	26		22	1	4
Lymph node pain		2		2		
Splenitis	1	1			1	1
Thrombocytopenia		2				2
	2	31		24	2	7

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	2	3			2	3
Atrial fibrillation	2	3			2	3
Bradycardia		1				1
Cardiac disorder	1	1			1	1
Cardiac flutter	2	3			2	3
Myocardial infarction	2	2			2	2
Myocarditis	2	2			2	2
Palpitations	2	6	2	5		1
Pericardial effusion	1	1			1	1
Pericarditis		1				1
Tachycardia	3	12	2	6	1	6
Ventricular tachycardia		1				1
	17	36	4	11	13	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerumen impaction		1		1		
Deafness	1	2			1	2
Deafness unilateral	1	1			1	1
Ear discomfort	2	5	2	5		
Ear pruritus		1		1		
Ear swelling	1	1	1	1		
Excessive cerumen production		1		1		
Hypoacusis	1	3	1	3		
Motion sickness		1		1		
Tinnitus	5	11	2	7	3	4
Vertigo	2	4	1	3	1	1
	13	31	7	23	6	8

System Organ Class

**Endocrine disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Thyroid disorder	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness	1	1			1	1
Dermatochalasis	1	1	1	1		
Diplopia	1	2	1	1		1
Dry eye	1	1	1	1		
Eye irritation		1				1
Eyelid disorder	1	1	1	1		
Eyelid function disorder		1				1
Eyelid oedema		1				1
Eyelid ptosis	1	1			1	1
Eyelid sensory disorder		1		1		
Eyelids pruritus		1				1
Eye pain		1		1		
Eye pruritus		1		1		
Eye swelling	1	3	1	3		
Hypoaesthesia eye		1		1		
Lacrimation increased	2	3	2	3		
Ocular hyperaemia	1	1	1	1		
Periorbital swelling	2	3	2	3		
Swelling of eyelid		2		2		
Uveitis		1				1
Vision blurred	2	6	1	4	1	2
Visual impairment		2		1		1
Vitreous detachment		1				1
Vitreous floaters		1		1		
	14	38	11	26	3	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3	1	3		
Abdominal distension		1		1		
Abdominal pain		4		3		1
Abdominal pain lower		2		2		
Abdominal pain upper	2	7	1	6	1	1
Aphthous ulcer		2		2		
Change of bowel habit		1		1		
Chapped lips		1		1		
Coeliac disease		1				1
Colitis ulcerative	1	1			1	1
Defaecation urgency		1		1		
Diarrhoea	7	27	5	24	2	3
Dry mouth	4	4	3	3	1	1
Dysphagia	5	10	3	8	2	2
Faeces soft	1	1	1	1		
Flatulence	1	1	1	1		
Gastric disorder		1		1		
Gastric ulcer	2	2			2	2
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal pain	1	1	1	1		
Gastrooesophageal reflux disease		1		1		
Haematemesis		1				1
Hiatus hernia	1	1	1	1		
Hyperaesthesia teeth		1		1		
Hypoaesthesia oral	3	8	2	3	1	5
Lip blister		1		1		
Lip disorder	1	1	1	1		
Lip haemorrhage		1		1		
Lip pain	1	2	1	2		
Lip pruritus		1		1		
Lip swelling	4	7	4	5		2
Mouth swelling		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	19	63	14	54	5	9
Odynophagia		1		1		
Oesophageal disorder		1				1
Oesophagitis	1	1			1	1
Oral discomfort	1	3	1	3		
Oral mucosal blistering		1		1		
Oral pain		1		1		
Paraesthesia oral	1	10	1	7		3
Rectal haemorrhage	1	1			1	1
Stomatitis		1		1		
Swollen tongue	3	8	3	6		2
Tongue disorder	1	5	1	4		1
Tongue pruritus		2		2		
Vomiting	11	23	7	17	4	6
Vomiting projectile		1		1		
	74	220	53	175	21	45

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	8	24	6	18	2	6
Axillary pain		5		5		
Chest discomfort	3	14	2	9	1	5
Chest pain		6		5		1
Chills	11	51	9	49	2	2
Condition aggravated	7	8	2	2	5	6
Death	1	2			1	2
Discomfort	1	3	1	3		
Disease recurrence	2	6		2	2	4
Drug ineffective	7	42			7	42
Drug interaction	2	2			2	2
Face oedema		1				1
Facial pain		3		3		
Fatigue	22	98	16	86	6	12
Feeling abnormal	6	14	6	14		
Feeling cold	1	4	1	2		2
Feeling drunk		1		1		
Feeling hot		10		9		1
Feeling of body temperature change	1	2	1	2		
Gait disturbance	3	3	1	1	2	2
Illness		1		1		
Inflammation	1	1	1	1		
Influenza like illness	2	8	1	7	1	1
Infusion site warmth	1	1	1	1		
Injection site bruising		1		1		
Injection site erythema	1	2	1	2		
Injection site hypersensitivity		1		1		
Injection site pain	3	13	3	13		
Injection site scar		1		1		
Injection site swelling		1		1		
Malaise	7	26	6	25	1	1
Mass		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mucosal discolouration	1	1	1	1		
Mucosal disorder		1		1		
Necrosis		1				1
No adverse event	2	3	2	3		
Oedema		2		1		1
Oedema peripheral		1		1		
Pain	11	38	7	33	4	5
Peripheral swelling	3	7	3	6		1
Pyrexia	14	61	11	56	3	5
Screaming	1	1	1	1		
Secretion discharge		2		2		
Shoulder injury related to vaccine administration	1	1	1	1		
Swelling		6		5		1
Swelling face	3	10	2	6	1	4
Tenderness		1		1		
Therapeutic response unexpected	2	4	2	4		
Thirst	2	3	2	3		
Vaccination site bruising		1		1		
Vaccination site discomfort	2	2	1	1	1	1
Vaccination site erythema	2	6	2	6		
Vaccination site induration		2		2		
Vaccination site inflammation		1		1		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		1		1		
Vaccination site movement impairment		1		1		
Vaccination site oedema		3		3		
Vaccination site pain	8	51	8	49		2
Vaccination site rash	2	3	2	3		
Vaccination site reaction		2		2		
Vaccination site swelling	1	8	1	8		
Vaccination site urticaria	1	5		3	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth	2	5	2	5		
	149	592	107	479	42	113

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Anaphylactic reaction	5	39			5	39
Anaphylactic shock	2	4			2	4
Autoimmune disorder	1	1			1	1
Hypersensitivity	6	17	3	5	3	12
Type I hypersensitivity		2				2
Type IV hypersensitivity reaction		1		1		
	14	65	3	7	11	58

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1				1
Beta haemolytic streptococcal infection		1				1
Bronchitis	1	1	1	1		
Cellulitis		1				1
Conjunctivitis		1		1		
COVID-19	7	47	1	3	6	44
COVID-19 pneumonia		1				1
Dermatitis infected	1	1	1	1		
Disseminated varicella zoster virus infection		1				1
Ear infection		1				1
Fungal skin infection		1		1		
Gastroenteritis		1		1		
Gastroenteritis viral		1		1		
Herpes simplex	1	1			1	1
Herpes zoster	6	9	5	7	1	2
Herpes zoster oticus	1	1			1	1
Infection		1		1		
Meningitis aseptic		1				1
Nasopharyngitis		3		3		
Oral candidiasis		1		1		
Oral herpes		2		2		
Parvovirus infection	1	1	1	1		
Pneumonia	1	2			1	2
Rash pustular		1		1		
Roseola		1		1		
Sepsis	2	2			2	2
Suspected COVID-19	3	3	2	2	1	1
Urinary tract infection		1		1		
Varicella		1		1		
Viral rash		1		1		
Vulvitis		1		1		
	24	92	11	32	13	60

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Circumstance or information capable of leading to medication error		2		2		
Contusion	3	6	3	4		2
Exposure during pregnancy	1	14	1	12		2
Exposure via breast milk		25		25		
Fall	4	6		1	4	5
Hip fracture	1	1			1	1
Inappropriate schedule of product administration	2	45	2	45		
Incomplete course of vaccination		2		2		
Incorrect dose administered		3		3		
Incorrect route of product administration		2		2		
Intentional product use issue		1		1		
Ligament sprain	1	1	1	1		
Maternal exposure before pregnancy	2	4	1	3	1	1
Maternal exposure during pregnancy	3	19	3	19		
Maternal exposure timing unspecified		2		2		
Muscle injury		1		1		
Off label use	3	80	3	79		1
Overdose		11		11		
Product administered at inappropriate site	1	5	1	5		
Product preparation error		2		2		
Product preparation issue		13		13		
Product use issue	1	41	1	40		1
Rib fracture	1	1			1	1
Skin injury		1		1		
Skin laceration	1	1	1	1		
Toxicity to various agents	1	1			1	1
Underdose	4	13	4	13		
Vaccination failure		3				3
Wrong product administered	1	2	1	2		
Wrong technique in product usage process		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	30	310	22	292	8	18

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased	2	2	1	1	1	1
Aspartate aminotransferase increased	1	1			1	1
Blood creatine phosphokinase increased	1	1			1	1
Blood glucose decreased	1	2			1	2
Blood glucose increased		1		1		
Blood pressure decreased	3	5		1	3	4
Blood pressure increased	2	3	1	2	1	1
Blood urine		1		1		
Blood urine present	1	2	1	2		
Body temperature increased		1		1		
C-reactive protein increased	2	2	1	1	1	1
Drug level increased	2	2	1	1	1	1
Eosinophil count increased		1		1		
Grip strength decreased		1		1		
Haemoglobin decreased	1	1	1	1		
Heart rate decreased	1	3			1	3
Heart rate increased	4	9	1	4	3	5
Hepatic enzyme increased	1	2			1	2
Liver function test increased		1				1
Monocyte count increased		1		1		
Neutrophil count decreased		1		1		
Oxygen saturation decreased		1				1
Pulse volume decreased		2		1		1
SARS-CoV-2 test positive		1				1
Troponin increased	1	1	1	1		
Vital functions abnormal		1				1
Vitamin B12 increased	1	1			1	1
Weight decreased		2		2		
Weight increased		1		1		
White blood cell count decreased		1		1		
	24	54	8	26	16	28

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	8	2	7		1
Dehydration		1		1		
Diabetes mellitus	1	1			1	1
Fluid retention	1	3	1	3		
Gout		2		2		
Hyperuricaemia	1	1	1	1		
Polydipsia		1		1		
	5	17	4	15	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	7	33	5	29	2	4
Axillary mass		2		2		
Back pain	2	6	2	4		2
Bursitis	1	1	1	1		
Facial asymmetry	1	1	1	1		
Fibromyalgia		1		1		
Joint noise		1		1		
Joint range of motion decreased		1		1		
Joint swelling	2	4	1	2	1	2
Limb discomfort		3		3		
Mobility decreased		2		2		
Muscle spasms		3		2		1
Muscle tightness		1		1		
Muscle twitching	1	2	1	2		
Muscular weakness	1	7	1	6		1
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	4	10	4	10		
Myalgia	7	48	6	45	1	3
Neck pain	4	11	4	10		1
Pain in extremity	8	50	8	45		5
Pain in jaw	1	3		2	1	1
Rheumatoid arthritis	2	4			2	4
Systemic lupus erythematosus		1				1
Temporomandibular joint syndrome		1		1		
Tendon disorder		1		1		
Tendonitis	1	2	1	2		
	42	200	35	175	7	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lipoma		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	4	2	4		
Anosmia	1	1	1	1		
Aphasia	1	2	1	2		
Ataxia	1	1	1	1		
Balance disorder	4	5	2	3	2	2
Burning sensation	1	2	1	2		
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cerebrovascular accident	3	5			3	5
Cognitive disorder		1		1		
Depressed level of consciousness	1	2			1	2
Disturbance in attention	4	7	3	6	1	1
Dizziness	20	51	13	40	7	11
Dysarthria	1	1			1	1
Dysgeusia	5	10	5	10		
Dyskinesia		1		1		
Dysstasia	1	1	1	1		
Facial paralysis	5	14			5	14
Generalised tonic-clonic seizure		1				1
Headache	30	112	24	103	6	9
Head discomfort		1		1		
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	1			1	1
Hyperaesthesia	1	4		3	1	1
Hypersomnia	2	4	2	4		
Hypoaesthesia	12	25	7	14	5	11
Hypokinesia		1		1		
Ischaemic stroke	1	1			1	1
IVth nerve paralysis		1				1
Lethargy		4		4		
Loss of consciousness	5	7			5	7
Memory impairment	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mental impairment	1	1			1	1
Migraine	2	11	1	9	1	2
Monoparesis	1	1			1	1
Multiple sclerosis	1	1			1	1
Multiple sclerosis relapse	1	1			1	1
Nervous system disorder	1	1			1	1
Neuralgia		2				2
Neurological symptom	1	1			1	1
Paraesthesia	6	28	2	15	4	13
Paralysis	1	1			1	1
Presyncope		7		4		3
Reflexes abnormal		1				1
Seizure	4	4			4	4
Sensory disturbance		1				1
Sensory loss		1		1		
Somnolence	2	8		4	2	4
Speech disorder	1	2	1	2		
Superior sagittal sinus thrombosis	1	1			1	1
Syncope	9	16			9	16
Taste disorder	1	3	1	3		
Tension headache	1	1	1	1		
Transient ischaemic attack	2	3	1	1	1	2
Tremor	1	6	1	5		1
Vertebral artery dissection		1				1
	141	377	71	247	70	130

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	1	3			1	3
Ectopic pregnancy		1				1
Foetal growth restriction	1	3			1	3
Gestational diabetes		1				1
Postpartum haemorrhage		1		1		
Threatened labour		1		1		
	2	10		2	2	8

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Oversensing		1		1
Product complaint	4	4	4	4
Product container issue		1		1
Product physical issue		1		1
Product quality issue		1		1
Product supply issue		2		2
	4	10	4	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect lability		1		1		
Agitation		1		1		
Anxiety	3	8	3	7		1
Confusional state	1	2	1	2		
Delirium	1	1			1	1
Depression	1	2	1	2		
Distractibility		1		1		
Fear		1		1		
Insomnia	3	5	3	5		
Nervousness		1				1
Psychotic disorder due to a general medical condition		1				1
Sleep disorder	2	3	2	3		
Stress	1	2	1	2		
Suicidal ideation	1	1			1	1
	13	30	11	25	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		1				1
Bladder spasm		1		1		
Chromaturia		1		1		
Dysuria	2	2	1	1	1	1
Haemorrhage urinary tract	3	4			3	4
Incontinence	1	1			1	1
Micturition urgency		1		1		
Polyuria		1		1		
Urinary incontinence		1				1
	6	13	1	5	5	8

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		2		1		1
Breast tenderness		1		1		
Dysmenorrhoea	1	2	1	2		
Menorrhagia	2	3	1	2	1	1
Menstrual disorder		1		1		
Menstruation delayed		1		1		
Menstruation irregular	1	3	1	3		
Penis disorder		1				1
Polymenorrhoea	1	3	1	3		
Testicular pain		1		1		
Testicular retraction		1				1
Vaginal discharge		1		1		
Vaginal haemorrhage		3		3		
Vulval disorder		1				1
	5	24	4	19	1	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm		1				1
Chronic obstructive pulmonary disease	1	1			1	1
Cough	3	10	2	8	1	2
Dysphonia	1	4	1	3		1
Dyspnoea	14	30	9	20	5	10
Laryngospasm		1				1
Lung disorder	1	2			1	2
Nasal congestion	1	2		1	1	1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	9	1	9		
Pharyngeal hypoaesthesia		3		2		1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	1	5	1	3		2
Pleural effusion	1	1			1	1
Productive cough	1	3	1	2		1
Pulmonary embolism	1	3			1	3
Pulmonary infarction		1				1
Pulmonary oedema	1	1			1	1
Pulmonary pain		1				1
Respiratory disorder	1	1	1	1		
Rhinorrhoea	4	7	4	6		1
Sinus pain		1		1		
Sneezing	1	3	1	3		
Tachypnoea		1		1		
Throat irritation	1	3	1	3		
Throat tightness	2	7	1	2	1	5
Upper-airway cough syndrome		1		1		
Wheezing		4		3		1
	37	108	24	70	13	38

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Angioedema	1	2			1	2
Cold sweat	2	4	1	3	1	1
Dermatitis	1	1			1	1
Eczema		1		1		
Erythema	6	12	4	8	2	4
Erythema multiforme		1				1
Hyperhidrosis		5		3		2
Leukoplakia		1		1		
Night sweats	2	2	1	1	1	1
Pain of skin	1	2	1	2		
Petechiae		2		2		
Pruritus	9	27	6	20	3	7
Purpura		1		1		
Rash	10	29	8	26	2	3
Rash erythematous	3	6	3	5		1
Rash macular		3		3		
Rash maculo-papular	1	2	1	1		1
Rash papular	1	2	1	1		1
Rash pruritic	1	6	1	4		2
Skin burning sensation		2		2		
Skin discolouration	1	1	1	1		
Skin exfoliation		1		1		
Skin lesion		1		1		
Skin reaction	1	2	1	2		
Skin warm		1		1		
Stevens-Johnson syndrome		1				1
Urticaria	10	31	7	25	3	6
	50	150	36	116	14	34

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired quality of life	1	1	1	1		
Impaired work ability		2		2		
Loss of personal independence in daily activities	3	4	3	3		1
	4	7	4	6		1

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Abortion induced	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angiopathy		1		1		
Deep vein thrombosis	1	1			1	1
Flushing		4		3		1
Hot flush	2	3	1	2	1	1
Hypertension	5	16	3	8	2	8
Hypertensive crisis		1				1
Hypotension	2	9	1	5	1	4
Lymphoedema		1		1		
Pallor	1	3	1	2		1
Peripheral arterial occlusive disease	1	1	1	1		
Peripheral coldness	1	2	1	1		1
Poor peripheral circulation	1	1	1	1		
Raynaud's phenomenon	1	1			1	1
Thrombosis	5	7			5	7
	20	51	9	25	11	26

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CAYMAN ISLANDS**

*System Organ Class*

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Palpitations		1		1
		1		1

*System Organ Class*

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Dyspepsia		1		1
		1		1

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
		1		1

*System Organ Class*

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle spasms		1		1
Muscle twitching		1		1
		2		2

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
		1		1

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Irritability		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CHILE**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	2	7	2	6		1
Lymph node pain		3		3		
Splenomegaly	1	1			1	1
	3	11	2	9	1	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Arrhythmia		1				1
Tachycardia	3	4	3	3		1
	4	6	3	3	1	3

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear discomfort		1		1
Tinnitus	1	1	1	1
Vestibular disorder		1		1
	1	3	1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye discharge	1	1	1	1		
Eye movement disorder	1	1			1	1
Eye pruritus		1				1
Eye swelling	1	2	1	1		1
Ocular hyperaemia		1				1
Photophobia		1				1
	3	7	2	2	1	5

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	2	2	2		
Abdominal pain upper	4	6	4	5		1
Abnormal faeces		1		1		
Colitis	1	1	1	1		
Diarrhoea	3	9	3	9		
Dry mouth		1				1
Dysbiosis		1				1
Glossitis		1		1		
Nausea	10	15	10	14		1
Pancreatitis		1				1
Swollen tongue		1		1		
Tongue movement disturbance	1	1			1	1
Toothache	1	1	1	1		
Vomiting	2	3	2	3		
	25	45	24	39	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	2	1	2		
Axillary pain		1		1		
Chest discomfort	2	2	2	2		
Chest pain	3	4	3	3		1
Chills	7	12	7	11		1
Crying		1				1
Cyst	1	1	1	1		
Discomfort	1	2	1	2		
Disease recurrence		1		1		
Drug ineffective	1	1			1	1
Face oedema		2				2
Fatigue	10	18	10	18		
Feeling abnormal		1		1		
Feeling cold	3	4	3	4		
Gait disturbance	3	4	2	3	1	1
Gait inability	1	1			1	1
Inflammation		1		1		
Localised oedema		1				1
Malaise	10	17	10	17		
Mass	1	1	1	1		
Oedema peripheral		1		1		
Pain	8	13	8	12		1
Peripheral swelling	3	4	2	3	1	1
Pyrexia	21	30	21	29		1
Stenosis	1	1	1	1		
Swelling face		1				1
Therapeutic response unexpected	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	3	2	3		
Vaccination site inflammation	3	4	3	4		
Vaccination site mass		1		1		
Vaccination site pain	10	21	9	18	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site swelling	1	1	1	1		
	95	161	90	145	5	16

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug-induced liver injury	1	1			1	1
Hepatic steatosis		1		1		
	1	2		1	1	1

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		3				3
Hypersensitivity	3	8	3	8		
	3	11	3	8		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Suspected COVID-19		1		1
	1	2	1	2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	2	2	2	2		
Exposure via breast milk	1	1	1	1		
Fall		1				1
Head injury		1				1
Inappropriate schedule of product administration	1	2	1	2		
Incomplete course of vaccination		9		9		
Incorrect route of product administration		1		1		
Maternal exposure during pregnancy		1		1		
Maternal exposure timing unspecified		1		1		
Off label use	1	3	1	3		
Overdose		1		1		
Product preparation error		1		1		
Product use issue	1	2	1	2		
Splenic rupture	1	1			1	1
Wound haemorrhage		1				1
Wrong product administered	2	2	2	2		
	9	30	8	26	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose decreased	1	1	1	1		
Blood glucose increased	1	1			1	1
Blood pressure increased	1	1	1	1		
Blood test abnormal		1		1		
Complement factor C3 decreased		1		1		
C-reactive protein decreased		1		1		
Hepatic enzyme increased		1				1
Monocyte count decreased		1		1		
Oxygen saturation decreased	1	1	1	1		
SARS-CoV-2 antibody test negative		1		1		
Transaminases increased	1	1	1	1		
Urine analysis abnormal		1				1
	5	12	4	9	1	3

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		2		2
Polydipsia		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	3	8	3	7		1
Arthritis		1				1
Axillary mass	1	1	1	1		
Back pain	1	3	1	3		
Bone pain	1	2	1	2		
Joint swelling		2		1		1
Limb discomfort	1	1	1	1		
Muscle discomfort	1	1	1	1		
Muscle spasms	1	3	1	3		
Muscular weakness		1		1		
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Myalgia	20	29	20	28		1
Neck pain	2	2	2	2		
Pain in extremity	7	10	7	10		
Rhabdomyolysis		1				1
Synovial cyst		1		1		
	40	68	40	63		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1			1	1
Burning sensation		2		2		
Dizziness	3	5	3	5		
Dysgeusia		1				1
Facial paralysis	1	1			1	1
Guillain-Barre syndrome		2				2
Headache	26	42	26	41		1
Head discomfort	1	1	1	1		
Hemiparaesthesia	1	1			1	1
Hemiparesis		1				1
Hemiplegia		1				1
Hyperaesthesia	2	2	2	2		
Hypertonia	1	1	1	1		
Hypoaesthesia	4	5	4	4		1
Loss of consciousness	1	2			1	2
Neuralgia	1	1			1	1
Paraesthesia	3	7	3	5		2
Seizure	1	2			1	2
Sensory loss		1		1		
Somnolence	2	3	2	3		
Syncope	1	1			1	1
	49	83	42	65	7	18

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply issue	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety	1	1	1	1
Aversion	1	1	1	1
Depressed mood	1	1	1	1
Discouragement		1		1
Emotional distress	1	1	1	1
Fear	1	1	1	1
Insomnia	3	3	3	3
Mental disorder		1		1
Panic attack	1	1	1	1
Panic reaction	1	1	1	1
Stress	1	1	1	1
	11	13	11	13

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast engorgement	1	1	1	1
Breast pain		1		1
Galactostasis	1	1	1	1
	2	3	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choking		1				1
Cough	1	2	1	2		
Dyspnoea	1	5	1	2		3
Hyperventilation		1				1
Nasal congestion	1	2	1	2		
Oropharyngeal pain	1	2	1	2		
Respiratory disorder		1				1
Respiratory distress		1				1
Rhinorrhoea	3	3	3	3		
Throat irritation	2	2	2	2		
	9	20	9	13		7

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Cold sweat	1	1	1	1		
Dermatitis allergic	1	5		4	1	1
Dry skin		1		1		
Erythema	1	3	1	3		
Erythema nodosum	1	1			1	1
Hyperhidrosis		1		1		
Pruritus	1	2	1	2		
Rash		2		1		1
Rash pruritic		1				1
Skin burning sensation	2	2	2	2		
Urticaria	1	2	1	1		1
	8	23	6	16	2	7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Loss of personal independence in daily activities		2		2
		2		2

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1	1	1		
Hot flush	1	1	1	1		
Hypertension	1	1	1	1		
Hypotension		1				1
Internal haemorrhage	1	1			1	1
Pallor		1				1
Vasculitis	1	1			1	1
Venous thrombosis		1				1
	5	8	3	3	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**COLOMBIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukocytosis		1		1
Lymphadenopathy	2	2	2	2
Lymph node pain	1	1	1	1
	3	4	3	4

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Tachycardia	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Eye pain		1		1
Ocular hyperaemia		1		1
		2		2

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Diarrhoea	1	2	1	1		1
Nausea	1	2	1	2		
Odynophagia		1		1		
Stomatitis		1		1		
Vomiting	1	3	1	2		1
	3	10	3	8		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	5	1	4		1
Chest pain	1	1	1	1		
Chills	3	7	3	6		1
Death	1	1			1	1
Discomfort		2		1		1
Fatigue		1				1
Feeling hot		3		3		
Gait inability		1		1		
Influenza like illness		1		1		
Malaise	6	11	6	10		1
Oedema	1	1	1	1		
Pain	1	2	1	2		
Puncture site pain	1	1	1	1		
Pyrexia	3	6	3	5		1
Secretion discharge	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	7	3	7		
	23	52	22	45	1	7

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		3				3
Anaphylactic shock		1				1
Drug hypersensitivity	1	1	1	1		
Hypersensitivity	2	4	2	4		
	3	9	3	5		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	1			1	1
Candida infection		1		1		
COVID-19	2	4	2	3		1
Gingivitis		1		1		
Influenza	1	2	1	2		
Oral candidiasis		1		1		
	4	10	3	8	1	2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure during pregnancy	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1
Off label use		1		1
Product use issue		1		1
Underdose	1	1	1	1
	3	5	3	5

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased		1		1
Lymph node palpable		1		1
Oxygen saturation decreased		1		1
		3		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	3	6	3	6
Back pain	1	1	1	1
Bone pain		1		1
Muscle spasms	1	1	1	1
Musculoskeletal pain		1		1
Myalgia	1	4	1	4
	6	14	6	14

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation		1		1		
Dizziness	1	3	1	3		
Headache	5	15	5	13		2
Hypoaesthesia		1		1		
Paraesthesia	1	3	1	3		
Seizure		1				1
Syncope		1				1
	7	25	7	21		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anxiety		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asphyxia		1				1
Cough	2	6	2	5		1
Dysphonia		1		1		
Dyspnoea	2	4	2	3		1
Oropharyngeal pain	1	2	1	2		
Pharyngeal erythema	1	1	1	1		
Respiratory distress		1				1
Rhinorrhoea	1	1	1	1		
Sneezing	1	1	1	1		
	8	18	8	14		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister		1		1		
Erythema	2	4	2	4		
Hyperhidrosis		1		1		
Pruritus		1		1		
Rash		5		3		2
Skin discolouration		1		1		
Skin plaque		1		1		
Urticaria	2	4	2	4		
	4	18	4	16		2

System Organ Class

**SOC Not Yet Coded**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis		1		1		
Hypertension		2		1		1
		3		2		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**COSTA RICA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune thrombocytopenia	1	1			1	1
Lymphadenopathy	1	3	1	3		
Lymph node pain		2		2		
Splenomegaly		1				1
	2	7	1	5	1	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	1	2			1	2
Tachycardia		3		3		
	1	5		3	1	2

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Ear discomfort	1	1	1	1		
Tinnitus	2	2	2	2		
	4	4	3	3	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye	1	1	1	1		
Erythema of eyelid	1	1	1	1		
Eye allergy		1		1		
Eye inflammation		1		1		
Eyelid irritation	1	1	1	1		
Eye pain		2		2		
Eye pruritus		2		2		
Miosis		1				1
Ocular hyperaemia		2		2		
Photopsia		1		1		
Vision blurred		1		1		
	3	14	3	13		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	4		1	1	3
Aphthous ulcer		1		1		
Constipation		2		2		
Diarrhoea	5	9	4	7	1	2
Dry mouth		1				1
Dyspepsia	1	2			1	2
Faeces soft		1		1		
Flatulence		1		1		
Gastric disorder		1		1		
Gastritis		2		1		1
Gastrointestinal pain		1		1		
Gastrointestinal sounds abnormal		1		1		
Gingival bleeding	1	1	1	1		
Gingival disorder	1	1	1	1		
Gingival pain	1	1	1	1		
Mouth swelling		1		1		
Nausea	2	10	1	8	1	2
Odynophagia	1	1	1	1		
Tooth disorder	1	1	1	1		
Vomiting	1	6		4	1	2
	17	50	11	36	6	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site inflammation		1		1		
Application site pain		3		3		
Asthenia	2	8	2	6		2
Axillary pain	1	1	1	1		
Chest discomfort		1				1
Chest pain		1				1
Chills	2	13	2	11		2
Condition aggravated		2		1		1
Death	2	2			2	2
Discomfort		2		1		1
Drug ineffective	3	6			3	6
Energy increased		1		1		
Extensive swelling of vaccinated limb		1		1		
Fatigue	15	34	14	31	1	3
Feeling abnormal	1	5		4	1	1
Feeling cold		5		5		
Feeling hot		1		1		
Hyperthermia		1		1		
Hypothermia		1				1
Influenza like illness		1				1
Malaise	2	8	2	7		1
Pain	9	20	9	20		
Peripheral swelling	2	3	2	3		
Pyrexia	8	25	7	23	1	2
Sensation of foreign body		1		1		
Swelling face		1		1		
Thirst		2				2
Vaccination site discomfort		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site induration		1		1		
Vaccination site mass		1		1		
Vaccination site movement impairment		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site nodule	1	1	1	1		
Vaccination site pain	23	43	23	43		
Vaccination site urticaria		1		1		
	72	200	64	173	8	27

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Anaphylactic shock	1	2			1	2
Hypersensitivity		1		1		
	1	4		1	1	3

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	6	11	1	2	5	9
Gingivitis	1	1	1	1		
Infection	1	2	1	2		
Influenza	1	2	1	2		
Lymphangitis		1				1
Nasopharyngitis		1		1		
Suspected COVID-19		1		1		
	9	19	4	9	5	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	2		1	1	1
Fall		1				1
Incorrect route of product administration		2		2		
Vaccination failure	2	2			2	2
	3	7		3	3	4

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1	1	1		
Fibrin D dimer increased		1		1		
Heart rate increased		1				1
Heart rate irregular		1		1		
Hepatic enzyme increased		1				1
Oxygen saturation abnormal	2	2	1	1	1	1
Oxygen saturation decreased		3				3
Platelet count abnormal	2	2			2	2
Red blood cell sedimentation rate increased		1		1		
SARS-CoV-2 antibody test negative		1		1		
	5	14	2	6	3	8

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	8	1	8		
Back pain	1	2	1	2		
Bone pain		1		1		
Joint range of motion decreased		1				1
Joint swelling	1	1	1	1		
Limb discomfort	2	4	2	4		
Mobility decreased	1	3	1	2		1
Muscle contracture		1		1		
Muscle spasms		3		3		
Myalgia	4	22	4	20		2
Neck pain	1	1	1	1		
Pain in extremity	13	29	13	29		
	24	76	24	72		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation		2		2		
Cerebrovascular accident	3	3			3	3
Dizziness	3	9	2	6	1	3
Dysgeusia		3		2		1
Dysstasia		1		1		
Encephalopathy		1				1
Headache	9	37	8	33	1	4
Hypersomnia		1		1		
Hypoaesthesia		2		2		
Hyposmia	1	1	1	1		
Incoherent		1		1		
Lethargy	2	2	2	2		
Migraine		4		3		1
Nervous system disorder		1		1		
Paraesthesia	1	3	1	3		
Seizure		1				1
Somnolence	2	4	2	4		
Syncope	1	1			1	1
Tremor		1		1		
	22	78	16	63	6	15

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Communication disorder		1		1
Depression		1		1
Euphoric mood		1		1
Insomnia		1		1
Sleep disorder		1		1
		5		5

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Renal disorder	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Adnexa uteri pain		2		2
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1		1		
Bronchospasm	1	1	1	1		
Cough	3	4	3	4		
Dysphonia	1	2	1	2		
Dyspnoea	2	8	2	6		2
Epistaxis	2	2	1	1	1	1
Lung disorder	1	2	1	1		1
Nasal congestion	1	1	1	1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	3	4	3	4		
Pleural effusion		1				1
Pleuritic pain		1		1		
Pneumonitis		1				1
Respiratory disorder	1	1			1	1
Respiratory distress		1				1
Respiratory tract congestion	1	1	1	1		
Rhinorrhoea		1		1		
Tachypnoea	1	2	1	2		
Throat clearing		1		1		
Throat irritation	2	2	2	2		
Throat tightness		1				1
	19	39	17	29	2	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Dermatitis allergic		2		1		1
Ecchymosis	1	1	1	1		
Erythema		1		1		
Hyperhidrosis		3		2		1
Petechiae	2	2	1	1	1	1
Pruritus	5	7	5	7		
Rash	1	4	1	4		
Rash papular	1	1	1	1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Skin lesion		1		1		
Urticaria		1		1		
	10	26	9	23	1	3

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Impaired work ability		1		1
Loss of personal independence in daily activities	1	2	1	2
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage	1	1			1	1
Hypertension		1				1
Hypertensive crisis		1				1
Ischaemia	1	1	1	1		
Vasculitis		1		1		
Venous thrombosis		1				1
	2	6	1	2	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CROATIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Lymphadenitis		2		1		1
Lymphadenopathy	2	9	1	7	1	2
Lymph node pain	1	3	1	2		1
Lymphopenia		1		1		
Thrombocytopenia		1				1
	3	17	2	11	1	6

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Arrhythmia	5	7			5	7
Atrial fibrillation		2				2
Cardiac arrest		1				1
Cardiac disorder	1	1			1	1
Cardiac failure		3				3
Cardiac failure acute	1	1			1	1
Cardiac failure congestive		1				1
Cardiomyopathy		1				1
Cardio-respiratory arrest	1	1			1	1
Palpitations	4	12	2	5	2	7
Stress cardiomyopathy	1	1			1	1
Tachycardia	5	13	2	6	3	7
	19	45	4	11	15	34

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness bilateral		1				1
Deafness unilateral	1	1			1	1
Ear canal erythema		1				1
Ear pain	1	3	1	1		2
Ear pruritus		1				1
Hypoacusis		1		1		
Tinnitus	1	6		3	1	3
Vertigo	2	5	1	3	1	2
	5	19	2	8	3	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage	1	3			1	3
Conjunctivitis allergic		1				1
Dry eye	1	1			1	1
Eye haematoma		1				1
Eye haemorrhage		1				1
Eyelid function disorder		1				1
Eyelid oedema		2		1		1
Eyelid pain		1		1		
Eyelid ptosis		2				2
Eye opacity		1		1		
Eye pain	1	3	1	3		
Lacrimation increased	1	2	1	2		
Ocular discomfort	2	2	2	2		
Ocular hyperaemia		1		1		
Vision blurred		1				1
Visual impairment		1				1
Vitreous detachment		1				1
	6	25	4	11	2	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain		1				1	
Abdominal pain upper	1	3	1	3			
Aphthous ulcer		1		1			
Defaecation urgency	1	1	1	1			
Diarrhoea	3	6	2	4	1		2
Dry mouth		2		1			1
Dyspepsia	1	1	1	1			
Dysphagia		3					3
Eructation		1		1			
Gastritis	1	1	1	1			
Gastrointestinal pain		1		1			
Gingival bleeding		1		1			
Hypoaesthesia oral	1	2	1	1			1
Irritable bowel syndrome		1		1			
Lip disorder		1					1
Lip oedema	1	2			1		2
Lip swelling		1					1
Melaena	1	1			1		1
Nausea	6	28	4	21	2		7
Oedema mouth		1					1
Oral mucosal erythema		1		1			
Oral pain		1		1			
Paraesthesia oral	1	6		2	1		4
Rectal haemorrhage		1					1
Retching	1	3	1	3			
Salivary hypersecretion		1					1
Swollen tongue		3					3
Tongue disorder		1					1
Tongue oedema		3					3
Vomiting	6	12	4	7	2		5
	24	91	16	52	8		39

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site oedema		1		1		
Asthenia	7	32	5	24	2	8
Axillary pain	1	1			1	1
Chest discomfort	2	7	1	2	1	5
Chest pain	3	6	1	3	2	3
Chills	12	51	10	44	2	7
Condition aggravated		2				2
Death	1	3			1	3
Discomfort		1		1		
Drug ineffective	1	2			1	2
Extensive swelling of vaccinated limb	2	21			2	21
Facial pain		1		1		
Fatigue	10	37	7	30	3	7
Feeling abnormal	1	3		2	1	1
Feeling cold		1		1		
Feeling hot	1	10	1	6		4
Gait disturbance	1	2			1	2
General physical health deterioration		1				1
Illness		1		1		
Localised oedema		1		1		
Malaise	4	20	4	17		3
Moaning		1				1
Multi-organ disorder		1				1
Oedema peripheral	1	3	1	1		2
Pain	2	6	2	6		
Peripheral swelling		3		2		1
Pyrexia	20	89	12	64	8	25
Sensation of foreign body		1		1		
Swelling face		2				2
Vaccination site erythema	5	37	3	27	2	10
Vaccination site haematoma		3		3		
Vaccination site hypersensitivity		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	1	6	1	4		2
Vaccination site joint erythema		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy	2	3	2	3		
Vaccination site mass		1				1
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema	2	11	1	8	1	3
Vaccination site pain	12	103	8	87	4	16
Vaccination site pruritus		4		3		1
Vaccination site reaction		1		1		
Vaccination site swelling	1	19	1	13		6
Vaccination site warmth		1		1		
	93	503	60	361	33	142

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to chemicals		1		1		
Anaphylactic reaction		2				2
Anaphylactic shock		2				2
Hypersensitivity		4				4
Immune system disorder		1		1		
Serum sickness		1				1
Type I hypersensitivity	1	20			1	20
	1	31		2	1	29

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		1				1
COVID-19	14	18		2	14	16
Ear infection	1	1			1	1
Escherichia urinary tract infection		1				1
Nasopharyngitis		1		1		
Pneumonia		2				2
Pneumonia klebsiella		1				1
Pneumonia staphylococcal		1				1
Urinary tract infection		1				1
Viral infection		1		1		
	15	28		4	15	24

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy	1	1	1	1		
Fall	2	3			2	3
Incorrect dose administered		1				1
Incorrect route of product administration	1	1	1	1		
Off label use		1		1		
Overdose		1		1		
Product preparation error		1		1		
Product use issue		1		1		
Underdose		1				1
Vaccination error		1		1		
Vaccination failure	13	14			13	14
Wrong technique in product usage process		1		1		
	17	27	2	8	15	19

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased	1	2	1	2		
Blood glucose increased	3	3	2	2	1	1
Blood pressure decreased	1	2	1	2		
Blood pressure increased	7	16	3	5	4	11
Body temperature increased	2	18	1	16	1	2
Breath sounds abnormal		1				1
Heart rate increased	1	3	1	2		1
Intraocular pressure increased		1		1		
Neutrophil count increased	1	1	1	1		
Oxygen saturation decreased		1				1
Pulse absent		1				1
Respiratory rate decreased	1	1	1	1		
Rheumatoid factor positive		1		1		
SARS-CoV-2 antibody test positive		1		1		
White blood cell count increased	1	1	1	1		
	18	53	12	35	6	18

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	6	1	5		1
Diabetes mellitus		1				1
Feeding disorder		1		1		
	1	8	1	6		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	17		15	2	2
Back pain		5		3		2
Bone pain	2	7	2	7		
Fibromyalgia		1				1
Joint swelling		1		1		
Muscle spasms	2	3	2	2		1
Muscle tightness		1		1		
Muscular weakness	1	5	1	3		2
Musculoskeletal stiffness	1	2	1	1		1
Myalgia	9	51	5	45	4	6
Myosclerosis		1				1
Neck pain	1	6	1	5		1
Pain in extremity	4	23	2	18	2	5
Spinal pain		1		1		
	22	124	14	102	8	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia	1	1			1	1
Balance disorder	2	2			2	2
Burning sensation		3				3
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	1	1			1	1
Cerebrovascular accident	1	2			1	2
Cerebrovascular disorder	1	1			1	1
Coma	1	1			1	1
Disturbance in attention		2		2		
Dizziness	1	11		8	1	3
Dysarthria	1	1	1	1		
Dysgeusia		2		1		1
Dyskinesia		1				1
Encephalitis post immunisation		1				1
Epilepsy		1				1
Extensor plantar response	1	1	1	1		
Extrapyramidal disorder		1				1
Facial nerve disorder		1		1		
Facial paralysis		1				1
Facial paresis	3	9		1	3	8
Headache	14	82	10	61	4	21
Head discomfort		1				1
Head titubation	1	1			1	1
Hemiparesis	2	2			2	2
Hemiplegia	1	1			1	1
Hyperaesthesia		1		1		
Hypoaesthesia	2	5	1	4	1	1
Hypogeusia		1		1		
Hypokinesia		1		1		
Hyporesponsive to stimuli		1				1
Ischaemic cerebral infarction		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke	1	1			1	1
Loss of consciousness	3	5			3	5
Memory impairment	1	1	1	1		
Migraine		1		1		
Monoparesis		1				1
Muscle contractions involuntary		2		1		1
Neuritis		1		1		
Neurological symptom	1	1	1	1		
Nystagmus		1				1
Paraesthesia	1	12	1	7		5
Paresis		1				1
Presyncope	1	3		1	1	2
Sensory disturbance		1				1
Sensory loss		1				1
Sleep paralysis		1		1		
Somnolence		4		2		2
Speech disorder	1	2			1	2
Syncope	3	4			3	4
Transient ischaemic attack	1	1			1	1
Tremor	2	11	2	9		2
Unresponsive to stimuli		1				1
	50	199	18	108	32	91

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Communication disorder		1				1
Confusional state		3		2		1
Disorganised speech	1	1			1	1
Disorientation		1				1
Fear		1				1
Insomnia	2	5	2	5		
Organic brain syndrome		1				1
Panic attack		2				2
Restlessness		1				1
Sleep terror		1		1		
Tension		1		1		
	3	18	2	9	1	9

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal pain		1		1		
Urinary incontinence		1				1
Urine odour abnormal		1		1		
		3		2		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast pain	1	1	1	1
Menstrual disorder		1		1
Polymenorrhoea		1		1
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Bronchospasm		4				4
Catarrh	1	1			1	1
Choking sensation		1				1
Cough	3	9	3	5		4
Diaphragmatic spasm		1				1
Dysphonia		1				1
Dyspnoea	4	20	1	5	3	15
Dyspnoea exertional		1		1		
Hypopnoea		1				1
Hypoxia	1	1			1	1
Nasal congestion		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	3	4	3	4		
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1		1		
Pleural effusion		1				1
Pulmonary embolism	1	2			1	2
Pulmonary pain		1		1		
Rales		1				1
Respiratory distress	1	1			1	1
Respiratory failure		1				1
Respiratory tract oedema		1				1
Rhinorrhoea	2	4	1	3	1	1
Sneezing		1				1
Snoring	1	2		1	1	1
Stridor		2				2
Suffocation feeling		1				1
Tachypnoea		1				1
Throat tightness	1	2			1	2
Use of accessory respiratory muscles		2				2
Wheezing		4				4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	18	76	8	23	10	53

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Blister		1				1
Cold sweat		2		1		1
Dermatitis allergic		2		1		1
Erythema	2	21		4	2	17
Haemorrhage subcutaneous		1				1
Hyperhidrosis	3	9	2	6	1	3
Livedo reticularis		1				1
Night sweats		1		1		
Pain of skin		1				1
Pruritus	1	13		4	1	9
Psoriasis		1		1		
Rash	1	14		4	1	10
Rash erythematous	1	2	1	1		1
Rash macular	1	3			1	3
Rash maculo-papular		4				4
Skin burning sensation	1	3		1	1	2
Skin discolouration	1	1			1	1
Skin hypertrophy	1	1			1	1
Skin oedema		1		1		
Skin reaction		1				1
Skin sensitisation		1		1		
Skin tightness	1	2			1	2
Urticaria		6		1		5
	13	94	3	27	10	67

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Loss of personal independence in daily activities	2	2	2	2
	2	2	2	2

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Capillary fragility		1		1		
Cyanosis	1	4			1	4
Deep vein thrombosis	1	2			1	2
Haematoma	1	1	1	1		
Hot flush		2		1		1
Hypertension	5	11		1	5	10
Hypertensive crisis	1	1			1	1
Hypotension		4		1		3
Pallor		3				3
Peripheral coldness	3	3	1	1	2	2
Poor peripheral circulation	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
	15	35	2	6	13	29

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CYPRUS**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy		6		5		1
		6		5		1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Bradycardia		1				1
Myocardial infarction		2				2
Tachyarrhythmia		1				1
Tachycardia		2		1		1
	1	7		1	1	6

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear discomfort		1		1
Ear pain		1		1
Hypoacusis		1		1
Vertigo		1		1
		4		4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis		1		1		
Eye pain		1		1		
Hypoesthesia eye		1				1
		3		2		1

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Diarrhoea	1	2	1	2		
Dysphagia		1		1		
Gastric haemorrhage		1				1
Hypoesthesia oral		3		1		2
Nausea	3	10	3	10		
Swollen tongue		2		2		
Vomiting	3	7	2	6	1	1
	8	27	7	23	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		6		6		
Axillary pain		2		2		
Chest pain	1	1	1	1		
Chills	3	18	3	18		
Condition aggravated		2		2		
Death	1	1			1	1
Discomfort		1		1		
Drug ineffective	2	6			2	6
Drug interaction		1		1		
Face oedema		2		1		1
Fatigue	5	15	5	15		
Gait disturbance		2		2		
Gait inability		1		1		
Inflammation		1		1		
Influenza like illness	1	3	1	3		
Injection site pain	1	1	1	1		
Malaise	4	14	4	14		
Multiple organ dysfunction syndrome	1	1			1	1
Pain	1	3	1	3		
Peripheral swelling		1		1		
Pyrexia	3	18	3	18		
Sluggishness		1		1		
Therapeutic response unexpected	1	1	1	1		
Vaccination site oedema	1	3	1	3		
Vaccination site pain	1	16	1	16		
Vaccination site swelling		2		2		
	26	123	22	114	4	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		2				2
Hypersensitivity		1		1		
		3		1		2

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial sepsis	1	1			1	1
COVID-19	2	13		1	2	12
Gastrointestinal infection	1	1			1	1
Influenza		1		1		
Myelitis		1				1
Nasopharyngitis		1		1		
Sialoadenitis		1				1
Viral sepsis	1	1			1	1
	5	20		3	5	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion		2		2		
Inappropriate schedule of product administration	1	2	1	2		
Off label use	1	2	1	2		
Overdose		1		1		
Product use issue		1		1		
Vaccination failure		1				1
	2	9	2	8		1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
Body temperature increased		1		1		
C-reactive protein increased	1	1	1	1		
Fibrin D dimer increased		1		1		
Oxygen saturation decreased		3		1		2
SARS-CoV-2 antibody test negative		1				1
	1	8	1	4		4

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration	1	1			1	1
Hyponatraemia	1	2	1	2		
	2	3	1	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	3	17	3	17		
Back pain		2		2		
Bone pain		1		1		
Mobility decreased		1		1		
Muscle contracture		1		1		
Muscular weakness	1	2		1	1	1
Myalgia	9	31	9	31		
Neck pain		1		1		
Pain in extremity		1		1		
	13	57	12	56	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Cerebrovascular accident	1	1			1	1
Dizziness		8		8		
Dysaesthesia		1				1
Dysgeusia		2		2		
Facial paralysis		2				2
Facial paresis		6				6
Generalised tonic-clonic seizure		1				1
Guillain-Barre syndrome		1				1
Headache	2	17	2	17		
Head titubation		1		1		
Hypoaesthesia	2	5	2	4		1
Migraine		2		2		
Paraesthesia		1		1		
Syncope		3				3
Tremor		1		1		
Unresponsive to stimuli	1	1			1	1
	6	54	4	37	2	17

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state		2		2
Insomnia	1	3	1	3
	1	5	1	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	1	1	1
Urinary retention	1	1	1	1
	2	2	2	2

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Cervix oedema		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Cough		1		1		
Dyspnoea	2	7	2	5		2
Epistaxis		1				1
Nasal congestion		1		1		
Oropharyngeal pain		1		1		
Pharyngeal oedema		1		1		
Pulmonary embolism	4	6			4	6
Pulmonary oedema	1	1			1	1
Respiratory distress		1				1
Respiratory tract oedema		1				1
Sinus congestion		1		1		
Upper respiratory tract congestion		1		1		
	8	24	2	11	6	13

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dermatitis atopic		1		1
Eczema		1		1
Erythema		1		1
Hyperhidrosis		3		3
Rash		2		2
Rash erythematous		1		1
		9		9

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**SOC Not Yet Coded**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Hypertension	1	2	1	1		1
Hypotension	1	3			1	3
Pallor		1		1		
Shock	1	1			1	1
Vasculitis	1	2		1	1	1
	5	10	1	3	4	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CZECH REPUBLIC**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		3		1		2
Coagulopathy		1				1
Leukocytosis	1	2	1	2		
Leukopenia	1	2			1	2
Lymphadenitis	1	5		1	1	4
Lymphadenopathy	12	77	7	34	5	43
Lymph node pain		15		11		4
Neutropenia		1				1
Splenic infarction		1				1
Thrombocytopenia		1				1
	15	108	8	49	7	59

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Angina pectoris	1	5		1	1	4
Arrhythmia	1	5			1	5
Atrial fibrillation	3	5			3	5
Atrial flutter		1				1
Bradycardia		5				5
Bundle branch block right	1	1			1	1
Cardiac arrest	2	3			2	3
Cardiac disorder	1	1			1	1
Cardiac failure	3	4			3	4
Cardiac failure congestive	1	1			1	1
Cardiomyopathy		1				1
Cardio-respiratory arrest	1	2			1	2
Extrasystoles		1		1		
Myocardial infarction	2	3			2	3
Myocarditis		1				1
Palpitations	5	21	1	7	4	14
Sinus bradycardia		1		1		
Sinus tachycardia	1	1			1	1
Supraventricular tachycardia		1				1
Tachycardia	9	32	1	16	8	16
Ventricular tachycardia		1				1
	32	97	2	26	30	71

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome		1				1
Deafness		1				1
Deafness neurosensory	1	2			1	2
Deafness unilateral	1	2			1	2
Ear discomfort	2	10	2	5		5
Ear pain	1	3	1	3		
Ear pruritus		1				1
Ear swelling		1				1
Hyperacusis	1	1			1	1
Hypoacusis	2	4	1	2	1	2
Tinnitus	6	12	3	3	3	9
Vertigo	11	45	4	30	7	15
	25	83	11	43	14	40

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness		2				2
Conjunctivitis allergic	1	1	1	1		
Diplopia		2		1		1
Dry eye		1				1
Eye haemorrhage	3	3			3	3
Eye inflammation		1		1		
Eye irritation	2	3			2	3
Eyelid function disorder		1				1
Eyelid oedema	2	4			2	4
Eye movement disorder		1		1		
Eye pain	5	10	4	8	1	2
Eye pruritus		2		1		1
Eye swelling	2	4	1	2	1	2
Gaze palsy		1				1
Glaucoma	1	1			1	1
Lacrimation increased	2	3	1	2	1	1
Lagophthalmos		1		1		
Mydriasis		1				1
Ocular discomfort		2				2
Ocular hyperaemia		1		1		
Orbital oedema	1	1			1	1
Photophobia	2	5	1	4	1	1
Photopsia		2		1		1
Swelling of eyelid	1	2			1	2
Vision blurred	9	18	1	6	8	12
Visual impairment		3		1		2
	31	76	9	31	22	45

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	5	1	2	1	3
Abdominal pain	3	15	1	7	2	8
Abdominal pain lower	2	2	1	1	1	1
Abdominal pain upper	2	7	2	5		2
Anaesthesia oral		1				1
Anal incontinence		1		1		
Aphthous ulcer	2	4			2	4
Constipation	1	3		2	1	1
Diarrhoea	10	42	6	29	4	13
Dry mouth	2	5		3	2	2
Duodenal ulcer		1				1
Dyspepsia	4	9	2	5	2	4
Dysphagia	3	10		2	3	8
Flatulence	1	3	1	2		1
Frequent bowel movements		1		1		
Functional gastrointestinal disorder		1		1		
Gastric ulcer	2	2			2	2
Gastrointestinal disorder	1	2	1	2		
Gastrointestinal hypermotility		1				1
Gastrointestinal necrosis		1				1
Gastrointestinal pain	1	1	1	1		
Gastrooesophageal reflux disease		1				1
Gingival pain	1	1	1	1		
Haematochezia		2				2
Hypoaesthesia oral		3		1		2
Intestinal infarction		1				1
Lip dry	1	1	1	1		
Lip oedema		1				1
Lip swelling	2	7		1	2	6
Melaena		1				1
Mesenteric arterial occlusion		1				1
Mesenteric vascular insufficiency		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	24	99	18	81	6	18
Oedema mouth		1				1
Oesophageal irritation		1		1		
Oral discomfort	2	4	2	2		2
Oral mucosal blistering		1		1		
Oral pruritus		2		2		
Palatal swelling	2	2			2	2
Pancreatic infarction		1				1
Paraesthesia oral	13	27		1	13	26
Retching	4	7	2	3	2	4
Salivary hypersecretion		1				1
Swollen tongue	3	6			3	6
Tongue discomfort	1	3	1	2		1
Tongue oedema	3	8			3	8
Toothache	2	5	2	4		1
Truncus coeliacus thrombosis		1				1
Vomiting	14	58	11	39	3	19
	108	364	54	204	54	160

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site coldness		1				1
Application site erythema	1	2	1	1		1
Asthenia	27	89	21	64	6	25
Axillary pain	2	9	2	7		2
Chest discomfort	7	20	4	9	3	11
Chest pain	4	15	2	8	2	7
Chills	39	182	33	156	6	26
Condition aggravated		2		1		1
Death	1	3			1	3
Decreased activity	1	2	1	2		
Discomfort	1	1	1	1		
Disease recurrence	3	5	1	1	2	4
Drug ineffective	9	18			9	18
Drug interaction	1	1			1	1
Face oedema	1	2			1	2
Facial pain		2		1		1
Fatigue	57	228	45	183	12	45
Feeling abnormal	1	8	1	7		1
Feeling cold	2	3	2	3		
Feeling hot	4	15	1	8	3	7
Gait disturbance	4	9		3	4	6
Gait inability	2	4	1	2	1	2
Generalised oedema		1		1		
General physical health deterioration	5	9	2	3	3	6
Hyperpyrexia	1	1			1	1
Induration		1		1		
Inflammation		2		1		1
Influenza like illness	46	91	37	66	9	25
Injected limb mobility decreased		2		2		
Injection site erythema		1				1
Injection site pain		1		1		
Localised oedema	2	5			2	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Local reaction		1
Malaise	6	29
Mass	1	2
Mucosal disorder		1
Mucosal dryness		2
Multiple organ dysfunction syndrome		2
Nodule	1	1
Oedema	1	3
Oedema peripheral	5	13
Pain	9	28
Peripheral swelling	4	14
Puncture site oedema		1
Pyrexia	71	275
Sensation of foreign body	1	4
Sudden death		3
Swelling	1	7
Swelling face	7	24
Tenderness	1	2
Thirst		1
Vaccination site anaesthesia		1
Vaccination site atrophy		2
Vaccination site bruising		2
Vaccination site discolouration		1
Vaccination site discomfort		4
Vaccination site erythema	16	78
Vaccination site extravasation	1	1
Vaccination site haematoma	1	3
Vaccination site hypersensitivity		1
Vaccination site induration	4	10
Vaccination site joint movement impairment	1	3
Vaccination site joint pain		2
Vaccination site lymphadenopathy		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
4	23	2	6
	1	1	1
			1
	1		1
			2
		1	1
1	3		
4	6	1	7
6	21	3	7
3	6	1	8
	1		
38	171	33	104
		1	4
			3
1	5		2
1	2	6	22
1	1		1
	1		
			1
	1		1
	3		1
8	38	8	40
1	1		
1	1		2
			1
3	5	1	5
	1	1	2
	2		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site mass		4		1		3
Vaccination site movement impairment	1	5	1	4		1
Vaccination site oedema	8	36	4	19	4	17
Vaccination site pain	29	152	23	115	6	37
Vaccination site papule		1				1
Vaccination site paraesthesia		2		2		
Vaccination site pruritus	6	18	4	13	2	5
Vaccination site rash	2	5	1	2	1	3
Vaccination site reaction		6		4		2
Vaccination site swelling	10	35	5	20	5	15
Vaccination site urticaria	2	3			2	3
Vaccination site warmth	1	12	1	7		5
	411	1,536	266	1017	145	519

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gallbladder disorder	1	1	1	1		
Hepatic function abnormal		1				1
Hepatic infarction		1				1
Hepatitis		1				1
Jaundice		1		1		
	1	5	1	2		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	1	1			1	1
Allergy to vaccine	1	6		1	1	5
Anaphylactic reaction	4	13			4	13
Anaphylactoid reaction	1	1			1	1
Drug hypersensitivity	3	4		1	3	3
Hypersensitivity	21	48	5	14	16	34
Immune system disorder		1				1
Renal transplant failure	1	1			1	1
	32	75	5	16	27	59

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess of salivary gland		1				1
Bacterial rhinitis		1				1
Bronchitis		1				1
COVID-19	23	47	2	11	21	36
COVID-19 pneumonia		7				7
Diverticulitis		1				1
Eczema herpeticum		1				1
Enterococcal infection	1	1			1	1
Erysipelas	1	2			1	2
Escherichia infection		1				1
Gastroenteritis		1		1		
Herpes dermatitis	1	1			1	1
Herpes simplex	1	2			1	2
Herpes virus infection		1		1		
Herpes zoster	6	13			6	13
Hordeolum	1	1			1	1
Infection	1	1	1	1		
Influenza		1		1		
Klebsiella infection		1				1
Myelitis		1				1
Nasopharyngitis	1	1	1	1		
Oral herpes	2	2	1	1	1	1
Pneumonia	3	6			3	6
Pulpitis dental	1	1			1	1
Rash pustular		1		1		
Rhinitis	4	6	4	6		
Sepsis		2				2
Splenic infection		1				1
Sputum purulent	1	1			1	1
Suspected COVID-19	1	1			1	1
Tooth infection		1				1
Urinary tract infection	2	4		1	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infection enterococcal		1				1
Urogenital infection bacterial	1	1			1	1
Urosepsis		1				1
Vaccination site cellulitis	1	1			1	1
Vaccination site pustule	1	1	1	1		
Vestibular neuronitis		1				1
Viral infection		2		1		1
	53	121	10	27	43	94

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Airway burns		2				2
Concussion		1				1
Contusion	2	3			2	3
Exposure via breast milk		1		1		
Fall	4	10		4	4	6
Inappropriate schedule of product administration	2	7	2	7		
Incorrect route of product administration	1	5	1	5		
Ligament sprain		1				1
Maternal exposure during pregnancy		1		1		
Off label use		11		11		
Overdose	1	4	1	4		
Poor quality product administered		83		83		
Product administered at inappropriate site		3		3		
Product preparation error	1	83	1	83		
Product preparation issue		1		1		
Product use issue		7		7		
Vaccination complication		3		2		1
Vaccination failure	9	13			9	13
	20	239	5	212	15	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Antibody test abnormal		1		1		
Aspartate aminotransferase increased		1		1		
Bacterial test positive	1	1	1	1		
Blood chloride increased		1		1		
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	2	2			2	2
Blood pressure diastolic increased		1		1		
Blood pressure increased	4	13		5	4	8
Blood pressure systolic increased	1	4		2	1	2
Blood urine present	2	2	2	2		
Body temperature decreased		1		1		
Body temperature increased	2	9	1	6	1	3
C-reactive protein increased		5		2		3
Electrocardiogram abnormal	2	2	1	1	1	1
Glomerular filtration rate decreased		1		1		
Heart rate increased	2	4			2	4
Heart rate irregular	1	2	1	2		
Immunoglobulins increased		1		1		
International normalised ratio increased		2		1		1
Laboratory test abnormal	1	1	1	1		
Oxygen saturation decreased	2	5		2	2	3
Pulse abnormal		1		1		
Red blood cell sedimentation rate increased		1		1		
SARS-CoV-2 antibody test negative	1	2			1	2
SARS-CoV-2 test positive	1	4		2	1	2
Troponin I increased		1				1
	23	72	7	39	16	33

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	14	34	11	25	3	9
Dehydration		2		1		1
Fluid intake reduced		1		1		
Food intolerance		1				1
Gout		1		1		
Hyperglycaemia	3	5		1	3	4
Hyperphagia		1		1		
Hypoglycaemia	1	2		1	1	1
Hypokalaemia	2	5			2	5
Hypophagia		1		1		
	20	53	11	32	9	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	49	163	36	120	13	43
Axillary mass	1	1	1	1		
Back pain	7	23	5	20	2	3
Bone pain	1	2		1	1	1
Facial asymmetry	1	1			1	1
Flank pain	1	1	1	1		
Groin pain	1	1	1	1		
Joint effusion		1				1
Joint instability		1				1
Joint range of motion decreased	1	4	1	3		1
Joint stiffness		2		1		1
Joint swelling	3	6	2	5	1	1
Joint warmth		1		1		
Ligament pain	1	1	1	1		
Limb discomfort	3	3	1	1	2	2
Mobility decreased	1	5		4	1	1
Muscle atrophy		1				1
Muscle spasms	3	5	1	2	2	3
Muscle tightness	1	1	1	1		
Muscle twitching	2	4		2	2	2
Muscular weakness	5	15	2	10	3	5
Musculoskeletal chest pain	1	2	1	2		
Musculoskeletal disorder		1		1		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	3	12	1	8	2	4
Myalgia	26	116	22	87	4	29
Myosclerosis		1				1
Myositis	1	1			1	1
Neck pain	2	7		5	2	2
Nuchal rigidity		1		1		
Pain in extremity	36	93	27	72	9	21
Pain in jaw	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polyarthritis	2	3			2	3
Posture abnormal	1	1	1	1		
Rheumatoid arthritis	2	2			2	2
Spinal disorder		1				1
Spinal pain	3	7	1	3	2	4
Tendon pain	1	1			1	1
	160	493	107	357	53	136

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostate cancer		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	4		2	1	2
Akathisia	1	1	1	1		
Akinesia	1	1			1	1
Altered state of consciousness	3	5			3	5
Amnesia		2				2
Anosmia	3	8	1	5	2	3
Aphasia	3	5	1	2	2	3
Balance disorder	1	1			1	1
Basal ganglia haemorrhage		1				1
Brain oedema	1	2			1	2
Burning sensation	3	5	3	4		1
Burning sensation mucosal		2		2		
Carpal tunnel syndrome	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	8	14			8	14
Cognitive disorder	1	1			1	1
Coma		1				1
Coordination abnormal		1				1
Cranial nerve palsies multiple	1	1			1	1
Dementia	1	1			1	1
Disturbance in attention	2	6		2	2	4
Dizziness	12	38	8	29	4	9
Dizziness postural	1	1			1	1
Dysaesthesia		1				1
Dysarthria	1	3		1	1	2
Dysgeusia	3	4	2	2	1	2
Dyskinesia	1	1			1	1
Dysstasia	1	1			1	1
Epilepsy	1	2			1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Facial paralysis	5	9
Facial paresis	1	5
Febrile convulsion		1
Formication		3
Guillain-Barre syndrome	1	1
Haemorrhage intracranial	1	1
Headache	41	201
Head discomfort		2
Hemiparesis	2	2
Hemiplegia	1	2
Hyperaesthesia	1	1
Hypersomnia	1	4
Hypoaesthesia	2	12
Hypokinesia	1	3
Hypotonia		1
Hypotonic-hyporesponsive episode	1	1
Ischaemic stroke	1	3
Language disorder		1
Lethargy	1	1
Loss of consciousness	6	15
Memory impairment		1
Migraine	4	12
Migraine with aura		1
Monoparesis	1	2
Monoplegia		2
Movement disorder	1	1
Multiple sclerosis		1
Multiple sclerosis relapse		1
Muscle spasticity		1
Narcolepsy	2	2
Neuralgia		1
Neuropathy peripheral	1	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
		5	9
		1	5
			1
	2		1
		1	1
		1	1
35	171	6	30
	1		1
		2	2
		1	2
1	1		
		1	4
	5	2	7
1	3		
	1		
		1	1
		1	3
			1
1	1		
		6	15
			1
2	6	2	6
	1		
		1	2
			2
		1	1
			1
	1		
		2	2
			1
		1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nystagmus	1	2	1	2		
Paraesthesia	15	61	3	22	12	39
Paraesthesia mucosal		1				1
Paralysis	1	3			1	3
Paraparesis		1				1
Paresis	1	2			1	2
Paresis cranial nerve		1				1
Parosmia	1	2		1	1	1
Peripheral nerve palsy	1	1			1	1
Poor quality sleep		1		1		
Presyncope	2	12		2	2	10
Psychomotor hyperactivity	1	1			1	1
Quadriparesis		1				1
Radiculitis brachial		1				1
Radiculopathy		1				1
Seizure	3	7			3	7
Sleep deficit		1				1
Somnolence	8	28	4	18	4	10
Speech disorder	1	4		2	1	2
Syncope	8	21			8	21
Taste disorder	1	2		1	1	1
Tension headache	1	4		2	1	2
Transient ischaemic attack	1	2			1	2
Transverse sinus thrombosis	1	1			1	1
Tremor	6	16	1	8	5	8
Visual field defect	1	2			1	2
	182	595	65	302	117	293

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
Foetal death		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		2		2		
Anxiety	1	10	1	7		3
Apathy	2	7	1	2	1	5
Attention deficit hyperactivity disorder	1	1	1	1		
Bradyphrenia		2		1		1
Communication disorder		1				1
Confusional state	2	9	1	3	1	6
Decreased interest		1		1		
Delirium		3				3
Depression	1	3		1	1	2
Disorganised speech	1	1			1	1
Disorientation	2	7		2	2	5
Dysphemia	1	1			1	1
Eating disorder		2		1		1
Fear	1	1	1	1		
Hallucination		2				2
Hallucinations, mixed	1	1			1	1
Illusion		1		1		
Insomnia	8	19	6	13	2	6
Irritability		1		1		
Logorrhoea		1		1		
Mental disorder		1		1		
Nervousness		2		1		1
Restlessness	1	4	1	4		
Sleep disorder		3		2		1
Sleep talking		1		1		
Sopor		1				1
	22	88	12	47	10	41

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		1				1
Anuria		1				1
Cystitis noninfective		1		1		
Dysuria	1	1			1	1
Renal disorder		1		1		
Renal failure	1	3			1	3
Renal impairment	1	2			1	2
Renal pain	2	2	2	2		
Urinary incontinence	1	2			1	2
Urinary tract inflammation	1	3	1	1		2
	7	17	3	5	4	12

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain	1	4	1	2		2
Breast swelling	1	2		1	1	1
Menstrual disorder		1		1		
Menstruation delayed		1		1		
Metrorrhagia		1		1		
	2	9	1	6	1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	2			1	2
Aphonia		1				1
Apnoea	1	1			1	1
Asthma		2		1		1
Bronchospasm	1	1			1	1
Choking sensation		1				1
Cough	11	30	7	23	4	7
Dry throat	1	1			1	1
Dysphonia		1		1		
Dyspnoea	25	73	5	18	20	55
Dyspnoea at rest		1				1
Dyspnoea exertional	1	2	1	1		1
Epistaxis	4	7	1	3	3	4
Grunting		1				1
Haemoptysis	1	1			1	1
Hyperventilation		1		1		
Hypoxia		2				2
Laryngeal oedema		1				1
Laryngospasm	1	1			1	1
Nasal congestion	3	4	3	4		
Nasal discomfort		1				1
Nasal oedema		1		1		
Oropharyngeal discomfort		3		2		1
Oropharyngeal pain	5	10	4	8	1	2
Pharyngeal oedema		2				2
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	2	6			2	6
Pneumonitis	1	1			1	1
Productive cough	1	4		1	1	3
Prolonged expiration		1		1		
Pulmonary embolism	2	4			2	4
Pulmonary oedema	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary pain	1	2		1	1	1
Pulmonary sensitisation		2		1		1
Respiration abnormal		1				1
Respiratory acidosis		1		1		
Respiratory depression		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory failure	1	4			1	4
Respiratory tract oedema	1	2			1	2
Rhinalgia	1	1	1	1		
Rhinorrhoea	3	11	2	9	1	2
Sinus pain	1	1	1	1		
Sneezing		1		1		
Sputum discoloured	1	1			1	1
Stridor		1		1		
Tachypnoea	2	6		2	2	4
Throat irritation	3	5	1	2	2	3
Throat tightness	2	8		2	2	6
Wheezing		2		2		
	78	221	26	89	52	132

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	1	1	1		
Alopecia		2		1		1
Angioedema	1	2			1	2
Blister	2	2			2	2
Cold sweat		2		2		
Dermatitis	1	2	1	1		1
Dermatitis allergic	6	9		1	6	8
Drug eruption	2	4			2	4
Dry skin	1	2			1	2
Eczema	1	1			1	1
Erythema	9	33	4	20	5	13
Erythema nodosum	1	1			1	1
Hyperhidrosis	6	25	6	21		4
Livedo reticularis	1	1	1	1		
Night sweats	1	4		3	1	1
Pain of skin		3		2		1
Petechiae	4	4			4	4
Photosensitivity reaction		1		1		
Pruritus	13	42	6	15	7	27
Purpura	1	1			1	1
Rash	16	50	2	17	14	33
Rash erythematous	1	3			1	3
Rash macular	6	11		1	6	10
Rash maculo-papular	1	4			1	4
Rash pruritic	4	13	2	3	2	10
Rash vesicular	1	1	1	1		
Scab	1	2	1	2		
Skin burning sensation	6	6	3	3	3	3
Skin discolouration		1		1		
Skin disorder	1	2			1	2
Skin exfoliation	1	2	1	1		1
Skin mass		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin reaction		1		1		
Urticaria	5	11		2	5	9
Yellow skin	1	1			1	1
	95	251	29	102	66	149

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability		1				1
Loss of personal independence in daily activities		2		2		
Patient uncooperative	1	1	1	1		
Sitting disability		1				1
	1	5	1	3		2

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Limb immobilisation		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm	1	1			1	1
Aortic arteriosclerosis		1				1
Aortic stenosis	1	1			1	1
Arteriosclerosis		1				1
Blood pressure fluctuation		2		1		1
Circulatory collapse	3	8			3	8
Cyanosis		1				1
Deep vein thrombosis	2	2			2	2
Flushing		3		1		2
Haematoma	3	4	1	1	2	3
Haemorrhage		1				1
Hot flush	5	16	1	9	4	7
Hyperaemia		1		1		
Hypertension	19	36	2	9	17	27
Hypotension	3	22		5	3	17
Jugular vein distension		1		1		
Lymphoedema		1		1		
Pallor	3	8	2	5	1	3
Peripheral coldness	2	10	1	8	1	2
Shock		2				2
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	1			1	1
Vascular pain		1				1
Vena cava thrombosis		1				1
Venous thrombosis limb	1	1			1	1
White coat hypertension	1	1	1	1		
	46	128	8	43	38	85

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**DENMARK**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		2		1		1
Disseminated intravascular coagulation	1	1			1	1
Haemolysis		1				1
Haemorrhagic diathesis	1	1			1	1
Immune thrombocytopenia		1				1
Leukocytosis		1		1		
Leukopenia		1				1
Lymphadenitis		2		1		1
Lymphadenopathy	1	29	1	20		9
Lymph node pain		4		4		
Lymphopenia	1	3	1	1		2
Myelosuppression		1				1
Pancytopenia	1	1			1	1
Splenic haemorrhage	1	1			1	1
Splenic infarction	1	1			1	1
Thrombocytopenia	3	4			3	4
Thrombocytosis	1	1			1	1
	11	55	2	28	9	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	3	5			3	5
Angina pectoris		1				1
Atrial fibrillation	5	9			5	9
Atrial flutter		2				2
Bradycardia	2	4			2	4
Cardiac arrest	7	8			7	8
Cardiac failure	1	1			1	1
Cardiogenic shock		1				1
Cardiovascular disorder	2	2			2	2
Coronary artery thrombosis	2	2			2	2
Myocardial infarction	1	1			1	1
Myocarditis		1				1
Palpitations	2	28	2	16		12
Pericarditis	2	2			2	2
Sinus tachycardia		2		2		
Stress cardiomyopathy		1				1
Tachycardia	1	8		2	1	6
Ventricular tachycardia	1	1			1	1
	29	79	2	20	27	59

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling		1		1		
Ear discomfort		2		2		
Ear pruritus		1				1
Hyperacusis		2		1		1
Hypoacusis	1	4		2	1	2
Meniere's disease		1				1
Tinnitus	1	6		4	1	2
Vertigo		3		1		2
	2	20		11	2	9

System Organ Class

**Endocrine disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Adrenal insufficiency		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1		1		
Diplopia	2	3			2	3
Dry eye		1		1		
Eye irritation		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		2				2
Eye pain		7		7		
Eye pruritus		5		4		1
Eye swelling		1		1		
Lacrimation increased		3		3		
Mydriasis		1		1		
Ocular hyperaemia		1		1		
Periorbital swelling	1	3		1	1	2
Photophobia	2	5		1	2	4
Photopsia		3		1		2
Retinal vascular thrombosis	1	1			1	1
Swelling of eyelid		2		1		1
Vision blurred		4		1		3
Visual impairment		2		1		1
	6	48		27	6	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension		1		1		
Abdominal pain	5	18	1	9	4	9
Abdominal pain lower		1				1
Abdominal pain upper	1	9		4	1	5
Abdominal tenderness		1				1
Colitis	2	2	1	1	1	1
Diarrhoea	9	37	4	22	5	15
Dry mouth		5		4		1
Dyspepsia		1				1
Dysphagia	2	8	1	2	1	6
Faeces soft		1		1		
Flatulence		1		1		
Gastric ulcer	1	1			1	1
Gastrointestinal disorder		1		1		
Gastrointestinal necrosis	1	1			1	1
Gastrooesophageal reflux disease	1	3		2	1	1
Glossodynia		1		1		
Haematemesis	1	1			1	1
Haematochezia	1	1			1	1
Hyperchlorhydria		1		1		
Hypoaesthesia oral		2				2
Ileus paralytic		1				1
Intestinal ischaemia	1	1			1	1
Lip pruritus		1				1
Lip swelling	1	4			1	4
Melaena	1	1			1	1
Mesenteric artery thrombosis	1	1			1	1
Nausea	15	147	10	93	5	54
Odynophagia		3		2		1
Oesophageal spasm		1		1		
Oral discomfort		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral mucosal blistering		1		1		
Oral mucosal eruption		1		1		
Oral pruritus		2		2		
Pancreatitis acute		1				1
Paraesthesia oral	4	15	2	8	2	7
Salivary gland enlargement		1		1		
Salivary gland pain		1		1		
Salivary hypersecretion		1				1
Stomatitis		1		1		
Swollen tongue	1	11		2	1	9
Tongue discomfort		1		1		
Tongue pruritus		2				2
Vomiting	7	48	4	25	3	23
	55	347	23	192	32	155

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	23	1	6	3	17
Axillary pain		5		5		
Chest discomfort	2	23		8	2	15
Chest pain	7	17		4	7	13
Chills	3	64	1	46	2	18
Condition aggravated	1	11			1	11
Crying		1				1
Death	8	16			8	16
Discomfort	3	14	1	4	2	10
Disease recurrence		2		2		
Drug ineffective	1	9			1	9
Drug interaction		1				1
Face oedema		2				2
Facial pain		1		1		
Fatigue	24	181	9	124	15	57
Feeling abnormal	1	6		4	1	2
Feeling cold	1	13		8	1	5
Feeling drunk		1		1		
Feeling hot	1	27	1	14		13
Feeling of body temperature change		3				3
Foaming at mouth		2		1		1
Gait disturbance	2	3		1	2	2
General physical health deterioration	6	18	1	2	5	16
Hypothermia		2				2
Illness		1		1		
Influenza like illness	3	27		18	3	9
Injected limb mobility decreased		1		1		
Injection site erythema		1		1		
Injection site pain		2		2		
Injection site swelling		1		1		
Loss of control of legs		2				2
Malaise	17	136	4	72	13	64

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Multimorbidity	1	1
Oedema	1	2
Oedema peripheral	4	7
Pain	5	29
Peripheral swelling	3	10
Pyrexia	22	225
Sensation of foreign body	2	4
Sudden cardiac death		1
Sudden death	1	4
Swelling	1	8
Swelling face	1	19
Systemic inflammatory response syndrome		1
Tenderness	3	12
Therapeutic response unexpected		1
Vaccination site discolouration		1
Vaccination site discomfort	1	3
Vaccination site erythema	7	36
Vaccination site haematoma		3
Vaccination site haemorrhage		1
Vaccination site hypoaesthesia		1
Vaccination site induration		2
Vaccination site inflammation		4
Vaccination site irritation		2
Vaccination site lymphadenopathy		1
Vaccination site movement impairment		2
Vaccination site necrosis		1
Vaccination site nodule		1
Vaccination site pain	20	195
Vaccination site paraesthesia		3
Vaccination site pruritus	2	10
Vaccination site rash		6
Vaccination site reaction		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	2
1	3	3	4
3	20	2	9
1	5	2	5
8	147	14	78
		2	4
			1
		1	4
1	7		1
1	7		12
			1
1	7	2	5
	1		
			1
1	3		
7	33		3
	3		
	1		
	2		
	4		
	1		1
	1		
	2		
	1		
18	178	2	17
	3		
2	9		1
	3		3
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	4	50	4	44		6
Vaccination site thrombosis		1				1
Vaccination site warmth	2	17	2	16		1
	164	1,281	68	830	96	451

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Immune-mediated hepatitis	1	1	1	1
	1	1	1	1

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1				1
Anaphylactic reaction	6	23			6	23
Anaphylactic shock	1	6			1	6
Hypersensitivity	2	24	2	7		17
Immune-mediated adverse reaction		1				1
Immunisation reaction		1		1		
Reaction to excipient	2	2			2	2
Seasonal allergy		1		1		
Systemic immune activation	2	2			2	2
Type I hypersensitivity		1				1
	13	62	2	9	11	53

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal wall abscess		1				1
Appendicitis		3				3
Bacteraemia		1				1
Bacterial infection		1				1
Bronchitis		1				1
Chorioretinitis		1				1
COVID-19	5	22	3	4	2	18
Cystitis		1		1		
Erysipelas		1				1
Herpes zoster		2		1		1
Infection	1	3	1	2		1
Influenza	1	11		6	1	5
Lymphangitis	1	1			1	1
Myelitis		1				1
Nasopharyngitis		3		3		
Oral fungal infection		1		1		
Pharyngitis		1				1
Pneumonia	8	20			8	20
Pneumonia bacterial		1				1
Respiratory tract infection bacterial		1				1
Rhinitis		1		1		
Sepsis	1	2			1	2
Septic shock		1				1
Severe acute respiratory syndrome		1				1
Staphylococcal infection		1				1
Upper respiratory tract infection		1		1		
Urinary tract infection	1	3			1	3
Urinary tract infection bacterial		1				1
Urosepsis	1	1			1	1
Vaccination site abscess		1				1
Viral infection		1		1		
Wound infection	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	20	92	4	21	16	71

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Carbon monoxide poisoning	1	1			1	1
Contusion	1	2		1	1	1
Exposure via breast milk		1		1		
Exposure via skin contact		1		1		
Fall	4	9			4	9
Femur fracture		1				1
Head injury		2				2
Inappropriate schedule of product administration	2	6	2	6		
Incorrect route of product administration		4		3		1
Maternal exposure during pregnancy	1	3	1	2		1
Off label use	2	10	2	10		
Product administration error		1		1		
Product preparation issue		1		1		
Product use issue		7		7		
Scratch		1				1
Skin abrasion	1	1			1	1
Toxicity to various agents		1				1
Transplant failure		1				1
Underdose		2		2		
Vaccination complication		2		1		1
Wound		1				1
Wound complication		1		1		
	12	60	5	38	7	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Blood albumin decreased		1		1		
Blood bilirubin decreased		1		1		
Blood chloride increased		1		1		
Blood count abnormal		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine increased		1				1
Blood glucose increased		2		2		
Blood lactate dehydrogenase abnormal		1		1		
Blood lactic acid increased		1		1		
Blood potassium decreased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased		4		2		2
Blood pressure increased	1	9		3	1	6
Blood pressure systolic increased	1	3		1	1	2
Blood sodium decreased		1		1		
Blood urea decreased		1				1
Blood uric acid abnormal		1		1		
Body temperature increased	1	6		5	1	1
Breath sounds abnormal		1				1
Calcium ionised increased		1		1		
C-reactive protein increased	5	17	2	5	3	12
Electrocardiogram QT prolonged		1				1
Electrocardiogram ST segment depression		1				1
Fibrin D dimer increased	3	3	1	1	2	2
Glomerular filtration rate decreased		1				1
Haematology test abnormal	1	1			1	1
Haemoglobin decreased		3				3
Heart rate abnormal		1		1		
Heart rate decreased		3		3		
Heart rate increased	6	14	3	9	3	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate irregular	1	1			1	1
Hepatic enzyme increased	1	2	1	2		
Neutrophil count increased		1		1		
Oxygen saturation decreased	3	8	1	1	2	7
Pulmonary arterial pressure increased	1	1	1	1		
Pulse abnormal	1	1			1	1
Respiratory rate decreased		1				1
Rheumatoid factor increased	1	1			1	1
SARS-CoV-2 test positive		1				1
Troponin I increased		2		1		1
Troponin increased	1	2			1	2
Weight increased	1	1	1	1		
	28	108	10	51	18	57

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	7		2	1	5
Dehydration	1	2			1	2
Fluid intake reduced	1	3		1	1	2
Hyperglycaemia		1				1
Hypoglycaemia		2		1		1
Hypokalaemia		2				2
Hypophagia		2		2		
Ketoacidosis		1				1
Metabolic acidosis	1	1			1	1
Metabolic alkalosis		1		1		
	4	22		7	4	15

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	7	53	1	32	6	21
Arthritis		1		1		
Arthritis reactive		1				1
Back pain		10		8		2
Bursitis		1				1
Groin pain	1	2	1	2		
Joint stiffness		2		1		1
Joint swelling		5		2		3
Joint warmth		1		1		
Limb discomfort	1	10		5	1	5
Mobility decreased	2	6	1	3	1	3
Muscle discomfort		2		1		1
Muscle fatigue	2	4	2	4		
Muscle spasms	1	6		3	1	3
Muscle tightness		2		1		1
Muscle twitching		2		1		1
Muscular weakness	3	12	2	4	1	8
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness		2				2
Myalgia	8	122	1	89	7	33
Neck pain	3	9	1	6	2	3
Pain in extremity	7	46	2	38	5	8
Periarthritis		2		2		
Rhabdomyolysis		1				1
Rheumatoid arthritis	1	1			1	1
Temporomandibular joint syndrome		1				1
	36	305	11	204	25	101

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

*System Organ Class*

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute leukaemia		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Altered state of consciousness	2	4			2	4
Amnesia	3	5			3	5
Anosmia		1		1		
Aphasia	2	2			2	2
Balance disorder	1	2			1	2
Basilar artery occlusion	1	1			1	1
Burning sensation	1	6	1	4		2
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis	2	3			2	3
Cerebrovascular accident	12	17			12	17
Clonic convulsion		1				1
Cognitive disorder	1	1			1	1
Coma		1				1
Coordination abnormal		3				3
Dementia	1	1			1	1
Depressed level of consciousness	3	11			3	11
Disturbance in attention	3	6		2	3	4
Dizziness	12	138	6	75	6	63
Dizziness exertional		1		1		
Dizziness postural		2				2
Dysaesthesia		2		1		1
Dysarthria	2	4			2	4
Dysgeusia	1	4		2	1	2
Dysstasia		1				1
Epilepsy	2	2			2	2
Facial paralysis	3	4			3	4
Facial paresis	2	4		1	2	3
Generalised tonic-clonic seizure	1	4			1	4
Guillain-Barre syndrome		1				1
Haemorrhage intracranial		1				1
Headache	37	293	21	209	16	84

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort		3		2		1
Hemiparesis	4	6			4	6
Hemiplegia	2	2			2	2
Hypersomnia	2	4		1	2	3
Hypertonia		1				1
Hypoaesthesia	2	8	2	4		4
Hypotonia	1	1	1	1		
Idiopathic intracranial hypertension	1	1			1	1
Illrd nerve paresis		1				1
Lethargy		3		3		
Loss of consciousness	1	7			1	7
Memory impairment	1	1			1	1
Migraine	2	7	1	4	1	3
Monoparesis	1	2			1	2
Monoplegia		2				2
Motor dysfunction		1				1
Nervous system disorder		1				1
Neuralgia		1				1
Paraesthesia	2	38		23	2	15
Paraesthesia mucosal		1				1
Paralysis	1	1			1	1
Paresis		1				1
Parkinson's disease		1				1
Parosmia		1		1		
Poor quality sleep		1		1		
Presyncope	4	25	3	8	1	17
Seizure	1	4			1	4
Sensory disturbance	2	9	1	7	1	2
Sensory loss		2				2
Somnolence	2	12	1	8	1	4
Speech disorder	1	3		1	1	2
Syncope	5	18			5	18

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		4		3		1
Tonic convulsion		1				1
Transient ischaemic attack	1	2			1	2
Tremor	4	20		7	4	13
Tunnel vision		2				2
Unresponsive to stimuli	1	1			1	1
Vlth nerve paralysis	1	1			1	1
White matter lesion		1		1		
	135	729	37	372	98	357

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion missed	1	2	1	2
	1	2	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	2			1	2
Anxiety	1	5		2	1	3
Confusional state	5	12		1	5	11
Delirium	3	8			3	8
Delusion		1				1
Derealisation	1	5		4	1	1
Disorientation		1				1
Eating disorder		1		1		
Hallucination, visual		1				1
Initial insomnia		1		1		
Insomnia	1	5	1	5		
Panic attack		1				1
Restlessness	1	10		7	1	3
Sleep disorder	2	3	2	3		
Thinking abnormal		1				1
	15	57	3	24	12	33

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	4			1	4
Anti-glomerular basement membrane disease	1	1			1	1
Dysuria	1	1			1	1
Haematuria	1	2	1	1		1
Micturition urgency		1				1
Renal colic		1		1		
Renal failure	1	4			1	4
Renal pain		1				1
Urinary incontinence		1				1
Urine odour abnormal	1	1			1	1
	6	17	1	2	5	15

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1		1		
Postmenopausal haemorrhage		1				1
Vaginal discharge		1		1		
Vaginal haemorrhage	1	2		1	1	1
Vulvovaginal pain		1		1		
Vulvovaginal pruritus		1		1		
	1	7		5	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute respiratory distress syndrome		1				1	
Acute respiratory failure		1				1	
Aspiration		1				1	
Asthma	1	5		1	1	4	
Bronchospasm	2	3			2	3	
Choking sensation		1				1	
Chronic obstructive pulmonary disease	3	7			3	7	
Cough	5	26	1	14	4	12	
Dry throat	1	1	1	1			
Dysphonia		8		6		2	
Dyspnoea	25	99	2	24	23	75	
Dyspnoea at rest		1				1	
Dyspnoea exertional	2	7	1	5	1	2	
Emphysema	1	1			1	1	
Epistaxis	1	4		1	1	3	
Hyperventilation		5				5	
Hypoxia		1				1	
Idiopathic pulmonary fibrosis	1	1			1	1	
Lung disorder	2	2			2	2	
Lung infiltration	1	1			1	1	
Nasal congestion		5		5			
Nasal discomfort		1				1	
Nasal obstruction		1		1			
Nasal pruritus	1	3	1	1		2	
Obliterative bronchiolitis		1				1	
Obstructive airways disorder	1	3			1	3	
Oropharyngeal discomfort		3		2		1	
Oropharyngeal pain	3	21	1	17	2	4	
Painful respiration		2		2			
Pharyngeal oedema		1				1	
Pharyngeal paraesthesia		2		2			
Pharyngeal swelling	1	11		2	1	9	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion		2				2
Pleuritic pain	1	1	1	1		
Pneumonia aspiration		1				1
Pneumonitis		1				1
Productive cough	2	3		1	2	2
Prolonged expiration		1				1
Pulmonary arterial hypertension		1				1
Pulmonary embolism	18	23			18	23
Pulmonary fibrosis	1	2			1	2
Pulmonary oedema	2	6			2	6
Pulmonary pain		1		1		
Rales		1				1
Respiration abnormal	1	2			1	2
Respiratory acidosis	2	4			2	4
Respiratory arrest	2	3			2	3
Respiratory disorder		1		1		
Respiratory distress	1	1			1	1
Respiratory failure	4	14			4	14
Rhinalgia		1		1		
Rhinorrhoea	1	7		5	1	2
Sneezing		6		6		
Sputum discoloured	1	1			1	1
Stridor		1				1
Tachypnoea		2				2
Throat irritation	2	10	1	5	1	5
Throat tightness		5		2		3
Tonsillar hypertrophy		1		1		
Tracheal stenosis	1	1			1	1
Wheezing		1				1
	90	334	9	108	81	226

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		7				7
Cold sweat	1	6		4	1	2
Dermatitis allergic		2				2
Dry skin		1		1		
Eczema	1	1	1	1		
Erythema	2	39	1	24	1	15
Hand dermatitis		1		1		
Hyperhidrosis	3	15		8	3	7
Livedo reticularis	1	2			1	2
Night sweats		1		1		
Pain of skin		5		2		3
Photosensitivity reaction	1	1	1	1		
Pruritus	3	45	3	32		13
Rash	4	40	4	27		13
Rash erythematous	1	19		12	1	7
Rash macular		2		2		
Rash morbilliform		1		1		
Rash papular		1		1		
Rash pruritic	3	12		8	3	4
Rash vesicular		1		1		
Skin burning sensation		1				1
Skin haemorrhage	1	1			1	1
Skin lesion		1		1		
Urticaria	8	40	4	25	4	15
	29	245	14	153	15	92

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation		1		1		
Circulatory collapse		1				1
Deep vein thrombosis	8	9			8	9
Flushing	1	11	1	5		6
Haematoma		1		1		
Haemodynamic instability	1	1			1	1
Hot flush		6		6		
Hypertension	3	19	1	7	2	12
Hypotension	3	11		1	3	10
Infarction	1	1			1	1
Pallor	1	11		3	1	8
Peripheral coldness	1	2			1	2
Phlebitis deep	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	9	11			9	11
Vasculitis	1	1	1	1		
Vasodilatation		1				1
	31	89	3	25	28	64

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ECUADOR**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Angina pectoris	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pain		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	4	1	4
Lip oedema		1		1
Vomiting		1		1
	1	6	1	6

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
Discomfort	3	4	3	4		
Drug ineffective	1	4			1	4
Face oedema		1		1		
Fatigue	2	2	2	2		
Pain	1	1	1	1		
Pyrexia	5	6	5	6		
Vaccination site pain	4	6	4	6		
	17	25	16	21	1	4

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	7		2	1	5
Laryngitis		2		2		
Suspected COVID-19		1				1
Tracheitis		1		1		
	1	11		5	1	6

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	1	2	1	2
SARS-CoV-2 test positive		1		1
	1	3	1	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Limb discomfort	1	1	1	1
Musculoskeletal disorder		1		1
Myalgia	1	1	1	1
	3	4	3	4

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness		2		2		
Headache	1	1	1	1		
Thrombotic stroke	1	1			1	1
	2	4	1	3	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Depressed mood		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Lung infiltration	1	1	1	1
Oropharyngeal pain		1		1
	2	3	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred  
**EGYPT**

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Drug ineffective	1	1	1	1
	1	1	1	1

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ESTONIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	5	1	5
	1	5	1	5

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Bradycardia		1				1
Cardiac failure congestive	1	1			1	1
Hypertensive heart disease	1	1			1	1
Palpitations		3		3		
Supraventricular tachycardia		1				1
Tachycardia	1	3	1	3		
Ventricular extrasystoles		1				1
	4	12	1	6	3	6

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorder	1	1	1	1		
Ear pain	1	1	1	1		
Tinnitus	1	2	1	1		1
	3	4	3	3		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral	1	1			1	1
Diplopia	1	1	1	1		
Ocular discomfort	1	1	1	1		
Photopsia	1	1	1	1		
Retinal vascular thrombosis	1	1			1	1
Vision blurred	1	2	1	2		
Visual impairment		1				1
	6	8	4	5	2	3

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Abdominal pain upper		1				1
Diarrhoea	1	3	1	3		
Dyspepsia	1	1	1	1		
Dysphagia	1	2		1	1	1
Hypoaesthesia oral		2		2		
Lip swelling		1				1
Mouth swelling		1				1
Nausea	4	16	4	12		4
Paraesthesia oral		3		3		
Retching		1				1
Vomiting	1	2	1	2		
	10	35	9	26	1	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	8	23	8	17		6
Chest discomfort		1		1		
Chest pain	3	5	3	3		2
Chills	8	23	8	22		1
Condition aggravated	1	1	1	1		
Death	2	2			2	2
Disease recurrence	1	2	1	1		1
Drug ineffective	4	6			4	6
Extensive swelling of vaccinated limb		1		1		
Facial pain	1	2	1	2		
Fatigue	3	14	3	13		1
Feeling hot	1	2	1	2		
Hypothermia	3	5			3	5
Influenza like illness	1	1	1	1		
Malaise		10		7		3
Pain	1	2	1	1		1
Peripheral swelling	1	1	1	1		
Pyrexia	13	38	13	36		2
Vaccination site erythema	1	7	1	7		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	1	2	1	2		
Vaccination site oedema	2	7	2	7		
Vaccination site pain	4	35	4	35		
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash	1	2	1	2		
Vaccination site swelling	1	4	1	4		
	62	199	53	169	9	30

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug hypersensitivity		1				1
Hypersensitivity		4		1		3
Immunisation reaction		1				1
Type I hypersensitivity		1				1
Type IV hypersensitivity reaction	1	1			1	1
	1	8		1	1	7

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1				1
COVID-19	24	27		1	24	26
COVID-19 pneumonia	1	1			1	1
Oral herpes		2		2		
Pneumonia		1				1
Rhinitis	1	1	1	1		
Suspected COVID-19	1	1			1	1
Vaccine breakthrough infection	1	1			1	1
	28	35	1	4	27	31

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone contusion		1				1
Contusion		1				1
Exposure during pregnancy	2	4	2	4		
Fall		2		2		
Fracture		1				1
Maternal exposure during pregnancy		3		3		
Off label use		1		1		
Product use issue		1		1		
Road traffic accident		1		1		
Spinal cord injury		1				1
Underdose		1		1		
Vaccination failure	20	21			20	21
Wound		1				1
	22	39	2	13	20	26

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1		1		
Blood pressure increased		1				1
Body temperature decreased	1	1	1	1		
C-reactive protein increased	1	1	1	1		
Heart rate increased		1				1
	2	5	2	3		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	2	1	2		
Hypoglycaemia	1	1			1	1
Increased appetite		1		1		
	2	4	1	3	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	6	14	6	14		
Back pain		3		1		2
Bone pain		2		1		1
Joint range of motion decreased	1	1	1	1		
Joint stiffness	1	1	1	1		
Joint swelling	1	1	1	1		
Muscle spasms		1		1		
Muscular weakness	1	3	1	3		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness		1				1
Myalgia	6	15	6	14		1
Neck pain		2				2
Pain in extremity	2	8	2	8		
Tendon pain	1	1	1	1		
	19	54	19	47		7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute disseminated encephalomyelitis		1				1
Ageusia	1	2	1	2		
Balance disorder	1	2	1	2		
Cerebral haemorrhage		1				1
Cerebral infarction	1	1			1	1
Cerebrovascular accident		1				1
Cognitive disorder		1		1		
Demyelination		1				1
Dizziness	6	14	6	10		4
Dysgeusia		6		4		2
Facial nerve disorder		1		1		
Facial paralysis		1				1
Headache	9	38	9	34		4
Hypoaesthesia		4		4		
Illrd nerve disorder	1	1			1	1
Loss of consciousness		1				1
Migraine with aura		1		1		
Myelitis transverse		1				1
Paraesthesia	2	18	2	15		3
Peripheral sensory neuropathy		1				1
Presyncope		1				1
Seizure		1				1
Somnolence	1	9	1	8		1
Speech disorder		1				1
Syncope	5	11			5	11
Tremor	1	2	1	2		
Trigeminal nerve disorder	1	1			1	1
	29	123	21	84	8	39

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Syringe issue		1		1
		1		1

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1				1
Immunisation anxiety related reaction		10		9		1
Insomnia	4	5	4	5		
Nervousness		1				1
Panic attack		1		1		
Restlessness		3		3		
	4	21	4	18		3

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Dysuria		1		1
Urinary retention		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	1	1			1	1
Chronic obstructive pulmonary disease	1	1			1	1
Cough	1	3	1	3		
Dyspnoea	6	12	5	10	1	2
Hypopnoea		1				1
Intranasal paraesthesia		1		1		
Laryngeal oedema	1	2			1	2
Nasal congestion		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	2	3	2	3		
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Pulmonary embolism	1	2			1	2
Pulmonary oedema	1	1			1	1
Respiration abnormal		1				1
Respiratory failure	3	3			3	3
Respiratory symptom		1		1		
Rhinorrhoea	3	3	3	3		
Sputum increased	1	1	1	1		
Throat tightness		1				1
	21	42	12	26	9	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1				1
Hyperhidrosis	3	3	3	3		
Pruritus	1	1	1	1		
Psoriasis		1				1
	4	6	4	4		2

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	1	1			1	1
Flushing		1		1		
Haematoma		1		1		
Hypertension		4		3		1
Hypotension		2				2
Pallor		1				1
Thrombophlebitis	1	1	1	1		
	2	11	1	6	1	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FINLAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune thrombocytopenia	1	1			1	1
Increased tendency to bruise	1	1			1	1
Lymphadenopathy	4	50	1	22	3	28
Lymph node pain	1	9	1	3		6
Neutropenia		1				1
Platelet disorder	1	1			1	1
Thrombocytosis		1				1
	8	64	2	25	6	39

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Arrhythmia	4	21			4	21
Atrial fibrillation	4	6			4	6
Cardiac arrest	1	1			1	1
Cardiac failure	2	6			2	6
Cardiac flutter	1	1			1	1
Cardiac hypertrophy	1	1			1	1
Congestive cardiomyopathy		1				1
Coronary artery thrombosis	1	1			1	1
Extrasystoles		6		3		3
Myocardial infarction		2				2
Myocarditis		1				1
Palpitations	3	19		6	3	13
Right ventricular failure	2	2			2	2
Sinus tachycardia		2				2
Tachycardia	2	9		1	2	8
Ventricular fibrillation	1	1			1	1
	22	81		10	22	71

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Porphyria	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral	2	3			2	3
Ear canal erythema		1		1		
Ear discomfort	1	4		3	1	1
Ear pain		7		6		1
Ear pruritus		1		1		
Hyperacusis	1	1			1	1
Hypoacusis	3	4	2	3	1	1
Meniere's disease		1				1
Sudden hearing loss		1				1
Tinnitus	1	6		4	1	2
Tympanic membrane hyperaemia		1		1		
Vertigo	1	5		1	1	4
	9	35	2	20	7	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accommodation disorder		1		1		
Amaurosis fugax	1	1			1	1
Asthenopia		2				2
Blepharitis		1				1
Conjunctival hyperaemia	1	1			1	1
Diplopia	2	2	2	2		
Dry eye		1				1
Erythema of eyelid	1	2			1	2
Eye disorder		1				1
Eye haematoma		1				1
Eye irritation		1		1		
Eyelid irritation		1				1
Eyelid oedema		5		1		4
Eyelid ptosis		1				1
Eye movement disorder		1		1		
Eye pain	1	9		3	1	6
Gaze palsy		2				2
Iritis		1				1
Keratitis	1	1			1	1
Macular oedema	1	1			1	1
Mydriasis		1		1		
Ocular discomfort		1		1		
Ocular hyperaemia		2				2
Ophthalmic vein thrombosis	1	1			1	1
Photophobia		4		1		3
Photopsia	1	2			1	2
Pigmentary glaucoma	1	1			1	1
Retinal haemorrhage	1	1			1	1
Retinal tear		1				1
Retinal vascular occlusion	1	1			1	1
Retinal vascular thrombosis	1	1			1	1
Retinal vein thrombosis	2	2			2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Strabismus		1				1
Swelling of eyelid		2				2
Ulcerative keratitis		1				1
Vision blurred		4		1		3
Visual acuity reduced	1	1			1	1
Visual impairment	2	6		1	2	5
	19	69	2	14	17	55

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3				3
Abdominal distension	1	3		2	1	1
Abdominal pain	2	12		3	2	9
Abdominal pain lower	1	4	1	2		2
Abdominal pain upper		6		1		5
Abdominal symptom		2		1		1
Cheilitis		1		1		
Crohn's disease		1				1
Diarrhoea	4	20		9	4	11
Dry mouth		3				3
Dyspepsia	1	1			1	1
Dysphagia		9		2		7
Flatulence		1		1		
Gastric disorder		1		1		
Gastrointestinal necrosis	1	1			1	1
Gingival swelling		1		1		
Glossodynia		1				1
Haematochezia		1				1
Hypoaesthesia oral	1	13	1	5		8
Hypoaesthesia teeth		1		1		
Intestinal ischaemia	1	1			1	1
Lip oedema	3	4	2	3	1	1
Lip pain		2		2		
Lip pruritus		1				1
Lip swelling		2		1		1
Mesenteric artery thrombosis	1	1			1	1
Mouth haemorrhage	1	1			1	1
Mouth swelling		2				2
Nausea	14	79	3	26	11	53
Noninfective sialoadenitis		1				1
Oral discomfort		2		2		
Oral disorder		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral mucosal blistering		2		2		
Oral pruritus		4				4
Paraesthesia oral	1	18	1	9		9
Rectal haemorrhage	1	1			1	1
Rectal ulcer		1				1
Salivary gland enlargement		1				1
Salivary hypersecretion		1				1
Stiff tongue		1				1
Swollen tongue	1	2			1	2
Tongue discolouration	1	1			1	1
Tongue discomfort	1	3		1	1	2
Tongue disorder		1				1
Tongue erythema	1	1			1	1
Tongue oedema	1	4			1	4
Toothache		1		1		
Vomiting	8	37	2	11	6	26
	46	261	10	88	36	173

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	10	55	1	11	9	44
Axillary pain		14		6		8
Chest discomfort	3	17		5	3	12
Chest pain	1	10		2	1	8
Chills	6	45		17	6	28
Condition aggravated		4				4
Death	1	12			1	12
Discomfort		4		1		3
Disease recurrence	2	5			2	5
Drug ineffective	1	1			1	1
Exercise tolerance decreased	1	2			1	2
Extensive swelling of vaccinated limb		2		2		
Face oedema	2	12		1	2	11
Facial pain		4		2		2
Fatigue	16	121		38	16	83
Feeling abnormal	3	14		2	3	12
Feeling cold	2	16		4	2	12
Feeling drunk	1	1			1	1
Feeling hot	2	26		9	2	17
Foaming at mouth		1				1
Gait disturbance	1	8		2	1	6
Gait inability		1				1
General physical health deterioration	7	28		2	7	26
Hypothermia		4				4
Illness		1				1
Inflammation	1	1			1	1
Influenza like illness	2	3			2	3
Irritability postvaccinal		1		1		
Localised oedema		4		2		2
Loss of control of legs		3				3
Malaise	11	58	2	16	9	42
Nodule	2	3	1	2	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Obstruction		2					2
Oedema peripheral	2	8	1	2	1		6
Pain	7	30		3	7		27
Peripheral swelling	1	1	1	1			
Pyrexia	18	155	1	45	17		110
Secretion discharge		2		1			1
Sensation of foreign body	2	9		2	2		7
Sudden death		3					3
Swelling	1	8		4	1		4
Swelling face		4		1			3
Vaccination site bruising		2					2
Vaccination site erythema	1	33	1	21			12
Vaccination site haematoma		5		5			
Vaccination site hyperaesthesia		6		1			5
Vaccination site hypoaesthesia		2		1			1
Vaccination site induration		5		4			1
Vaccination site joint movement impairment		1		1			
Vaccination site macule		1		1			
Vaccination site mass		6		2			4
Vaccination site movement impairment		9		2			7
Vaccination site oedema		19		17			2
Vaccination site pain	4	67	1	35	3		32
Vaccination site plaque		1		1			
Vaccination site pruritus		7		5			2
Vaccination site rash		1		1			
Vaccination site reaction	1	4		2	1		2
Vaccination site swelling		7		2			5
Vaccination site urticaria		1		1			
Vaccination site warmth	1	15		9	1		6
	113	895	9	295	104		600

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cholelithiasis		1		1
Jaundice		1		1
		2		2

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		2			2	
Anaphylactic reaction	4	16			4	16
Anaphylactic shock		3				3
Food allergy		2				2
Hypersensitivity	3	17		1	3	16
Type IV hypersensitivity reaction		1		1		
	7	41		2	7	39

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis		1				1
Borrelia infection		1				1
Bronchitis		2				2
Corneal infection	1	1			1	1
COVID-19	3	3			3	3
Cystitis	1	1			1	1
Diverticulitis	1	2			1	2
Encephalitis		2				2
Erysipelas		2				2
Eye infection	1	1			1	1
Gastrointestinal viral infection	1	1			1	1
Herpes ophthalmic	1	1			1	1
Herpes virus infection		1		1		
Herpes zoster	3	12		6	3	6
Herpes zoster cutaneous disseminated		1				1
Herpes zoster oticus		1				1
Infection	1	2			1	2
Influenza	2	3	1	1	1	2
Nasopharyngitis	2	9		1	2	8
Oral herpes		1		1		
Perichondritis		1		1		
Pneumonia	3	11			3	11
Pseudomonal sepsis	1	1			1	1
Pyelonephritis		2				2
Respiratory tract infection		1				1
Rhinitis		2				2
Sialoadenitis		1				1
Subcutaneous abscess		1				1
Urinary tract infection	3	6	1	1	2	5
Vaccination site abscess		1				1
Vaginal infection		1				1
Vestibular neuronitis		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral infection		2				
	24	79	2	12	22	67

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	2		1	1	1
Fall	4	12		1	4	11
Head injury		2		1		1
Hip fracture	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	1	11	1	11		
Joint injury	1	1			1	1
Limb injury	2	2			2	2
Maternal exposure during pregnancy		1		1		
Muscle strain		1				1
Off label use	1	3	1	3		
Poor quality product administered		12		12		
Post procedural haemorrhage	1	1			1	1
Product preparation error		12		12		
Product use issue		1		1		
Skull fractured base		1				1
Vaccination failure	2	2			2	2
Wrong technique in product usage process		1		1		
	15	67	3	45	12	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1				1
Bacterial test positive	2	3			2	3
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatine increased	1	1			1	1
Blood creatinine increased		1				1
Blood glucose decreased	1	1			1	1
Blood glucose increased		1				1
Blood lactic acid decreased		1		1		
Blood pressure decreased	3	9		1	3	8
Blood pressure diastolic decreased		1				1
Blood pressure diastolic increased		2				2
Blood pressure increased	5	24		3	5	21
Blood pressure systolic decreased		1				1
Blood uric acid increased		1				1
Body temperature decreased		2				2
Body temperature fluctuation		1				1
Body temperature increased		2		1		1
Breath sounds abnormal		2		1		1
Chest X-ray abnormal	1	1			1	1
Coma scale abnormal		2				2
C-reactive protein increased		13		2		11
CSF immunoglobulin increased	1	1			1	1
CSF protein increased		1				1
Electrocardiogram ST segment depression	1	1			1	1
Electrocardiogram T wave inversion	1	1			1	1
Eosinophil count increased		1				1
Fibrin D dimer increased	1	1	1	1		
Grip strength decreased		1				1
Haemoglobin decreased	1	2			1	2
Heart rate decreased		2		1		1
Heart rate increased	2	22		2	2	20

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate irregular	1	4		1	1	3
Inflammatory marker increased		1				1
International normalised ratio decreased	3	3	1	1	2	2
Lymph nodes scan abnormal		1				1
Oxygen saturation decreased	1	3			1	3
Peak expiratory flow rate decreased		3				3
Red blood cell sedimentation rate increased		1				1
Red blood cells urine	1	1			1	1
Red blood cells urine positive	1	1			1	1
Respiratory rate decreased		1				1
Respiratory rate increased	1	1			1	1
Rinne tuning fork test abnormal		1		1		
SARS-CoV-2 test negative	2	4		1	2	3
Synovial fluid white blood cells positive		1				1
Troponin I increased	1	1			1	1
Urine porphobilinogen increased	1	1			1	1
Weber tuning fork test abnormal		1		1		
Weight decreased		1		1		
White blood cell count increased	1	3			1	3
White blood cells urine	1	1			1	1
White blood cells urine positive	1	1			1	1
	35	140	2	19	33	121

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Decreased appetite	6	9	6	9
Dehydration	1	1	1	1
Feeding disorder		1		1
Fluid intake reduced		1		1
Food aversion		1		1
Hyperlactacidaemia	1	1	1	1
Hypernatraemia		1		1
Hypokalaemia		5		5
Hyponatraemia	1	1	1	1
Hypophagia		1		1
	9	22	9	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Ankylosing spondylitis		1					1
Arthralgia	11	68	1	24	10	44	
Arthritis		1				1	
Arthritis reactive	1	2			1	2	
Autoimmune arthritis	1	1			1	1	
Back pain	2	19	1	10	1	9	
Bone pain		3		1		2	
Cervical spinal stenosis		1				1	
CREST syndrome		1				1	
Flank pain		2				2	
Groin pain		1				1	
Intervertebral disc disorder		1		1			
Joint effusion		1				1	
Joint range of motion decreased		3		2		1	
Joint stiffness		1		1			
Joint swelling	1	1	1	1			
Limb discomfort	1	2	1	2			
Mobility decreased	1	4		1	1	3	
Muscle disorder	1	1			1	1	
Muscle fatigue		2				2	
Muscle spasms		6		1		5	
Muscle tightness		2		1		1	
Muscle twitching		9		3		6	
Muscular weakness	8	27	1	3	7	24	
Musculoskeletal discomfort		1				1	
Musculoskeletal disorder		2		1		1	
Musculoskeletal pain		3		1		2	
Musculoskeletal stiffness	6	15	2	8	4	7	
Myalgia	12	103	1	28	11	75	
Neck pain	3	14	1	3	2	11	
Nuchal rigidity		2		2			
Osteoarthritis		1		1			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	14	89	6	32	8	57
Polyarthritis	1	1			1	1
Polymyalgia rheumatica	1	1			1	1
Rheumatoid arthritis		1				1
Spinal pain		2		1		1
Tendon pain	1	2			1	2
Trismus	1	1	1	1		
	66	398	16	129	50	269

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Malignant lymphoid neoplasm		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1				1
Amnesia		1				1
Anaesthesia		1		1		
Aphasia	1	2			1	2
Areflexia		1				1
Balance disorder		2				2
Burning sensation	1	9		3	1	6
Central nervous system inflammation	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral infarction	7	12			7	12
Cerebrovascular accident		2				2
Cerebrovascular disorder	1	1			1	1
Clumsiness		2		2		
Cognitive disorder		3		1		2
Coordination abnormal	1	1	1	1		
Dementia Alzheimer's type		4				4
Demyelination	1	1			1	1
Depressed level of consciousness		6				6
Disturbance in attention		1				1
Dizziness	13	65	1	16	12	49
Dysarthria	7	11	1	1	6	10
Dysgeusia	1	3		1	1	2
Dyskinesia		1		1		
Dysmetria	1	1			1	1
Dysstasia		2				2
Epilepsy		4				4
Facial paralysis	2	14			2	14
Facial paresis		2				2
Headache	13	135	2	41	11	94
Head discomfort	2	9	1	3	1	6
Hemianaesthesia	1	19			1	19

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hemihyperaesthesia		1
Hemiparaesthesia		3
Hemiparesis	4	6
Hemiplegia	2	2
Hyperaesthesia		4
Hypersomnia		2
Hypoaesthesia	10	39
Hyporeflexia		1
Hyposmia	1	1
Hypotonia	1	3
Lethargy	1	1
Loss of consciousness	1	7
Memory impairment	1	2
Mental impairment	1	2
Migraine	3	12
Migraine with aura	1	1
Monoparesis		1
Movement disorder		1
Muscle spasticity		2
Narcolepsy	1	1
Neuralgia	1	13
Neuritis	1	1
Neurological symptom	1	2
Opisthotonus		1
Paraesthesia	7	36
Paraparesis		1
Paresis	1	1
Petit mal epilepsy	1	1
Poor quality sleep	1	1
Presyncope	1	5
Reduced facial expression	1	1
Seizure	1	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			3
		4	6
		2	2
			4
	1		1
2	14	8	25
			1
1	1		
		1	3
		1	1
		1	7
	1	1	1
		1	2
	1	3	11
		1	1
			1
			1
		1	1
1	4		9
		1	1
		1	2
			1
1	11	6	25
			1
		1	1
		1	1
	1	1	4
1	1		
		1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory disturbance		1		1		
Sensory loss		1				1
Slow speech		1				1
Somnolence	2	6		1	2	5
Speech disorder	1	3			1	3
Stupor		1				1
Syncope	4	15			4	15
Thrombotic cerebral infarction	1	1			1	1
Transient aphasia	1	2			1	2
Transient ischaemic attack	1	2			1	2
Tremor	2	15		2	2	13
Trigeminal palsy	1	1			1	1
Unresponsive to stimuli		2				2
	110	529	12	110	98	419

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issue	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1				1
Confusional state	1	6		2	1	4
Delirium	1	1			1	1
Delusion		2		2		
Derealisation		1		1		
Eating disorder	1	1	1	1		
Fear		1		1		
Hallucination		1				1
Hallucination, auditory		2				2
Helplessness		1		1		
Impaired reasoning		1				1
Initial insomnia		1				1
Insomnia	2	11		3	2	8
Irritability		2				2
Middle insomnia	1	7		3	1	4
Self-injurious ideation		1				1
Stress	1	1			1	1
	7	41	1	14	6	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anuria	2	2			2	2
Dysuria		2		1		1
Haematuria	1	1			1	1
Renal failure	1	1			1	1
Urinary retention	1	1			1	1
Urogenital haemorrhage	1	1			1	1
	6	8		1	6	7

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Breast cyst		1		1
Breast pain		1		1
Breast swelling		1		1
Breast tenderness		1		1
Female genital tract fistula		1		1
Menstrual disorder		1		1
Vulvovaginal inflammation		1		1
		7		7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		3		1		2
Apnoea		3				3
Asthma		1				1
Choking sensation		1				1
Chronic obstructive pulmonary disease		1				1
Cough	4	21	1	3	3	18
Dysphonia	1	5		2	1	3
Dyspnoea	14	81		9	14	72
Dyspnoea exertional	1	4			1	4
Epistaxis	1	4		1	1	3
Hyperventilation		1				1
Hypopnoea		1				1
Increased upper airway secretion		6				6
Laryngeal pain		1				1
Lung disorder	1	2			1	2
Nasal congestion	1	5		2	1	3
Nasal oedema		2				2
Nasal pruritus		1		1		
Oropharyngeal discomfort		5		1		4
Oropharyngeal oedema		2		1		1
Oropharyngeal pain	1	16		9	1	7
Painful respiration		1				1
Paranasal sinus discomfort		1				1
Pharyngeal hypoaesthesia		4		1		3
Pharyngeal oedema	1	7		1	1	6
Pharyngeal paraesthesia		3		1		2
Pharyngeal swelling	2	6			2	6
Pneumonia aspiration		1				1
Productive cough		3				3
Pulmonary embolism	8	10			8	10
Pulmonary haemorrhage	1	1			1	1
Pulmonary infarction		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pulmonary oedema		1					1
Pulmonary pain	1	6		1	1		5
Rales		1					1
Respiratory arrest		2					2
Respiratory tract irritation		1					1
Rhinorrhoea		3		2			1
Rhonchi		1					1
Sinus disorder		1					1
Sneezing	1	1			1		1
Snoring		1					1
Sputum discoloured	1	1			1		1
Stridor		2					2
Suffocation feeling	1	2			1		2
Throat irritation		11		3			8
Throat tightness	1	6			1		6
Wheezing	1	6		1	1		5
	42	250	1	40	41		210

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	1	3		2	1	1
Cold sweat		3		1		2
Eczema		2				2
Erythema	3	38	1	12	2	26
Erythema multiforme		1				1
Fixed eruption		2		2		
Hyperhidrosis	1	11		3	1	8
Night sweats		1		1		
Pain of skin		5		1		4
Papule		1		1		
Photosensitivity reaction		1				1
Pruritus	2	15		9	2	6
Rash	3	12	1	3	2	9
Rash erythematous	1	5		2	1	3
Rash macular		4		1		3
Rash pruritic	2	4	1	3	1	1
Scab	1	1			1	1
Skin reaction	1	1	1	1		
Skin sensitisation	1	1			1	1
Skin striae	1	1			1	1
Skin warm	1	2		1	1	1
Urticaria	3	25		7	3	18
	21	139	4	50	17	89

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		1				1
Impaired work ability	5	16		1	5	15
Loss of personal independence in daily activities		2				2
	5	19		1	5	18

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Resuscitation	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortitis	1	1			1	1
Blood pressure fluctuation		1				1
Circulatory collapse	2	2			2	2
Cyanosis		1				1
Deep vein thrombosis	2	4			2	4
Flushing		8		2		6
Giant cell arteritis	1	1			1	1
Haematoma	1	3		2	1	1
Haemodynamic instability	1	1			1	1
Hot flush		2				2
Hypertension	1	7		1	1	6
Hypotension	2	3			2	3
Pallor		6		1		5
Pelvic venous thrombosis		1				1
Peripheral coldness		1				1
Peripheral embolism	1	1			1	1
Thrombophlebitis superficial		1				1
Thrombosis	3	4			3	4
Venous thrombosis	2	2			2	2
	17	50		6	17	44

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FRANCE**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia	2	2			2	2
Agranulocytosis	1	2			1	2
Anaemia	4	12		2	4	10
Anaemia macrocytic	1	1			1	1
Aplastic anaemia	1	1			1	1
Autoimmune haemolytic anaemia		1				1
Blood loss anaemia	1	1			1	1
Disseminated intravascular coagulation	1	1			1	1
Eosinophilia	2	5			2	5
Haemolytic anaemia	2	2			2	2
Haemorrhagic diathesis	1	1			1	1
Haemorrhagic disorder	1	1			1	1
Hyperleukocytosis	7	18			7	18
Immune thrombocytopenia	6	10			6	10
Iron deficiency anaemia		1				1
Leukocytosis	1	3	1	2		1
Leukopenia	4	5	1	1	3	4
Lymphadenitis	3	11	2	7	1	4
Lymphadenopathy	23	123	9	58	14	65
Lymphadenopathy mediastinal	1	1	1	1		
Lymph node pain	1	6	1	2		4
Lymphopenia	9	18	5	7	4	11
Monocytosis	2	2	1	1	1	1
Myelocytosis		1				1
Neutropenia	4	9			4	9
Neutrophilia	1	3	1	3		
Normochromic anaemia	1	1			1	1
Normochromic normocytic anaemia	1	1	1	1		
Normocytic anaemia		1				1
Pancytopenia	1	4			1	4
Splenic infarction	1	1			1	1
Thrombocytopenia	16	29	1	1	15	28

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombocytopenic purpura		1				1
Thrombocytosis	1	1	1	1		
	100	280	25	87	75	193

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	9	20			9	20
Acute myocardial infarction	2	5			2	5
Angina pectoris	4	13			4	13
Angina unstable	1	2			1	2
Aortic valve calcification	1	1			1	1
Aortic valve incompetence	3	4			3	4
Arrhythmia	25	69			25	69
Arrhythmia supraventricular	1	5			1	5
Arteriosclerosis coronary artery	1	1			1	1
Atrial fibrillation	46	105			46	105
Atrial flutter	3	6	1	1	2	5
Atrial thrombosis	1	1			1	1
Atrioventricular block	3	7		1	3	6
Atrioventricular block complete		3				3
Atrioventricular block second degree	1	1			1	1
Bradycardia	16	49			16	49
Bundle branch block		1				1
Bundle branch block left		4				4
Bundle branch block right	1	7	1	3		4
Cardiac arrest	7	23			7	23
Cardiac discomfort	1	2			1	2
Cardiac disorder	2	3	1	1	1	2
Cardiac failure	34	87			34	87
Cardiac failure acute	1	5			1	5
Cardiac failure congestive	2	3			2	3
Cardiac fibrillation	1	2			1	2
Cardiac flutter		2				2
Cardiac tamponade	1	1			1	1
Cardiogenic shock	1	5			1	5
Cardiomegaly		1				1
Cardiomyopathy	1	1			1	1
Cardiopulmonary failure	2	3			2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Cardiac disorders**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		12	38
		1	1
		1	4
			1
			1
1		1	2
1		1	1
1		1	1
2		2	4
1		1	1
11		19	
1		1	
1		2	
		1	1
1		1	1
1		2	
1		1	1
1		3	
1		2	2
1		1	1
1		1	1
1		2	4
1		1	1
8		8	36
			5
			1
1		1	8
18		12	39
5		5	8
1		1	1
10		10	25
1		1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus arrest		1				1
Sinus bradycardia		2				2
Sinus tachycardia	7	19	2	4	5	15
Stress cardiomyopathy	1	3			1	3
Supraventricular extrasystoles	1	5			1	5
Supraventricular tachyarrhythmia		1				1
Supraventricular tachycardia	2	10			2	10
Tachyarrhythmia	1	6		2	1	4
Tachycardia	54	241	17	60	37	181
Tachycardia paroxysmal	1	1			1	1
Tricuspid valve incompetence		1				1
Ventricular arrhythmia	1	1			1	1
Ventricular extrasystoles	5	14	1	3	4	11
Ventricular failure	1	1			1	1
Ventricular fibrillation	2	5			2	5
Ventricular hypokinesia	2	2			2	2
Ventricular tachycardia	1	7			1	7
	335	1,006	34	108	301	898

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Congenital, familial and genetic disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aplasia		1				1
Cystic lymphangioma		1				1
Factor II mutation	1	1	1	1		
Familial mediterranean fever		1				1
Hyperglycinaemia		1				1
Hypertrophic cardiomyopathy	1	2			1	2
Macroglossia	1	3			1	3
	3	10	1	1	2	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome	2	6		1	2	5
Auditory disorder		1				1
Deafness	2	7			2	7
Deafness neurosensory		1				1
Deafness unilateral	3	10			3	10
Ear discomfort		2		1		1
Ear disorder	1	2	1	2		
Ear haemorrhage	1	1	1	1		
Ear pain	9	21	4	8	5	13
Ear swelling	2	3		1	2	2
Hyperacusis	1	1	1	1		
Hypoacusis	3	9		2	3	7
Inner ear disorder		2		1		1
Meniere's disease	1	1			1	1
Otolithiasis		1				1
Paraesthesia ear	1	1			1	1
Sudden hearing loss	5	6			5	6
Tinnitus	15	46	6	13	9	33
Vertigo	29	119	11	36	18	83
Vertigo positional	3	11			3	11
Vestibular disorder	1	5	1	2		3
	79	256	25	69	54	187

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal insufficiency	1	1			1	1
Adrenal mass	1	1	1	1		
Adrenocortical insufficiency acute		1				1
Autoimmune thyroiditis	1	4			1	4
Basedow's disease	1	1			1	1
Diabetes insipidus		1				1
Goitre		1		1		
Hyperthyroidism	1	5			1	5
Hypothyroidism	1	1			1	1
Thyroid disorder		1		1		
Thyroid mass		1		1		
	6	18	1	4	5	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	1	1	1	1		
Accommodation disorder		1				1
Age-related macular degeneration	1	1			1	1
Amaurosis	1	2			1	2
Amaurosis fugax		2				2
Blindness	2	2			2	2
Blindness transient	1	1			1	1
Blindness unilateral	2	4			2	4
Cataract	1	1			1	1
Conjunctival haemorrhage	4	15			4	15
Conjunctival hyperaemia	1	1	1	1		
Conjunctival irritation		1		1		
Conjunctival oedema	1	1	1	1		
Diplopia	7	16	2	2	5	14
Dry eye	1	4	1	3		1
Endocrine ophthalmopathy	1	1			1	1
Erythema of eyelid		1				1
Exophthalmos	1	1			1	1
Eye discharge	1	1			1	1
Eye disorder		1				1
Eye haemorrhage	1	6			1	6
Eye irritation	1	3		2	1	1
Eyelid disorder		2		1		1
Eyelid function disorder		1				1
Eyelid haematoma		1		1		
Eyelid irritation		1		1		
Eyelid myoclonus	1	1			1	1
Eyelid oedema	3	16		4	3	12
Eyelid ptosis		3		1		2
Eye movement disorder	1	1	1	1		
Eye oedema		2		1		1
Eye pain	4	10	4	5		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye swelling	2	4
Gaze palsy	1	2
Glaucoma	1	1
Hyperaesthesia eye		1
Iridocyclitis		1
Lacrimation increased	1	7
Macular oedema	1	1
Metamorphopsia	1	2
Miosis		1
Mydriasis	1	5
Noninfective chorioretinitis		1
Ocular discomfort	1	6
Ocular hyperaemia	2	6
Ocular myasthenia		1
Ocular vascular disorder	1	1
Optic ischaemic neuropathy	1	2
Orbital haematoma		1
Parophthalmia	1	1
Periorbital oedema		1
Periorbital pain	1	2
Periorbital swelling	1	1
Photophobia	1	12
Photopsia	1	4
Pupils unequal		1
Retinal artery occlusion	3	5
Retinal fovea disorder	1	1
Retinal vein occlusion	5	7
Scleral disorder	1	1
Scleritis		1
Swelling of eyelid	1	1
Uveitis		1
Vision blurred	8	21

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	2	3
		1	2
		1	1
	1		
			1
1	4		3
		1	1
	1	1	1
			1
1	2		3
			1
1	5		1
		2	6
			1
		1	1
		1	2
			1
		1	1
1	1		1
		1	1
1	2		10
	1	1	3
	1		
		3	5
		1	1
		5	7
		1	1
			1
		1	1
			1
	5	8	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual acuity reduced	1	5			1	5
Visual acuity reduced transiently	1	1			1	1
Visual brightness		1				1
Visual impairment	3	20	1	4	2	16
Vitreous floaters		1				1
	79	236	17	54	62	182

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3	1	2		1
Abdominal distension	2	8	2	5		3
Abdominal mass	1	1	1	1		
Abdominal pain	17	94	7	36	10	58
Abdominal pain lower	3	3	2	2	1	1
Abdominal pain upper	9	35		11	9	24
Abdominal rigidity		2				2
Abnormal faeces		1		1		
Acute abdomen		1				1
Aerophagia	1	1			1	1
Anaesthesia oral		4		2		2
Aphthous ulcer	1	6		3	1	3
Colitis	1	3		1	1	2
Colitis ulcerative	1	1			1	1
Constipation	4	9	4	8		1
Crohn's disease	1	1			1	1
Diarrhoea	40	188	12	62	28	126
Diarrhoea haemorrhagic	3	5			3	5
Diverticulum intestinal	2	2	1	1	1	1
Dry mouth	2	8	1	4	1	4
Dyspepsia		7		1		6
Dysphagia	7	26	4	9	3	17
Enlarged uvula		1				1
Enterocolitis haemorrhagic	1	1			1	1
Eructation		4				4
Faecaloma	1	2			1	2
Faecal vomiting		2				2
Faeces discoloured		2		2		
Faeces soft		2		2		
Flatulence	2	2	1	1	1	1
Functional gastrointestinal disorder	1	4			1	4
Gastric volvulus		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gastritis		1					1
Gastrointestinal disorder	3	12	2	4	1		8
Gastrointestinal haemorrhage	1	3			1		3
Gastrointestinal hypermotility		1		1			
Gastrointestinal inflammation		1					1
Gastrointestinal motility disorder	1	3	1	2			1
Gastrointestinal pain	2	5	1	3	1		2
Gastrointestinal sounds abnormal		1		1			
Gastrointestinal wall thickening	1	1	1	1			
Gastrooesophageal reflux disease		4		2			2
Gingival bleeding	1	1			1		1
Gingival discomfort	1	2	1	1			1
Glossitis	1	2	1	1			1
Glossodynia	1	1	1	1			
Haematemesis	4	7			4		7
Haematochezia	1	5			1		5
Haemorrhoids		1					1
Haemorrhoids thrombosed		1					1
Hypoesthesia oral	1	7		1	1		6
Intestinal ischaemia	5	5			5		5
Intestinal obstruction		2					2
Lip erosion		1					1
Lip haematoma	1	1			1		1
Lip haemorrhage	1	1			1		1
Lip oedema	2	17		3	2		14
Lip pain	1	2			1		2
Lip pruritus		1					1
Lip swelling	1	7		1	1		6
Melaena		1					1
Mesenteric vein thrombosis	1	1			1		1
Mouth haemorrhage	1	2		1	1		1
Mouth ulceration	1	2	1	2			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mucous stools		1		1		
Nausea	79	368	25	132	54	236
Necrotising colitis	1	1			1	1
Noninfective gingivitis		2		1		1
Obstruction gastric		1				1
Odynophagia	2	4	2	3		1
Oedema mouth		1				1
Oesophageal pain		1				1
Oesophageal spasm		1				1
Oral blood blister	1	1			1	1
Oral discomfort	1	1	1	1		
Oral disorder		1		1		
Oral dysaesthesia	2	3	1	2	1	1
Oral pain		4		4		
Oral pruritus		3		1		2
Palatal oedema		5				5
Pancreatitis	1	2			1	2
Pancreatitis acute	4	8			4	8
Paraesthesia oral	3	21		9	3	12
Peptic ulcer		1				1
Pneumoperitoneum		1				1
Proctitis	1	1	1	1		
Rectal haemorrhage	3	8			3	8
Salivary gland disorder		1		1		
Salivary hypersecretion		4		2		2
Stomatitis	1	2	1	1		1
Subileus		2				2
Swollen tongue		6		2		4
Thrombosis mesenteric vessel	1	1			1	1
Tongue coated	1	2			1	2
Tongue discolouration		1				1
Tongue discomfort		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue disorder		1				1
Tongue dry		1				1
Tongue haematoma		2		2		
Tongue movement disturbance		1				1
Tongue oedema	2	8	1	3	1	5
Toothache		2		1		1
Uvulitis		1				1
Vomiting	58	219	14	55	44	164
	294	1,227	91	402	203	825

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Application site warmth		1		1		
Asthenia	145	667	49	228	96	439
Axillary pain		14		9		5
Chest discomfort	11	57	3	23	8	34
Chest pain	31	126	7	23	24	103
Chills	47	273	17	104	30	169
Condition aggravated	23	62	2	11	21	51
Crepitations	1	3	1	2		1
Death	22	106			22	106
Deformity		1		1		
Discomfort	16	58	6	17	10	41
Disease progression		1				1
Disease recurrence	21	71		3	21	68
Drug ineffective	57	209	1	1	56	208
Drug interaction	2	2	1	1	1	1
Extensive swelling of vaccinated limb	2	12	2	10		2
Face oedema	13	39	1	3	12	36
Facial pain		7		2		5
Fatigue	91	355	38	165	53	190
Fat tissue increased		1		1		
Feeling abnormal	5	21	3	10	2	11
Feeling cold	4	24	1	10	3	14
Feeling drunk	2	9		3	2	6
Feeling hot	6	26		9	6	17
Feeling of body temperature change	2	4		2	2	2
Foaming at mouth		1				1
Gait disturbance	8	25	4	10	4	15
Gait inability	5	10		2	5	8
Generalised oedema		1				1
General physical health deterioration	20	54	6	10	14	44
High-pitched crying		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthermia	12	62	5	19	7	43
Hypothermia	1	16			1	16
Ill-defined disorder		1				1
Illness	1	4	1	1		3
Induration	1	3		1	1	2
Inflammation	17	32	8	13	9	19
Inflammatory pain	1	2			1	2
Influenza like illness	112	467	18	75	94	392
Injected limb mobility decreased	7	30	1	7	6	23
Injection site erythema		3		3		
Injection site hyperaesthesia		1		1		
Injection site pain		6		6		
Injection site paraesthesia		1		1		
Injection site pruritus	1	3	1	3		
Injection site rash		1				1
Injection site reaction		2		1		1
Injection site swelling		2		2		
Lithiasis		1		1		
Localised oedema	2	8	1	3	1	5
Local reaction	2	3	2	3		
Malaise	82	340	28	95	54	245
Mass		1				1
Moaning		1				1
Mucosal discolouration	1	1			1	1
Mucosal pain		1		1		
Multiple organ dysfunction syndrome	4	6			4	6
Necrosis	1	1			1	1
No adverse event	2	2	2	2		
Oedema	3	12	1	5	2	7
Oedema mucosal		1		1		
Oedema peripheral	17	43	4	8	13	35
Pain	35	182	13	76	22	106

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Peripheral swelling	8	21
Polyp	1	1
Polyserositis	1	1
Pyrexia	110	611
Rebound effect		1
Sense of oppression	1	2
Shoulder injury related to vaccine administration	1	1
Sluggishness		2
Sudden death	15	57
Swelling		6
Swelling face	2	7
Systemic inflammatory response syndrome	2	2
Tenderness		1
Terminal state		1
Therapeutic response unexpected	1	2
Thirst	2	8
Vaccination site bruising		1
Vaccination site coldness		1
Vaccination site dermatitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort		1
Vaccination site dysaesthesia	1	2
Vaccination site eczema		1
Vaccination site erythema	8	55
Vaccination site exfoliation		1
Vaccination site granuloma	1	1
Vaccination site haematoma	3	12
Vaccination site haemorrhage		3
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity		19
Vaccination site hypoaesthesia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	6	6	15
1	1		
		1	1
38	213	72	398
			1
		1	2
		1	1
	2		
		15	57
	4		2
	2	2	5
		2	2
	1		
			1
1	2		
1	4	1	4
	1		
	1		
			1
			1
			1
	1	1	1
			1
6	37	2	18
			1
		1	1
1	5	2	7
	2		1
			1
	19		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	6	21	4	16	2	5
Vaccination site inflammation	4	30	2	13	2	17
Vaccination site joint inflammation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site joint pain		3		1		2
Vaccination site lymphadenopathy		2		1		1
Vaccination site mass	2	3	2	2		1
Vaccination site movement impairment	3	18		7	3	11
Vaccination site nodule		3		1		2
Vaccination site oedema	3	19	2	7	1	12
Vaccination site pain	62	388	21	201	41	187
Vaccination site papule		1		1		
Vaccination site paraesthesia		11		6		5
Vaccination site plaque		1				1
Vaccination site pruritus	4	27	3	14	1	13
Vaccination site rash	1	5		2	1	3
Vaccination site reaction	4	17	1	9	3	8
Vaccination site recall reaction		1		1		
Vaccination site swelling	4	23	1	14	3	9
Vaccination site thrombosis		1				1
Vaccination site urticaria		4		3		1
Vaccination site warmth	3	18	1	9	2	9
Vascular stent thrombosis	1	1			1	1
	1,091	4,906	315	1601	776	3305

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune hepatitis	1	1			1	1
Cholecystitis	1	3			1	3
Cholestasis	2	5			2	5
Cholestatic liver injury		1				1
Hepatic cyst	1	1			1	1
Hepatic function abnormal	1	2	1	2		
Hepatic haematoma		1				1
Hepatic infarction	1	1			1	1
Hepatic lesion		1		1		
Hepatic pain		1		1		
Hepatic steatosis	2	2	1	1	1	1
Hepatitis		1				1
Hepatitis acute	2	2			2	2
Hepatitis cholestatic	1	2			1	2
Hepatocellular injury	7	17			7	17
Hepatomegaly	1	2			1	2
Hyperbilirubinaemia	2	4			2	4
Jaundice		4				4
Jaundice cholestatic	1	1			1	1
Liver injury		1				1
Portal vein thrombosis	1	1			1	1
	24	54	2	5	22	49

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	6	1	3		3
Anaphylactic reaction	10	39			10	39
Anaphylactic shock	4	13			4	13
Anaphylactoid reaction		2				2
Anti-neutrophil cytoplasmic antibody positive vasculitis		1				1
Drug hypersensitivity	1	2			1	2
Haemophagocytic lymphohistiocytosis	3	4			3	4
Hypersensitivity	10	73	1	25	9	48
Hypogammaglobulinaemia	1	1			1	1
Immunodeficiency	1	1			1	1
Serum sickness	1	1			1	1
Type I hypersensitivity	1	3			1	3
Type II hypersensitivity		1				1
Type III immune complex mediated reaction	1	1			1	1
	34	148	2	28	32	120

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute sinusitis	1	1	1	1		
Aerococcus urinae infection		1				1
Appendicitis		2				2
Appendicitis perforated	1	1			1	1
Asymptomatic COVID-19	20	31	2	3	18	28
Atypical pneumonia		1				1
Bacterial infection		1				1
Bacterial pyelonephritis		1				1
Bacterial sepsis	2	2			2	2
Blastocystis infection		1				1
Bone abscess		1				1
Breast abscess		1				1
Bronchiolitis	1	2			1	2
Bronchitis		10		2		8
Cellulitis		1				1
Citrobacter infection	1	1			1	1
Conjunctivitis	2	7	1	3	1	4
Conjunctivitis bacterial	1	1			1	1
Coronavirus infection		3		2		1
COVID-19	157	407	22	65	135	342
COVID-19 pneumonia	12	22			12	22
Cystitis	1	1			1	1
Cystitis klebsiella		1				1
Cytomegalovirus infection	1	2			1	2
Dermo-hypodermatitis	3	6			3	6
Diarrhoea infectious	2	2			2	2
Diverticulitis	1	2			1	2
Ear infection		2				2
Encephalitis	1	2			1	2
Encephalitis viral		1				1
Enterococcal infection		1				1
Epstein-Barr virus infection		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epstein-Barr virus infection reactivation		1				1
Erysipelas	5	10			5	10
Escherichia bacteraemia		1				1
Escherichia infection	1	1			1	1
Escherichia urinary tract infection	2	3			2	3
Gangrene	1	1			1	1
Gastroenteritis		2				2
Genital herpes	2	2			2	2
Genital herpes zoster	1	1			1	1
Gingivitis		1				1
Hepatic cyst infection		1				1
Hepatitis B	1	1			1	1
Hepatitis infectious mononucleosis		1				1
Hepatitis viral		1				1
Herpangina	1	1	1	1		
Herpes ophthalmic	1	3			1	3
Herpes pharyngitis	1	1			1	1
Herpes simplex		4		2		2
Herpes virus infection	1	1	1	1		
Herpes zoster	33	108	1	37	32	71
Herpes zoster cutaneous disseminated	1	1			1	1
Herpes zoster meningoencephalitis	2	2			2	2
Herpes zoster reactivation		1		1		
Infection	3	8	2	3	1	5
Infectious mononucleosis		1				1
Influenza	13	55	6	14	7	41
Klebsiella infection		2				2
Lactobacillus infection		1				1
Large intestine infection	1	2			1	2
Laryngitis		2				2
Lower respiratory tract infection		1				1
Lung abscess		1				1

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lyme disease	1	2			1	2
Lymphangitis	2	2			2	2
Meningitis	1	2			1	2
Meningitis aseptic		2				2
Meningoencephalitis herpetic	2	2			2	2
Mononucleosis syndrome		1				1
Moraxella infection		1				1
Myelitis		1				1
Nasal herpes		1				1
Nasopharyngitis	2	9	2	7		2
Ophthalmic herpes zoster	10	23			10	23
Oral fungal infection	1	1	1	1		
Oral herpes		1				1
Oropharyngeal candidiasis	1	1			1	1
Otitis externa	1	3	1	2		1
Parotitis	1	1			1	1
Pharyngitis	2	2	2	2		
Pneumococcal sepsis		1				1
Pneumonia	13	34			13	34
Pneumonia bacterial	3	4			3	4
Pneumonia moraxella		1				1
Pneumonia pneumococcal		1				1
Pulmonary sepsis		1				1
Pulpitis dental		1				1
Pyelonephritis	4	5			4	5
Rash pustular	1	1			1	1
Respiratory tract infection		3				3
Respiratory tract infection bacterial	1	1			1	1
Rhinitis	3	10	2	7	1	3
Sepsis	4	10			4	10
Septic shock	1	6			1	6
Sialoadenitis		1				1

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 \* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinusitis	1	3			1	3
Staphylococcal bacteraemia	2	3			2	3
Staphylococcal sepsis	1	1			1	1
Superinfection	2	2			2	2
Superinfection bacterial	1	1			1	1
Suspected COVID-19	2	7	1	1	1	6
Tonsillitis	1	2			1	2
Tooth abscess		2		1		1
Tooth infection		1		1		
Toxocariasis	1	1			1	1
Toxoplasmosis	1	1	1	1		
Urinary tract candidiasis		1				1
Urinary tract infection	2	8		1	2	7
Urinary tract infection bacterial	2	3			2	3
Urosepsis		1				1
Vaccination site abscess		2		1		1
Vaccination site cellulitis		1				1
Vaccination site infection	1	1			1	1
Vestibular neuritis	2	8			2	8
Vestibulitis		1				1
Viral infection		4		3		1
	350	930	47	163	303	767

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		2		2		
Arteriovenous fistula thrombosis		1				1
Brain contusion	1	1			1	1
Burn oral cavity	1	2			1	2
Cerebral hyperperfusion syndrome		1				1
Chest injury		1				1
Chillblains		3		2		1
Circumstance or information capable of leading to medication error	1	1	1	1		
Contraindicated product administered	1	1			1	1
Contusion	1	2	1	2		
Electric shock		1				1
Exposure during pregnancy	1	1			1	1
Exposure to SARS-CoV-2		1				1
Exposure via breast milk	1	4		3	1	1
Exposure via skin contact		1		1		
Extradural haematoma		1				1
Eye contusion		1		1		
Eye injury	1	2			1	2
Face injury	2	2			2	2
Facial bones fracture	2	2			2	2
Fall	34	92	8	17	26	75
Femoral neck fracture		1				1
Femur fracture	1	4			1	4
Fracture	1	1			1	1
Frostbite		1		1		
Head injury	7	19	1	1	6	18
Humerus fracture	1	1			1	1
Inappropriate schedule of product administration	7	21	6	19	1	2
Incorrect dose administered		5		5		
Incorrect route of product administration	4	15	3	14	1	1
Intercepted product preparation error		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint dislocation	1	1			1	1
Joint injury		1				1
Ligament sprain		1				1
Maternal exposure during pregnancy		3		2		1
Maternal exposure timing unspecified		1		1		
Medication error		1		1		
Neck injury	1	1			1	1
Nerve injury		1				1
Occupational exposure to product		2		2		
Off label use	5	28	4	27	1	1
Overdose	2	11	2	11		
Pelvic fracture		1				1
Periorbital haematoma	1	1			1	1
Poor quality product administered	2	188	2	188		
Product administered at inappropriate site		2		1		1
Product administration error		1				1
Product label confusion	1	1	1	1		
Product preparation error	1	10	1	10		
Product preparation issue	2	19	2	19		
Product storage error	1	1	1	1		
Product use issue	1	16	1	16		
Recalled product administered	1	1	1	1		
Rib fracture	1	3			1	3
Road traffic accident	3	6	1	1	2	5
Spinal compression fracture		2				2
Sternal fracture	1	1			1	1
Subdural haematoma	2	3			2	3
Sunburn		1				1
Tendon rupture	1	1			1	1
Thermal burns of eye		1				1
Toxicity to various agents	1	2			1	2
Transcription medication error		1		1		

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose	1	27	1	27		
Vaccination complication	1	7		3	1	4
Vaccination failure	120	135			120	135
Vasoplegia syndrome	1	1			1	1
Wound	1	1			1	1
Wrong patient received product		1		1		
Wrong technique in product usage process		4		4		
	219	681	37	388	182	293

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time abnormal	1	1			1	1
Activated partial thromboplastin time prolonged		1				1
Activated partial thromboplastin time shortened	1	1			1	1
Alanine aminotransferase increased		5		4		1
Anticoagulation drug level below therapeutic	2	2	1	1	1	1
Antinuclear antibody positive		1				1
Aortic bruit		1		1		
Aspartate aminotransferase increased		5		4		1
Bacterial test positive	1	2		1	1	1
Beta 2 microglobulin increased		1		1		
Bilirubin conjugated increased		1		1		
Blood albumin decreased	1	1	1	1		
Blood alkaline phosphatase increased	2	4	2	4		
Blood bicarbonate decreased		1				1
Blood bilirubin abnormal	1	1	1	1		
Blood bilirubin increased		1		1		
Blood bilirubin unconjugated increased		1		1		
Blood calcium decreased	1	1	1	1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	1	2	1	2		
Blood culture positive	1	1			1	1
Blood folate decreased	1	1			1	1
Blood glucose fluctuation		1		1		
Blood glucose increased	3	8	3	6		2
Blood lactate dehydrogenase increased	1	2	1	2		
Blood parathyroid hormone increased	1	1	1	1		
Blood potassium increased	1	1	1	1		
Blood pressure abnormal	1	3	1	1		2
Blood pressure decreased	4	23		5	4	18
Blood pressure diastolic decreased	1	3		2	1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	3	29	2	7	1	22
Blood pressure systolic decreased	1	3	1	2		1
Blood pressure systolic increased	3	7	1	1	2	6
Blood sodium decreased	1	1	1	1		
Blood sodium increased	1	3		1	1	2
Blood thyroid stimulating hormone decreased	1	1	1	1		
Blood thyroid stimulating hormone increased	3	5	1	3	2	2
Blood uric acid increased		1		1		
Blood urine present		1		1		
Body temperature decreased		3		1		2
Body temperature increased	3	11	1	2	2	9
Brain natriuretic peptide increased	3	4	2	2	1	2
Brain scan abnormal		1				1
Breath sounds abnormal	1	1			1	1
Carcinoembryonic antigen increased		1				1
Chest X-ray abnormal	1	2			1	2
Coma scale abnormal	1	1			1	1
C-reactive protein increased	18	50	8	25	10	25
Creatinine renal clearance decreased		1				1
Culture urine positive	1	1	1	1		
Cytomegalovirus test positive		1		1		
Ejection fraction decreased		1				1
Electrocardiogram abnormal		1				1
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex prolonged	1	1			1	1
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality		2				2
Electrocardiogram ST segment depression		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T segment abnormal		1				1
Electrocardiogram T wave abnormal		1		1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Electrocardiogram T wave inversion		2					
Electroencephalogram abnormal		1					2
Eosinophil count increased		1		1			1
Epstein-Barr virus test positive		1		1			
Escherichia test positive	1	2	1	2			
Fibrin D dimer increased	2	6			2		6
Gamma-glutamyltransferase increased	5	10	4	8	1		2
Gastric pH decreased	1	1	1	1			
Glomerular filtration rate decreased	1	5	1	1			4
Glycosylated haemoglobin increased		1		1			
Haemoglobin decreased	4	8	2	4	2		4
Heart rate decreased	4	8	2	5	2		3
Heart rate increased	2	17	2	8			9
Heart rate irregular	2	5			2		5
Heart sounds abnormal		4		1			3
Hepatic enzyme increased	1	3	1	1			2
Herpes simplex test positive	1	1	1	1			
Hormone level abnormal	1	1			1		1
Immunoglobulins increased	1	1	1	1			
International normalised ratio abnormal		3		1			2
International normalised ratio increased	3	6			3		6
Laboratory test abnormal		1					1
Left ventricular end-diastolic pressure increased		1					1
Lipase increased		2		2			
Liver function test increased	1	1			1		1
Low density lipoprotein increased		1					1
Lymphocyte count decreased	1	2	1	1			1
Mean cell volume decreased	1	2		1	1		1
Monoclonal immunoglobulin increased		1					1
Muscle strength abnormal		1					1
Myocardial necrosis marker increased		2					2
Nerve conduction studies abnormal	1	1	1	1			

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neurological examination abnormal		1					1
Neutrophil count abnormal		1					1
Neutrophil count decreased		3		1			2
Neutrophil count increased	2	5	2	4			1
Nitrite urine present	1	1	1	1			
N-terminal prohormone brain natriuretic peptide increased	2	5		1	2		4
Oxygen saturation abnormal		1					1
Oxygen saturation decreased	25	113	5	12	20		101
Oxygen saturation increased	1	1			1		1
Platelet count decreased	2	4	1	2	1		2
Platelet count increased		1					1
Protein C increased	1	1			1		1
Prothrombin level abnormal	1	1			1		1
Prothrombin time shortened	2	2	1	1	1		1
Pulmonary arterial pressure increased	1	2			1		2
Pulse abnormal		1		1			
Pulse absent	1	3	1	2			1
Red blood cell sedimentation rate increased		2		2			
Red blood cells urine positive		1					1
Respiratory rate decreased	1	1			1		1
Respiratory rate increased	1	3	1	2			1
Rheumatoid factor increased	1	1			1		1
Romberg test positive		1		1			
SARS-CoV-2 antibody test negative	3	14	3	14			
SARS-CoV-2 antibody test positive		5		5			
SARS-CoV-2 test false positive	1	1	1	1			
SARS-CoV-2 test positive	19	33	6	9	13		24
Serology negative	1	1	1	1			
Serum ferritin increased		1		1			
Thyroxine free decreased	1	1	1	1			
Transaminases increased		1					1

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\* AE=Adverse Event

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System Organ Class

Investigations

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tri-iodothyronine free decreased	1	1	1	1		
Troponin increased	5	14	2	4	3	10
Varicella virus test positive	1	1			1	1
Venous oxygen saturation decreased	1	2			1	2
Von Willebrand's factor activity decreased		1				1
Weight decreased	7	14	1	2	6	12
Weight increased	3	4	1	1	2	3
White blood cell count decreased	3	5	1	2	2	3
White blood cell count increased	1	4		2	1	2
	190	580	81	210	109	370

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis hyperchloraemic		1				1
Adult failure to thrive		1				1
Cell death	4	4			4	4
Decreased appetite	19	70	10	32	9	38
Dehydration	13	26	5	8	8	18
Diabetes mellitus	6	9			6	9
Diabetes mellitus inadequate control	7	12			7	12
Diabetic ketoacidosis	1	4			1	4
Diabetic ketosis		1				1
Diabetic metabolic decompensation		2				2
Dyslipidaemia		2		2		
Failure to thrive		1				1
Fluid retention		1				1
Food aversion	1	2		1	1	1
Food craving	1	1			1	1
Gout	1	4	1	2		2
Hypercalcaemia	1	1	1	1		
Hyperchloraemia	1	1			1	1
Hypercholesterolaemia		1		1		
Hyperferritinaemia	1	1			1	1
Hyperglycaemia	5	12	2	5	3	7
Hyperkalaemia	3	7			3	7
Hyperlactacidaemia	1	1			1	1
Hypernatraemia	3	7	1	3	2	4
Hyperuricaemia	1	1	1	1		
Hypervitaminosis B12		1				1
Hypoalbuminaemia	1	1			1	1
Hypocalcaemia		1				1
Hypoglycaemia	2	11		1	2	10
Hypokalaemia	2	7			2	7
Hyponatraemia	1	1	1	1		
Hypophagia		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insulin-requiring type 2 diabetes mellitus		1				1
Lactic acidosis		2				2
Malnutrition	1	3		1	1	2
Polydipsia		2		1		1
Tetany		1				1
Type 1 diabetes mellitus	2	2			2	2
Type 2 diabetes mellitus		1				1
Vitamin D deficiency	1	2	1	1		1
	79	210	23	62	56	148

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amyotrophy	1	1			1	1
Ankylosing spondylitis	1	5			1	5
Antisynthetase syndrome		1				1
Arthralgia	43	204	14	80	29	124
Arthritis	3	9	1	2	2	7
Arthritis reactive	3	4			3	4
Arthropathy		1		1		
Back pain	14	48	6	18	8	30
Bone pain	2	6	1	1	1	5
Bone swelling		2		2		
Bursal fluid accumulation		1		1		
Bursal haematoma		1				1
Bursitis	1	4		1	1	3
Chondrocalcinosis	1	1			1	1
Facial asymmetry	1	2			1	2
Flank pain	1	2		1	1	1
Groin pain		1		1		
Haemarthrosis	1	2			1	2
Haematoma muscle	2	2			2	2
Intervertebral disc compression		1				1
Intervertebral disc disorder	1	1	1	1		
Intervertebral disc protrusion	1	1	1	1		
Joint ankylosis		1				1
Joint effusion	2	5		2	2	3
Joint range of motion decreased	1	2			1	2
Joint stiffness	1	5		1	1	4
Joint swelling	5	8	1	3	4	5
Joint warmth	1	1			1	1
Limb discomfort	6	13	2	8	4	5
Mobility decreased	6	14	3	5	3	9
Muscle contracture	1	7		3	1	4
Muscle disorder		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle fatigue	2	5	1	3	1	2
Muscle rigidity		2		2		
Muscle spasms	3	18	1	7	2	11
Muscle tightness		2		2		
Muscular weakness	17	35	5	11	12	24
Musculoskeletal chest pain		7		2		5
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder		2		1		1
Musculoskeletal pain	2	3	2	3		
Musculoskeletal stiffness	21	96	4	24	17	72
Myalgia	61	341	18	132	43	209
Myalgia intercostal		1				1
Myokymia		1		1		
Myositis	1	3		1	1	2
Neck pain	9	28	5	11	4	17
Osteoarthritis	3	4	3	3		1
Pain in extremity	38	137	12	56	26	81
Pain in jaw	5	11		2	5	9
Periarthritis		4				4
Polyarthritis	2	3			2	3
Polychondritis	1	1			1	1
Polymyalgia rheumatica	2	2			2	2
Psoriatic arthropathy		1				1
Rhabdomyolysis	4	5			4	5
Rheumatic disorder	1	2		1	1	1
Rheumatic fever	1	1			1	1
Rheumatoid arthritis	4	12			4	12
Rotator cuff syndrome		2		1		1
Sjogren's syndrome	3	3			3	3
SLE arthritis		1				1
Spinal osteoarthritis		1		1		
Spinal pain	1	4	1	1		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spondylitis		1				1
Synovial cyst		2				2
Systemic lupus erythematosus		1				1
Tendon disorder		2				2
Tendonitis	1	8		2	1	6
Tendon pain		2		2		
Tenosynovitis		1		1		
Torticollis	1	3	1	1		2
Trismus		2		2		
	282	1,118	83	407	199	711

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myeloid leukaemia	1	2			1	2
B-cell lymphoma	1	1			1	1
Benign breast neoplasm		1		1		
Brain neoplasm	1	1			1	1
Fibroma		1		1		
Lipoma		2				2
Metastases to peritoneum		1				1
Monoclonal gammopathy	2	2			2	2
Myelodysplastic syndrome	1	1			1	1
Myelofibrosis		1				1
Neoplasm		1				1
Phaeochromocytoma		1				1
Tumour perforation		1				1
	6	16		2	6	14

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	6	11	4	7	2	4
Agnosia	1	1			1	1
Alexia		1				1
Altered state of consciousness	3	14			3	14
Amnesia	4	7	1	1	3	6
Amnesic disorder		2				2
Anaesthesia		1				1
Anosmia	3	7	2	3	1	4
Anterograde amnesia	1	1			1	1
Aphasia	7	25	1	6	6	19
Ataxia	8	10	5	5	3	5
Aura		2				2
Balance disorder	5	24	2	4	3	20
Brain hypoxia	1	1			1	1
Brain stem haemorrhage		1				1
Burning sensation	4	21	3	10	1	11
Carotid artery occlusion	3	3			3	3
Carotid artery stenosis	1	1			1	1
Carotid artery thrombosis	3	3			3	3
Central nervous system lesion		1				1
Cerebellar ataxia	1	1	1	1		
Cerebellar haematoma	1	1			1	1
Cerebellar infarction		2				2
Cerebellar stroke		1				1
Cerebellar syndrome	1	3			1	3
Cerebral amyloid angiopathy		1				1
Cerebral arteriosclerosis	1	1			1	1
Cerebral artery stenosis		1				1
Cerebral atrophy	1	2			1	2
Cerebral disorder		1				1
Cerebral haematoma	3	8			3	8
Cerebral haemorrhage	5	9			5	9

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cerebral infarction	6	9
Cerebral ischaemia		1
Cerebral thrombosis	1	2
Cerebral venous thrombosis	2	2
Cerebrovascular accident	22	48
Cervical cord compression	1	1
Cervical radiculopathy	1	3
Cervicobrachial syndrome		3
Circadian rhythm sleep disorder	1	1
Clonus		2
Clumsiness		1
Cluster headache	1	1
Cognitive disorder	1	4
Coma	6	15
Complex regional pain syndrome		1
Coordination abnormal	1	2
Dementia	1	3
Demyelination		1
Depressed level of consciousness	3	16
Diabetic coma		1
Diabetic hyperosmolar coma	1	1
Diplegia		1
Disturbance in attention	4	11
Dizziness	51	189
Dizziness postural		3
Drooling		2
Drop attacks		1
Dropped head syndrome		1
Dysaesthesia	4	13
Dysarthria	8	20
Dysgeusia	7	28
Dysgraphia	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		6	9
			1
		1	2
		2	2
		22	48
		1	1
	2	1	1
	1		2
1	1		
	1		1
			1
		1	1
	2	1	2
		6	15
	1		
	1	1	1
		1	3
			1
		3	16
			1
		1	1
			1
1	3	3	8
16	60	35	129
			3
	2		
			1
			1
1	6	3	7
1	3	7	17
1	13	6	15
		2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dyskinesia	2	4
Dysmetria	1	1
Dysstasia	1	9
Embolic stroke	4	4
Epilepsy	11	28
Extensor plantar response		1
Extrapyramidal disorder	3	3
Facial paralysis	48	113
Facial paresis	1	6
Febrile convulsion		1
Fine motor skill dysfunction	1	1
Focal dyscognitive seizures	1	2
Formication	2	10
Generalised onset non-motor seizure		1
Generalised tonic-clonic seizure	6	11
Gross motor delay		1
Guillain-Barre syndrome	3	5
Haemorrhagic stroke	9	19
Haemorrhagic transformation stroke		1
Headache	150	683
Head discomfort		6
Hemianaesthesia		1
Hemianopia	1	3
Hemianopia homonymous	1	3
Hemiapraxia	1	1
Hemiparaesthesia		3
Hemiparesis	7	16
Hemiplegia	9	19
Hippocampal atrophy		1
Hoffmann's sign		1
Horner's syndrome		1
Hyperaesthesia	2	9

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2	1	2
		1	1
	2	1	7
		4	4
		11	28
			1
1	1	2	2
		48	113
1	3		3
			1
1	1		
		1	2
	4	2	6
			1
		6	11
			1
		3	5
		9	19
			1
47	250	103	433
	4		2
			1
		1	3
		1	3
		1	1
			3
		7	16
		9	19
			1
	1		
			1
2	4		5

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersomnia	3	6	2	3	1	3
Hypertensive encephalopathy		1				1
Hypertonia	1	2			1	2
Hypoaesthesia	20	42	9	18	11	24
Hypokinesia	1	5		1	1	4
Hypotonia	4	8	1	2	3	6
Illrd nerve paralysis		2				2
Incoherent	6	6	3	3	3	3
Intercostal neuralgia		1				1
Intracranial haematoma		1				1
Intracranial pressure increased		1				1
Ischaemic stroke	41	81			41	81
Lacunar infarction		1				1
Lacunar stroke	2	2			2	2
Language disorder	1	3			1	3
Leukoencephalopathy	2	5			2	5
Loss of consciousness	34	102		1	34	101
Memory impairment	3	8		1	3	7
Meningeal disorder		1				1
Meningoradiculitis	1	1			1	1
Meningorrhagia	1	1			1	1
Mental impairment	1	3			1	3
Migraine	5	27	2	10	3	17
Migraine with aura	2	7	1	4	1	3
Mononeuropathy multiplex	1	1			1	1
Monoparesis	1	5		1	1	4
Monoplegia	2	4			2	4
Motor dysfunction	11	19		2	11	17
Movement disorder	3	6	1	2	2	4
Muscle contractions involuntary		3		1		2
Myasthenia gravis	2	2			2	2
Myasthenia gravis crisis	2	2			2	2

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Myoclonus	2	5
Nerve compression	1	1
Nervous system disorder	3	6
Neuralgia	9	40
Neuralgic amyotrophy	1	1
Neuritis	1	3
Neurological decompensation	1	2
Neurological symptom		1
Neuromuscular pain		2
Neuromyopathy		2
Neuropathy peripheral	3	4
Normal pressure hydrocephalus	1	1
Nystagmus		3
Occipital neuralgia	1	3
Optic neuritis	1	1
Paraesthesia	45	147
Paralysis	3	6
Paresis		3
Parkinsonism	1	2
Parkinson's disease	1	1
Parosmia		3
Partial seizures	1	6
Peripheral sensory neuropathy	1	1
Persistent postural-perceptual dizziness	1	1
Petit mal epilepsy	3	8
Polyneuropathy	2	5
Posterior reversible encephalopathy syndrome	1	1
Post herpetic neuralgia		1
Presyncope	11	40
Progressive supranuclear palsy	1	1
Psychomotor hyperactivity		1
Psychomotor skills impaired	1	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	5
1	1		
1	1	2	5
2	12	7	28
		1	1
	2	1	1
1	1		1
			1
	1		1
			2
		3	4
		1	1
	1		2
		1	3
		1	1
7	42	38	105
		3	6
			3
		1	2
		1	1
	3		
		1	6
		1	1
		1	1
		3	8
		2	5
		1	1
	1		
3	15	8	25
		1	1
			1
	2	1	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Quadriparesis	1	1			1	1
Quadriplegia	1	2			1	2
Radial nerve palsy	1	1			1	1
Retrograde amnesia	1	1			1	1
Sciatica	1	3	1	1		2
Sedation	1	1	1	1		
Seizure	7	25			7	25
Seizure anoxic		1				1
Sensorimotor disorder	1	4	1	1		3
Sensory disturbance	3	7	1	2	2	5
Sensory loss	4	11	1	4	3	7
Somnolence	15	43	5	19	10	24
Speech disorder	6	20		2	6	18
Spinal cord infarction	2	2			2	2
Spinal cord ischaemia	1	1			1	1
Status epilepticus	3	8			3	8
Status migrainosus		1				1
Subarachnoid haemorrhage	3	3			3	3
Sudden onset of sleep	1	2			1	2
Syncope	8	39			8	39
Taste disorder		1		1		
Temporal lobe epilepsy	1	1			1	1
Tension headache		1				1
Thermohypoaesthesia		1		1		
Tongue biting	2	3	1	1	1	2
Tongue paralysis	1	1			1	1
Tonic clonic movements	1	7			1	7
Tonic convulsion	1	2			1	2
Transient global amnesia		2				2
Transient ischaemic attack	18	36			18	36
Tremor	13	61	3	18	10	43
Trigeminal neuralgia	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ulnar nerve palsy	1	1			1	1
Unresponsive to stimuli		2				2
Vagus nerve disorder		1				1
Vascular encephalopathy		1				1
Visual field defect	2	3			2	3
Vlth nerve paralysis	1	3			1	3
White matter lesion		1				1
	799	2,496	141	587	658	1909

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	6	9			6	9
Morning sickness		1		1		
Small for dates baby	1	1			1	1
	7	11		1	7	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue	1	3	1	3
Product complaint		15		15
Product contamination physical		1		1
Product packaging quantity issue		1		1
Product physical issue		1		1
Product quality issue	1	1	1	1
Product temperature excursion issue		164		164
	2	186	2	186

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	2	3	2	2		1
Affective disorder	1	1	1	1		
Aggression	4	6	1	1	3	5
Agitation	6	19	1	6	5	13
Anxiety	5	21	1	7	4	14
Anxiety disorder		1		1		
Apathy	3	7	2	4	1	3
Behaviour disorder	5	10		1	5	9
Bipolar disorder		1				1
Bradyphrenia	1	2			1	2
Clinomania	1	1	1	1		
Confusional state	24	44	5	7	19	37
Daydreaming	2	2			2	2
Decreased interest		1				1
Delirium	1	8			1	8
Delusion	1	4		2	1	2
Depression		2		1		1
Disinhibition		1				1
Disorientation	12	23	4	6	8	17
Dysphemia		3				3
Eating disorder		2		1		1
Enuresis		1				1
Euphoric mood		1		1		
Fear	1	2	1	1		1
Fear of death		1				1
Generalised anxiety disorder		1				1
Hallucination	3	13			3	13
Hallucination, auditory	3	5			3	5
Hallucination, olfactory		1				1
Hallucinations, mixed		2				2
Hallucination, visual	9	11			9	11
Hostility	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illusion	1	1			1	1
Initial insomnia		1				1
Insomnia	18	59	7	25	11	34
Irritability		2		1		1
Listless		1				1
Logorrhoea		1				1
Loss of libido	1	1	1	1		
Major depression	1	1			1	1
Mental fatigue		1				1
Middle insomnia	4	8		3	4	5
Mutism	1	2	1	1		1
Near death experience	1	3			1	3
Nervousness		1				1
Nightmare	1	2		1	1	1
Panic attack	1	2		1	1	1
Persecutory delusion	1	2		1	1	1
Persistent depressive disorder		1				1
Phonophobia		2		1		1
Pseudodementia		1				1
Psychomotor retardation		1				1
Restlessness	2	11	1	5	1	6
Sleep disorder	4	12	2	4	2	8
Sleep disorder due to general medical condition, insomnia type	1	3	1	2		1
Sleep talking		1		1		
Staring		1				1
Stereotypy		2				2
Stress		6		5		1
Suicidal ideation		1				1
Tension		5		3		2
	122	336	32	98	90	238

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	7	23			7	23
Albuminuria		1				1
Anuria		2				2
Bladder dilatation	1	1			1	1
Chromaturia		2		1		1
Chronic kidney disease	1	1			1	1
Costovertebral angle tenderness		1				1
Dysuria	2	7	1	3	1	4
Glomerulonephritis		1				1
Haematuria	3	6			3	6
Haemoglobinuria		1				1
Incontinence	1	1			1	1
Leukocyturia	2	4	2	3		1
Nephropathy	1	1			1	1
Nephrotic syndrome	1	1			1	1
Nocturia	1	1	1	1		
Oliguria		1		1		
Pollakiuria	1	2	1	2		
Prerenal failure	1	2			1	2
Proteinuria		3		1		2
Renal artery stenosis		1				1
Renal colic	2	2			2	2
Renal cyst	1	1			1	1
Renal cyst haemorrhage		1				1
Renal failure	7	19			7	19
Renal impairment		3				3
Renal infarct	1	1			1	1
Renal pain	1	2			1	2
Urinary incontinence	6	7	1	1	5	6
Urinary retention	3	4			3	4
Urinary tract discomfort	1	1	1	1		
Urine odour abnormal	2	2	2	2		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	46	106	9	16	37	90

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea	1	1			1	1
Benign prostatic hyperplasia	2	2	1	1	1	1
Breast induration	1	1			1	1
Breast mass	1	1			1	1
Breast pain	1	4	1	1		3
Breast swelling		1		1		
Erectile dysfunction	1	3			1	3
Genital haemorrhage	1	1			1	1
Menorrhagia		1				1
Menstruation delayed		1				1
Metrorrhagia		2				2
Oedema genital	1	1			1	1
Pelvic pain	1	4			1	4
Priapism		1				1
Prostatitis	3	4	2	2	1	2
Testicular pain	1	1	1	1		
Vaginal haemorrhage		1				1
	14	30	5	6	9	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	6	23			6	23
Acute respiratory distress syndrome	5	17			5	17
Acute respiratory failure	2	16			2	16
Aphonia		3				3
Apnoea		2				2
Asphyxia		1				1
Aspiration	2	4			2	4
Asthma	6	14	1	1	5	13
Asthmatic crisis	2	8			2	8
Atelectasis		1				1
Bronchial obstruction		1				1
Bronchial secretion retention		1		1		
Bronchopneumopathy	1	4	1	1		3
Bronchospasm		8				8
Choking	2	5			2	5
Choking sensation		1		1		
Chronic obstructive pulmonary disease	1	15		2	1	13
Cough	30	91	14	33	16	58
Dry throat		2		1		1
Dysphonia	3	13		6	3	7
Dyspnoea	47	193	10	31	37	162
Dyspnoea at rest	2	7			2	7
Dyspnoea exertional	11	24	3	6	8	18
Emphysema		1				1
Eosinophilic bronchitis	1	1			1	1
Epistaxis	12	26	3	9	9	17
Haemoptysis	2	5			2	5
Haemothorax		1				1
Hypercapnia	1	2			1	2
Hyperventilation		3		2		1
Hypoventilation		1				1
Hypoxia	4	23			4	23

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Increased bronchial secretion	1	3
Interstitial lung disease	3	6
Laryngeal discomfort	2	5
Laryngeal dyspnoea		2
Laryngeal oedema	4	12
Laryngitis allergic		1
Larynx irritation		1
Lower respiratory tract congestion	2	5
Lung disorder	10	34
Lung opacity		2
Nasal congestion		4
Nocturnal dyspnoea	1	1
Obstructive airways disorder		1
Oropharyngeal discomfort	1	4
Oropharyngeal oedema		1
Oropharyngeal pain	4	18
Oropharyngeal swelling		1
Orthopnoea	1	3
Painful respiration		1
Pharyngeal disorder		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		5
Pharyngeal swelling		1
Pleural effusion	6	7
Pleurisy	1	1
Pneumonia aspiration	7	28
Pneumonitis		4
Pneumothorax	2	3
Productive cough	2	8
Pulmonary alveolar haemorrhage	1	1
Pulmonary arterial hypertension	1	2
Pulmonary artery dilatation	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
		3	6
	1	2	4
			2
		4	12
			1
			1
		2	5
4	6	6	28
			2
	3		1
		1	1
	1		
1	3		1
			1
3	15	1	3
			1
		1	3
			1
	1		4
	1		
2	2	4	5
		1	1
		7	28
	1		3
		2	3
	3	2	5
		1	1
		1	2
		1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pulmonary congestion		2					2
Pulmonary embolism	73	112			73		112
Pulmonary hypertension	1	1			1		1
Pulmonary infarction	3	4			3		4
Pulmonary oedema	5	13			5		13
Pulmonary pain	1	2		1	1		1
Rales	6	13	1	1	5		12
Respiration abnormal	1	2			1		2
Respiratory acidosis	1	1			1		1
Respiratory alkalosis	1	3			1		3
Respiratory arrest	1	2			1		2
Respiratory depression		4					4
Respiratory disorder	2	14		1	2		13
Respiratory distress	9	39			9		39
Respiratory failure	2	13			2		13
Respiratory fatigue		1					1
Respiratory tract congestion		1					1
Respiratory tract oedema		1					1
Rhinalgia	1	1			1		1
Rhinorrhoea	2	15	1	5	1		10
Rhonchi		3		1			2
Sinus disorder		1					1
Sinus pain		1					1
Sleep apnoea syndrome	1	2		1	1		1
Snoring		1		1			
Stertor		1					1
Suffocation feeling		7		2			5
Tachypnoea	3	16	1	2	2		14
Throat irritation	2	10	1	6	1		4
Throat tightness	2	5			2		5
Tonsillar hypertrophy		1		1			
Upper-airway cough syndrome		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wheezing	4	7	1	1	3	6
	311	985	47	154	264	831

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	2	1	2		
Acute febrile neutrophilic dermatosis		1				1
Angioedema	21	59		1	21	58
Blister	1	3			1	3
Cold sweat	4	9	3	5	1	4
Cutaneous lupus erythematosus	1	1			1	1
Cutaneous vasculitis		1				1
Decubitus ulcer	2	3	1	1	1	2
Dermal cyst		1				1
Dermatitis bullous	1	3			1	3
Dermatitis exfoliative generalised	1	2			1	2
Dermatomyositis	1	2			1	2
Drug eruption	1	1	1	1		
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry skin	1	1	1	1		
Dyshidrotic eczema		2		2		
Eczema	1	5		2	1	3
Eczema nummular	1	1			1	1
Erythema	19	94	4	40	15	54
Erythema multiforme	1	3			1	3
Erythema nodosum	2	3		1	2	2
Erythrosis		1		1		
Guttate psoriasis		1		1		
Hair colour changes		1		1		
Henoch-Schonlein purpura		1		1		
Hyperhidrosis	14	71	4	20	10	51
Hypersensitivity vasculitis	1	2			1	2
Lichen planus		1				1
Livedo reticularis	3	10	2	3	1	7
Lividity		1				1
Macule		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Madarosis		1					1
Neutrophilic dermatosis		1					1
Night sweats	2	7	2	3			4
Pain of skin	1	5		1	1		4
Papule		2		1			1
Peau d'orange		1		1			
Pemphigoid	3	4			3		4
Pernio-like erythema		2		2			
Petechiae	5	9	2	6	3		3
Photosensitivity reaction		1		1			
Piloerection		1					1
Pruritus	13	80	3	32	10		48
Psoriasis	2	2			2		2
Purpura	6	9	2	2	4		7
Rash	10	60	2	26	8		34
Rash erythematous	6	19	2	6	4		13
Rash macular	2	7		1	2		6
Rash maculo-papular	4	15		6	4		9
Rash papular	1	7		3	1		4
Rash pruritic	5	13	1	6	4		7
Rash vesicular	1	3		1	1		2
Skin discolouration	1	3	1	2			1
Skin disorder		1		1			
Skin exfoliation		2		1			1
Skin fissures		1					1
Skin hyperpigmentation	1	1			1		1
Skin induration	1	1			1		1
Skin lesion	3	7	2	3	1		4
Skin mass		2		1			1
Skin necrosis	1	1			1		1
Skin plaque	1	4	1	3			1
Skin reaction	2	5	2	3			2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin ulcer	1	2		1	1	1
Skin warm		3		3		
Target skin lesion		1				1
Toxic skin eruption	1	2			1	2
Urticaria	14	72	5	28	9	44
Urticaria chronic		1				1
Vascular purpura	2	8		2	2	6
Yellow skin		1		1		
	167	655	42	231	125	424

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		1		1		
Impaired driving ability	1	1			1	1
Impaired work ability	4	21	1	3	3	18
Loss of personal independence in daily activities	7	9	2	2	5	7
Walking disability		2				2
	12	34	3	6	9	28

System Organ Class

**SOC Not Yet Coded**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthrodesis	1	1	1	1		
Bed rest	1	1			1	1
Dermabrasion		1		1		
Thrombolysis	1	1			1	1
	3	4	1	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Air embolism	1	1			1	1
Aneurysm ruptured		1				1
Aortic arteriosclerosis		1				1
Aortic dissection		2				2
Aortic stenosis	1	1			1	1
Arterial disorder	1	1			1	1
Arterial thrombosis	2	2			2	2
Arteriosclerosis	1	2			1	2
Axillary vein thrombosis	1	1	1	1		
Blood pressure fluctuation	3	6	2	3	1	3
Blood pressure inadequately controlled		1				1
Blue toe syndrome		1		1		
Circulatory collapse	2	6			2	6
Claudication of jaw muscles	1	1			1	1
Cyanosis	2	10	1	2	1	8
Deep vein thrombosis	34	45			34	45
Dependent rubor	1	1			1	1
Embolism		1				1
Embolism venous		1				1
Extremity necrosis	2	2	1	1	1	1
Flushing	5	16	1	5	4	11
Giant cell arteritis	6	8			6	8
Haematoma	8	16	1	3	7	13
Haemodynamic instability	1	2	1	2		
Haemorrhage		1				1
Hot flush	8	49	3	23	5	26
Hypertension	162	471	12	56	150	415
Hypertensive crisis	52	150			52	150
Hypertensive urgency		1				1
Hypoperfusion		2		1		1
Hypotension	34	140	9	29	25	111
Hypotensive crisis		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
		2	4
			1
		1	1
			1
		1	2
			1
1	3	1	1
			1
			1
			3
5	25		23
3	3	3	3
2	10		3
1	1	1	1
7	10		9
2	2	1	1
12	15	5	9
2	2	2	
1	3		1
	5		5
2	2	2	2
1	1	1	1
	1		1
	1		1
9	9	1	8
11	14	4	9
1	1		1
9	12		12
1	1	1	
1	1		1
	2		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasodilatation		1		1		
Vein rupture	1	2			1	2
Vena cava thrombosis	2	2			2	2
Venous thrombosis	1	4			1	4
Venous thrombosis limb	7	7	1	1	6	6
Withdrawal hypertension		2		1		1
	416	1,104	50	162	366	942

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FRENCH POLYNESIA**

*System Organ Class*

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cardiopulmonary failure		1		1
		1		1

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Asthenia		2		2
Hyperthermia		1		1
		3		3

*System Organ Class*

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Staphylococcal sepsis		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Oxygen saturation decreased		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Arthralgia		1		1
		1		1

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Dysstasia		1		1
Hyperaesthesia		1		1
Memory impairment		1		1
Movement disorder		1		1
		4		4

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Confusional state		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Dyspnoea		1		1
Haemoptysis		1		1
Pulmonary embolism		1		1
		4		4

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dermatitis bullous		1		1
Dermatosis		1		1
Toxic epidermal necrolysis		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FRENCH SOUTHERN TERRITORIES**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**GEORGIA**

*System Organ Class*

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Pneumonia	1	1	1	1
Sepsis	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**GERMANY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Agranulocytosis		1						1
Anaemia	2	3				1	2	2
Blood disorder		1						1
Coagulopathy	1	2					1	2
Disseminated intravascular coagulation		1						1
Eosinophilia	1	1					1	1
Evans syndrome		1						1
Factor VIII inhibition		1						1
Haemolytic uraemic syndrome		1						1
Immune thrombocytopenia	4	9					4	9
Leukocytosis		1						1
Leukopenia		1						1
Lymphadenitis	3	6			3	4		2
Lymphadenopathy	27	79		1	27	75		4
Lymph node pain	4	23			4	23		
Lymphocytic infiltration		1						1
Lymphopenia	1	4				1	1	3
Microcytic anaemia		2						2
Monocytosis		1						1
Neutropenia	1	2					1	2
Pancytopenia	2	2					2	2
Thrombocytopenia	2	8					2	8
	48	151		1	34	104	14	47

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute coronary syndrome	2	5					2	5
Acute myocardial infarction	6	20					6	20
Acute right ventricular failure	1	1					1	1
Angina pectoris	2	16					2	16
Arrhythmia	9	40		1			9	40
Atrial fibrillation	3	22					3	22
Atrial flutter		1				1		
Atrial tachycardia		1						1
Atrioventricular block complete	2	5					2	5
Atrioventricular block first degree		1				1		
Bradyarrhythmia	1	1					1	1
Bradycardia	1	6					1	6
Bundle branch block right	1	2					1	2
Cardiac aneurysm		1						1
Cardiac arrest	6	19					6	19
Cardiac discomfort	1	2			1	1		1
Cardiac failure	9	39					9	39
Cardiac failure acute		1						1
Cardiac failure congestive		4						4
Cardiac fibrillation		2						2
Cardiogenic shock	1	7					1	7
Cardiomyopathy		1						1
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		2						2
Cardiovascular disorder	6	40			6	26		14
Cardiovascular insufficiency	3	7					3	7
Coronary artery disease	1	1					1	1
Coronary artery dissection	1	1					1	1
Coronary artery stenosis	1	1					1	1
Coronary artery thrombosis		1						1
Cor pulmonale		1						1
Extrasystoles	1	3				1	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ischaemic cardiomyopathy	1	1					1	1
Left ventricular failure		1						1
Myocardial infarction	2	10					2	10
Myocardial ischaemia	1	1					1	1
Myocarditis	3	12					3	12
Palpitations	15	62		4	9	40	6	22
Pericardial effusion	1	1					1	1
Pericarditis		1						1
Sinus tachycardia	1	6			1	1		5
Supraventricular extrasystoles	1	3				2	1	1
Supraventricular tachycardia		2				1		1
Tachyarrhythmia		4				1		3
Tachycardia	23	102		6	22	53	1	49
Tachycardia induced cardiomyopathy		1						1
Ventricular extrasystoles	2	2			1	1	1	1
Ventricular fibrillation		4						4
Ventricular tachycardia	1	2					1	2
	109	470		11	40	129	69	341

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Huntington's disease		3		3
		3		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	4	7			4	7
Deafness bilateral		1				1
Deafness transitory		1				1
Deafness unilateral		2				2
Ear discomfort		4		2		2
Ear pain	2	7	2	7		
Hyperacusis	1	1	1	1		
Hypoacusis		2		1		1
Presbycusis		1				1
Sudden hearing loss	1	9			1	9
Tinnitus	2	9	1	5	1	4
Vertigo		10		9		1
	10	54	4	25	6	29

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune thyroiditis	2	2	2	2
Basedow's disease	1	1	1	1
Hyperthyroidism	1	2	1	2
Hypothyroidism	1	1	1	1
Thyroiditis acute		1		1
	5	7	5	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amaurosis fugax		1				1
Asthenopia		1		1		
Blepharitis		1		1		
Blindness unilateral	1	1			1	1
Conjunctival haemorrhage		2				2
Conjunctival hyperaemia	1	1			1	1
Dark circles under eyes	1	1	1	1		
Diplopia	4	6	2	3	2	3
Dry age-related macular degeneration	1	1			1	1
Dry eye	1	2	1	2		
Episcleritis		1		1		
Eye haemorrhage		4				4
Eye irritation	2	6	2	5		1
Eyelid oedema	2	4	1	1	1	3
Eye pain	2	6	2	6		
Eye pruritus	1	8		3	1	5
Eye swelling		5		4		1
Iridocyclitis	2	2			2	2
Keratoconus	1	1			1	1
Lacrimation increased	1	9		6	1	3
Ocular discomfort	1	4		3	1	1
Ocular hyperaemia		5		4		1
Oculogyric crisis		1				1
Ophthalmic vein thrombosis	4	4			4	4
Optic ischaemic neuropathy	1	1			1	1
Optic neuropathy		1				1
Papilloedema	1	1			1	1
Photopsia		2		2		
Pupillary disorder	1	1	1	1		
Pupils unequal		1				1
Retinal artery occlusion	1	1			1	1
Retinal disorder		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal tear		2				2
Retinal vein thrombosis	1	1			1	1
Retinopathy		1				1
Sudden visual loss		1				1
Swelling of eyelid		3		2		1
Vision blurred	1	11		6	1	5
Visual acuity reduced		1				1
Visual impairment	9	30	3	9	6	21
Vitreous disorder		1				1
	40	137	13	61	27	76

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	2	4			2	4		
Abdominal distension		1				1		
Abdominal pain	10	30		1	6	19	4	11
Abdominal pain lower	1	7				5	1	2
Abdominal pain upper	5	19			3	13	2	6
Abnormal faeces	2	14			2	13		1
Acute abdomen	1	3					1	3
Anorectal disorder	1	1					1	1
Aphthous ulcer		1						1
Ascites		1						1
Bowel movement irregularity		1				1		
Colitis ulcerative		4						4
Constipation		2				2		
Diarrhoea	45	123		11	40	100	5	23
Dry mouth	4	11			2	6	2	5
Dyspepsia	1	4			1	4		
Dysphagia	7	22			4	12	3	10
Enteritis		2						2
Faeces discoloured		1				1		
Flatulence	2	5		1	1	4	1	1
Frequent bowel movements		1				1		
Functional gastrointestinal disorder		1				1		
Gastrointestinal disorder	1	2			1	1		1
Gastrointestinal motility disorder		1				1		
Gastrointestinal necrosis	1	3					1	3
Gastrointestinal pain		3		1				3
Gingival bleeding	1	2					1	2
Gingival swelling		2				1		1
Haematemesis		4						4
Haematochezia	2	4					2	4
Hypoaesthesia oral	3	13			3	10		3
Ileus		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ileus paralytic		2
Intestinal haemorrhage	1	1
Intestinal infarction		1
Intestinal ischaemia	1	2
Intestinal obstruction	1	2
Lip oedema		2
Lip pain		1
Lip swelling		11
Mesenteric vein thrombosis	2	4
Mouth haemorrhage	1	1
Mouth swelling		4
Nausea	63	208
Obstructive pancreatitis	1	1
Odynophagia	1	1
Oesophageal irritation		1
Oral discomfort		2
Oral mucosa erosion		1
Oral mucosal blistering		1
Oral mucosal eruption	1	1
Oral pain		1
Palatal swelling		1
Pancreatitis acute		1
Paraesthesia oral	9	22
Rectal haemorrhage		1
Rectal polyp		1
Retching	2	6
Salivary gland enlargement		2
Stomatitis	2	3
Subileus	1	2
Swollen tongue	7	19
Tongue coated	1	1
Tongue discomfort		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
					1
				1	2
				1	2
			1		1
			1		
			2		9
				2	4
		1	1		
			1		3
	35	58	166	5	42
				1	1
	1	1	1		
					1
			2		
			1		
			1		
		1	1		
					1
					1
		9	18		4
					1
			1		
		2	5		1
			2		
				2	3
		1	1		1
		6	9	1	10
		1	1		
			2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue disorder		1				1		
Tongue oedema		2						2
Tongue pruritus		1						1
Toothache		1				1		
Trichoglossia		1				1		
Upper gastrointestinal haemorrhage		2						2
Visceral venous thrombosis		1						1
Vomiting	25	102		8	18	64	7	38
	208	713		58	163	484	45	229

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute phase reaction	1	1			1	1		
Adverse event	2	2			1	1	1	1
Application site vesicles		1						1
Asthenia	61	168			54	137	7	31
Axillary pain	3	10			3	9		1
Brain death	1	2					1	2
Cardiac death	1	1					1	1
Chest discomfort	3	16			3	10		6
Chest pain	12	29			11	20	1	9
Chills	98	277		25	90	248	8	29
Condition aggravated	3	12				4	3	8
Crepitations		1						1
Death	46	208					46	208
Discomfort		3		3		2		1
Disease progression	1	1					1	1
Disease recurrence	5	13			2	5	3	8
Drug ineffective	39	282				2	39	280
Drug interaction	2	4				2	2	2
Effusion	1	1					1	1
Enanthema		1						1
Exercise tolerance decreased				1				
Face oedema	2	3			2	2		1
Facial pain	2	3			2	3		
Fatigue	112	464		55	103	431	9	33
Feeling abnormal	7	16			6	15	1	1
Feeling cold	10	39			9	33	1	6
Feeling drunk	1	1			1	1		
Feeling hot	13	38			8	25	5	13
Feeling jittery				1				
Feeling of body temperature change	2	11			2	11		
Gait disturbance	1	12				6	1	6
Gait inability		2				1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
General physical health deterioration	8	61
Hunger		1
Hyperpyrexia		1
Hyperthermia		1
Hypothermia	2	4
Illness	2	5
Impaired healing	1	1
Induration		1
Inflammation	1	3
Influenza like illness	23	85
Injected limb mobility decreased	1	2
Injection site discomfort		1
Injection site erythema		1
Injection site pain	2	7
Injection site pruritus		1
Injection site rash		1
Injection site swelling		1
Local reaction	8	17
Malaise	32	117
Multimorbidity		1
Multi-organ disorder		1
Multiple organ dysfunction syndrome	1	9
Necrosis		1
No adverse event		4
Nodule		1
Oedema		3
Oedema peripheral		3
Organ failure		1
Pain	19	65
Performance status decreased		4
Peripheral swelling	7	23
Pseudoallergic reaction	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	17	4	44
			1		
					1
					1
				2	4
		1	4	1	1
				1	1
			1		
				1	3
		23	80		5
		1	2		
			1		
			1		
		2	7		
			1		
			1		
			1		
		6	13	2	4
	50	28	89	4	28
					1
					1
			4		
			1		
					3
			2		1
					1
		17	48	2	17
			2		2
		5	16	2	7
		1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	93	388
Sensation of blood flow		1
Sensation of foreign body	3	18
Sense of oppression		1
Sudden cardiac death	1	3
Sudden death	3	28
Swelling	8	23
Swelling face	8	25
Systemic inflammatory response syndrome		1
Tenderness	1	1
Therapeutic response unexpected	5	9
Thirst	1	3
Vaccination site bruising		4
Vaccination site dermatitis		1
Vaccination site discolouration		1
Vaccination site discomfort	1	8
Vaccination site dysaesthesia		1
Vaccination site erythema	17	41
Vaccination site granuloma	1	1
Vaccination site haematoma	1	7
Vaccination site haemorrhage		2
Vaccination site hyperaesthesia		4
Vaccination site hypersensitivity	2	2
Vaccination site hypoaesthesia		1
Vaccination site induration	3	7
Vaccination site inflammation		
Vaccination site irritation		1
Vaccination site joint movement impairment		3
Vaccination site joint pain		2
Vaccination site lymphadenopathy	2	4
Vaccination site movement impairment	3	11
Vaccination site oedema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	26	84	298	9	90
			1		
		2	4	1	14
			1		
				1	3
				3	28
		7	19	1	4
	3	5	12	3	13
					1
		1	1		
		5	9		
	1	1	3		
			4		
			1		
			1		
		1	8		
			1		
	1	15	37	2	4
		1	1		
		1	6		1
			2		
			4		
		2	2		
					1
		3	7		
	1				
			1		
			2		1
			2		
		2	4		
		3	11		
		1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pain	122	521		53	121	508	1	13
Vaccination site papule	1	1			1	1		
Vaccination site paraesthesia	2	6			2	6		
Vaccination site pruritus	4	14			4	13		1
Vaccination site rash	1	4			1	3		1
Vaccination site reaction	5	13			4	11	1	2
Vaccination site swelling	24	65		12	23	60	1	5
Vaccination site urticaria	1	3			1	3		
Vaccination site warmth	5	23		1	4	21	1	2
	857	3,304		233	681	2331	176	973

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholelithiasis		1		1		
Hepatic cirrhosis	1	1			1	1
Hepatic failure		4				4
Hepatic pain		1		1		
Hepatitis cholestatic		2				2
Jaundice		2		1		1
Ocular icterus	1	1	1	1		
	2	12	1	4	1	8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Allergic oedema		3				1			2
Allergy to vaccine		5				2			3
Anaphylactic reaction	7	89					7		89
Anaphylactic shock	3	16		1			3		16
Anaphylactoid reaction		2							2
Autoimmune disorder		1							1
Hypersensitivity	24	91		4	17	35	7		56
Reaction to excipient		1				1			
Seasonal allergy	1	1			1	1			
Type IV hypersensitivity reaction		4				4			
	35	213		5	18	44	17		169

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abscess		1					1	
Abscess limb	1	1				1	1	
Abscess neck	1	1				1	1	
Appendicitis	1	1		1		1	1	
Asymptomatic COVID-19	2	6				1	5	
Atypical pneumonia		1					1	
Blister infected		1				1		
Bronchitis		4				2	2	
Bronchitis bacterial		2					2	
Cellulitis		1					1	
Conjunctivitis	1	5			1	3	2	
Coronavirus infection	7	11			7	8	3	
COVID-19	97	448		1	49	121	48	327
COVID-19 pneumonia	3	21					3	21
Creutzfeldt-Jakob disease	2	2					2	2
Cystitis		1				1		
Diverticulitis	1	2					1	2
Encephalitis	1	3					1	3
Epstein-Barr virus infection reactivation		3						3
Erysipelas	2	4					2	4
Escherichia infection		1						1
Febrile infection		3						3
Genital herpes		1				1		
Gingivitis	2	2					2	2
Haematoma infection		1						1
Herpes dermatitis		1				1		
Herpes simplex	1	3			1	2		1
Herpes simplex encephalitis		1						1
Herpes virus infection		1				1		
Herpes zoster	7	49			3	38	4	11
Herpes zoster infection neurological		2						2
Herpes zoster meningitis	1	2					1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Herpes zoster oticus		3
Herpes zoster reactivation		1
Hordeolum		1
Infection	3	8
Infective exacerbation of chronic obstructive airways disease		2
Influenza	6	8
Intestinal gangrene		1
Localised infection		1
Lymphangitis		1
Meningitis		1
Meningitis aseptic		1
Meningitis viral		1
Myelitis	1	2
Myocarditis infectious		1
Myocarditis septic		1
Nasopharyngitis	6	35
Ophthalmic herpes zoster		2
Oral candidiasis	1	1
Oral fungal infection		1
Oral herpes		4
Otitis media		1
Pathogen resistance		1
Peritonitis		1
Pharyngitis	1	2
Pneumonia	6	38
Pneumonia bacterial		2
Pneumonia viral	1	1
Pulmonary sepsis		2
Pustule	2	6
Rash pustular	1	1
Respiratory tract infection		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
			1		
			1		
	1	1	3	2	5
					2
		5	6	1	2
					1
			1		
					1
					1
					1
				1	2
					1
					1
	1	6	29		6
					2
				1	1
					1
			3		1
			1		
					1
		1	2		
				6	38
					2
				1	1
					2
	1	2	4		2
		1	1		
					6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Respiratory tract infection viral	1	1			1	1		
Rhinitis		2				2		
SARS-CoV-2 sepsis		1						1
Sepsis		3						3
Septic arthritis staphylococcal	1	1					1	1
Septic shock		3						3
Sialoadenitis		1						1
Sinusitis		2				2		
Soft tissue infection		1						1
Staphylococcal sepsis		2						2
Subcutaneous abscess	1	1					1	1
Superinfection bacterial	2	3					2	3
Suspected COVID-19		4						4
Tonsillitis bacterial		2						2
Upper respiratory tract infection	1	5			1	1		4
Urinary tract infection	1	3				1	1	2
Urosepsis		1						1
Varicella		1				1		
Varicella zoster virus infection		1				1		
Vestibular neuronitis	1	1			1	1		
Viral rash	1	2			1	2		
Vulvitis	1	1					1	1
Vulvovaginal mycotic infection	1	1					1	1
	169	766		5	81	244	88	522

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Accidental exposure to product		1				1			
Accidental overdose	1	14			1	11			3
Booster dose missed		2				2			
Cerebral ventricle collapse		1							1
Circumstance or information capable of leading to medication error		2				2			
Contusion		4				1			3
Craniocerebral injury	1	1					1		1
Exposure during pregnancy		3				3			
Exposure via breast milk		5				5			
Fall	3	20				2	3		18
Femoral neck fracture		1							1
Femur fracture	1	2					1		2
Fracture		1							1
Head injury	2	3					2		3
Inadequate aseptic technique in use of product	1	1			1	1			
Inappropriate schedule of product administration	9	29			9	29			
Incorrect dose administered		3				3			
Incorrect route of product administration	27	76			27	75			1
Intentional product misuse	1	2			1	2			
Maternal exposure during pregnancy	2	35			2	34			1
Maternal exposure timing unspecified		2				2			
Medication error	1	1			1	1			
Muscle strain				1					
Occupational exposure to product		1				1			
Off label use	8	34			8	34			
Overdose	1	2					1		2
Pelvic fracture	1	1					1		1
Peroneal nerve injury		1							1
Poisoning	1	1					1		1
Poor quality product administered	5	41			5	39			2
Product administered at inappropriate site		1				1			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Product administered to patient of inappropriate age		1				1			
Product dose omission issue	1	3			1	2			1
Product preparation error		3				3			
Product preparation issue		9				9			
Product storage error	2	3			2	3			
Product use issue	1	18			1	18			
Respiratory fume inhalation disorder	1	1					1		1
Scratch	1	2			1	2			
Skin abrasion		1							1
Skin laceration	1	1					1		1
Subdural haematoma		1							1
Tendon rupture	1	1					1		1
Toxicity to various agents		1							1
Underdose		21				21			
Vaccination complication	1	4					1		4
Vaccination failure	11	33					11		33
Wound		1				1			
Wrong technique in product usage process	1	3			1	3			
	86	398		1	61	312	25		86

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Alanine aminotransferase increased	1	2					1	2
Amino acid level decreased		1				1		
Antibody test abnormal		3				3		
Aspartate aminotransferase increased	1	2			1	1		1
Blood calcium decreased	1	3				2	1	1
Blood cholesterol increased		1				1		
Blood count abnormal	1	1					1	1
Blood creatine phosphokinase increased		2				1		1
Blood creatine phosphokinase MB increased		1				1		
Blood creatinine increased		1						1
Blood glucose abnormal		1				1		
Blood glucose decreased	2	4				2	2	2
Blood glucose fluctuation	1	3			1	3		
Blood glucose increased		2				2		
Blood immunoglobulin M increased		1				1		
Blood lactate dehydrogenase increased		2						2
Blood methaemoglobin present		1				1		
Blood potassium decreased		4				1		3
Blood pressure abnormal		1				1		
Blood pressure decreased	6	16		1	3	6	3	10
Blood pressure immeasurable		1						1
Blood pressure increased	10	32		2	6	17	4	15
Blood pressure systolic increased	1	1					1	1
Blood sodium decreased	1	2				1	1	1
Blood test abnormal	1	1			1	1		
Blood thyroid stimulating hormone increased		1				1		
Blood urine present	1	2					1	2
Body temperature decreased	2	2			2	2		
Body temperature increased	12	59			12	49		10
Capillary nail refill test abnormal		2				1		1
Carbon dioxide decreased	1	1					1	1
Chest X-ray abnormal		1						1

\* I=Interval, C=Cumulative  
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coagulation time prolonged		1
Complement factor C3 increased		1
Coronavirus test positive		2
C-reactive protein increased	6	11
Digestive enzyme abnormal	1	1
Eastern Cooperative Oncology Group performance status worsened	1	1
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment depression		1
Electrocardiogram T wave inversion		1
Fibrin D dimer increased	2	3
Gamma-glutamyltransferase increased	1	1
General physical condition abnormal	1	9
Glomerular filtration rate decreased		2
Haematocrit decreased		2
Haemoglobin decreased	1	5
Heart rate decreased	1	2
Heart rate increased	3	13
Hepatic enzyme increased	2	4
HIV test positive	1	1
Inflammatory marker increased		1
International normalised ratio decreased		1
International normalised ratio increased		1
Lipase increased		1
Liver function test increased		2
Low density lipoprotein increased		1
Muscle strength abnormal		1
Myoglobin blood increased		1
Oxygen saturation decreased		15
Platelet count decreased		2
PO2 decreased	1	1
Protein urine present		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		1
		5	7	1	4
		1	1		
		1	1		
					1
					1
					1
		2	2		1
				1	1
				1	9
			2		
			2		
			2	1	3
				1	2
		1	7	2	6
		2	2		2
				1	1
					1
			1		
			1		
					1
					2
			1		
			1		
					1
			2		13
					2
				1	1
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Pulse waveform abnormal		1				1			
Red blood cell count decreased		2				2			
Red blood cell sedimentation rate increased	1	2			1	2			
Respiratory rate decreased	1	1			1	1			
Respiratory rate increased	1	2			1	2			
SARS-CoV-2 antibody test	1	1			1	1			
SARS-CoV-2 antibody test negative	4	21			4	20			1
SARS-CoV-2 antibody test positive	4	35			4	34			1
SARS-CoV-2 test false positive		4				4			
SARS-CoV-2 test positive	8	51			8	34			17
Sensory level abnormal		4				3			1
Transaminases increased		3				2			1
Tryptase increased		1							1
Weight decreased	2	2					2		2
Weight increased	1	1			1	1			
White blood cell count decreased	1	3			1	3			
White blood cell count increased	1	4			1	2			2
	88	385		3	61	248		27	137

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis		1				1
Decreased appetite	10	25	8	19	2	6
Dehydration	1	6		1	1	5
Diabetes mellitus		2				2
Diabetes mellitus inadequate control		1				1
Diet refusal		6				6
Electrolyte depletion		1		1		
Electrolyte imbalance		1				1
Fluid retention	1	1	1	1		
Food refusal		3		1		2
Gout		1		1		
Hypercalcaemia		2				2
Hyperglycaemia		2				2
Hyperkalaemia		1				1
Hypoglycaemia	1	2	1	2		
Hyponatraemia		5		2		3
Hypophagia	1	2			1	2
Lipid metabolism disorder		1		1		
Marasmus		1				1
Metabolic acidosis		1				1
Metabolic disorder		1				1
Polydipsia	1	1			1	1
Tetany		1				1
Type 1 diabetes mellitus	1	2			1	2
	16	70	10	29	6	41

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous					
			Non Interventional Study		Nonserious		Serious	
			I	C	I	C	I	C
Arthralgia	45	118		22	44	104	1	14
Arthritis	1	1					1	1
Arthritis reactive		1						1
Arthropathy		1						1
Back pain	11	26			10	23	1	3
Bone pain	9	23			9	21		2
Bursitis	2	2		1	1	1	1	1
Fistula		1						1
Flank pain		1				1		
Groin pain		2				2		
Jaw clicking		1						1
Joint range of motion decreased	1	4			1	3		1
Joint swelling		3				1		2
Limb discomfort	10	35			7	28	3	7
Mobility decreased	5	17			4	13	1	4
Muscle discomfort		1				1		
Muscle mass	1	1			1	1		
Muscle spasms	6	12			4	7	2	5
Muscle swelling		2				2		
Muscle tightness	2	3		1	2	3		
Muscle twitching	6	12			6	9		3
Muscular weakness	2	18				11	2	7
Musculoskeletal chest pain	1	6			1	2		4
Musculoskeletal discomfort	1	1			1	1		
Musculoskeletal disorder	1	1			1	1		
Musculoskeletal pain	2	4			1	2	1	2
Musculoskeletal stiffness	1	4			1	4		
Myalgia	59	222		35	58	206	1	16
Myosclerosis		2						2
Myositis	1	2			1	1		1
Neck pain	7	28			7	26		2
Nuchal rigidity	1	2			1	1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Oligoarthritis		1						1
Osteoporosis	1	1			1	1		
Pain in extremity	84	341			76	314	8	27
Pain in jaw		2				2		
Polyarthritis		1						1
Polymyalgia rheumatica	1	2					1	2
Rhabdomyolysis		3						3
Rheumatic disorder	1	2			1	1		1
Rheumatoid arthritis		2						2
Spinal pain	1	3				1	1	2
Systemic lupus erythematosus	1	1					1	1
Temporomandibular joint syndrome		1				1		
Tendonitis	1	1					1	1
Tendon pain		1						1
Tenosynovitis		1				1		
Vertebral wedging		1						1
Weight bearing difficulty		1						1
	265	922		59	239	796	26	126

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute myeloid leukaemia	1	1	1	1
Leukaemia	1	1	1	1
Malignant melanoma		1		1
Malignant pleural effusion	1	1	1	1
Neoplasm	1	1	1	1
	4	5	4	5

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ageusia	2	14
Allodynia	1	1
Altered state of consciousness	1	6
Amnesia	1	7
Amnesic disorder	1	1
Anaesthesia		1
Anosmia	1	8
Aphasia	4	18
Ataxia		7
Autonomic nervous system imbalance	1	2
Balance disorder	1	2
Basal ganglia haemorrhage	1	1
Basal ganglia infarction		1
Basilar artery occlusion		1
Basilar artery thrombosis	1	2
Brain injury		1
Brain oedema	1	3
Brain stem infarction	1	1
Burning sensation	8	18
Carotid artery occlusion	1	1
Cerebellar ataxia		1
Cerebellar syndrome		2
Cerebral atrophy		1
Cerebral haemorrhage	4	15
Cerebral infarction	6	14
Cerebral ischaemia	2	6
Cerebral thrombosis	2	2
Cerebral venous sinus thrombosis	4	7
Cerebral venous thrombosis	1	2
Cerebrovascular accident	17	48
Cerebrovascular disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	13		1
		1	1		
	1			1	6
			1	1	6
				1	1
					1
		1	7		1
			5	4	13
					7
		1	1		1
			1	1	1
				1	1
					1
				1	2
					1
				1	3
				1	1
		5	9	3	9
				1	1
					1
					2
					1
				4	15
				6	14
				2	6
				2	2
				4	7
				1	2
				17	48
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Clonus	1	1
Cognitive disorder		2
Coma		2
Coordination abnormal		1
Cranial nerve disorder		2
Dementia	1	6
Dementia of the Alzheimer's type, with delirium		1
Depressed level of consciousness	2	8
Disturbance in attention	8	39
Dizziness	66	254
Dizziness postural		2
Dysaesthesia	1	10
Dysarthria	1	5
Dysgeusia	6	13
Dysgraphia		1
Dyskinesia		1
Dyslalia		1
Dysstasia	1	2
Embolic cerebral infarction	1	1
Embolic stroke	1	1
Encephalitis autoimmune	1	1
Epilepsy	4	31
Essential tremor		1
Extrapyramidal disorder	1	2
Facial nerve disorder		2
Facial paralysis	10	39
Facial paresis	9	33
Formication		1
Generalised tonic-clonic seizure		3
Guillain-Barre syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		1
					2
					1
			2		
				1	6
					1
				2	8
		7	26	1	13
	41	53	180	13	74
			1		1
		1	5		5
		1	1		4
		5	10	1	3
			1		
					1
					1
		1	2		
				1	1
				1	1
				1	1
				4	31
					1
			1	1	1
			1		1
				10	39
		5	17	4	16
			1		
					3
					2

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Headache	164	622
Head discomfort	6	11
Hemiparaesthesia	1	3
Hemiparesis	5	20
Hemiplegia	2	4
Hyperaesthesia	4	6
Hypersomnia	1	5
Hypertonia		2
Hypoaesthesia	13	48
Hypokinesia		1
Hyporesponsive to stimuli		1
Hypotonia	9	16
Idiopathic intracranial hypertension	1	2
IIIrd nerve paresis	1	1
Intracranial aneurysm		1
Ischaemic cerebral infarction	1	4
Ischaemic stroke	2	5
IVth nerve disorder		1
IVth nerve paresis		1
Language disorder		2
Lhermitte's sign	1	1
Loss of consciousness	6	25
Memory impairment	1	5
Meningism	1	3
Mental impairment		1
Migraine	3	11
Monoparesis	2	3
Monoplegia	1	4
Motor dysfunction		1
Movement disorder	3	12
Multiple sclerosis		2
Multiple sclerosis relapse	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	56	148	546	16	76
		6	9		2
				1	3
				5	20
				2	4
		3	5	1	1
		1	3		2
			1		1
	2	10	38	3	10
			1		
					1
		6	10	3	6
				1	2
				1	1
					1
				1	4
				2	5
					1
					1
					2
		1	1		
				6	25
			2	1	3
		1	1		2
					1
		3	9		2
		1	1	1	2
				1	4
					1
		2	6	1	6
					2
				2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle contractions involuntary		1
Muscle spasticity		1
Myasthenia gravis		1
Myoclonus		2
Nervous system disorder		5
Neuralgia	3	10
Neuralgic amyotrophy		5
Neuritis		4
Neuropathy peripheral	1	2
Nystagmus		1
Occipital neuralgia		1
Optic neuritis		2
Orthostatic intolerance	1	2
Paraesthesia	27	92
Paralysis	2	4
Paresis	2	7
Parkinsonian rest tremor		1
Parkinsonism		1
Parkinson's disease		2
Parosmia	2	3
Partial seizures	1	2
Petit mal epilepsy		1
Pleocytosis	1	3
Polyneuropathy	3	5
Poor quality sleep	1	7
Postictal state		1
Presyncope	4	17
Psychomotor hyperactivity		2
Pyramidal tract syndrome		1
Quadriparesis		2
Radiculopathy		2
Resting tremor		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
			1		1
			1		4
		3	10		
			1		4
			3		1
				1	2
					1
			1		
					2
		1	1		1
	3	21	56	6	36
				2	4
		1	3	1	4
			1		
					1
					2
		2	2		1
				1	2
					1
			1	1	2
				3	5
			5	1	2
					1
		3	11	1	6
					2
					1
			1		1
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retrograde amnesia	1	2			1	1		1
Reversible cerebral vasoconstriction syndrome		1						1
Seizure	4	34					4	34
Sensory disturbance	12	27			10	23	2	4
Sensory loss		2				1		1
Somnolence	11	34			8	20	3	14
Speech disorder	3	7			1	3	2	4
Spinal cord ischaemia	1	1					1	1
Status epilepticus		7						7
Stupor		1						1
Subarachnoid haemorrhage	2	3					2	3
Sudden onset of sleep		1						1
Superior sagittal sinus thrombosis		1						1
Syncope	20	64		1			20	64
Taste disorder	3	7			3	5		2
Tension headache	1	2			1	1		1
Thalamic infarction		1						1
Tonic convulsion		1						1
Transient aphasia	1	1					1	1
Transient global amnesia		2				1		1
Transient ischaemic attack	3	5					3	5
Tremor	10	36			6	18	4	18
Trigeminal neuralgia	1	2			1	2		
Unresponsive to stimuli	2	10					2	10
Vascular dementia		1						1
Vascular encephalopathy		1						1
Visual field defect		3				1		2
Vlth nerve paralysis	1	1					1	1
	530	1,941		104	327	1094	203	847

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion missed		1				1
Abortion spontaneous	1	4			1	4
Pregnancy		1		1		
Pregnancy with contraceptive device	1	1			1	1
	2	7		1	2	6

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Embedded device	1	1			1	1
Product complaint	1	6	1	6		
Product leakage		1		1		
Product quality issue		1		1		
Product supply issue		2		2		
Product temperature excursion issue	5	35	5	33		2
Suspected counterfeit product		1		1		
	7	47	6	44	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute stress disorder	1	1			1	1
Aggression	1	3			1	3
Agitation		5		1		4
Anxiety	2	6	2	4		2
Apathy	1	9	1	5		4
Automatism		1				1
Communication disorder		1		1		
Confusional state	3	16	1	5	2	11
Delirium	1	6			1	6
Delusion		2				2
Depressed mood		1				1
Depression	4	5	4	5		
Disorientation	1	8	1	4		4
Eating disorder		2		2		
Emotional disorder		1				1
Fear		1				1
Hallucination	1	4			1	4
Hallucination, auditory		1				1
Hallucinations, mixed		1				1
Initial insomnia		2		2		
Insomnia	4	12	4	11		1
Listless	2	3	2	2		1
Mental disorder	2	4	1	2	1	2
Middle insomnia		3		3		
Nervousness		1		1		
Panic attack	1	4	1	1		3
Panic disorder	1	1	1	1		
Panic reaction	1	3		2	1	1
Paranoia		1				1
Personality change	1	8		1	1	7
Psychological factor affecting medical condition		1				1
Psychomotor retardation	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restlessness	5	13	4	10	1	3
Sleep disorder	1	11	1	11		
Somatic symptom disorder		1				1
Sopor		1				1
Stress		4		3		1
Tension		1		1		
	34	149	23	78	11	71

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	15			1	15
Bladder discomfort	1	2	1	2		
Bladder dysfunction	1	1			1	1
Bladder pain		1		1		
Chronic kidney disease		2				2
Cystitis haemorrhagic	1	1			1	1
Dysuria	1	2			1	2
Glomerulonephritis minimal lesion		1				1
Haematuria		1		1		
Incontinence		1				1
Micturition disorder	1	1	1	1		
Micturition urgency	1	1	1	1		
Nephrolithiasis	1	1			1	1
Nephrotic syndrome		1				1
Oliguria		1				1
Pollakiuria	1	2	1	2		
Polyuria	1	1			1	1
Proteinuria		1				1
Renal disorder		2				2
Renal failure	2	13			2	13
Renal impairment	1	1			1	1
Renal pain		4		2		2
Urinary retention		1				1
Urinary tract inflammation		1				1
Urine odour abnormal	1	1	1	1		
	14	59	5	11	9	48

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breast pain	2	2		1	2	2		
Cervix haematoma uterine	1	1					1	1
Genital haemorrhage	1	1					1	1
Menorrhagia		1				1		
Menstrual disorder		5				5		
Menstruation irregular		1				1		
Pelvic pain		1				1		
Vulvovaginal discomfort	1	1					1	1
Vulvovaginal pain	1	1					1	1
Vulvovaginal swelling	1	1			1	1		
	7	15		1	3	11	4	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute respiratory distress syndrome	1	5					1	5
Acute respiratory failure	1	4					1	4
Aspiration		4						4
Asthma	7	21			6	12	1	9
Bronchial disorder		1				1		
Bronchial obstruction	1	2					1	2
Bronchitis chronic	1	1			1	1		
Bronchospasm		5				1		4
Chronic obstructive pulmonary disease	2	8				1	2	7
Cough	15	59		1	13	43	2	16
Diaphragmalgia		1				1		
Dry throat		1				1		
Dysphonia	2	12			2	9		3
Dyspnoea	42	167		2	23	68	19	99
Dyspnoea at rest		2						2
Dyspnoea exertional	5	13			2	5	3	8
Emphysema	1	1					1	1
Epistaxis	3	7		1	2	5	1	2
Haemoptysis	2	3			1	2	1	1
Haemothorax		1						1
Hyperventilation	1	11			1	4		7
Hypoventilation		1						1
Hypoxia	2	3					2	3
Increased upper airway secretion		1				1		
Irregular breathing		2						2
Laryngeal obstruction	1	1					1	1
Laryngeal oedema	1	6					1	6
Laryngospasm		1						1
Lower respiratory tract congestion		1				1		
Lung disorder	1	2			1	2		
Lung infiltration		1						1
Nasal congestion	1	7			1	6		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Obstructive airways disorder	2	3
Oropharyngeal blistering		2
Oropharyngeal discomfort		1
Oropharyngeal pain	6	26
Oropharyngeal swelling	1	1
Orthopnoea		2
Painful respiration	2	2
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngeal swelling	2	12
Pleural effusion		2
Pleurisy		1
Pleuritic pain	1	1
Pneumonia aspiration		3
Pulmonary artery thrombosis		1
Pulmonary embolism	43	64
Pulmonary fibrosis		1
Pulmonary haemorrhage	1	1
Pulmonary hypertension	1	1
Pulmonary infarction	2	2
Pulmonary oedema	1	4
Pulmonary pain		2
Pulmonary sarcoidosis	1	1
Pulmonary vasculitis		1
Rales		1
Respiration abnormal	1	3
Respiratory distress	22	94
Respiratory failure		21
Respiratory symptom		1
Respiratory tract inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					2
			1		
	1	6	23		3
				1	1
					2
		2	2		
			2		
			1		
					1
	1		3	2	9
					2
					1
		1	1		
					3
					1
				43	64
					1
	1			1	1
	1			1	1
	2			2	2
	1			1	4
			1		1
	1			1	1
					1
					1
		1	3		
	22			22	94
					21
			1		
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Respiratory tract oedema		1						1
Rhinalgia		2			2			
Rhinitis allergic		1			1			
Rhinorrhoea	5	24			5	23		1
Rhonchi		2						2
Sinus congestion		2				2		
Sneezing		7				7		
Snoring	2	2			2	2		
Stridor		6						6
Tachypnoea		4				1		3
Throat irritation	6	17		1	6	16		1
Throat tightness	6	26			5	13	1	13
Tonsillar hypertrophy	1	1			1	1		
Wheezing		6				2		4
	196	716		7	82	273	114	443

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne		1				1		
Acute febrile neutrophilic dermatosis	1	2					1	2
Acute generalised exanthematous pustulosis	1	1					1	1
Alopecia	1	3				1	1	2
Alopecia areata		1				1		
Angioedema	9	34					9	34
Blister	2	7			1	5	1	2
Circumoral oedema	1	1			1	1		
Cold sweat	4	12			3	5	1	7
Dermatitis allergic	4	10			3	6	1	4
Dermatitis atopic		1				1		
Dermatitis bullous	1	1					1	1
Drug eruption	1	2			1	1		1
Dry skin		1				1		
Eczema	3	11			3	10		1
Erythema	18	71		2	16	52	2	19
Erythema multiforme		1						1
Hyperhidrosis	10	36		1	9	31	1	5
Hypersensitivity vasculitis	3	6					3	6
Livedo reticularis		1				1		
Neurodermatitis	1	4			1	4		
Night sweats	1	6			1	6		
Onychoclasia		1				1		
Pain of skin	1	3			1	3		
Pemphigus	2	2					2	2
Perioral dermatitis		1				1		
Petechiae	5	12			3	5	2	7
Photosensitivity reaction		1				1		
Prurigo		1				1		
Pruritus	27	73		2	20	47	7	26
Pruritus allergic		2				1		1
Psoriasis		2				1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Purpura		1							1
Rash	22	85		4	14	43	8		42
Rash erythematous	2	5			2	5			
Rash macular	2	6			2	6			
Rash maculo-papular	1	5			1	5			
Rash papular	1	2			1	2			
Rash pruritic	6	14			6	12			2
Rash vesicular	1	4			1	4			
Rosacea		1							1
Sensitive skin		1				1			
Skin burning sensation	2	5			2	3			2
Skin discolouration	1	4			1	3			1
Skin disorder		1							1
Skin exfoliation	1	3			1	3			
Skin haemorrhage		1							1
Skin irritation	1	1			1	1			
Skin lesion		1							1
Skin necrosis	1	1					1		1
Skin reaction	1	2			1	2			
Skin swelling	1	2			1	2			
Skin ulcer	1	1			1	1			
Skin warm	1	1			1	1			
Urticaria	19	42		1	15	28	4		14
	160	500		10	114	310	46		190

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		2		1		1
Impaired work ability		2		1		1
Loss of personal independence in daily activities		2		2		
		6		4		2

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cranial nerve decompression		1		1
Ileectomy	1	1	1	1
Resuscitation		1		1
Thrombectomy	1	1	1	1
	2	4	2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic aneurysm	1	3					1	3
Aortic dissection	1	2					1	2
Arterial occlusive disease		1						1
Arterial thrombosis		2						2
Arteriosclerosis		2				1		1
Blood pressure fluctuation	1	5			1	5		
Bloody discharge	1	1			1	1		
Circulatory collapse	11	49		1			11	49
Cyanosis	2	9			2	3		6
Deep vein thrombosis	24	32					24	32
Embolism	1	1					1	1
Embolism arterial		1						1
Femoral artery embolism		1						1
Flushing	10	41			9	19	1	22
Giant cell arteritis		1						1
Haematoma	2	11			1	5	1	6
Haemorrhage	5	7					5	7
Hot flush	6	14			4	12	2	2
Hypertension	15	72		3	8	26	7	46
Hypertensive crisis	4	19					4	19
Hypertensive emergency		1						1
Hypotension	12	43			10	20	2	23
Infarction		1						1
Internal haemorrhage	1	1					1	1
Ischaemia	2	3					2	3
Lymphoedema	1	2			1	2		
Microembolism		1						1
Microscopic polyangiitis	1	2					1	2
Orthostatic hypotension	2	2			2	2		
Pallor	3	7			1	2	2	5
Pelvic venous thrombosis	2	2					2	2
Peripheral circulatory failure	6	9			4	4	2	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Peripheral coldness	1	3
Peripheral embolism	2	3
Peripheral ischaemia	1	1
Peripheral vascular disorder	6	33
Phlebitis	1	1
Raynaud's phenomenon	1	2
Secondary hypertension	1	1
Shock	1	3
Subclavian artery thrombosis		1
Subclavian vein thrombosis	2	2
Thrombophlebitis	3	3
Thrombophlebitis superficial	3	3
Thrombosis	13	17
Varicose vein	1	1
Vascular occlusion	1	1
Vasculitis		4
Venous occlusion	1	1
Venous thrombosis	3	4
Venous thrombosis in pregnancy	1	1
Venous thrombosis limb	2	3
	158	436

Non Interventional Study		Spontaneous				
Serious		Nonserious		Serious		
I	C	I	C	I	C	
		1	3			
			1	2	2	
				1	1	
	1	5	12	1	21	
		1	1			
		1	2			
		1	1			
				1	3	
					1	
				2	2	
		2	2	1	1	
		2	2	1	1	
				13	17	
		1	1			
				1	1	
			1		3	
				1	1	
				3	4	
				1	1	
				2	3	
		5	58	128	100	308

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**GREECE**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	2	2	1	1	1	1
Leukocytosis	1	2	1	1		1
Lymphadenitis	7	23	2	6	5	17
Lymphadenopathy	12	39	8	21	4	18
Lymph node pain		4		3		1
Lymphopenia		1		1		
Paratracheal lymphadenopathy	1	1			1	1
	23	72	12	33	11	39

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	3			1	3
Angina pectoris	1	1			1	1
Arrhythmia	5	12	1	1	4	11
Atrial fibrillation	3	6			3	6
Bradycardia		2				2
Cardiac arrest	3	8			3	8
Cardiac discomfort		1				1
Cardiac failure	1	1			1	1
Cardiac valve disease		1				1
Coronary artery stenosis		1				1
Extrasystoles	1	5		3	1	2
Left ventricular hypertrophy		1				1
Myocardial infarction	1	3			1	3
Myocarditis		1				1
Palpitations	5	29		14	5	15
Tachycardia	11	62	4	29	7	33
Ventricular arrhythmia		1				1
	32	138	5	47	27	91

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertrophic cardiomyopathy		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Deafness unilateral		2				2
Ear pain		4		2		2
Hypoacusis		1				1
Tinnitus	2	9	1	6	1	3
Vertigo	2	12	1	8	1	4
	4	29	2	16	2	13

System Organ Class

**Endocrine disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Goitre	1	1			1	1
Thyroid cyst		1				1
Thyroiditis	1	2		1	1	1
Thyroiditis acute		1				1
	2	5		1	2	4

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharitis		1		1		
Blepharospasm		1		1		
Conjunctival hyperaemia		2		2		
Diplopia		2				2
Dry eye	1	1	1	1		
Episcleritis		1				1
Eye disorder	1	1	1	1		
Eye haemorrhage	1	1			1	1
Eye irritation	1	2	1	2		
Eyelid irritation		1				1
Eyelid oedema	2	5	2	4		1
Eyelid ptosis		2				2
Eyelids pruritus	1	2	1	1		1
Eye oedema		1				1
Eye pain	1	1			1	1
Eye pruritus		2		1		1
Eye swelling		1				1
Iridocyclitis	1	1			1	1
Lacrimation increased		1		1		
Ocular hyperaemia	2	4		1	2	3
Ophthalmic artery thrombosis	1	1			1	1
Papilloedema		1				1
Periorbital oedema	1	2	1	2		
Periorbital swelling	1	1	1	1		
Photophobia	1	1			1	1
Scleritis	1	1			1	1
Uveitis	4	5			4	5
Vision blurred		2		2		
Visual impairment	2	2	1	1	1	1
	22	49	9	22	13	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal discomfort		1		1			
Abdominal distension	1	1	1	1			
Abdominal pain	1	12		6	1		6
Abdominal pain upper		7		6			1
Constipation		1		1			
Defaecation urgency		1					1
Diarrhoea	3	27	3	17			10
Dry mouth	2	8	2	6			2
Dyspepsia	1	5		3	1		2
Dysphagia	4	25	1	7	3		18
Enlarged uvula	2	3			2		3
Epigastric discomfort		1					1
Eructation	1	5		3	1		2
Flatulence		2					2
Gastrointestinal disorder	1	10		9	1		1
Gastrointestinal haemorrhage	1	1			1		1
Gastrointestinal hypermotility		1					1
Glossodynia	2	2			2		2
Haematochezia	1	1			1		1
Hypoaesthesia oral	1	28	1	12			16
Impaired gastric emptying	1	1			1		1
Lip oedema	1	9		3	1		6
Lip pain	2	2			2		2
Lip swelling		3		2			1
Nausea	4	47	2	32	2		15
Oral discomfort	1	1	1	1			
Oral mucosal erythema		1		1			
Pancreatitis		2					2
Parotid gland enlargement	1	2		1	1		1
Salivary gland enlargement	1	1			1		1
Salivary gland pain	1	2	1	2			
Teething		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue discomfort		1				1
Tongue oedema	2	5			2	5
Tongue ulceration		1		1		
Vomiting	6	25	3	12	3	13
	41	246	15	127	26	119

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	42	2	26	2	16
Axillary pain	1	2		1	1	1
Brain death	1	2			1	2
Chest discomfort	2	8		2	2	6
Chest pain	5	18	2	7	3	11
Chills	10	89	7	43	3	46
Condition aggravated	1	4			1	4
Crying		1		1		
Death	2	6			2	6
Discomfort	1	7		4	1	3
Disease recurrence	2	4			2	4
Drowning		1				1
Drug ineffective	3	22			3	22
Drug interaction		1				1
Face oedema	1	5	1	2		3
Fatigue	23	106	16	60	7	46
Feeling abnormal		1				1
Feeling cold	1	3	1	3		
Feeling drunk		1				1
Feeling hot		5		3		2
Gait disturbance	3	8		4	3	4
Gait inability	1	2			1	2
Hypothermia	1	2			1	2
Illness	1	2	1	1		1
Impaired self-care		1				1
Inflammation	1	4	1	1		3
Influenza like illness		1		1		
Injection site hypoaesthesia		1		1		
Injection site pain		2		2		
Localised oedema		3		1		2
Local reaction		2		2		
Malaise	7	32	5	20	2	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Mucosal dryness		1					1
No adverse event		10		10			
Oedema		4		2			2
Oedema peripheral	2	4		2	2		2
Pain	1	28	1	14			14
Peripheral swelling	1	2	1	2			
Pyrexia	38	174	28	105	10		69
Sensation of foreign body		1					1
Sudden death		3					3
Swelling	3	5	1	2	2		3
Swelling face	1	4	1	1			3
Terminal state	1	1			1		1
Therapeutic response unexpected		4		4			
Thirst	1	1	1	1			
Vaccination site bruising	1	1	1	1			
Vaccination site discomfort	2	5	2	5			
Vaccination site erythema	1	5		3	1		2
Vaccination site haemorrhage		1		1			
Vaccination site hyperaesthesia		1		1			
Vaccination site hypoaesthesia	1	4		3	1		1
Vaccination site induration		1		1			
Vaccination site inflammation		1		1			
Vaccination site irritation		1					1
Vaccination site lymphadenopathy		1					1
Vaccination site movement impairment		1		1			
Vaccination site oedema		8		7			1
Vaccination site pain	9	100	7	87	2		13
Vaccination site pruritus		2		1			1
Vaccination site rash	1	3	1	3			
Vaccination site reaction		1		1			
Vaccination site swelling		1		1			
Vaccination site warmth	1	3		2	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	135	770	80	447	55	323

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholelithiasis		1		1
Hepatitis		1		1
		2		2

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		4		1		3
Anaphylactic reaction	4	15			4	15
Anaphylactic shock	1	7			1	7
Anaphylactoid reaction		2				2
Hypersensitivity	3	36		15	3	21
Reaction to excipient		1				1
Sarcoidosis	1	1			1	1
	9	66		16	9	50

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	3	5			3	5
Conjunctivitis		1		1		
COVID-19	5	35		10	5	25
Diverticulitis	1	1			1	1
Gastroenteritis		1				1
Genital herpes zoster		1				1
Herpes dermatitis		1				1
Herpes ophthalmic	1	2			1	2
Herpes simplex reactivation	1	1	1	1		
Herpes zoster	2	17	1	9	1	8
Hordeolum	1	1	1	1		
Infection	1	1	1	1		
Lower respiratory tract infection	1	1			1	1
Meningomyelitis herpes		1				1
Myelitis	1	2			1	2
Nasopharyngitis		1		1		
Oral herpes	1	4	1	3		1
Parotitis		1		1		
Pharyngitis		1		1		
Pneumonia		1				1
Respiratory tract infection	1	3			1	3
Rhinitis	1	1	1	1		
Sputum purulent		1				1
Suspected COVID-19		2		1		1
Tonsillitis	1	1	1	1		
Urinary tract infection	1	3		1	1	2
Viral infection		2		2		
	22	92	7	35	15	57

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriovenous graft thrombosis	1	1			1	1
Back injury	1	1			1	1
Circumstance or information capable of leading to medication error		2		2		
Contusion	1	1			1	1
Expired product administered		1		1		
Exposure via breast milk		1		1		
Fall	1	6		2	1	4
Femur fracture	1	1			1	1
Incomplete course of vaccination		1		1		
Incorrect route of product administration	1	4	1	4		
Injury		1		1		
Limb injury		1		1		
Maternal exposure during pregnancy	3	4	3	4		
Mouth injury	1	1	1	1		
Muscle injury		1		1		
Occupational exposure to product	1	1	1	1		
Off label use	1	5	1	5		
Overdose		1		1		
Poor quality product administered		5		5		
Product preparation error		1		1		
Product use issue	1	4	1	4		
Vaccination failure	1	4			1	4
Wrong technique in product usage process		2		2		
	14	50	8	38	6	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		2		2		
Aspartate aminotransferase increased		1		1		
Audiogram abnormal	1	1	1	1		
Auscultation		1		1		
Blood calcium decreased		1		1		
Blood creatine phosphokinase increased		1		1		
Blood gases abnormal	1	1			1	1
Blood glucose abnormal		3		2		1
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood potassium decreased		1		1		
Blood pressure abnormal	1	2			1	2
Blood pressure decreased	1	7		3	1	4
Blood pressure diastolic increased		2		2		
Blood pressure increased	16	55	3	26	13	29
Blood pressure systolic		1				1
Blood pressure systolic abnormal	1	1			1	1
Blood pressure systolic increased	2	5		1	2	4
Blood triglycerides increased	1	1			1	1
Blood urea increased		1		1		
Body temperature increased		1		1		
Carbohydrate antigen 125 increased		1		1		
Carcinoembryonic antigen increased		1				1
C-reactive protein increased		2		2		
CSF polymorphonuclear cell count increased	1	1			1	1
Ear, nose and throat examination abnormal	1	1	1	1		
Electrocardiogram repolarisation abnormality	1	1			1	1
Electromyogram abnormal	1	1	1	1		
Fibrin D dimer increased		2		1		1
Gamma-glutamyltransferase increased		1				1
Glycosylated haemoglobin decreased		1		1		
Haematocrit decreased	2	2	1	1	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased		1		1		
Heart rate abnormal	1	1		1	1	1
Heart rate decreased	3	5			3	5
Heart rate increased	3	24	2	16	1	8
Heart rate irregular		1				1
Immunoglobulins increased	1	1			1	1
Oxygen saturation abnormal	1	1			1	1
Oxygen saturation decreased	4	8		1	4	7
Platelet count increased		1		1		
Protein total decreased		1		1		
Prothrombin time prolonged		1		1		
Pulse abnormal	1	2		1	1	1
Pulse absent		1				1
SARS-CoV-2 antibody test positive	1	2	1	2		
SARS-CoV-2 test positive		1		1		
White blood cell count decreased		1		1		
	45	156	10	80	35	76

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia		4				4
Decreased appetite	1	4		3	1	1
Dehydration	1	1			1	1
Diabetes mellitus inadequate control	2	4			2	4
Eating disorder symptom	1	1	1	1		
Feeding disorder	1	1	1	1		
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	4		3	1	1
Hypokalaemia	2	2			2	2
Hyponatraemia	2	3		1	2	2
Insulin resistance		1				1
Polydipsia		1		1		
	11	27	2	11	9	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ankylosing spondylitis	1	1			1	1
Arthralgia	9	68	6	32	3	36
Arthritis		1		1		
Arthritis enteropathic		1				1
Back pain	4	10	3	8	1	2
Bone pain	1	4		1	1	3
Bursitis	1	2		1	1	1
Fibromyalgia		1		1		
Foot deformity	1	1			1	1
Intervertebral disc degeneration	1	1	1	1		
Intervertebral disc protrusion	1	1	1	1		
Joint effusion	1	1			1	1
Joint range of motion decreased		1		1		
Joint stiffness		1				1
Joint swelling		1		1		
Limb discomfort		3		1		2
Muscle discomfort		1				1
Muscle fatigue		1		1		
Muscle spasms	1	5		1	1	4
Muscle tightness	1	2		1	1	1
Muscular weakness	4	11		3	4	8
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness	2	3	2	2		1
Myalgia	13	116	9	71	4	45
Neck pain	3	6	2	4	1	2
Pain in extremity	13	40	11	34	2	6
Pain in jaw		2		1		1
Polyarthritis	1	1			1	1
Psoriatic arthropathy		1				1
Rheumatoid arthritis		2				2
Sjogren's syndrome	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Soft tissue swelling		2		1		1
Spinal pain	2	4			2	4
Temporomandibular joint syndrome	1	2	1	2		
Trismus		1		1		
	63	301	37	173	26	128

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Leukaemia	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1				1
Anosmia		2		1		1
Aphasia	1	1			1	1
Autonomic nervous system imbalance	1	1	1	1		
Balance disorder		2		1		1
Burning sensation	8	31	6	22	2	9
Burning sensation mucosal		1				1
Carotid artery occlusion		1				1
Cerebral haemorrhage		1				1
Cerebral ischaemia	1	1			1	1
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	2	4			2	4
Cervical radiculopathy		1				1
Cholinergic syndrome	1	4			1	4
Clonus	1	1			1	1
Coma	1	1			1	1
Complex regional pain syndrome	2	5		1	2	4
Diplegia	1	3			1	3
Disturbance in attention		1				1
Dizziness	14	85	7	52	7	33
Dysarthria	1	3			1	3
Dysgeusia	1	15		8	1	7
Dyskinesia		5		4		1
Dysstasia	2	4		1	2	3
Epilepsy	1	1			1	1
Facial paralysis	3	6			3	6
Facial paresis	9	12	3	3	6	9
Fine motor skill dysfunction		1				1
Guillain-Barre syndrome	3	6			3	6
Headache	19	136	14	86	5	50
Head discomfort	1	4		3	1	1
Hemiparesis	1	3			1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	19	85	8	45	11	40
Hyporeflexia	1	1			1	1
Hypotonia	1	6		3	1	3
Intercostal neuralgia	1	1	1	1		
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke		1				1
Lethargy	1	5		3	1	2
Loss of consciousness	3	9			3	9
Memory impairment	1	2			1	2
Meningism		1		1		
Migraine	1	8	1	6		2
Monoparesis	1	1			1	1
Movement disorder	1	1	1	1		
Neuralgia		1				1
Neuritis		1				1
Neuropathy peripheral	1	2			1	2
Nystagmus		1		1		
Paraesthesia	2	4		2	2	2
Paralysis		2				2
Paraparesis	1	1			1	1
Paresis	1	1			1	1
Parosmia	1	1			1	1
Petit mal epilepsy		1				1
Polyneuropathy	2	3			2	3
Poor quality sleep		1		1		
Post herpetic neuralgia		1				1
Presyncope	2	13	1	5	1	8
Reflexes abnormal	1	1			1	1
Sciatica		1				1
Seizure		1				1
Sensory loss	1	1			1	1
Somnolence	2	21	2	15		6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	3	6	1	3	2	3
Syncope	1	13			1	13
Taste disorder	1	3			1	3
Transient ischaemic attack		1				1
Tremor	4	18	3	12	1	6
Trigeminal neuralgia		1				1
	129	566	49	282	80	284

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue		4		4
Product quality issue		1		1
Product temperature excursion issue		1		1
		6		6

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression		1				1
Agitation		1				1
Anxiety	1	2	1	2		
Body dysmorphic disorder		1				1
Communication disorder	1	1	1	1		
Confusional state	2	10		2	2	8
Depression		1		1		
Disorientation	1	2	1	1		1
Dysphoria	2	4			2	4
Eating disorder	2	2	1	1	1	1
Insomnia	2	6	1	4	1	2
Irritability		1		1		
Middle insomnia		1		1		
Nervousness		1				1
Panic reaction		1				1
Restlessness		1		1		
Stress		1		1		
Tension		2		2		
	11	39	5	18	6	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematuria		1				1
Pollakiuria		1		1		
Polyuria		1		1		
Renal failure	1	1			1	1
Renal impairment	1	1			1	1
Urinary incontinence	1	2	1	1		1
	3	7	1	3	2	4

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1		1		
Cervix erythema		1				1
Menorrhagia		1				1
Menstruation delayed		1		1		
Menstruation irregular		2		1		1
Metrorrhagia	1	2	1	2		
Polymenorrhoea		2		2		
	1	10	1	7		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Aspiration	1	1			1	1
Asthmatic crisis		1				1
Bronchial hyperreactivity	1	1			1	1
Bronchospasm		10				10
Catarrh		1		1		
Choking sensation	1	1			1	1
Cough	3	30	2	13	1	17
Dry throat	2	12	1	3	1	9
Dysphonia	3	16	2	4	1	12
Dyspnoea	11	46	1	14	10	32
Epistaxis	1	1	1	1		
Haemoptysis	2	3		1	2	2
Laryngeal oedema		6				6
Laryngeal pain		1				1
Laryngospasm	1	5			1	5
Nasal congestion	1	2	1	2		
Nasal pruritus		1		1		
Oropharyngeal discomfort		2		2		
Oropharyngeal pain	3	13	1	7	2	6
Pharyngeal oedema		1		1		
Pulmonary embolism	1	2			1	2
Pulmonary mass	1	1			1	1
Pulmonary oedema		1				1
Pulmonary thrombosis		2				2
Respiratory failure	1	1			1	1
Rhinitis allergic		1		1		
Rhinorrhoea	1	2		1	1	1
Sputum increased	1	1			1	1
Tachypnoea		2		2		
Throat irritation	3	12	1	8	2	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Throat tightness		1					
Tonsillar hypertrophy		1					1
Wheezing		1		1			
	38	184	10	63	28		121

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	1	1	1		
Alopecia		1		1		
Angioedema	3	15			3	15
Blister		4		4		
Circumoral oedema		1				1
Cold sweat	1	1			1	1
Dermatitis allergic		3				3
Dermatomyositis	1	1			1	1
Eczema		1		1		
Erythema	8	65	4	43	4	22
Granuloma annulare	1	1	1	1		
Hyperhidrosis	6	26	2	12	4	14
Hypersensitivity vasculitis	1	1			1	1
Lichenoid keratosis	1	1	1	1		
Livedo reticularis		1		1		
Mechanical urticaria		1		1		
Nail discolouration		2		2		
Onycholysis		1		1		
Petechiae	1	2		1	1	1
Pruritus	9	64	3	35	6	29
Pruritus allergic		1				1
Psoriasis		1		1		
Purpura	1	1			1	1
Rash	11	73	5	31	6	42
Rash erythematous		2		2		
Rash macular	1	2	1	2		
Rash maculo-papular	1	4		1	1	3
Rash papular	1	1			1	1
Rash pruritic	2	12	2	8		4
Skin burning sensation	1	3		2	1	1
Skin irritation		1		1		
Skin lesion		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin reaction		1				1
Urticaria	1	6	1	4		2
	52	302	21	157	31	145

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability		1				1
Loss of personal independence in daily activities		1		1		
Walking disability	1	1			1	1
Water pollution	1	1			1	1
	2	4		1	2	3

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system stimulation		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		1				1
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Capillary disorder		1		1		
Cyanosis		3		2		1
Deep vein thrombosis	3	4			3	4
Diastolic hypertension		1				1
Flushing	3	30		13	3	17
Haematoma		1				1
Hot flush	1	2			1	2
Hypertension	4	36		16	4	20
Hypertensive crisis		15				15
Hypertensive emergency		1				1
Hypotension	1	20		6	1	14
Lymphoedema		1				1
Orthostatic hypotension		2		1		1
Pallor	1	3		2	1	1
Peripheral coldness	2	8	1	1	1	7
Peripheral venous disease	1	1			1	1
Raynaud's phenomenon	1	1			1	1
Shock		1				1
Thrombosis	2	3			2	3
Vascular pain	1	1			1	1
Vasculitis	1	1			1	1
Vasoconstriction	1	1			1	1
Venous thrombosis limb	1	1			1	1
	23	141	1	44	22	97

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**GUINEA**

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headache	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertension	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**HOLY SEE (VATICAN CITY STATE)**

*System Organ Class*

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Periorbital oedema		1		1
		1		1

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Extensive swelling of vaccinated limb		1		1
Injected limb mobility decreased		1		1
Oedema peripheral		2		2
Vaccination site pain		1		1
		6		6

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Pain in extremity		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**HONG KONG**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	2	2	2	2
	2	2	2	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronary artery disease	1	2			1	2
Myocardial ischaemia		1				1
Palpitations	10	12	2	2	8	10
	11	15	2	2	9	13

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2			2	2
Nausea	3	3	1	1	2	2
Vomiting	2	2	1	1	1	1
	7	7	2	2	5	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	3	1	2	1	1
Chest discomfort	6	7	3	4	3	3
Chest pain	5	6			5	6
Fatigue	1	2	1	2		
Injection site pain	1	1	1	1		
Malaise		1		1		
Pyrexia	2	2	1	1	1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	3	2	2	1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
	23	28	12	16	11	12

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2	1	1	1	1
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	1			1	1
Drug hypersensitivity	1	1	1	1		
Hypersensitivity	2	3	1	1	1	2
	6	8	3	3	3	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Contusion	1	1	1	1
Fall	2	2	2	2
Injury	1	1	1	1
Lip injury	1	1	1	1
	5	5	5	5

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	4	5	2	3	2	2
	4	5	2	3	2	2

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Back pain	1	1			1	1
Muscle twitching	1	1	1	1		
Muscular weakness	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
	6	6	4	4	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1	1	1		
Burning sensation	1	1	1	1		
Cerebrovascular accident		1				1
Dizziness	21	23	8	8	13	15
Facial paralysis	3	3			3	3
Headache	4	4	2	2	2	2
Hypoaesthesia	10	11	3	3	7	8
Ischaemic stroke	1	1			1	1
Loss of consciousness	11	11			11	11
Migraine	1	1	1	1		
Movement disorder	1	1	1	1		
Neuralgia		1		1		
Paraesthesia	1	1	1	1		
Paralysis	1	1			1	1
Paresis		1				1
Presyncope	1	1			1	1
Seizure	6	6			6	6
Syncope	7	8			7	8
Tremor	1	1	1	1		
	71	78	19	20	52	58

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	2	5	1	2	1	3
Hyperventilation	2	2			2	2
Pharyngeal swelling	1	1	1	1		
	5	8	2	3	3	5

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	2	2	2	2		
Pruritus	1	1	1	1		
Rash	12	14	7	7	5	7
Urticaria	1	1			1	1
	16	18	10	10	6	8

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Essential hypertension	1	1			1	1
Hypertension	13	13	2	2	11	11
	14	14	2	2	12	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**HUNGARY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	2	2	1	1	1	1
Lymphadenitis		3		3		
Lymphadenopathy	4	38	2	31	2	7
Lymph node pain		10		9		1
Monocytosis	1	1			1	1
Thrombocytopenia	1	1			1	1
	8	55	3	44	5	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Angina pectoris	3	5			3	5
Arrhythmia		1				1
Atrial fibrillation	2	4			2	4
Bezold-Jarisch reflex		1		1		
Bradycardia		1				1
Cardiac disorder	2	2			2	2
Cardiac failure	1	5			1	5
Cardiomegaly	2	2	1	1	1	1
Cardiopulmonary failure	1	1			1	1
Extrasystoles		1				1
Left ventricular failure		1				1
Palpitations	2	8	1	6	1	2
Pericarditis	1	1			1	1
Pulseless electrical activity		1				1
Tachycardia		8		4		4
Tricuspid valve incompetence	1	1			1	1
	15	44	2	12	13	32

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear discomfort	2	4	1	3	1	1
Ear pain		3		3		
Ear pruritus		3		3		
Ear swelling	1	1			1	1
Tinnitus	1	4	1	4		
	4	15	2	13	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune thyroiditis	1	1			1	1
Thyroiditis subacute		1		1		
	1	2		1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia	1	1	1	1		
Blepharospasm	1	1	1	1		
Blindness		1				1
Dry eye		2		2		
Eye haemorrhage		2				2
Eye inflammation	1	2		1	1	1
Eye irritation		1		1		
Eyelid oedema	1	1	1	1		
Eye oedema		2				2
Eye pain	1	2	1	2		
Lacrimation increased		3		3		
Macular oedema		1				1
Periorbital disorder	1	1			1	1
Photopsia		1		1		
Swelling of eyelid	1	2	1	2		
Uveitis		1				1
Vision blurred		2		2		
Visual impairment		2		1		1
	7	28	5	18	2	10

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		3		
Abdominal distension		3		3		
Abdominal pain		7		7		
Abdominal pain upper		1		1		
Anal incontinence		1				1
Aphthous ulcer		1		1		
Constipation		1		1		
Defaecation urgency		1		1		
Diarrhoea	4	24	2	22	2	2
Diarrhoea haemorrhagic		1				1
Dry mouth	1	3	1	2		1
Dysphagia	2	12	1	3	1	9
Enteritis	1	1			1	1
Functional gastrointestinal disorder		1		1		
Gastritis erosive	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Gingival pain		1		1		
Glossitis		1		1		
Glossodynia		1		1		
Haematochezia		1				1
Hypoaesthesia oral	4	8	3	6	1	2
Lip oedema		1				1
Lip swelling	1	3	1	1		2
Megacolon		1				1
Melaena	1	1			1	1
Mouth swelling		1				1
Nausea	9	44	9	40		4
Noninfective gingivitis		1		1		
Odynophagia		1		1		
Retching		2		2		
Swollen tongue	1	1	1	1		
Toothache	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tooth disorder		1				1
Vomiting	2	15	2	12		3
	29	147	21	113	8	34

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	9	68	5	52	4	16
Axillary pain	1	4	1	4		
Chest discomfort	2	6	1	5	1	1
Chest pain	3	13	1	11	2	2
Chills	13	59	13	58		1
Condition aggravated	3	7	1	2	2	5
Death	2	6			2	6
Discomfort	1	1	1	1		
Disease recurrence	1	1			1	1
Drug ineffective	13	27			13	27
Drug interaction	1	1	1	1		
Face oedema	1	3	1	1		2
Facial pain		1		1		
Fatigue	9	44	9	43		1
Feeling abnormal	1	11	1	9		2
Feeling cold		2		2		
Feeling hot	1	8		6	1	2
Feeling of body temperature change		1		1		
Foaming at mouth		1				1
Gait disturbance		3		3		
General physical health deterioration	1	1	1	1		
Illness	1	3	1	3		
Induration		1		1		
Inflammation	1	1	1	1		
Influenza like illness	1	4	1	4		
Injection site discolouration		1		1		
Injection site erythema		1		1		
Injection site pain		1		1		
Injection site swelling		1		1		
Injection site urticaria	1	1	1	1		
Localised oedema		1		1		
Local reaction		2		2		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	9	47	9	44		3
Mucosal inflammation	1	1			1	1
Oedema peripheral		3		1		2
Pain	2	8	2	8		
Peripheral swelling	3	9	1	7	2	2
Potentiating drug interaction	1	1	1	1		
Pyrexia	20	103	17	94	3	9
Sensation of foreign body		5				5
Swelling	1	4	1	4		
Swelling face		2		2		
Therapeutic response unexpected		1		1		
Thirst		2		1		1
Vaccination site coldness		1		1		
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site erythema	8	30	8	30		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site induration	1	2	1	2		
Vaccination site inflammation		1		1		
Vaccination site macule	1	1	1	1		
Vaccination site mass		1		1		
Vaccination site movement impairment	2	6	2	6		
Vaccination site nodule	1	4	1	4		
Vaccination site oedema		2		2		
Vaccination site pain	11	63	11	62		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		4		4		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	6	21	6	21		
Vaccination site warmth		5		5		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	135	619	103	528	32	91

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Biliary tract disorder		1		1
Cholecystitis	1	1	1	1
	1	2	1	2

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1				1
Anaphylactic reaction		3				3
Anaphylactic shock		1				1
Drug hypersensitivity		2		2		
Hypersensitivity	3	11	1	8	2	3
Type IV hypersensitivity reaction		1				1
	3	19	1	10	2	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis	2	2	1	1	1	1
Cellulitis	1	1			1	1
COVID-19	15	34	1	5	14	29
COVID-19 pneumonia		1				1
Erysipelas	1	1			1	1
Herpes virus infection		1		1		
Herpes zoster		11		11		
Influenza		1		1		
Nasopharyngitis		2		2		
Oral herpes		2		2		
Pharyngitis		1		1		
Pneumonia	3	4			3	4
Pulpitis dental		1		1		
Sinusitis		1		1		
Suspected COVID-19		1				1
Upper respiratory tract infection		1		1		
	22	65	2	27	20	38

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event following immunisation		1		1		
Cartilage injury		1				1
Craniofacial fracture		1				1
Exposure during pregnancy		1		1		
Exposure via breast milk		5		5		
Fall	1	5		1	1	4
Femoral neck fracture		1				1
Heat stroke		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect product formulation administered	1	1	1	1		
Incorrect route of product administration	1	2	1	2		
Lower limb fracture		1				1
Maternal exposure during breast feeding		1		1		
Maternal exposure during pregnancy		2		1		1
Muscle strain		2		2		
Off label use	1	3	1	3		
Overdose	1	1	1	1		
Poor quality product administered	1	1	1	1		
Product administered at inappropriate site		1		1		
Product use issue		3		3		
Vaccination failure	2	4			2	4
Wound	2	3	2	3		
	11	42	8	29	3	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Investigations

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

		Spontaneous			
		Nonserious		Serious	
		I	C	I	C
Alanine aminotransferase increased	1	1	1		
Antibody test negative			1		
Antibody test normal	1	1	1		
Aspartate aminotransferase increased	1	1	1		
Blood glucose decreased	1	1	1		
Blood glucose increased			3		1
Blood pressure decreased	1	3	2	1	1
Blood pressure increased	5	24	14	4	10
Blood pressure systolic increased		1			1
Blood thyroid stimulating hormone decreased			1		
Blood urine present	1	1		1	1
Body temperature increased			2		
C-reactive protein increased	1	1	1		
Fibrin D dimer increased	1	1		1	1
Full blood count abnormal	1	1		1	1
Gamma-glutamyltransferase increased	1	1	1		
Glomerular filtration rate decreased	1	1	1		
Heart rate decreased		1	1		
Heart rate increased	2	10	8		2
Heart rate irregular	1	1	1		
Hepatic enzyme increased	1	1	1		
Iodine uptake decreased		1	1		
Lymphocyte count decreased		1	1		
Monocyte count increased		1	1		
Oxygen consumption increased		1	1		
Oxygen saturation decreased		2	1		1
Pulmonary arterial pressure increased	1	1		1	1
Red blood cell sedimentation rate increased	1	2	2		
SARS-CoV-2 antibody test negative		1	1		
SARS-CoV-2 antibody test positive		2	2		
SARS-CoV-2 test positive	3	9	3	3	6
Serum ferritin increased		1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroxine free increased		1		1		
Tri-iodothyronine free increased		1		1		
Weight decreased	1	1			1	1
	26	84	13	57	13	27

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	3	8	3	7		1
Dehydration	1	1			1	1
Feeding disorder		2				2
Hypoglycaemia		1		1		
Metabolic acidosis		1				1
	4	13	3	8	1	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	20	3	16	2	4
Arthritis reactive		1				1
Axillary mass		1		1		
Back pain	2	10	2	10		
Bone pain	1	2	1	2		
Bursitis		1		1		
Intervertebral disc protrusion		1		1		
Joint range of motion decreased		1		1		
Limb discomfort		1		1		
Mastication disorder	1	1	1	1		
Mobility decreased		1		1		
Muscle fatigue		1		1		
Muscle spasms	1	1	1	1		
Muscle tightness		1		1		
Muscle twitching	1	1			1	1
Muscular weakness	1	7	1	7		
Musculoskeletal chest pain		2		2		
Musculoskeletal stiffness		3		2		1
Myalgia	9	47	9	46		1
Neck pain	1	3	1	3		
Pain in extremity	9	60	9	58		2
Periarthritis		1		1		
Polyarthritis		2				2
Spinal osteoarthritis		1		1		
	31	170	28	158	3	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

*System Organ Class*

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Neoplasm progression		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		2		2		
Anosmia		4		4		
Ataxia		1		1		
Burning sensation	2	9	1	8	1	1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	1	2			1	2
Cervical neuritis		1		1		
Coordination abnormal	1	1	1	1		
Dementia	1	1			1	1
Disturbance in attention	2	2	1	1	1	1
Dizziness	8	45	6	39	2	6
Dysgeusia	1	7	1	6		1
Facial paralysis		3				3
Facial paresis		3		2		1
Guillain-Barre syndrome		1				1
Headache	18	95	17	88	1	7
Head discomfort	1	1	1	1		
Hemiparesis		1				1
Hyperaesthesia		3		3		
Hypoaesthesia	7	22	6	19	1	3
Hypokinesia		1				1
Hyporeflexia		2		2		
Hypotonia	1	1			1	1
Ischaemic stroke		1				1
Lethargy	1	5		4	1	1
Lhermitte's sign		1		1		
Loss of consciousness	1	5			1	5
Memory impairment	1	2		1	1	1
Migraine		5		4		1
Monoplegia		2				2
Myelopathy		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia	1	3	1	2		1
Paraesthesia		4		2		2
Paralysis		1				1
Peripheral nerve paresis		1				1
Polyneuropathy		1				1
Poor quality sleep		1		1		
Radiculopathy		1		1		
Sciatica		1				1
Sensory loss		1		1		
Somnolence	4	11	2	8	2	3
Speech disorder	1	1	1	1		
Syncope	3	7			3	7
Taste disorder		1		1		
Tension headache	1	1	1	1		
Thrombotic stroke		1				1
Transient ischaemic attack		1				1
Tremor	2	10	1	7	1	3
White matter lesion		1		1		
	58	280	40	214	18	66

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion	1	1	1	1
Abortion missed	1	2	1	2
	2	3	2	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue	1	1	1	1
Product complaint	1	1	1	1
	2	2	2	2

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	1			1	1
Anxiety		1		1		
Bradyphrenia		1		1		
Confusional state	2	4	1	2	1	2
Depressed mood		1		1		
Depression		1		1		
Dysphemia	1	1			1	1
Fear of death		1		1		
Feeling of despair		1		1		
Insomnia	2	8	2	8		
Irritability		1		1		
Listless		1				1
Mood altered		2		2		
Panic attack		1		1		
Psychiatric symptom	1	2			1	2
Restlessness		1		1		
Sleep disorder	1	2	1	2		
Stress		2		2		
Tension	1	2	1	2		
	9	34	5	27	4	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anuria	1	1			1	1
Chromaturia		2		2		
Dysuria		1		1		
Haematuria	1	2	1	1		1
Micturition urgency		2		2		
Pollakiuria	1	1			1	1
Renal impairment	1	1			1	1
Renal pain		2		2		
Urinary incontinence	1	1	1	1		
Urinary tract pain		1		1		
	5	14	2	10	3	4

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Breast mass	1	1			1	1
Lactation disorder	1	1	1	1		
Menstruation delayed		1		1		
Menstruation irregular		1		1		
Nipple pain		1		1		
Vaginal discharge		1		1		
	2	7	1	6	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	2			1	2
Asphyxia	1	4			1	4
Choking	1	1			1	1
Chronic obstructive pulmonary disease		1		1		
Cough	6	12	4	10	2	2
Dysphonia	2	4		1	2	3
Dyspnoea	3	19	2	10	1	9
Dyspnoea exertional	1	1			1	1
Emphysema		1				1
Epistaxis		1		1		
Haemoptysis	1	1			1	1
Laryngeal oedema		1				1
Nasal congestion		2		2		
Oropharyngeal pain	5	13	2	10	3	3
Painful respiration		1		1		
Paranasal sinus discomfort		1		1		
Pharyngeal oedema		2		2		
Pharyngeal swelling	2	3	1	2	1	1
Productive cough	1	3	1	3		
Pulmonary embolism	1	1			1	1
Respiratory disorder	1	1	1	1		
Respiratory distress		2		1		1
Respiratory failure	1	1			1	1
Rhinorrhoea	1	9	1	9		
Stridor		1				1
Tachypnoea		1				1
Throat irritation		2		2		
Throat tightness		2				2
Wheezing	1	1			1	1
	29	94	12	57	17	37

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia		1		1		
Angioedema		2				2
Blister		2		2		
Capillaritis		1		1		
Cold sweat		2		2		
Cutaneous symptom		1				1
Decubitus ulcer		1				1
Dermal cyst		1		1		
Dermatitis allergic		1		1		
Dermatitis herpetiformis		1		1		
Eczema		1		1		
Erythema	2	15	2	14		1
Erythema multiforme		1				1
Hyperhidrosis	1	9	1	8		1
Night sweats		1		1		
Oedema blister	1	1			1	1
Pain of skin	1	5	1	5		
Petechiae	1	2		1	1	1
Pityriasis rosea		1		1		
Pruritus	1	14	1	13		1
Rash	1	11	1	8		3
Rash erythematous	2	8	1	7	1	1
Rash macular	1	2	1	2		
Rash maculo-papular		3		2		1
Rash pruritic	2	7	1	6	1	1
Rash vesicular		1		1		
Sensitive skin		3		3		
Skin burning sensation		5		4		1
Skin discolouration	2	2	1	1	1	1
Skin disorder		1		1		
Skin haemorrhage	1	1			1	1
Skin hypertrophy		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion		1		1		
Skin sensitisation	1	1	1	1		
Skin ulcer	1	1			1	1
Skin warm		1		1		
Urticaria	2	10	1	8	1	2
	20	122	12	100	8	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		1				1
Blood pressure fluctuation	1	4	1	2		2
Circulatory collapse	1	3			1	3
Cyanosis		1				1
Deep vein thrombosis	1	2			1	2
Flushing		5		4		1
Haematoma	2	4		1	2	3
Haemorrhage		2				2
Hot flush	3	4	2	3	1	1
Hyperaemia		1		1		
Hypertension	1	3	1	2		1
Hypertensive crisis		1				1
Hypotension		7		2		5
Lymphoedema		1		1		
Pallor	1	5	1	4		1
Peripheral coldness		2		2		
Peripheral venous disease	1	1			1	1
Thrombophlebitis	2	2	1	1	1	1
Thrombophlebitis superficial	1	1			1	1
Varicose vein		2		2		
Vasculitis		1		1		
Vasoconstriction	1	1			1	1
White coat hypertension		1		1		
	15	55	6	27	9	28

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ICELAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	5	1	5
	1	5	1	5

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Atrial fibrillation		1				1
Bradycardia		1				1
Cardiac failure		2				2
Myocardial infarction		1				1
Tachycardia		2		1		1
Ventricular tachycardia	1	1			1	1
	2	10		1	2	9

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anencephaly	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain		1		1
		1		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular discomfort		1		1
Periorbital swelling		1		1
Visual impairment	1	1	1	1
	1	3	1	3

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anal incontinence		1		1
Dry mouth		1		1
Gastrointestinal pain		1		1
Nausea	3	12	3	12
Noninfective sialoadenitis		1		1
Salivary gland enlargement		1		1
Vomiting		2		2
	3	19	3	19

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		7		7		
Axillary pain		3		3		
Chest discomfort		2		2		
Chest pain		3		2		1
Chills	1	13	1	13		
Death		6				6
Discomfort	1	2	1	2		
Disease progression		1				1
Disease recurrence		1		1		
Fatigue	1	17		16	1	1
Feeling abnormal	1	3	1	3		
Feeling cold		2		2		
Feeling hot		1		1		
Influenza like illness	1	1	1	1		
Injection site pain		1		1		
Malaise	1	26	1	21		5
Oedema peripheral		1		1		
Pain		2		2		
Peripheral swelling	1	1			1	1
Pyrexia	2	43	2	39		4
Sluggishness		1		1		
Sudden death		2				2
Swelling		1		1		
Thirst		1		1		
Vaccination site erythema		6		6		
Vaccination site inflammation		3		3		
Vaccination site pain	2	21	2	21		
Vaccination site reaction		1		1		
Vaccination site swelling	1	3	1	3		
Vaccination site warmth		2		2		
	12	177	10	156	2	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasopharyngitis		5		5		
Pneumonia		4				4
Sepsis		1				1
		10		5		5

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion		1				1
Fall	1	1	1	1		
Maternal exposure during pregnancy	2	2	2	2		
Off label use		4		4		
Product use in unapproved indication		2		2		
Product use issue		3		3		
	3	13	3	12		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Blood pressure increased		1		1		
Breath sounds abnormal		1				1
Fibrin D dimer increased	1	1			1	1
Heart rate increased		2		2		
Hepatic enzyme increased		2		1		1
Oxygen saturation decreased		2				2
	1	10		4	1	6

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		4		4		
Fluid overload		1				1
		5		4		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		5		5		
Arthritis		1		1		
Back pain	1	3	1	3		
Bone pain		2		2		
Joint stiffness		1		1		
Joint swelling		2		2		
Limb discomfort		1		1		
Muscle twitching		2		2		
Muscular weakness	1	1	1	1		
Myalgia	1	26	1	26		
Pain in extremity	3	8	1	6	2	2
	6	52	4	50	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		2		1		1
Balance disorder	1	1			1	1
Cerebrovascular accident		1				1
Depressed level of consciousness		1				1
Dizziness	1	10	1	10		
Dysgeusia		1		1		
Headache	2	36	2	36		
Head discomfort		1		1		
Hypersomnia		1		1		
Hypoaesthesia		5		5		
Loss of consciousness	1	3			1	3
Memory impairment	1	1	1	1		
Migraine		1		1		
Motor dysfunction	1	1			1	1
Poor quality sleep		1		1		
Sensory loss		1		1		
Syncope	2	2			2	2
Transient ischaemic attack	1	2			1	2
Tremor		1		1		
	10	72	4	60	6	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	1	1			1	1
Delirium	2	3			2	3
Insomnia	1	2	1	2		
Personality change		1				1
Sleep disorder	1	1			1	1
	5	8	1	2	4	6

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary incontinence		1		1		
Urine flow decreased		1				1
		2		1		1

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Breast inflammation		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Chronic obstructive pulmonary disease		1				1
Cough		5		4		1
Dry throat		1		1		
Dyspnoea		6		4		2
Hypercapnia		1				1
Hypoxia		2				2
Lung infiltration		1				1
Oropharyngeal pain		6		6		
Painful respiration		1		1		
Pharyngeal swelling		1		1		
Pneumonia aspiration		1				1
Productive cough		1		1		
Pulmonary oedema		1				1
Pulmonary pain		1		1		
Respiration abnormal		1				1
Respiratory arrest		1				1
Respiratory failure		1				1
Rhinorrhoea		3		3		
		36		22		14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Erythema		5		5		
Hyperhidrosis		3		2		1
Pruritus		6		6		
Rash		4		4		
Sensitive skin		2		2		
Skin burning sensation		1		1		
Skin discolouration		1		1		
		23		22		1

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm		1				1
Deep vein thrombosis	1	1			1	1
Hot flush		1		1		
Hypertension		1		1		
Hypoperfusion		1				1
Pallor		2		2		
Peripheral artery thrombosis		1				1
Peripheral embolism	1	1			1	1
	2	9		4	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**INDIA**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vomiting	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenia	1	1	1	1
Drug ineffective	1	1	1	1
Fatigue	1	1	1	1
Pain	1	1	1	1
Vaccination site pain	1	1	1	1
	5	5	5	5

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect product administration duration	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Oxygen saturation decreased	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dizziness	1	1	1	1
Headache	1	1	1	1
Loss of consciousness	1	1	1	1
	3	3	3	3

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Suspected counterfeit product		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**IRAQ**

*System Organ Class*

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Nausea	1	1	1	1
	1	1	1	1

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Pyrexia	2	2	2	2
Vaccination site pain	2	2	2	2
	5	5	5	5

*System Organ Class*

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Insomnia	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**IRELAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Lymphadenopathy		23		2		21
Lymph node pain		7				7
Neutropenia		1				1
		32		2		30

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute cardiac event		1				1
Atrial fibrillation	1	1			1	1
Bradycardia		1				1
Cardiac arrest	3	3			3	3
Cardiac failure	1	1			1	1
Cardiac failure congestive		1				1
Coronary artery occlusion	1	1			1	1
Coronary artery thrombosis	1	1			1	1
Myocardial infarction		2				2
Myocardial ischaemia	1	1			1	1
Myocarditis	1	1			1	1
Palpitations	1	17	1	2		15
Supraventricular tachycardia	2	3			2	3
Tachycardia	1	21	1	1		20
	13	55	2	3	11	52

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	2			1	2
Ear discomfort		1				1
Ear pain		2				2
Tinnitus	2	4	2	2		2
Vertigo	1	4		2	1	2
	4	13	2	4	2	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm		1				1
Blindness		1				1
Blindness transient		1				1
Dark circles under eyes		1				1
Diplopia	2	3	1	1	1	2
Dry eye		2				2
Erythema of eyelid		1				1
Excessive eye blinking		1				1
Eye discharge		1				1
Eye irritation	1	2	1	1		1
Eyelids pruritus		1				1
Eye movement disorder		3				3
Eye pain		4				4
Eye pruritus		1				1
Eye swelling	2	3	1	1	1	2
Lacrimation decreased		1				1
Lacrimation increased		1				1
Mydriasis	1	1	1	1		
Periorbital discomfort	1	1	1	1		
Periorbital oedema		1		1		
Periorbital swelling		1				1
Photophobia		2				2
Photopsia	1	1			1	1
Pupils unequal	1	1	1	1		
Swelling of eyelid		2		1		1
Vision blurred		3		1		2
Visual impairment		4		1		3
Vitreous floaters		3				3
	9	48	6	10	3	38

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	4	2	2	1	2
Abdominal distension	1	3	1	1		2
Abdominal pain	1	6		1	1	5
Abdominal pain upper	1	5	1	1		4
Breath odour	1	1			1	1
Cheilitis		1				1
Constipation		1				1
Diarrhoea	3	21	1	4	2	17
Dry mouth		1				1
Dysphagia		2				2
Faeces discoloured		1				1
Faeces pale		1				1
Flatulence		2		1		1
Gastric disorder		1				1
Gastroesophageal reflux disease		1				1
Glossodynia		1		1		
Haematemesis		1				1
Haematochezia		1				1
Hypoesthesia oral	1	10	1	1		9
Irritable bowel syndrome		1				1
Lip discolouration		1				1
Lip dry		1				1
Lip swelling	2	11			2	11
Melaena		1				1
Nausea	16	96	8	22	8	74
Oral pruritus	1	1	1	1		
Pancreatitis relapsing		1				1
Paraesthesia oral	3	11	3	4		7
Retching	1	4			1	4
Salivary hypersecretion	1	2	1	2		
Swollen tongue		6				6
Tongue disorder		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue movement disturbance		1				1
Upper gastrointestinal haemorrhage		1				1
Vomiting	3	41	1	6	2	35
	38	244	20	47	18	197

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	8	53	5	12	3	41
Axillary pain		7		1		6
Chest discomfort	2	18	1	2	1	16
Chest pain	5	19	2	2	3	17
Chills	11	53	4	7	7	46
Condition aggravated		1				1
Death	4	9			4	9
Decreased activity		1				1
Discomfort	1	10		1	1	9
Disease recurrence		4				4
Drug ineffective		5				5
Extensive swelling of vaccinated limb		1		1		
Facial pain		3		2		1
Fatigue	22	103	14	33	8	70
Feeling abnormal	1	12	1	3		9
Feeling cold		10		2		8
Feeling drunk		2				2
Feeling hot	3	19		3	3	16
Feeling of body temperature change		3				3
Gait disturbance	1	4			1	4
Gait inability	1	3	1	1		2
General physical health deterioration	3	4			3	4
Hangover		1		1		
Hyperpyrexia		1				1
Illness		3		2		1
Inflammation		2				2
Influenza like illness	4	15	3	6	1	9
Injected limb mobility decreased	1	2	1	1		1
Injection site movement impairment		1				1
Injection site pain		2				2
Injury associated with device	1	2	1	2		
Loss of control of legs		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	9	46	3	10	6	36
Mass		1				1
No adverse event	1	3	1	3		
Pain	9	59	7	9	2	50
Peripheral swelling		7				7
Pyrexia	18	98	11	20	7	78
Sensation of foreign body		2				2
Sudden death	1	3			1	3
Swelling	1	7	1	1		6
Swelling face	1	8		1	1	7
Tenderness		2				2
Thirst		1				1
Vaccination site bruising		1				1
Vaccination site discharge		1		1		
Vaccination site discolouration		1				1
Vaccination site discomfort	2	2	1	1	1	1
Vaccination site erythema		9		2		7
Vaccination site inflammation		1		1		
Vaccination site irritation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site mass		3				3
Vaccination site pain	16	35	15	19	1	16
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus		5		1		4
Vaccination site swelling		5		1		4
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth		5		1		4
	127	684	73	155	54	529

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Jaundice		1		1
		1		1

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		2				2
Anaphylactic reaction		9				9
Anaphylactic shock		1				1
Hypersensitivity	1	7	1	1		6
Type III immune complex mediated reaction	1	1			1	1
Type IV hypersensitivity reaction		1				1
	2	21	1	1	1	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Cellulitis	1	4			1	4
Complicated appendicitis		1				1
Conjunctivitis	1	1	1	1		
COVID-19	5	12		1	5	11
Ear infection		1				1
Encephalitis		1				1
Furuncle		1				1
Herpes zoster		2				2
Herpes zoster reactivation		1				1
Hordeolum		1				1
Infection		1		1		
Influenza		1				1
Lower respiratory tract infection		1				1
Mastitis	1	2			1	2
Nasopharyngitis		1		1		
Oral herpes	3	4	2	2	1	2
Pneumonia		2				2
Pulmonary sepsis		1				1
Respiratory tract infection	2	3			2	3
Rhinitis	1	2			1	2
Sinusitis		1				1
Suspected COVID-19		2		1		1
Upper respiratory tract infection	1	1	1	1		
Urinary tract infection		1		1		
	15	49	4	9	11	40

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product	1	3	1	3		
Accidental overdose	1	1	1	1		
Chillblains	1	1			1	1
Circumstance or information capable of leading to medication error	1	1	1	1		
Contusion		1		1		
Expired product administered	1	1	1	1		
Exposure during pregnancy		2		2		
Exposure via breast milk	1	6	1	5		1
Exposure via skin contact	1	2	1	2		
Face injury		1				1
Fall	1	1			1	1
Inappropriate schedule of product administration	1	5	1	5		
Incorrect dose administered	1	1	1	1		
Injury		1				1
Maternal exposure during breast feeding		2		2		
Maternal exposure during pregnancy	3	8	2	6	1	2
Nerve injury		1				1
Off label use	1	10	1	10		
Poor quality product administered	12	12	12	12		
Product preparation error	1	1	1	1		
Product preparation issue		6		6		
Product use issue		5		5		
Road traffic accident		1				1
Skin laceration	1	1	1	1		
Underdose		10		10		
Vaccination error	1	1	1	1		
Vaccination failure	1	1			1	1
Wound		1		1		
Wrong technique in product usage process	11	11	11	11		
	41	98	37	88	4	10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1				1
Blood bilirubin increased		1				1
Blood glucose fluctuation		1				1
Blood lactic acid increased		1				1
Blood pH decreased	1	1			1	1
Blood pressure diastolic increased		1				1
Blood pressure increased	2	10			2	10
Blood pressure systolic increased		1		1		
Blood urine present		1				1
Body temperature decreased		1				1
Body temperature increased	1	2	1	1		1
Carbon dioxide increased	1	1			1	1
Corneal reflex decreased	1	1			1	1
C-reactive protein increased		2				2
Eosinophil count increased		1				1
General physical condition abnormal	1	1			1	1
Haemoglobin decreased		1				1
Heart rate decreased		1				1
Heart rate increased	3	11		1	3	10
Heart rate irregular	1	3			1	3
Liver function test increased		1				1
Oxygen saturation decreased	1	9			1	9
Platelet count decreased		1				1
Pulse abnormal		2				2
Quality of life decreased		1				1
Respiratory rate decreased	1	3			1	3
Respiratory rate increased		2				2
SARS-CoV-2 test positive		1				1
Tidal volume decreased	1	1			1	1
Troponin increased		1				1
Weight decreased		1				1
White blood cell count increased	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	15	67	2	4	13	63

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	3	11	1	1	2	10
Dehydration	1	2	1	1		1
Feeding disorder		1				1
Hypoglycaemia		2				2
Metabolic acidosis		1				1
	4	17	2	2	2	15

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	12	44	9	13	3	31
Axillary mass		1				1
Back pain	4	20	2	4	2	16
Bone pain	2	7		2	2	5
Flank pain		4				4
Joint range of motion decreased	1	1			1	1
Joint stiffness	1	5	1	1		4
Joint swelling		2				2
Limb discomfort	1	7		2	1	5
Mobility decreased		3				3
Muscle fatigue	1	1	1	1		
Muscle spasms		5		1		4
Muscle tightness		1				1
Muscle twitching	1	7	1	1		6
Muscular weakness		6				6
Musculoskeletal chest pain	1	2			1	2
Musculoskeletal discomfort		1				1
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	5	10	5	6		4
Myalgia	7	56	5	12	2	44
Myokymia		1				1
Neck mass		1				1
Neck pain	2	9	1	1	1	8
Pain in extremity	11	53	8	19	3	34
Pain in jaw		1		1		
Periarthritis		1				1
Weight bearing difficulty	1	1			1	1
	50	251	33	65	17	186

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Skin papilloma		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		4		1		3
Anosmia		2		1		1
Aphasia	1	2			1	2
Balance disorder		1		1		
Burning sensation		6		1		5
Cerebral infarction		1				1
Cerebrovascular accident	2	3			2	3
Cerebrovascular insufficiency	1	1			1	1
Cluster headache		1		1		
Depressed level of consciousness		2				2
Disturbance in attention		4		2		2
Dizziness	12	65	6	13	6	52
Dysarthria		4				4
Dysgeusia	2	6	2	2		4
Dyskinesia	1	1	1	1		
Dysstasia		2				2
Facial nerve disorder		1		1		
Facial paralysis	2	16			2	16
Facial paresis		1				1
Formication		1				1
Headache	19	149	11	30	8	119
Hemiparesis	1	3			1	3
Hyperaesthesia		1				1
Hypoaesthesia	8	30	5	9	3	21
Hypotonia		2				2
IVth nerve paralysis		1				1
Lethargy		11		1		10
Loss of consciousness	3	10			3	10
Memory impairment	1	2			1	2
Migraine	1	7		2	1	5
Migraine with aura	1	1			1	1
Myelitis transverse		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nerve compression		1				1
Nervous system disorder	1	1			1	1
Neuralgia		4				4
Neuritis cranial		1				1
Neuropathy peripheral		1				1
Nystagmus	1	1			1	1
Paraesthesia	4	41	4	11		30
Poor quality sleep		1		1		
Presyncope	3	8	3	4		4
Psychomotor hyperactivity		1				1
Seizure	1	3			1	3
Sensory disturbance	1	1	1	1		
Sensory loss		2				2
Somnolence		6		1		5
Speech disorder		1				1
Sudden onset of sleep	1	1			1	1
Syncope	6	21			6	21
Tardive dyskinesia		1				1
Taste disorder		2				2
Tension headache		1				1
Tongue biting		1				1
Tonic clonic movements		1				1
Transient ischaemic attack	2	3			2	3
Tremor	1	9		1	1	8
Trigeminal nerve disorder		2				2
Trigeminal neuralgia		1				1
Unresponsive to stimuli		4				4
Visual field defect		1		1		
	76	463	33	86	43	377

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	2	3	2	3
	2	3	2	3

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product temperature excursion issue	1	1	1	1
Suspected product quality issue		5		5
	1	6	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1				1
Anxiety		5				5
Confusional state	2	8			2	8
Depressed mood	1	1			1	1
Disorientation	1	3			1	3
Emotional distress		2				2
Hallucination	1	1			1	1
Insomnia	2	17		2	2	15
Irritability	1	1			1	1
Mood swings	1	1			1	1
Negative thoughts	1	1			1	1
Nervousness		2		1		1
Panic attack	1	3			1	3
Sleep disorder		1				1
Stress		1		1		
	11	48		4	11	44

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chromaturia	1	3	1	1		2
Micturition urgency		1		1		
Pollakiuria		1				1
Urinary incontinence		1				1
Urinary retention		1				1
Urine odour abnormal	1	1	1	1		
	2	8	2	3		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		1				1
Breast pain		3				3
Breast swelling		3				3
Breast tenderness	1	1	1	1		
Menorrhagia	1	1	1	1		
Menstrual disorder	1	2	1	1		1
Metrorrhagia	1	3			1	3
Oligomenorrhoea	1	1	1	1		
Vaginal haemorrhage		3				3
	5	18	4	4	1	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aspiration		1				1
Asthma		2				2
Choking sensation		1		1		
Cough	3	12	1	2	2	10
Dry throat		2				2
Dysphonia		1				1
Dyspnoea	2	23		1	2	22
Dyspnoea at rest	1	2			1	2
Dyspnoea exertional		2				2
Epistaxis	1	2			1	2
Hyperventilation		1				1
Hypopnoea		2				2
Hypoxia		1				1
Nasal congestion		3		1		2
Oropharyngeal discomfort		1				1
Oropharyngeal pain		10		2		8
Paranasal sinus discomfort		1				1
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal paraesthesia	2	5	2	3		2
Pharyngeal swelling		3				3
Pneumonitis		1				1
Pulmonary embolism		2				2
Rales		1				1
Respiration abnormal		1				1
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Sinus congestion	1	1			1	1
Sinus pain		2		1		1
Stridor		3				3
Throat irritation	1	3	1	1		2
Throat tightness		4		1		3
Wheezing		7				7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	14	103	5	14	9	89

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	2	4			2	4
Blister		1				1
Cold sweat		5		1		4
Dermatitis	2	2	1	1	1	1
Dermatitis allergic		1				1
Eczema	1	1			1	1
Erythema	2	7	1	3	1	4
Hyperhidrosis	1	21	1	2		19
Night sweats		2		1		1
Pruritus	1	19	1	5		14
Rash	5	26	2	6	3	20
Rash erythematous		8		1		7
Rash macular		2				2
Rash pruritic	2	4	2	2		2
Sensitive skin		1				1
Skin burning sensation		2				2
Skin discolouration	1	2		1	1	1
Skin exfoliation		1				1
Skin tightness		1				1
Skin warm		1				1
Skin wrinkling		1				1
Urticaria	2	17	2	4		13
Urticarial vasculitis		1				1
Urticaria papular		1		1		
	19	131	10	28	9	103

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		1				1
Impaired driving ability		3				3
Impaired work ability	3	20	1	2	2	18
Loss of personal independence in daily activities		5		2		3
	3	29	1	4	2	25

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Bloody discharge		1				1
Cyanosis		3		1		2
Deep vein thrombosis	4	6			4	6
Flushing		7		1		6
Hypertension	1	18		2	1	16
Hypotension	3	10	3	3		7
Orthostatic hypotension	1	1			1	1
Pallor	1	11	1	3		8
Thrombosis		1				1
	11	59	4	10	7	49

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ISRAEL**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	2		1	1	1
Autoimmune haemolytic anaemia		1				1
Disseminated intravascular coagulation	1	1			1	1
Haemolytic anaemia		1				1
Immune thrombocytopenia	1	2			1	2
Leukocytosis	3	7			3	7
Leukopenia		1				1
Lymphadenopathy	4	20	1	16	3	4
Lymphocytosis		1		1		
Lymphopenia		1				1
Neutropenia	1	1			1	1
Pancytopenia	1	1			1	1
Thrombocytopenia	1	1			1	1
	13	40	1	18	12	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	2	4			2	4
Angina pectoris		4				4
Arrhythmia		4				4
Atrial fibrillation	3	8			3	8
Cardiac arrest		12				12
Cardiac disorder		2				2
Cardiac failure	4	7			4	7
Cardiac failure chronic	1	1			1	1
Cardiac flutter		1				1
Cardiac tamponade	1	1			1	1
Cardiogenic shock	1	1			1	1
Myocardial infarction	2	7			2	7
Myocarditis	53	70			53	70
Palpitations	2	13		11	2	2
Pericardial effusion	1	2			1	2
Pericarditis	28	43			28	43
Pulseless electrical activity		1				1
Right ventricular enlargement		1		1		
Sinus tachycardia		2		1		1
Tachycardia		8		5		3
Ventricular fibrillation		2				2
	98	194		18	98	176

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Syndactyly		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	3			1	3
Deafness neurosensory	4	4			4	4
Deafness unilateral	3	3			3	3
Ear discomfort	3	6	1	4	2	2
Ear pain		5		5		
Hypoacusis	2	2	1	1	1	1
Sudden hearing loss	4	4			4	4
Tinnitus	8	11	3	4	5	7
Vertigo	4	8	1	4	3	4
	29	46	6	18	23	28

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Basedow's disease	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia		1		1		
Blindness transient	1	1			1	1
Conjunctival disorder		1				1
Dyschromatopsia		1		1		
Eye disorder		1		1		
Eye haemorrhage		1				1
Eye irritation		2		1		1
Eyelid function disorder		1		1		
Eyelid oedema		1		1		
Eye pain		7		4		3
Eye swelling		5		2		3
Lacrimation increased		2		1		1
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Photopsia		1		1		
Pupil fixed		1				1
Uveitis		1				1
Vision blurred		5		5		
	1	34		21	1	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		9		8		1
Abdominal pain upper	1	4	1	4		
Anaesthesia oral		1		1		
Anal haemorrhage	1	2	1	2		
Anorectal discomfort		1		1		
Aphthous ulcer		1		1		
Cheilitis	1	1	1	1		
Diarrhoea	8	22	8	20		2
Dry mouth		1		1		
Dyspepsia		7		7		
Dysphagia		6		4		2
Eosinophilic oesophagitis		1		1		
Gastric haemorrhage		1				1
Gastrointestinal necrosis		1				1
Gingival bleeding	1	1			1	1
Gingival pain		1		1		
Haematemesis		1				1
Haematochezia		1				1
Hypoaesthesia oral	1	13	1	11		2
Hypoaesthesia teeth		1		1		
Lip disorder		1		1		
Lip pruritus		2		2		
Lip swelling	1	3	1	2		1
Nausea	3	54	2	48	1	6
Odynophagia		3		2		1
Oedema mouth		1				1
Oral discomfort	1	2	1	2		
Oral pain		1		1		
Pancreatitis		1				1
Paraesthesia oral	1	16	1	14		2
Swollen tongue		4				4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue discomfort		1		1		
Tongue oedema		1				1
Toothache		2		2		
Vomiting	6	21	4	17	2	4
	25	190	21	157	4	33

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adverse event	1	3			1	3		
Asthenia	20	147			15	132	5	15
Axillary pain		1				1		
Brain death		1						1
Cardiac death		1						1
Chest discomfort	3	7			2	5	1	2
Chest pain	21	35			11	22	10	13
Chills	10	86			7	81	3	5
Condition aggravated		3				2		1
Crying		2				1		1
Death	2	31					2	31
Decreased activity		1				1		
Discomfort	2	7			2	7		
Disease recurrence		5				3		2
Drug ineffective	20	55		1			20	55
Extensive swelling of vaccinated limb		2				2		
Facial pain		2				1		1
Fatigue	8	85			7	81	1	4
Feeling abnormal	3	19			1	12	2	7
Feeling cold	1	16			1	16		
Feeling hot	1	6			1	6		
Feeling of body temperature change		1				1		
Gait disturbance	3	7			1	2	2	5
General physical health deterioration	2	4					2	4
Hangover		1				1		
Hypothermia		1						1
Illness		2				2		
Inflammation	1	4			1	2		2
Influenza like illness		14				14		
Injection site erythema		1				1		
Injection site pain		4				4		
Malaise	1	32			1	26		6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Multiple organ dysfunction syndrome		1						1
No adverse event	1	2			1	2		
Oedema		1						1
Oedema peripheral	1	2			1	1		1
Pain	9	43			5	35	4	8
Peripheral swelling	1	6				4	1	2
Pyrexia	27	122			17	101	10	21
Sudden cardiac death		1						1
Sudden death		1						1
Swelling	1	3			1	3		
Swelling face	1	3				2	1	1
Systemic inflammatory response syndrome	2	10					2	10
Tenderness		1				1		
Therapeutic response unexpected	3	8			3	8		
Thirst		2				1		1
Vaccination site bruising		1				1		
Vaccination site discomfort		1				1		
Vaccination site erythema	1	12			1	11		1
Vaccination site hypersensitivity		2				2		
Vaccination site inflammation		1				1		
Vaccination site joint movement impairment		1				1		
Vaccination site lymphadenopathy		2				2		
Vaccination site movement impairment	1	4			1	4		
Vaccination site pain	5	112			5	112		
Vaccination site paraesthesia		1				1		
Vaccination site pruritus		1				1		
Vaccination site reaction		1				1		
Vaccination site swelling		14				13		1
Vaccination site vesicles	1	1			1	1		
	153	946		1	87	739	66	207

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholelithiasis		1		1		
Drug-induced liver injury		1				1
Hepatic failure	1	1			1	1
Hepatic function abnormal	1	2			1	2
Hepatitis		1				1
Hepatitis acute		1				1
Hyperbilirubinaemia		1				1
Jaundice		1		1		
Liver injury		1				1
	2	10		2	2	8

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		4		2		2
Anaphylactic reaction	1	6			1	6
Anaphylactic shock		1				1
Drug hypersensitivity		3		1		2
Hypersensitivity	6	14	2	4	4	10
	7	28	2	7	5	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Asymptomatic COVID-19	5	5					5	5
Coronavirus infection	2	7					2	7
COVID-19	23	63		1	2	10	21	53
Diverticulitis		1						1
Ear infection		1				1		
Encephalitis	1	1					1	1
Endocarditis		1						1
Eye infection		3				2		1
Gastroenteritis viral		1				1		
Gingivitis		1				1		
Herpes simplex		1				1		
Herpes virus infection	1	1			1	1		
Herpes zoster	9	25			7	21	2	4
Infection		1				1		
Influenza		3				3		
Laryngitis bacterial		1						1
Localised infection	1	1					1	1
Nasopharyngitis		5				5		
Ophthalmic herpes zoster	1	2					1	2
Oral herpes	2	8			2	6		2
Osteomyelitis		1						1
Otitis media		1				1		
Pneumonia	1	5					1	5
Pseudomonas infection	1	1					1	1
Pulpitis dental		1				1		
Sepsis		1						1
Septic shock		1						1
Streptococcal infection		1						1
Suspected COVID-19		1						1
Tonsillitis	1	1					1	1
Urinary tract infection		1				1		
Urosepsis	1	1					1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vaccination site cellulitis		2				1			1
Vestibular neuronitis		1							1
	49	151		1	12	57	37	94	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cartilage injury		1						1
Contusion	1	2			1	1		1
Drug exposure before pregnancy		1				1		
Exposure during pregnancy	2	6			1	5	1	1
Exposure to contaminated water	1	1			1	1		
Exposure to SARS-CoV-2				1				
Exposure via breast milk		5				5		
Face injury		1						1
Fall	1	7			1	3		4
Foetal exposure during pregnancy		1						1
Head injury		1						1
Hip fracture		1						1
Inappropriate schedule of product administration		8				8		
Incomplete course of vaccination		1				1		
Incorrect dose administered	1	2			1	2		
Inflammation of wound	1	1			1	1		
Intentional dose omission		1				1		
Limb injury	1	1			1	1		
Maternal exposure during pregnancy	1	6				5	1	1
Maternal exposure timing unspecified		1				1		
Off label use		8				8		
Overdose		5				5		
Pelvic fracture		1						1
Poor quality product administered	3	39			3	39		
Product administered at inappropriate site	1	3			1	3		
Product administered to patient of inappropriate age		2				2		
Product preparation error		4				4		
Product preparation issue	1	2			1	2		
Product use issue		5				5		
Recall phenomenon	2	2			2	2		
Rib fracture		1						1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Tooth injury		1				1			
Underdose		3				3			
Vaccination failure	8	9					8	9	
Wrong technique in product usage process	1	3			1	3			
	25	136		1	15	113	10	23	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time shortened	1	1			1	1
Antinuclear antibody positive	1	1	1	1		
Antiphospholipid antibodies positive	1	1			1	1
Blood chloride increased		2		1		1
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal	1	1	1	1		
Blood glucose increased		3		1		2
Blood immunoglobulin M increased		1		1		
Blood iron decreased	1	1			1	1
Blood lactate dehydrogenase increased		1				1
Blood pressure abnormal	1	1			1	1
Blood pressure decreased		2		1		1
Blood pressure increased		13		7		6
Blood pressure systolic increased		1		1		
Body temperature decreased		3		3		
C-reactive protein increased	1	4		2	1	2
Electrocardiogram abnormal	1	2	1	1		1
Electrocardiogram T wave inversion	1	1			1	1
Foetal heart rate abnormal		1				1
Glomerular filtration rate decreased		1				1
Heart rate increased		10		9		1
Hepatic enzyme increased	1	1			1	1
Hormone level abnormal		1		1		
Inflammatory marker increased		1				1
International normalised ratio decreased	1	1			1	1
International normalised ratio increased		2		1		1
Liver function test increased		1		1		
Lymphocyte count increased		1		1		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		3		2		1
Mean cell volume decreased		1		1		
Mean platelet volume increased		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophil count decreased		1		1		
Neutrophil count increased		1				1
Oxygen saturation decreased		2		1		1
Pulse abnormal		1				1
Red blood cell count increased		1		1		
Respiratory rate increased		1				1
SARS-CoV-2 antibody test negative	1	3	1	2		1
SARS-CoV-2 antibody test positive		1		1		
SARS-CoV-2 test positive		2				2
Troponin increased	1	2			1	2
Vitamin B12 decreased	1	1			1	1
Weight decreased		3		1		2
	14	85	4	45	10	40

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alcohol intolerance		1		1		
Decreased appetite	2	11	2	10		1
Diabetic ketoacidosis		1				1
Food craving		1		1		
Food refusal		1				1
Hyponatraemia	1	1			1	1
	3	16	2	12	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	39	4	33		6
Arthritis	1	1	1	1		
Arthritis reactive		1				1
Arthropathy		1		1		
Back pain	3	20	2	18	1	2
Bone pain		7		7		
Facial asymmetry		1		1		
Joint noise		1		1		
Joint swelling		3		2		1
Limb discomfort		2		2		
Mobility decreased		5		3		2
Muscle disorder		1		1		
Muscle rigidity		1		1		
Muscle spasms	2	2	2	2		
Muscle twitching		1		1		
Muscular weakness	4	9	1	5	3	4
Musculoskeletal chest pain	1	2	1	2		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	7	84	6	78	1	6
Neck pain	1	10	1	10		
Pain in extremity	6	58	5	56	1	2
Pain in jaw		3		3		
Psoriatic arthropathy	1	1			1	1
Rhabdomyolysis	1	1			1	1
	31	257	23	231	8	26

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Chronic lymphocytic leukaemia		1		1
Non-Hodgkin's lymphoma		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		2		2		
Anosmia		3		3		
Aphasia	2	2	1	1	1	1
Balance disorder		1		1		
Brain injury		1				1
Brain oedema		1				1
Burning sensation		1				1
Cerebellar haemorrhage		1				1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	6	12			6	12
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Depressed level of consciousness		1				1
Dizziness	5	51	3	41	2	10
Dysaesthesia		1		1		
Dysarthria		1				1
Dysgeusia		11		11		
Dyskinesia	3	6	2	4	1	2
Dysstasia	1	4	1	2		2
Epilepsy		1				1
Facial nerve disorder		1		1		
Facial paralysis	13	41			13	41
Facial paresis	2	2			2	2
Foetal movement disorder		1				1
Formication		3		3		
Guillain-Barre syndrome	3	4			3	4
Headache	15	135	12	125	3	10
Head discomfort		3		3		
Hemiparaesthesia	1	1			1	1
Hemiplegia		1				1
Hypersomnia		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
6	38	2	4
		1	1
			1
		4	12
	3		
			1
			1
1	4		1
		1	3
		1	4
	4		
			2
1	1		
	1		1
	2	1	1
	1		
7	42	5	9
		1	4
			1
	4		
			1
	2		
	3	1	1
	1		
	1		
			1
		7	17
	2		1
	1	1	2
			1
1	4		
	4	2	4

Hypoaesthesia	8	42
Illrd nerve paralysis	1	1
Ischaemic stroke		1
Loss of consciousness	4	12
Migraine		3
Monoplegia		1
Motor dysfunction		1
Movement disorder	1	5
Multiple sclerosis	1	3
Multiple sclerosis relapse	1	4
Muscle contractions involuntary		4
Myasthenia gravis		2
Nervous system disorder	1	1
Neuralgia		2
Neuralgic amyotrophy	1	3
Neuritis		1
Paraesthesia	12	51
Paralysis	1	4
Paraplegia		1
Parosmia		4
Polyneuropathy		1
Poor quality sleep		2
Presyncope	1	4
Psychomotor hyperactivity		1
Reduced facial expression		1
Ruptured cerebral aneurysm		1
Seizure	7	17
Sensory disturbance		3
Sensory loss	1	3
Slow speech		1
Somnolence	1	4
Speech disorder	2	8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	3	11			3	11
Taste disorder		2		2		
Tonic convulsion	1	1			1	1
Transient ischaemic attack	6	6			6	6
Tremor	1	11		10	1	1
Unresponsive to stimuli	1	1			1	1
Vlth nerve paralysis	1	1			1	1
	107	521	35	329	72	192

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	1	2			1	2
Foetal death	1	3			1	3
Premature labour	1	1			1	1
Stillbirth	1	1			1	1
Twin pregnancy		1		1		
Uterine contractions abnormal		1		1		
	4	9		2	4	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue		19		19
Product colour issue		1		1
Product complaint		1		1
Product deposit		1		1
Product packaging quantity issue		12		12
Product quality issue	2	2	2	2
	2	36	2	36

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1		1		
Anger		1		1		
Anxiety	4	8	2	6	2	2
Confusional state	2	4	1	2	1	2
Depressed mood		5		4		1
Depression		2		1		1
Dysphemia	1	1			1	1
Hallucination		1				1
Hallucination, auditory		1				1
Initial insomnia		1		1		
Insomnia		7		7		
Loss of libido		1		1		
Mental disorder		2		2		
Mood altered		1		1		
Nervousness	1	1	1	1		
Personality change		1		1		
Restlessness		2		1		1
Schizophrenia		1				1
Sleep disorder	1	2	1	2		
Sleep disorder due to general medical condition, insomnia type		1		1		
Stress		2		2		
Suicidal ideation		1				1
Thinking abnormal		1		1		
Tic		2		2		
	9	50	5	38	4	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	2	1	2
Nephrolithiasis	1	1	1	1
	2	3	2	3

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Breast inflammation		1		1		
Breast tenderness		1		1		
Dysmenorrhoea		1		1		
Menorrhagia		3		3		
Menstrual disorder		2		2		
Menstruation irregular	1	3	1	3		
Metrorrhagia		1		1		
Pelvic pain		1		1		
Premenstrual syndrome		1		1		
Testicular pain	1	1	1	1		
Uterine haemorrhage		1				1
Uterine pain		1		1		
Vaginal haemorrhage	4	10	1	5	3	5
	6	28	3	22	3	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Aphonia		1				1
Aspiration		1				1
Asthma		2		1		1
Atelectasis		1				1
Choking		4				4
Chronic obstructive pulmonary disease	1	2			1	2
Cough	4	14	1	11	3	3
Dry throat		1		1		
Dysphonia		1		1		
Dyspnoea	13	54	6	22	7	32
Dyspnoea exertional		3		3		
Epistaxis	1	2			1	2
Hyperventilation	1	1	1	1		
Hypoventilation		1				1
Laryngeal inflammation		1		1		
Lung disorder	1	2		1	1	1
Lung infiltration	1	1			1	1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	2	13	2	12		1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling	1	4		2	1	2
Pleural effusion	1	2			1	2
Pleuritic pain	1	2	1	1		1
Pneumonia aspiration	1	2			1	2
Productive cough	1	1	1	1		
Pulmonary embolism	5	6			5	6
Pulmonary oedema		2				2
Respiratory arrest		2				2
Respiratory disorder	2	4	1	1	1	3
Respiratory distress		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinalgia		1		1		
Rhinorrhoea		4		4		
Sneezing		3		2		1
Suffocation feeling	1	3			1	3
Throat irritation	1	1			1	1
Throat tightness		2		1		1
Tracheal oedema		1				1
Wheezing	1	3		1	1	2
Yawning		2		1		1
	41	155	13	71	28	84

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia		1		1		
Angioedema	2	4			2	4
Blister	1	1			1	1
Cold sweat	1	4	1	4		
Erythema	5	16	4	13	1	3
Hyperhidrosis	3	11	3	11		
Mechanical urticaria		1		1		
Miliaria		1		1		
Night sweats		1		1		
Palmar erythema		1		1		
Pruritus	3	14	3	10		4
Purpura	2	2	1	1	1	1
Rash	4	19	3	13	1	6
Rash macular		2		2		
Rash maculo-papular	1	1	1	1		
Rash pruritic		1		1		
Rash vesicular	1	1			1	1
Skin burning sensation	1	3	1	3		
Skin discolouration	2	3	2	3		
Skin disorder		1		1		
Skin exfoliation	1	1	1	1		
Skin reaction	1	1	1	1		
Urticaria	1	8		4	1	4
Yellow skin		1		1		
	29	99	21	75	8	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Impaired quality of life		1		1
Loss of personal independence in daily activities	1	2	1	2
	1	3	1	3

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial thrombosis		1			1	
Blood pressure fluctuation	1	1			1	1
Circulatory collapse		1				1
Deep vein thrombosis	3	3			3	3
Haemorrhage		2				2
Hot flush		1		1		
Hypertension		7		3		4
Hypotension	2	5	1	2	1	3
Pallor	1	2	1	2		
Peripheral artery occlusion	1	1			1	1
Peripheral coldness	1	4	1	4		
Peripheral ischaemia	1	1			1	1
Shock		1				1
Thrombosis		4				4
Vein discolouration	1	1	1	1		
	11	35	4	13	7	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ITALY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia	2	4				2	2	2
Anaemia macrocytic	1	1					1	1
Bone marrow oedema	1	1					1	1
Coagulopathy		1						1
Immune thrombocytopenia			1	1				
Leukocytosis	1	2		1	1	2		
Leukopenia	3	5		1			3	5
Lymphadenitis	2	33				20	2	13
Lymphadenopathy	83	915	10	14	63	735	20	180
Lymphatic obstruction	1	1					1	1
Lymph node pain	14	92	5	5	13	76	1	16
Lymphocytosis		2				2		
Lymphopenia		3						3
Neutropenia		1		1				1
Neutrophilia	2	2					2	2
Splenomegaly		1						1
Thrombocytopenia	14	21		1			14	21
	124	1,085	16	24	77	837	47	248

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

		Non Interventional Study		Spontaneous				
		Serious		Nonserious		Serious		
		I	C	I	C	I	C	
Acute coronary syndrome	3	8					3	8
Acute myocardial infarction	3	9					3	9
Angina pectoris		5						5
Arrhythmia	7	29					7	29
Arteriospasm coronary		1						1
Atrial fibrillation	11	24					11	24
Atrial flutter	2	5			1		2	4
Atrial tachycardia		2			2			
Atrioventricular block complete		1						1
Atrioventricular block first degree	1	1			1	1		
Bradycardia	1	21		1			1	21
Bundle branch block right		1						1
Cardiac arrest	12	19					12	19
Cardiac disorder	1	2					1	2
Cardiac failure	5	12					5	12
Cardiac failure congestive	2	3					2	3
Cardiac fibrillation	1	1					1	1
Cardiogenic shock		1						1
Cardiopulmonary failure	1	1					1	1
Cardio-respiratory arrest	5	8					5	8
Cardiovascular disorder		1			1			
Coronary artery disease	1	2					1	2
Coronary artery dissection	1	1					1	1
Coronary artery stenosis	1	2					1	2
Dilatation atrial	1	1					1	1
Extrasystoles	3	20			2	13	1	7
Hypertensive heart disease	3	3					3	3
Left ventricular dysfunction	1	1			1	1		
Left ventricular failure		1						1
Left ventricular hypertrophy	1	1					1	1
Mitral valve incompetence	3	4					3	4
Myocardial infarction	4	5					4	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Myocardial ischaemia	1	2					1	2
Myocarditis	2	6					2	6
Palpitations	6	42			4	25	2	17
Paroxysmal arrhythmia		1						1
Pericardial effusion	6	10					6	10
Pericarditis	2	11					2	11
Pleuropericarditis	1	1					1	1
Right ventricular dilatation	1	1			1	1		
Sinus bradycardia		1				1		
Sinus tachycardia	1	14	1	1	1	7		7
Supraventricular extrasystoles		1						1
Supraventricular tachycardia		1				1		
Tachyarrhythmia	1	3			1	3		
Tachycardia	39	352	1	5	18	206	21	146
Tachycardia paroxysmal	1	6		1		3	1	3
Tricuspid valve incompetence	2	2					2	2
Ventricular arrhythmia		1						1
Ventricular extrasystoles	1	9			1	6		3
Ventricular fibrillation	2	2					2	2
Ventricular tachycardia	1	2					1	2
Wandering pacemaker		1						1
	141	665	2	8	30	272	111	393

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Corneal dystrophy	1	1	1	1
Hypertrophic cardiomyopathy		1		1
Macroglossia		2		2
Thyroglossal cyst	1	1	1	1
	2	5	2	5

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Auditory disorder		1							1
Deafness	2	5					2		5
Deafness bilateral		1							1
Deafness neurosensory		2							2
Ear discomfort	2	13			2	9			4
Ear disorder	1	3			1	2			1
Ear haemorrhage	1	1			1	1			
Ear pain	1	33			1	20			13
Ear pruritus		6				6			
Ear swelling	1	3				2	1		1
Hyperacusis	1	2				1	1		1
Hypoacusis	4	11			2	2	2		9
Neurosensory hypoacusis	1	1					1		1
Paraesthesia ear	1	1					1		1
Sudden hearing loss		1							1
Tinnitus	5	31			1	16	4		15
Vertigo	31	301	2	3	15	217	16		84
Vertigo positional		2		1		1			1
Vestibular disorder		1							1
	51	419	2	4	23	277	28		142

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenomegaly	1	3	1	3		
Autoimmune thyroiditis	1	5			1	5
Basedow's disease		1				1
Goitre		2		1		1
Hyperthyroidism		1				1
Thyroid disorder		1		1		
Thyroiditis subacute	2	3	2	3		
Thyroid mass		1				1
Thyroid pain		1				1
	4	18	3	8	1	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accommodation disorder	1	2			1	1		1
Age-related macular degeneration	1	1					1	1
Amaurosis fugax	1	1					1	1
Arteriosclerotic retinopathy	1	1					1	1
Asthenopia	1	12				10	1	2
Binocular eye movement disorder	1	1					1	1
Blepharitis		1				1		
Blepharospasm		3				2		1
Blindness	1	5					1	5
Blindness unilateral	1	1					1	1
Conjunctival haemorrhage	1	9		2			1	9
Conjunctival hyperaemia		5				2		3
Conjunctival irritation		4				2		2
Conjunctivitis allergic		1				1		
Corneal bleeding		1						1
Corneal opacity		1						1
Diplopia	13	22			11	16	2	6
Dry eye	2	6			1	4	1	2
Episcleritis		1						1
Erythema of eyelid		3				2		1
Extraocular muscle paresis		1						1
Eye allergy		1				1		
Eye colour change		1						1
Eye disorder	1	3				2	1	1
Eye haematoma		1						1
Eye haemorrhage	1	2					1	2
Eye irritation	2	46		1	2	38		8
Eyelid function disorder		1						1
Eyelid myoclonus		2						2
Eyelid oedema	3	26		1	1	13	2	13
Eyelid pain		2				1		1
Eyelid ptosis	3	10			1	5	2	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid retraction		1
Eyelids pruritus		2
Eye movement disorder		2
Eye oedema		8
Eye pain	5	44
Eye paraesthesia		4
Eye pruritus	2	19
Eye swelling	2	8
Foreign body sensation in eyes		1
Gaze palsy	1	1
Iridocyclitis		1
Lacrimation disorder	1	1
Lacrimation increased	3	24
Lagophthalmos	2	3
Macular rupture		1
Maculopathy	1	2
Metamorphopsia		1
Miosis		1
Mydriasis	1	1
Ocular discomfort	1	6
Ocular hyperaemia	3	28
Oculogyric crisis		1
Optic ischaemic neuropathy	1	1
Optic neuropathy		1
Orbital haematoma		1
Orbital oedema		1
Papilloedema		2
Periorbital discomfort		1
Periorbital oedema	3	13
Periorbital pain		3
Periorbital swelling		9
Photophobia	1	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		
			1		1
			5		3
	1	4	33	1	11
			3		1
			10	2	9
		2	5		3
			1		
				1	1
					1
				1	1
		2	19	1	5
		1	1	1	2
					1
			1		
				1	1
		1	6		
		1	19	2	9
					1
				1	1
					1
					1
					2
					1
		1	7	2	6
			3		
			7		2
			22	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Photopsia	1	7			1	3		4
Retinal artery occlusion	2	2					2	2
Retinal degeneration		1						1
Retinal detachment		2						2
Retinal disorder		1						1
Retinal drusen	1	1					1	1
Retinal oedema	1	1					1	1
Retinal vascular thrombosis				1				
Retinal vein occlusion	1	1					1	1
Retinal vein thrombosis	3	3					3	3
Scintillating scotoma		2				2		
Scleral discolouration		1						1
Scleral hyperaemia		1				1		
Swelling of eyelid		8				6		2
Uveitis		7						7
Vision blurred	10	50			4	32	6	18
Visual acuity reduced		2		1		1		1
Visual impairment	10	25		2	1	10	9	15
Vitreoretinal traction syndrome		1						1
Vitreous detachment		4		1				4
Vitreous disorder		3				1		2
Vitreous floaters		3						3
Vitreous haemorrhage	1	1					1	1
Vitritis		1						1
Xanthopsia		1						1
Xerophthalmia	1	2					1	2
	92	528		10	35	302	57	226

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	9			1	7		2
Abdominal distension	4	20			1	13	3	7
Abdominal pain	27	238			14	184	13	54
Abdominal pain lower	1	3				2	1	1
Abdominal pain upper	11	115	2	2	8	87	3	28
Abdominal rigidity		3				3		
Acquired macroglossia		1						1
Acute abdomen	2	2					2	2
Anaesthesia oral		7				5		2
Anal erythema		1						1
Anal incontinence		3				1		2
Anal sphincter atony		1						1
Angular cheilitis		1				1		
Aphthous ulcer		12	1	1		10		2
Aptyalism		1				1		
Burning mouth syndrome	1	2				1	1	1
Colitis		2				2		
Colitis ischaemic	1	1					1	1
Constipation		8				7		1
Defaecation urgency		1				1		
Diarrhoea	36	462	2	3	25	356	11	106
Diarrhoea haemorrhagic		1						1
Dry mouth	9	79		1	5	53	4	26
Dysbiosis		1						1
Dyschezia	1	1					1	1
Dyspepsia	3	23			1	19	2	4
Dysphagia	10	100		3	3	52	7	48
Enteritis	1	2			1	2		
Enterocolitis		1						1
Eructation		2				2		
Faeces soft		2				1		1
Flatulence		5				5		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Frequent bowel movements		4
Functional gastrointestinal disorder	1	1
Gastric dilatation		1
Gastritis		1
Gastrointestinal disorder	10	34
Gastrointestinal haemorrhage		1
Gastrointestinal hypermotility		1
Gastrointestinal motility disorder		1
Gastrointestinal pain	3	9
Gastrointestinal sounds abnormal	1	2
Gastrooesophageal reflux disease		2
Gingival bleeding	2	3
Gingival discolouration	1	1
Gingival discomfort		
Gingival oedema		2
Gingival pain		1
Gingival swelling		2
Glossitis	2	6
Glossodynia	1	7
Haematemesis	1	2
Haematochezia		2
Haemoperitoneum		1
Hypertrophy of tongue papillae		3
Hypoaesthesia oral	3	46
Impaired gastric emptying		1
Infantile vomiting		1
Intestinal ischaemia	4	4
Intestinal obstruction		1
Intestinal pseudo-obstruction		1
Lip disorder	1	2
Lip dry		1
Lip erythema		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		
		1	1		
			1		
			1		
1	1	9	29	1	5
					1
					1
					1
		2	8	1	1
		1	2		
			2		
			1	2	2
				1	1
	1				
			1		1
			1		
			1		1
			4	2	2
			4	1	3
				1	2
					2
					1
			2		1
		2	36	1	10
					1
			1		
				4	4
					1
					1
				1	2
			1		
			2		1

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lip oedema	7	69
Lip pain		3
Lip pruritus	1	18
Lip swelling	4	32
Melaena		1
Mouth haemorrhage	1	2
Mouth swelling		5
Mouth ulceration		2
Mucous stools		1
Nausea	108	1,109
Noninfective gingivitis	1	2
Odynophagia		7
Oedema mouth	2	8
Oedematous pancreatitis		1
Oesophageal oedema		1
Oesophageal pain		1
Oesophageal spasm		2
Oral discomfort	2	23
Oral dysaesthesia		5
Oral mucosal erythema		2
Oral pain		5
Oral pruritus		13
Palatal disorder		1
Palatal oedema	2	23
Palatal swelling	1	5
Pancreatitis	2	4
Pancreatitis acute	1	1
Paraesthesia oral	10	230
Parotid gland enlargement		2
Plicated tongue		2
Rectal haemorrhage	1	2
Regurgitation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	4	38	3	31
			3		
			9	1	9
	1	2	20	2	12
					1
			1	1	1
			3		2
			1		1
			1		
4	11	72	832	36	277
			1	1	1
1	1		4		3
1	1	1	5	1	3
					1
					1
					1
					2
	1	1	18	1	5
			5		
			1		1
			3		2
			5		8
			1		
		2	14		9
			3	1	2
				2	4
				1	1
2	3	6	146	4	84
			1		1
			1		1
				1	2
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retching	7	26			4	16	3	10
Salivary hypersecretion	1	8			1	6		2
Stomatitis		2				1		1
Submaxillary gland enlargement		1				1		
Swollen tongue	5	37			1	16	4	21
Tongue blistering		1				1		
Tongue coated		2				2		
Tongue discolouration	1	2			1	1		1
Tongue discomfort	1	10				8	1	2
Tongue disorder		2				1		1
Tongue dry	1	6			1	4		2
Tongue eruption		1				1		
Tongue erythema		1						1
Tongue geographic		1				1		
Tongue movement disturbance	1	1					1	1
Tongue oedema	7	39	1	1	2	16	5	23
Tongue pruritus		9				4		5
Tongue ulceration	1	3				2	1	1
Toothache	1	4			1	4		
Volvulus		1						1
Vomiting	49	370	2	7	27	232	22	138
Vomiting projectile		3				1		2
	356	3,370	18	39	200	2351	156	1019

\* I=Interval, C=Cumulative  
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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Administration site erythema		2				2			
Administration site induration		1				1			
Administration site movement impairment	1	1					1	1	
Administration site oedema		14				14			
Administration site pain	1	46			1	46			
Administration site paraesthesia		1				1			
Administration site pruritus		2				2			
Administration site reaction		1						1	
Administration site swelling		2				2			
Application site coldness		1				1			
Application site paraesthesia		1				1			
Asthenia	137	1,415	4	10	85	1137	52	278	
Axillary pain	12	105	3	5	11	92	1	13	
Breakthrough pain		2				1		1	
Chest discomfort	8	76		2	3	42	5	34	
Chest pain	17	107		1	3	55	14	52	
Chills	105	1,376	3	7	64	1088	41	288	
Condition aggravated	6	19				2	6	17	
Crying	1	3				2	1	1	
Death	6	10					6	10	
Discomfort	3	22			2	17	1	5	
Disease recurrence	6	22		1		3	6	19	
Drug ineffective	22	109	1	1		1	22	108	
Drug interaction	1	1					1	1	
Effusion		1						1	
Enanthema		1						1	
Extensive swelling of vaccinated limb		5				3		2	
Face oedema	8	42			1	16	7	26	
Facial discomfort	1	3			1	3			
Facial pain	2	12			1	6	1	6	
Fatigue	92	999	4	5	55	777	37	222	
Feeling abnormal	5	25			2	17	3	8	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling cold	10	143
Feeling drunk		1
Feeling hot	19	170
Feeling jittery	1	5
Feeling of body temperature change		12
Foaming at mouth	2	2
Gait disturbance	12	37
Gait inability	2	7
Generalised oedema		1
General physical health deterioration	1	5
Hyperpyrexia	27	238
Hyperthermia	2	38
Hypothermia	4	20
Illness		8
Induration		9
Inflammation	1	9
Inflammatory pain		1
Influenza like illness	11	97
Infusion site pain		3
Injected limb mobility decreased	2	17
Injection site discomfort		3
Injection site erythema	1	43
Injection site haematoma		3
Injection site haemorrhage		1
Injection site hypersensitivity		2
Injection site induration		12
Injection site inflammation		2
Injection site joint pain		3
Injection site lymphadenopathy		1
Injection site muscle weakness		1
Injection site oedema		147
Injection site pain	8	1,001

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	9	120	1	23
			1		
		13	119	6	51
			3	1	2
			7		5
				2	2
		2	18	10	19
			2	2	5
			1		
			1	1	4
	3	2	2	25	236
		1	29	1	9
				4	20
			5		3
			9		
			6	1	3
					1
1	1	9	81	2	16
			3		
	1	2	16		1
			3		
		1	43		
			3		
			1		
			2		
			12		
			2		
			3		
			1		
			1		
			147		
		7	999	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Injection site paraesthesia		11
Injection site pruritus	1	19
Injection site rash		1
Injection site reaction		12
Injection site swelling		25
Injection site urticaria	2	24
Injection site warmth		6
Localised oedema	3	27
Local reaction		5
Loss of control of legs		1
Malaise	48	560
Mucosal dryness		3
Mucosal hyperaemia		1
Mucosal inflammation		1
Multiple organ dysfunction syndrome	1	3
No adverse event	3	5
Nodule		1
Non-cardiac chest pain	1	1
Non-pitting oedema		2
Obstruction		1
Oedema	1	27
Oedema mucosal		3
Oedema peripheral	7	39
Pain	39	452
Peripheral swelling	16	78
Pneumatosis	1	1
Puncture site induration		2
Puncture site pain		2
Pyrexia	280	3,214
Secretion discharge	1	1
Sensation of foreign body	2	21
Sense of oppression	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			11		
		1	19		
			1		
			12		
			25		
		2	23		1
			6		
	1	1	21	2	6
			5		
					1
	2	28	441	20	119
			3		
					1
			1		
	1			1	3
		3	5		
			1		
				1	1
			1		1
		1	23		4
					3
2	2	4	27	3	12
1	1	19	359	20	93
		9	56	7	22
				1	1
			2		
			2		
19	38	161	2399	119	815
				1	1
		1	12	1	9
		1	1		3

\* I=Interval, C=Cumulative  
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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sluggishness		1
Sudden death	9	18
Swelling	9	74
Swelling face	8	48
Temperature intolerance	1	1
Temperature regulation disorder		1
Tenderness	1	7
Therapeutic response unexpected		1
Thirst	1	5
Vaccination site anaesthesia		1
Vaccination site bruising		4
Vaccination site dermatitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort		4
Vaccination site eczema		1
Vaccination site erythema	17	131
Vaccination site extravasation		2
Vaccination site haematoma		8
Vaccination site hyperaesthesia	1	1
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia	1	14
Vaccination site induration	2	19
Vaccination site inflammation	1	11
Vaccination site irritation	1	1
Vaccination site ischaemia		1
Vaccination site joint erythema		2
Vaccination site joint movement impairment		7
Vaccination site joint pain	1	11
Vaccination site joint swelling	2	13
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	2	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1			9	18
		5	59	4	15
	1	5	28	3	20
		1	1		
			1		
		1	6		1
			1		
		1	5		
					1
			3		1
					1
			1		
			1		
			4		
			1		
		13	93	4	38
			1		1
			8		
				1	1
					1
		1	12		2
		1	15	1	4
			8	1	3
		1	1		
					1
			2		
			6		1
		1	11		
		2	13		
			1		
		2	20		5

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vaccination site mass		3				3			
Vaccination site movement impairment	1	25			1	24			1
Vaccination site nodule		2				2			
Vaccination site oedema	8	98	1	1	7	79	1		19
Vaccination site pain	195	1,535	1	5	162	1317	33		218
Vaccination site pallor		1				1			
Vaccination site paraesthesia	1	30				23	1		7
Vaccination site phlebitis	1	1			1	1			
Vaccination site pruritus	5	50			4	39	1		11
Vaccination site rash	1	13			1	10			3
Vaccination site reaction	2	35			1	28	1		7
Vaccination site swelling	16	143	1	2	10	97	6		46
Vaccination site urticaria	3	29			3	20			9
Vaccination site vesicles		5				4			1
Vaccination site warmth		34	1	1		24			10
Xerosis		1							1
	1,234	13,444	42	94	730	10403	504		3041

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System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic	1	1			1	1
Cholangitis		1				1
Cholelithiasis	1	1			1	1
Hepatic pain		2		2		
Hepatitis acute		2				2
Hyperbilirubinaemia	1	1			1	1
Hypertransaminaemia		2				2
Jaundice	1	3	1	1		2
Jaundice cholestatic		1				1
	4	14	1	3	3	11

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 \* AE=Adverse Event  
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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic reaction to excipient	1	1					1	1
Allergy to vaccine	1	9			1	3		6
Anaphylactic reaction	3	65	1	3			3	65
Anaphylactic shock		15		1				15
Anaphylactoid reaction		4						4
Drug hypersensitivity	1	7				1	1	6
Food allergy		1						1
Hypersensitivity	11	67		3	5	26	6	41
Immune system disorder		1				1		
Reaction to excipient		1						1
Sarcoidosis		1						1
Seasonal allergy		1						1
Sensitisation		1				1		
Type I hypersensitivity	1	8					1	8
Type IV hypersensitivity reaction	1	1					1	1
	19	183	1	7	6	32	13	151

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abscess		1						1
Asymptomatic COVID-19	11	25				1	11	24
Blister infected		1				1		
Breast abscess		1						1
Bronchitis		2						2
Bursitis infective		1						1
Conjunctivitis	1	26			1	18		8
COVID-19	60	222	1	2	6	47	54	175
COVID-19 pneumonia	8	10	1	2			8	10
Cystitis		3				2		1
Disseminated varicella zoster virus infection	1	1					1	1
Diverticulitis		1						1
Dysentery	14	177	5	6			14	177
Ear infection	2	9			1	7	1	2
Encephalitis	1	2					1	2
Erysipelas	2	2					2	2
Eye infection	1	1					1	1
Folliculitis		1				1		
Furuncle		1				1		
Gastroenteritis		4				3		1
Gastroenteritis viral	1	1					1	1
Genital herpes zoster		1						1
Gingivitis		2				2		
Herpes ophthalmic	1	7					1	7
Herpes simplex		6				5		1
Herpes simplex encephalitis		1						1
Herpes virus infection	1	8			1	5		3
Herpes zoster	6	45	1	1	1	24	5	21
Herpes zoster infection neurological		1						1
Herpes zoster oticus	1	2					1	2
Herpes zoster reactivation	1	3				2	1	1
HIV infection		1						1

\* I=Interval, C=Cumulative  
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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infected cyst		1
Infection	1	2
Influenza	3	31
Injection site infection		9
Intervertebral discitis		1
Labyrinthitis		5
Listeriosis		1
Lymphangitis	3	10
Lymph node abscess		1
Mastitis	2	6
Myringitis	1	1
Nasal herpes	1	2
Nasopharyngitis	10	42
Necrotising fasciitis		1
Ophthalmic herpes simplex		2
Ophthalmic herpes zoster	1	3
Oral candidiasis		1
Oral herpes	8	43
Orchitis	1	1
Otitis externa		1
Otitis media		1
Peritonsillar abscess		1
Pharyngitis		11
Pneumonia	8	15
Pneumonia bacterial	1	2
Pneumonia legionella		1
Pustule	1	4
Q fever	2	9
Rash pustular		1
Respiratory tract infection		1
Rhinitis	3	21
Root canal infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		1
		3	28		3
			9		
					1
			2		3
					1
				3	10
					1
				2	6
				1	1
		1	2		
		7	29	3	13
					1
					2
				1	3
			1		
		4	28	4	15
				1	1
			1		
					1
1	1		7		4
				8	15
				1	2
					1
		1	2		2
				2	9
			1		
					1
		2	15	1	6
			1		

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous					
			Serious		Nonserious		Serious			
			I	C	I	C	I	C		
Scarlet fever			1	1						
Sepsis	1	3					1	3		
Septic shock	2	4					2	4		
Severe acute respiratory syndrome	2	3					2	3		
Sinusitis		2				1				1
Soft tissue infection		1								1
Subcutaneous abscess		1								1
Superinfection bacterial	1	2					1	2		
Suspected COVID-19	2	3					2	3		
Tonsillitis		2				1				1
Tooth infection		1				1				
Tracheitis		1								1
Upper respiratory tract infection	1	1					1	1		
Urinary tract infection		2				2				
Urinary tract infection bacterial	1	1					1	1		
Urosepsis	1	1					1	1		
Vaccination site cellulitis		1								1
Vaginal infection	1	2			1	2				
Vestibular neuronitis	2	4				1	2	3		
Viral corneal ulcer		1								1
Viral infection	1	1			1	1				
Virologic failure	1	1			1	1				
Vulvovaginal candidiasis		2				2				
	174	841	10	13	32	258	142	583		

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropod sting		1						1
Barotrauma		1				1		
Burn oral cavity		1						1
Central cord syndrome		1						1
Cerebral ventricle collapse	1	1					1	1
Chillblains	3	6			3	5		1
Circumstance or information capable of leading to medication error		1				1		
Cold burn		1				1		
Contraindicated product administered	1	1					1	1
Contusion	3	5			2	4	1	1
Electric shock		1						1
Epicondylitis		1				1		
Exposure during pregnancy		4				4		
Exposure to SARS-CoV-2	1	3			1	3		
Exposure via breast milk	3	6				3	3	3
Face injury	1	2					1	2
Facial bones fracture		1						1
Fall	6	15				1	6	14
Foreign body in throat		1						1
Head injury	1	2					1	2
Heat stroke		3				2		1
Inappropriate schedule of product administration	6	13			5	12	1	1
Incorrect dosage administered		1				1		
Incorrect dose administered	1	5			1	5		
Incorrect drug administration rate		1				1		
Incorrect route of product administration	11	31			11	31		
Injection related reaction		1				1		
Injury	1	3			1	2		1
Intentional product misuse	1	1			1	1		
Jaw fracture		1						1
Joint dislocation		1						1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Maternal exposure before pregnancy	1	1			1	1		
Maternal exposure during pregnancy	7	19			6	17	1	2
Medication error		1				1		
Nerve injury	1	1			1	1		
Occupational exposure to product		1				1		
Off label use	7	30			6	28	1	2
Overdose	9	48			7	44	2	4
Poor quality product administered		2				2		
Product administered at inappropriate site	1	8			1	8		
Product administered to patient of inappropriate age		1				1		
Product administration error		2				2		
Product label confusion		1				1		
Product preparation issue		7				7		
Product use issue	3	19			3	17		2
Skin laceration	3	4			1	2	2	2
Stoma site pain		1						1
Subcutaneous haematoma		1						1
Subdural haematoma	1	1					1	1
Thermal burns of eye		1						1
Traumatic fracture		1						1
Underdose		12				12		
Upper limb fracture	1	1					1	1
Vaccination complication		69		2		54		15
Vaccination error		1				1		
Vaccination failure	50	87	1	2			50	87
Wound		1						1
Wrong schedule		1				1		
Wrong technique in product usage process		2				2		
	124	440	1	4	51	283	73	157

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Alanine aminotransferase increased	1	3				2	1	1
Alpha globulin increased		1				1		
Alpha tumour necrosis factor increased	1	1					1	1
Amylase increased		2						2
Antibody test abnormal		3				3		
Antinuclear antibody positive		1						1
Anti-thyroid antibody positive		1				1		
Blood alkaline phosphatase increased		1						1
Blood bilirubin increased	1	1					1	1
Blood calcium decreased		1				1		
Blood creatinine increased	1	1			1	1		
Blood fibrinogen increased	1	1			1	1		
Blood glucose abnormal	1	1					1	1
Blood glucose decreased		1				1		
Blood glucose increased		3				2		1
Blood lactate dehydrogenase increased	1	1					1	1
Blood potassium decreased		1				1		
Blood pressure abnormal	1	1			1	1		
Blood pressure decreased		15		1		8		7
Blood pressure diastolic increased		1				1		
Blood pressure increased	11	103			5	57	6	46
Blood pressure systolic increased	2	9				4	2	5
Blood thyroid stimulating hormone increased	1	1			1	1		
Body temperature abnormal	1	1			1	1		
Body temperature decreased	1	3				2	1	1
Body temperature increased	2	34	1	1	2	29		5
Breath sounds		2				1		1
Breath sounds abnormal		3				1		2
Chest expansion decreased		1				1		
Coagulation factor increased	1	1					1	1
Coma scale abnormal		1						1
C-reactive protein abnormal	1	2				1	1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
C-reactive protein increased	3	8
Electrocardiogram abnormal	2	4
Electrocardiogram T wave inversion		
Eosinophil count decreased		1
Eosinophil count increased		1
Fibrin D dimer increased	6	7
Full blood count increased	1	1
Gamma-glutamyltransferase increased		1
Grip strength decreased	1	2
Haematocrit decreased		1
Haemoglobin decreased		4
Haptoglobin increased		1
Heart rate abnormal		1
Heart rate decreased	1	7
Heart rate increased	9	24
Heart rate irregular		2
Hepatic enzyme increased		
Hepatitis A antibody positive		1
Hepatitis B antibody positive		1
Inspiratory capacity abnormal		1
International normalised ratio increased	2	3
Laboratory test abnormal		1
Lipase increased		3
Lymph node palpable		1
Lymphocyte count decreased		1
Lymphocyte count increased		1
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1
Mean cell volume increased		1
Monocyte count decreased		1
Monocyte count increased		1
Myocardial necrosis marker increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	2	4
		1	1	1	3
	1				
					1
					1
		3	4	3	3
		1	1		
					1
			1	1	1
			1		
			2		2
					1
					1
			4	1	3
		5	11	4	13
					2
	1				
			1		
			1		
			1		
			1	2	2
					1
			1		2
			1		
			1		
					1
			1		
			1		
					1
			1		
					1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neutrophil count increased	1	2
Neutrophil percentage increased		1
Oxygen saturation abnormal		
Oxygen saturation decreased	14	59
Parvovirus B19 test positive		1
Platelet count decreased	1	1
Platelet count increased	1	1
PO2 decreased	1	1
Procalcitonin increased	1	1
Pulse abnormal		1
Pulse volume decreased		1
Quality of life decreased	1	5
Red blood cell count decreased		1
Red blood cell count increased		1
Red blood cell sedimentation rate increased	3	4
Red cell distribution width increased		1
Respiratory rate increased		1
SARS-CoV-2 antibody test	2	2
SARS-CoV-2 antibody test negative	1	8
SARS-CoV-2 antibody test positive	1	7
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	10	26
Serratia test positive		1
Sinus rhythm		1
Stenotrophomonas test positive		1
Thyroglobulin increased		1
Thyroid hormones increased		1
Transaminases increased	1	2
Troponin I increased	1	1
Troponin increased	1	1
Troponin T increased	2	3
Urine output decreased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
					1
1	1				
	1	1	9	13	50
			1		
		1	1		
				1	1
				1	1
		1	1		
					1
			1		
			2	1	3
					1
			1		
			1	3	3
			1		
					1
				2	2
		1	7		1
		1	6		1
			1		
			8	10	18
					1
			1		
					1
					1
		1	1		1
				1	1
				1	1
				2	3
				1	2

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System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Weight decreased	1	4				1	1	3
White blood cell count decreased		1				1		
White blood cell count increased	1	3			1	1		2
	98	434	2	6	31	208	67	226

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Decreased appetite	11	80	1	1	4	59	7	21
Dehydration		5						5
Electrolyte imbalance		1						1
Feeding disorder		1						1
Fluid retention		4				2		2
Food aversion		1				1		
Haemochromatosis		1				1		
Hypercreatininaemia	1	1					1	1
Hyperglycaemia	3	7			1	2	2	5
Hypoglycaemia	1	4			1	3		1
Hypokalaemia	2	2					2	2
Hyponatraemia	1	1					1	1
Hypovolaemia		1						1
Metabolic acidosis		1						1
Tetany	2	2			1	1	1	1
Type 1 diabetes mellitus	1	1					1	1
	22	113	1	1	7	69	15	44

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Arthralgia	115	1,419
Arthritis		3
Arthritis reactive		
Axillary mass		1
Back disorder		1
Back pain	12	131
Bone pain	12	130
Connective tissue disorder		1
Dactylitis	1	1
Enthesopathy	2	2
Extremity contracture		1
Facial asymmetry	1	1
Fasciitis		1
Fibromyalgia		2
Flank pain		3
Groin pain	1	4
Hand deformity		1
Joint contracture		1
Joint effusion	1	2
Joint hyperextension		1
Joint lock		3
Joint range of motion decreased	1	12
Joint stiffness		2
Joint swelling	2	5
Joint warmth		2
Limb discomfort	7	60
Mastication disorder	1	1
Mobility decreased	1	8
Muscle contracture		10
Muscle discomfort		1
Muscle disorder		1
Muscle fatigue	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
5	9	73	1114	42	305
			2		1
	1				
			1		
					1
	3	5	93	7	38
		8	94	4	36
					1
				1	1
				2	2
			1		
			1		
			1		
			1		
			1	1	1
			1		
			2		1
		1	5		7
			2		
			2	2	3
					2
		5	51	2	9
				1	1
		1	6		2
1	1		7		3
			1		
			1		
			3	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle oedema		3
Muscle rigidity	2	18
Muscle spasms	6	44
Muscle swelling		2
Muscle tightness		7
Muscle twitching		7
Muscular weakness	11	72
Musculoskeletal chest pain	3	20
Musculoskeletal discomfort		2
Musculoskeletal disorder	1	2
Musculoskeletal pain	8	237
Musculoskeletal stiffness	6	32
Myalgia	138	1,668
Myalgia intercostal		2
Myositis		4
Neck pain	15	110
Nuchal rigidity	3	16
Osteoarthropathy	1	1
Pain in extremity	99	817
Pain in jaw	1	12
Polyarthritits	1	4
Polymyalgia rheumatica	1	1
Psoriatic arthropathy	3	3
Rhabdomyolysis	1	1
Rheumatic disorder		1
Rheumatoid arthritis	2	5
Sacroiliitis	1	1
Sjogren's syndrome		1
Spinal pain	2	19
Systemic lupus erythematosus	1	2
Temporomandibular joint syndrome		3
Tendonitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		1	13	1	5
1	1	3	31	3	13
					2
			5		2
			5		2
		6	49	5	23
		2	12	1	8
			1		1
		1	1		1
	1	4	174	4	63
		4	18	2	14
7	12	87	1354	51	314
			1		1
	1		1		3
2	2	8	83	7	27
		2	8	1	8
		1	1		
1	2	67	681	32	136
		1	7		5
				1	4
				1	1
				3	3
				1	1
					1
				2	5
		1	1		
					1
		2	18		1
				1	2
			2		1
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tendon pain		1						1
Tenosynovitis	2	2			1	1	1	1
Torticollis		7				7		
Trigger finger		1				1		
Trismus		1				1		
	467	4,946	19	35	285	3876	182	1070

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Angiomyolipoma		1		1
Brain neoplasm		1		1
Leukaemia	1	1	1	1
Lung neoplasm malignant		1		1
Lymphoma	1	1	1	1
Testicular neoplasm	1	1	1	1
	3	6	3	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute motor axonal neuropathy	1	1					1	1
Acute polyneuropathy		1						1
Ageusia	8	34	2	2	6	23	2	11
Akathisia		1				1		
Akinesia	1	1					1	1
Allodynia		2				1		1
Altered state of consciousness	1	2					1	2
Amnesia	1	8			1	5		3
Anaesthesia	4	36			3	31	1	5
Anosmia	7	27	2	2	4	18	3	9
Anterograde amnesia		2						2
Aphasia	14	22	1	1		2	14	20
Ataxia	1	3					1	3
Aura		3				3		
Balance disorder	2	23	2	2	1	13	1	10
Band sensation		6				4		2
Bradykinesia	2	4				1	2	3
Brain compression	1	1					1	1
Brain stem haemorrhage		1						1
Brain stem stroke	1	1					1	1
Burning sensation	5	23			4	15	1	8
Carotid artery dissection	1	2					1	2
Central nervous system lesion	1	1					1	1
Central pain syndrome		1				1		
Cerebellar ataxia	1	1					1	1
Cerebellar haemorrhage		1						1
Cerebral artery occlusion	2	2					2	2
Cerebral artery thrombosis	1	1					1	1
Cerebral disorder		1						1
Cerebral haematoma		1						1
Cerebral haemorrhage	8	11					8	11
Cerebral infarction	1	2					1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cerebral ischaemia	12	12
Cerebral thrombosis	1	1
Cerebral venous sinus thrombosis		1
Cerebral venous thrombosis	1	1
Cerebrovascular accident	11	17
Cervical radiculopathy		2
Cervicobrachial syndrome		7
Clonus		6
Cluster headache		3
Cognitive disorder	1	1
Coma	1	4
Convulsions local		1
Coordination abnormal		1
Cramp-fasciculation syndrome	1	1
Cranial nerve disorder		3
Cranial nerve paralysis		1
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		2
Demyelination		1
Depressed level of consciousness	3	46
Diplegia		4
Disturbance in attention	3	24
Dizziness	48	346
Droling	1	2
Dysaesthesia	4	24
Dysarthria	6	11
Dysgeusia	6	115
Dysgraphia		2
Dyskinesia	1	4
Dyslalia		1
Dyslexia	1	1
Dysmetria	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				12	12
				1	1
					1
				1	1
1	1			11	17
			1		1
			5		2
			2		4
			3		
1	1			1	1
				1	4
					1
1	1				1
				1	1
			2		1
					1
					2
					1
	1			3	46
					4
1	1	1	13	2	11
	3	26	227	22	119
			1	1	1
		3	19	1	5
1	1		2	6	9
3	3	5	97	1	18
			1		1
			2	1	2
					1
				1	1
				1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysstasia	2	5
Embolic stroke	1	1
Encephalopathy		2
Epilepsy	4	13
Facial nerve disorder		6
Facial neuralgia		3
Facial paralysis	13	73
Facial paresis	3	34
Facial spasm		2
Febrile convulsion	1	13
Focal dyscognitive seizures	1	1
Generalised tonic-clonic seizure		4
Guillain-Barre syndrome	2	4
Haemorrhagic cerebral infarction		1
Haemorrhagic stroke	1	1
Headache	216	2,709
Head discomfort	1	21
Hemianaesthesia	1	9
Hemianopia	1	1
Hemianopia heteronymous		1
Hemianopia homonymous	1	1
Hemidysaesthesia		4
Hemihyperaesthesia		1
Hemiparaesthesia	2	26
Hemiparesis	7	26
Hemiplegia	5	10
Hydrocephalus	1	1
Hyperaesthesia		11
Hyperkinesia		1
Hyperreflexia		1
Hypersomnia	1	5
Hypertonia		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	3
				1	1
					2
				4	13
			3		3
			1		2
2	2		1	13	72
		3	17		17
			1		1
			7	1	6
				1	1
					4
				2	4
					1
				1	1
9	21	136	2158	80	551
			17	1	4
				1	9
				1	1
					1
				1	1
					4
					1
				2	26
				7	26
				5	10
				1	1
			9		2
			1		
					1
		1	5		
			3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoaesthesia	7	130
Hypogeusia		1
Hypoglossal nerve disorder		1
Hypokinesia	1	4
Hyporeflexia	1	2
Hyporesponsive to stimuli		3
Hyposmia		3
Hypotonia	1	9
Illrd nerve paralysis	1	2
Intraventricular haemorrhage	1	2
Ischaemic stroke	4	12
IVth nerve disorder	1	1
Lacunar stroke	1	1
Lateropulsion	1	1
Lethargy		3
Loss of consciousness	23	96
Memory impairment		5
Meningeal disorder		1
Mental impairment		2
Migraine	10	163
Migraine with aura	1	6
Monoparesis		7
Monoplegia	1	7
Motor dysfunction	6	20
Movement disorder	3	19
Multiple sclerosis		2
Muscle contractions involuntary		8
Myasthenia gravis		3
Myasthenia gravis crisis	1	2
Myoclonus		5
Narcolepsy	1	3
Nerve compression	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	4	97	3	33
			1		
					1
			2	1	2
				1	2
			2		1
			2		1
		1	5		4
				1	2
				1	2
				4	12
				1	1
				1	1
				1	1
			3		
				23	96
			1		4
			1		
					2
2	2	6	127	4	36
		1	5		1
			6		1
				1	7
		1	11	5	9
		1	8	2	11
					2
			6		2
					3
				1	2
			1		4
				1	3
		1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervous system disorder	2	3
Neuralgia	2	21
Neuralgic amyotrophy		1
Neuritis	1	10
Neurological symptom		2
Neurologic neglect syndrome	1	1
Neuropathy peripheral	4	15
Neurotoxicity		1
Nystagmus	1	3
Occipital neuralgia		1
Optic neuritis	1	6
Paraesthesia	65	617
Paraesthesia mucosal		2
Paralysis	1	5
Paraparesis	3	5
Paresis	2	6
Paresis cranial nerve		2
Parosmia	3	10
Partial seizures	1	2
Peripheral sensorimotor neuropathy		1
Peripheral sensory neuropathy		1
Petit mal epilepsy	1	2
Polyneuropathy		1
Poor quality sleep		1
Post herpetic neuralgia		1
Presyncope	21	148
Psychomotor hyperactivity	1	3
Psychomotor skills impaired	1	1
Quadriparesis		1
Radiculitis brachial		3
Radiculopathy		4
Reduced facial expression		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
	1	2	12		9
	1		1		
		1	7		3
	1		1		1
				1	1
				4	15
					1
				1	3
					1
				1	6
1	3	34	424	31	193
			1		1
				1	5
				3	5
			2	2	4
			1		1
		1	6	2	4
				1	2
					1
			1		
				1	2
					1
			1		
					1
	1	10	79	11	69
			2	1	1
				1	1
					1
			3		
			3		1
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restless legs syndrome		3
Retrograde amnesia		2
Sciatica		6
Sedation		5
Seizure	2	11
Seizure like phenomena		1
Sensorimotor disorder		1
Sensory disturbance	1	4
Sensory loss		8
Sinus headache		1
Slow speech	1	1
Somnolence	17	178
Speech disorder	9	18
Status epilepticus		1
Stupor	1	11
Subarachnoid haemorrhage	3	3
Sudden onset of sleep		2
Syncope	26	134
Taste disorder	2	15
Tension headache	1	6
Tongue paralysis		1
Tonic clonic movements		2
Tonic convulsion		1
Transient ischaemic attack	4	5
Tremor	18	133
Trigeminal nerve disorder	1	6
Trigeminal neuralgia	1	6
Trigeminal neuritis		1
Unresponsive to stimuli	2	3
Visual field defect		4
Vlth nerve paralysis	1	2
Vlth nerve paresis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
			1		1
			5		1
			3		2
				2	11
					1
					1
			1	1	3
			4		4
			1		
				1	1
1	2	10	140	7	38
1	1	1	6	8	12
					1
			4	1	7
				3	3
					2
1	4	1	1	25	133
			7	2	8
			4	1	2
					1
					2
				4	5
	2	8	70	10	63
		1	3		3
			4	1	2
					1
				2	3
			3		1
				1	2
		1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vocal cord paralysis		2						2
	698	5,853	33	62	279	3800	419	2053

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion	1	2	1	2
Abortion spontaneous	1	6	1	6
Ectopic pregnancy		1		1
Foetal growth restriction		1		1
	2	10	2	10

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Undersensing	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abnormal behaviour		1				1			
Agitation		29		1		20			9
Anxiety	2	31			1	20	1		11
Anxiety disorder due to a general medical condition		1				1			
Apathy		2							2
Bradyphrenia	1	1					1		1
Compulsions		1							1
Confusional state	22	106	4	6	7	59	15		47
Delirium		1							1
Delusion	1	2				1	1		1
Depersonalisation/derealisation disorder		1				1			
Depressed mood		2				2			
Disorientation	4	25		2	2	11	2		14
Dissociation		1				1			
Drug abuse	1	1					1		1
Dysphemia	1	1					1		1
Emotional disorder	1	1			1	1			
Euphoric mood		2				2			
Flat affect		1							1
Hallucination	1	9					1		9
Hallucination, auditory	1	3					1		3
Hallucination, olfactory		2							2
Hallucinations, mixed		1							1
Hallucination, visual	1	6					1		6
Immunisation anxiety related reaction		1				1			
Initial insomnia	2	6			1	3	1		3
Insomnia	16	163			7	136	9		27
Irritability		10				7			3
Logorrhoea	1	1					1		1
Loss of libido	1	1			1	1			
Mental disorder		2				1			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Middle insomnia	1	8			1	7		1
Mood altered		2				1		1
Nervousness	1	2				1	1	1
Nightmare		1				1		
Organic brain syndrome		1						1
Panic attack		8				5		3
Panic reaction		1				1		
Psychotic disorder	1	1					1	1
Restlessness		8				4		4
Sleep disorder	5	12			4	10	1	2
Soliloquy		1				1		
Sopor	4	11	1	2		4	4	7
Tension		3				2		1
Terminal insomnia		3				3		
Thought blocking		1						1
	68	478	5	11	25	309	43	169

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute kidney injury	2	4		1			2	4
Anuria		5						5
Azotaemia		1						1
Bladder dysfunction	1	1					1	1
Bladder obstruction		1						1
Chromaturia	1	2				1	1	1
Cystitis haemorrhagic	1	5					1	5
Dysuria	4	9				2	4	7
Glomerulonephritis		1						1
Haematuria	1	7				3	1	4
Incontinence	1	3				1	1	2
Micturition disorder		1				1		
Micturition urgency		1						1
Neurogenic bladder		1						1
Oliguria	1	3					1	3
Pollakiuria	2	4			1	2	1	2
Polyuria		5				3		2
Proteinuria		1				1		
Renal failure	1	3					1	3
Renal impairment		1						1
Renal pain	1	8				7	1	1
Urinary incontinence	1	5				1	1	4
Urinary retention	1	4					1	4
Urine flow decreased		1				1		
Urine odour abnormal		1				1		
	18	78		1	1	24	17	54

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		2		2		
Breast cyst		1		1		
Breast discomfort		3		2		1
Breast enlargement		1		1		
Breast oedema	1	5		4	1	1
Breast pain	1	15		9	1	6
Breast swelling	1	2			1	2
Endometriosis	1	1			1	1
Erectile dysfunction	2	4			2	4
Female sexual dysfunction	1	1	1	1		
Genital discomfort		1				1
Genital pain		1		1		
Genital rash		1		1		
Menorrhagia	3	6		2	3	4
Menstrual disorder		2		2		
Menstruation irregular		1		1		
Metrorrhagia	1	6	1	3		3
Pelvic pain		2		2		
Perineal pain	1	1	1	1		
Premenstrual pain		2		2		
Pruritus genital		2		2		
Scrotal erythema	1	1			1	1
Vaginal haemorrhage		2		1		1
Vulvovaginal burning sensation		1		1		
	13	64	3	39	10	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute pulmonary oedema	1	2					1	2
Acute respiratory distress syndrome	2	2					2	2
Acute respiratory failure	2	10					2	10
Allergic cough		1						1
Allergic respiratory symptom		1						1
Aphonia	2	11				6	2	5
Apnoea		1						1
Asphyxia		1						1
Asthma	2	23				7	2	16
Asthma exercise induced		1						1
Asthmatic crisis	3	12	2	3			3	12
Bronchial wall thickening		1						1
Bronchiectasis		1						1
Bronchospasm	1	32		1		9	1	23
Bronchostenosis		1						1
Catarrh	2	5			1	2	1	3
Choking		2						2
Choking sensation	2	4				1	2	3
Chronic obstructive pulmonary disease	1	1					1	1
Chronic respiratory failure		1						1
Cough	22	186		1	8	94	14	92
Diaphragmalgia		1				1		
Diaphragmatic spasm		2				1		1
Dry throat	3	7			2	5	1	2
Dysaesthesia pharynx		2				2		
Dysphonia	4	46		1	1	19	3	27
Dyspnoea	52	322	3	7	10	102	42	220
Dyspnoea at rest	1	3					1	3
Dyspnoea exertional	1	10				5	1	5
Emphysema		1						1
Epiglottic oedema		1						1
Epistaxis	1	17			1	13		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glottal incompetence		1
Grunting		1
Hiccups	1	1
Hypercapnia		1
Hyperventilation	1	9
Hypoxia	3	8
Increased upper airway secretion		1
Increased viscosity of bronchial secretion		1
Interstitial lung disease	3	6
Intranasal hyposaesthesia		1
Intranasal paraesthesia		2
Laryngeal discomfort		1
Laryngeal dyspnoea	1	4
Laryngeal obstruction		2
Laryngeal oedema	11	76
Laryngeal pain		1
Laryngeal stenosis		1
Laryngospasm	3	16
Larynx irritation		1
Lung disorder		1
Nasal congestion	4	13
Nasal discomfort		3
Nasal obstruction		3
Nasal oedema		2
Nasal pruritus		1
Obstructive airways disorder		4
Oropharyngeal discomfort	1	23
Oropharyngeal oedema		2
Oropharyngeal pain	10	99
Oropharyngeal plaque		1
Oropharyngeal spasm		1
Oropharyngeal swelling		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	1		
					1
	1	1	3		6
	3			3	8
			1		
					1
	3			3	6
			1		
			2		
					1
	1			1	4
					2
	11			11	76
			1		
					1
	3		4	3	12
			1		
					1
	4	2	9	2	4
			3		
			2		1
					2
			1		
			1		3
	1	1	16		7
					2
	10	1	72	4	27
					1
					1
			2		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orthopnoea		1
Painful respiration	1	1
Pharyngeal disorder		2
Pharyngeal erythema	1	8
Pharyngeal hypoaesthesia		2
Pharyngeal mass	1	2
Pharyngeal oedema	2	10
Pharyngeal paraesthesia	2	26
Pharyngeal swelling	2	15
Pleural effusion	8	9
Pleurisy		1
Pneumonitis	2	5
Pneumothorax	1	1
Productive cough	1	4
Pulmonary congestion		1
Pulmonary embolism	13	23
Pulmonary hypertension	1	1
Pulmonary hypoperfusion		1
Pulmonary infarction	1	1
Pulmonary mass	1	1
Pulmonary microemboli	1	1
Pulmonary oedema	1	2
Pulmonary pain		3
Rales	1	3
Respiration abnormal		1
Respiratory arrest	1	3
Respiratory depression		1
Respiratory disorder	2	15
Respiratory distress	2	22
Respiratory failure	12	19
Respiratory fatigue		8
Respiratory tract haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
			1		1
			4	1	4
			1		1
		1	1		1
	1		1	2	9
			10	2	16
		1	6	1	9
		1	1	7	8
					1
				2	5
				1	1
				1	4
					1
2	2			13	23
				1	1
					1
				1	1
				1	1
				1	2
			2		1
				1	3
			1		
				1	3
					1
			3	2	12
	1			2	22
				12	19
			1		7
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Respiratory tract oedema		3							3
Rhinalgia	1	2			1	1			1
Rhinitis allergic		1				1			
Rhinorrhoea	3	23				18	3		5
Rhonchi		1				1			
Sinus pain		1							1
Sneezing		4				3			1
Stertor		1							1
Stridor	1	1					1		1
Suffocation feeling	1	7				4	1		3
Tachypnoea		20				12			8
Throat irritation	6	57			4	29	2		28
Throat tightness	6	99		2	1	41	5		58
Tonsillar erythema		1				1			
Tonsillar hypertrophy	1	5			1	5			
Tracheal pain		2				1			1
Upper airway obstruction		2							2
Upper respiratory tract inflammation		2				1			1
Use of accessory respiratory muscles		5				1			4
Vasomotor rhinitis		1				1			
Vocal cord dysfunction		1							1
Wheezing	1	14				8	1		6
	217	1,448	7	21	45	548	172		900

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Acne		1				1			
Alopecia	1	4			1	1			3
Angioedema	9	55					9		55
Blister	2	12			2	10			2
Brow ptosis		1				1			
Butterfly rash		1							1
Circumoral oedema	1	6			1	6			
Circumoral swelling		2							2
Cold sweat	1	30				17	1		13
Cold urticaria	1	1			1	1			
Dermal cyst	1	2			1	2			
Dermatitis	1	8			1	7			1
Dermatitis acneiform		2				2			
Dermatitis allergic		8				4			4
Dermatitis atopic		1				1			
Dermatitis bullous	3	12	1	1			3		12
Dermatitis exfoliative		1							1
Dermatitis exfoliative generalised		2							2
Dermatitis herpetiformis		3				1			2
Drug eruption		1				1			
Dry skin		6				1			5
Ecchymosis	5	6			1	2	4		4
Eczema asteatotic		1				1			
Eczema nummular		1				1			
Erythema	31	349	1	2	15	232	16		117
Erythema multiforme	1	5					1		5
Erythema nodosum	3	4			2	2	1		2
Erythematotelangiectatic rosacea		1				1			
Guttate psoriasis		1							1
Haemorrhage subcutaneous		1							1
Hand dermatitis		2				2			
Hidradenitis		1							1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperhidrosis	13	175
Hypersensitivity vasculitis	1	1
Idiopathic urticaria		1
Lipodystrophy acquired		1
Livedo reticularis		1
Madarosis	1	1
Mechanical urticaria		8
Neurodermatitis		1
Night sweats		17
Pain of skin	1	3
Palpable purpura	1	2
Panniculitis		1
Papule		5
Pemphigoid		1
Perioral dermatitis		1
Petechiae	4	8
Photosensitivity reaction		3
Piloerection		1
Pityriasis rosea	1	3
Prurigo		1
Pruritus	28	375
Pruritus allergic		1
Psoriasis	1	2
Purpura		1
Pustular psoriasis	1	1
Rash	25	275
Rash erythematous	3	26
Rash macular	1	11
Rash maculo-papular	1	6
Rash maculovesicular		1
Rash morbilliform		2
Rash papular		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	4	120	9	55
			1	1	1
					1
	1		1		
				1	1
	2		5		3
			1		
			16		1
			2	1	1
			1	1	1
					1
			3		2
					1
			1		
	1	2	6	2	2
			1		2
					1
			2	1	1
			1		
1	2	18	280	10	95
			1		
		1	1		1
	1				1
				1	1
	3	13	176	12	99
	1	1	16	2	10
		1	8		3
		1	6		
			1		
			2		
			6		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rash pruritic	8	41			3	23	5	18
Rash vesicular		9				7		2
Rosacea		1						1
Scab		2				1		1
Seborrhoeic dermatitis		1				1		
Sensitive skin		1				1		
Skin burning sensation	1	9			1	7		2
Skin discolouration	1	7				3	1	4
Skin exfoliation	1	3			1	3		
Skin induration		1						1
Skin irritation		3				2		1
Skin lesion	1	9				6	1	3
Skin mass	1	3			1	3		
Skin oedema		1				1		
Skin reaction	5	22			2	13	3	9
Skin striae	1	1			1	1		
Skin swelling		1						1
Skin tightness		3				1		2
Skin warm		5				2		3
Toxic skin eruption	1	2					1	2
Umbilical haematoma	1	1					1	1
Urticaria	44	302			29	202	15	100
Urticaria papular	1	1			1	1		
Urticaria thermal	1	1			1	1		
Urticaria vesiculosa	1	1			1	1		
Vascular purpura	1	3			1	2		1
Vasculitic rash		1						1
Yellow skin	1	2			1	2		
	212	1,912	3	15	109	1239	103	673

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	1	1	1		
Immobile		1				1
Impaired quality of life	2	4	2	3		1
Impaired work ability		1				1
Loss of personal independence in daily activities	1	5	1	4		1
Sitting disability	1	1	1	1		
	5	13	5	9		4

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Immunisation		2		2
Joint stabilisation		1		1
Limb immobilisation		1		1
Therapy change		1		1
		5		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

		Non Interventional Study		Spontaneous			
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aneurysm ruptured							1
Angiopathy	1					1	1
Aortic dilatation	1			1	1		
Aortic dissection	1					1	1
Arteriosclerosis							1
Arteriovenous fistula	1					1	1
Blood pressure fluctuation	1				1	1	3
Bloody discharge	1					1	1
Capillary fragility							1
Circulatory collapse	1					1	4
Cyanosis	2				2	2	7
Deep vein thrombosis	11		1			11	17
Diastolic hypertension					1		
Diastolic hypotension							1
Embolism	1					1	3
Embolism venous							1
Fibromuscular dysplasia	1					1	1
Flushing	15			9	85	6	23
Haematoma	4			1	8	3	5
Haemorrhage	1					1	2
Hot flush	2			2	56		17
Hyperaemia	1			1	6		3
Hypertension	19			5	51	14	70
Hypertensive crisis	16		2			16	86
Hypotension	16		3	4	67	12	68
Hypotensive crisis	2					2	7
Infarction							1
Ischaemia	1					1	4
Lymphoedema					6		2
Orthostatic hypotension	1			1	3		1
Pallor	3		1	1	16	2	9
Peripheral artery thrombosis	1					1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	2	16	1	4
				1	1
				2	2
			1		
		5	5		2
		1	1	1	1
		1	2		
				1	3
			1		
					1
				1	1
		3	3	2	2
1	1	1	1	7	8
				6	9
					1
		7	7	2	3
				1	1
		1	3		5
			1	1	2
				3	3
	1	1	1	1	1
			1		
		3	10	47	346
		156	739	109	393

156

739

3

10

47

346

109

393

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**JAPAN**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	4	5	4	4		1
Disseminated intravascular coagulation	1	1			1	1
Leukopenia	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	11	12	9	10	2	2
Lymph node pain	2	2	1	1	1	1
Thrombocytopenic purpura	1	1			1	1
	21	23	15	16	6	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		2				2
Acute myocardial infarction	1	1			1	1
Angina pectoris		1				1
Angina unstable		1				1
Arrhythmia	7	9			7	9
Atrial fibrillation		1				1
Atrial tachycardia	1	1			1	1
Bradycardia	6	7			6	7
Bundle branch block right		1		1		
Cardiac discomfort		1		1		
Cardiac failure	3	4			3	4
Cardiac failure acute	1	1			1	1
Cardiac tamponade	1	1			1	1
Cardio-respiratory arrest	6	7			6	7
Cardiovascular disorder	3	3	3	3		
Extrasystoles	1	1	1	1		
Myocardial infarction	2	2			2	2
Myocarditis	5	7			5	7
Palpitations	108	147	68	84	40	63
Pericarditis	2	2			2	2
Sinus bradycardia	1	1	1	1		
Sinus tachycardia	3	4	2	2	1	2
Tachycardia	25	40	13	16	12	24
Ventricular extrasystoles	3	3	2	2	1	1
Ventricular fibrillation	1	1			1	1
Ventricular hypokinesia	1	1			1	1
	181	250	90	111	91	139

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Colour blindness		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autophony	1	1	1	1		
Deafness	2	2			2	2
Deafness neurosensory	1	1			1	1
Ear discomfort	5	8	4	4	1	4
Ear pruritus	1	1			1	1
Ear swelling	1	1			1	1
Hypoacusis	1	2	1	1		1
Motion sickness	2	2	1	1	1	1
Sudden hearing loss	6	10			6	10
Tinnitus	3	5	3	3		2
Vertigo	8	12	3	3	5	9
	31	45	13	13	18	32

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypothyroidism	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	4	5	3	3	1	2
Asthenopia	2	2			2	2
Blepharospasm	3	3			3	3
Chromatopsia	1	1			1	1
Conjunctival haemorrhage	1	2			1	2
Conjunctival hyperaemia	13	18	8	10	5	8
Diplopia	2	2	1	1	1	1
Erythema of eyelid	1	1	1	1		
Excessive eye blinking		1				1
Eye disorder	3	6	1	2	2	4
Eye haemorrhage	1	1			1	1
Eyelid function disorder	1	1			1	1
Eyelid irritation	1	1			1	1
Eyelid oedema	11	19	5	8	6	11
Eyelid ptosis	2	2			2	2
Eye movement disorder	1	1			1	1
Eye oedema		1		1		
Eye pain	2	3	1	1	1	2
Eye pruritus	9	11	5	6	4	5
Eye swelling	2	3	1	1	1	2
Gaze palsy	3	4			3	4
Lacrimation increased	4	6	2	4	2	2
Lid margin discharge	1	1	1	1		
Mydriasis	1	1	1	1		
Ocular hyperaemia	14	19	10	13	4	6
Optic atrophy	1	1			1	1
Periorbital oedema	1	1			1	1
Periorbital swelling	3	6	1	3	2	3
Photopsia	3	4	3	3		1
Pupils unequal	1	1	1	1		
Retinal haemorrhage	2	2			2	2
Scleritis	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling of eyelid	6	15	5	8	1	7
Vision blurred	4	5	3	4	1	1
Visual impairment	3	7	2	4	1	3
Vitreous floaters	1	1	1	1		
	109	159	56	77	53	82

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	17	26	9	13	8	13
Abdominal distension	1	1	1	1		
Abdominal pain	34	46	18	23	16	23
Abdominal pain lower	1	3		1	1	2
Abdominal pain upper	10	11	6	6	4	5
Abdominal symptom	1	1			1	1
Anal incontinence	1	1	1	1		
Ascites	1	1			1	1
Cheilitis	1	1	1	1		
Colitis	1	1			1	1
Colitis ischaemic		1				1
Colitis ulcerative	1	1			1	1
Diarrhoea	45	64	29	39	16	25
Diverticulum	1	1			1	1
Dry mouth	2	3	1	1	1	2
Dyspepsia	3	3	1	1	2	2
Dysphagia	4	5	1	1	3	4
Enteritis		1				1
Enterocolitis	3	4			3	4
Epigastric discomfort	3	3	2	2	1	1
Eructation		1		1		
Faeces soft	3	5	2	4	1	1
Frequent bowel movements	1	1	1	1		
Gastrointestinal disorder	2	3			2	3
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal hypermotility	1	3			1	3
Gastrointestinal motility disorder	1	1	1	1		
Gastrointestinal mucosal disorder	1	1			1	1
Gastrointestinal oedema	1	1			1	1
Glossodynia	1	1	1	1		
Haematochezia	3	5			3	5
Hypoaesthesia oral	12	22	9	15	3	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ileus paralytic	1	1			1	1
Lip erythema	1	1			1	1
Lip oedema	2	2	1	1	1	1
Lip pruritus	1	3	1	1		2
Lip swelling	7	14	5	9	2	5
Melaena	1	2			1	2
Mouth swelling	3	4	2	3	1	1
Nausea	177	253	98	128	79	125
Odynophagia		1				1
Oedema mouth		1				1
Oral discomfort	8	10	7	7	1	3
Oral mucosa erosion	1	1	1	1		
Oral mucosa haematoma	1	1	1	1		
Oral mucosal blistering	1	1	1	1		
Oral pain	1	1	1	1		
Oral pruritus	5	5	2	2	3	3
Paraesthesia oral	7	9	6	7	1	2
Rectal tenesmus	1	1			1	1
Salivary hypersecretion	1	1			1	1
Stomatitis	1	2	1	2		
Submaxillary gland enlargement	1	1	1	1		
Tongue disorder		1				1
Tongue oedema	1	1	1	1		
Toothache	1	1	1	1		
Upper gastrointestinal haemorrhage		1				1
Vomiting	78	108	44	55	34	53
	458	650	258	335	200	315

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site movement impairment	1	1	1	1		
Asthenia	23	33	13	17	10	16
Axillary pain	3	3	2	2	1	1
Cardiac death	1	1			1	1
Chest discomfort	20	29	13	15	7	14
Chest pain	7	9	3	3	4	6
Chills	86	106	59	68	27	38
Condition aggravated	6	6	1	1	5	5
Death	2	2			2	2
Discomfort	14	20	8	11	6	9
Disease recurrence	2	3	1	2	1	1
Drowning	1	1			1	1
Drug ineffective	6	7			6	7
Face oedema	3	8	2	3	1	5
Facial pain	3	4	2	2	1	2
Fatigue	9	13	8	10	1	3
Feeling abnormal	116	172	68	90	48	82
Feeling cold	15	22	7	9	8	13
Feeling hot	46	60	27	34	19	26
Feeling jittery	1	1			1	1
Gait disturbance	8	11	1	2	7	9
Gait inability		1				1
Generalised oedema	2	2	1	1	1	1
General physical health deterioration	1	1			1	1
Hyperpyrexia	4	4			4	4
Hyperthermia	4	4	2	2	2	2
Hypothermia	2	2			2	2
Induration	2	2	2	2		
Inflammation		2		1		1
Injected limb mobility decreased	2	5	1	4	1	1
Injection site discomfort		1		1		
Injection site hypoaesthesia	1	1	1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site muscle weakness	1	1	1	1		
Injection site pain	2	2	2	2		
Injection site pruritus	2	2	2	2		
Injection site rash	1	1	1	1		
Injection site swelling		1		1		
Injection site vesicles	1	1			1	1
Injection site warmth	1	1	1	1		
Local reaction	1	1	1	1		
Malaise	199	259	151	184	48	75
Mucosal disorder		1		1		
Mucosal haemorrhage	1	1	1	1		
Oedema	4	4			4	4
Oedema mucosal	1	1			1	1
Oedema peripheral	1	3		1	1	2
Pain	33	40	25	32	8	8
Peripheral swelling	6	7	6	7		
Physical deconditioning	5	9	2	5	3	4
Puncture site pain	1	1	1	1		
Pyrexia	262	334	199	251	63	83
Sensation of blood flow	1	1			1	1
Sensation of foreign body	6	6	5	5	1	1
Shoulder injury related to vaccine administration		1				1
Stenosis	2	2			2	2
Swelling	11	16	7	11	4	5
Swelling face	10	19	6	8	4	11
Temperature intolerance	1	1			1	1
Tenderness	1	1			1	1
Thirst	5	8	3	4	2	4
Vaccination site bruising		1		1		
Vaccination site coldness	1	1	1	1		
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema	17	26	13	17	4	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage	4	4	3	3	1	1
Vaccination site hypoaesthesia	3	5	2	4	1	1
Vaccination site induration	2	3	2	3		
Vaccination site joint discomfort	1	1	1	1		
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	7	9	4	6	3	3
Vaccination site necrosis	2	2			2	2
Vaccination site pain	133	178	116	156	17	22
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	2	2	2	2		
Vaccination site pruritus	14	22	11	18	3	4
Vaccination site rash	5	6	5	6		
Vaccination site reaction	2	3	2	3		
Vaccination site swelling	20	25	15	18	5	7
Vaccination site urticaria	1	6	1	5		1
Vaccination site vesicles		1				1
Vaccination site warmth	3	4	1	1	2	3
	1,170	1,564	819	1050	351	514

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic function abnormal	7	7	2	2	5	5
Liver disorder	1	1			1	1
	8	8	2	2	6	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	9	11	6	8	3	3
Anaphylactic reaction	466	728	2	2	464	726
Anaphylactic shock	15	21			15	21
Anaphylactoid reaction	4	10			4	10
Drug hypersensitivity	1	4		1	1	3
Hypersensitivity	34	52	22	27	12	25
Reaction to excipient		2				2
Seasonal allergy	1	1	1	1		
Serum sickness		1				1
Type I hypersensitivity	7	9			7	9
Type IV hypersensitivity reaction	1	1	1	1		
	538	840	32	40	506	800

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute endocarditis	1	1			1	1
Asymptomatic COVID-19	2	2			2	2
Cellulitis	5	5			5	5
COVID-19	6	8	1	2	5	6
Diverticulitis	2	2			2	2
Enteritis infectious	1	1			1	1
Gastroenteritis	1	1	1	1		
Gastroenteritis bacterial	1	1			1	1
Herpes virus infection	1	1			1	1
Herpes zoster	2	2			2	2
Herpes zoster oticus	2	2			2	2
Infection	1	1	1	1		
Infective spondylitis	1	1			1	1
Kaposi's varicelliform eruption	1	1			1	1
Lymphadenitis bacterial		1				1
Meningitis	3	3			3	3
Meningitis aseptic	3	7			3	7
Myelitis	1	1			1	1
Nasopharyngitis	2	2	2	2		
Parotitis	1	2	1	2		
Peritonitis	1	1			1	1
Pharyngitis bacterial	1	1			1	1
Pneumonia	1	3			1	3
Pneumonia viral	1	1			1	1
Sepsis	1	1			1	1
Sialoadenitis	1	1			1	1
Sputum purulent	2	2			2	2
Streptococcal infection	1	1			1	1
Suspected COVID-19	1	1			1	1
Vestibular neuronitis		1				1
Viral infection	1	1			1	1
	48	59	6	8	42	51

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accident	1	1			1	1
Exposure during pregnancy	1	1	1	1		
Fall	6	10	3	6	3	4
Foreign body in throat		2				2
Fracture	1	1	1	1		
Head injury		1				1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	3	3	3	3		
Incorrect route of product administration	5	6	5	6		
Injury		1				1
Maternal exposure during pregnancy	1	1	1	1		
Muscle strain	1	1	1	1		
Off label use	1	1	1	1		
Overdose		1		1		
Product administered at inappropriate site		1		1		
Product preparation issue		2		2		
Road traffic accident	1	1	1	1		
Skin abrasion	1	1			1	1
Spinal column injury	1	1	1	1		
Sunburn	1	1	1	1		
Tracheal obstruction	1	2			1	2
Underdose	1	5	1	5		
Vaccination complication	2	2	1	1	1	1
Vaccination failure	1	1			1	1
Vascular injury	1	1	1	1		
Wrong technique in product usage process	1	1			1	1
	32	50	23	35	9	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1		1		
Blood creatinine decreased		1		1		
Blood glucose decreased		1				1
Blood pressure abnormal	1	3	1	1		2
Blood pressure decreased	29	37	14	20	15	17
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure diastolic increased	2	4	1	2	1	2
Blood pressure immeasurable	1	1	1	1		
Blood pressure increased	90	128	47	60	43	68
Blood pressure systolic		1		1		
Blood pressure systolic abnormal	1	1			1	1
Blood pressure systolic increased	3	6	2	4	1	2
Body temperature abnormal		1		1		
Body temperature decreased	1	1	1	1		
Body temperature increased	8	10	8	10		
Breath sounds abnormal	1	2			1	2
Coma scale		1				1
C-reactive protein increased	1	1			1	1
CSF protein increased	1	1			1	1
Fibrin degradation products increased	1	1			1	1
Grip strength decreased	4	6	3	4	1	2
Heart rate decreased	4	4	3	3	1	1
Heart rate increased	18	30	11	19	7	11
HIV antibody positive	1	2	1	2		
Lymphocyte percentage decreased		1		1		
Monocyte percentage increased		1		1		
Oxygen saturation decreased	13	18	5	6	8	12
Oxygen saturation increased	1	1			1	1
Platelet count decreased	3	3			3	3
Protein total decreased		1		1		
Protein urine present	1	1	1	1		
Pulse abnormal	3	3	1	1	2	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Radial pulse abnormal	3	4	1	1	2	3
Radial pulse increased		1				1
Respiratory rate decreased	1	1	1	1		
Respiratory rate increased	3	4			3	4
Sinus rhythm	2	2			2	2
White blood cell count decreased	1	1			1	1
White blood cell count increased	1	2	1	1		1
	200	289	104	146	96	143

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis		1				1
Decreased appetite	10	16	2	6	8	10
Dehydration	3	4	1	1	2	3
Feeding disorder	4	5	1	1	3	4
Hypokalaemia	1	3			1	3
Hypophagia	2	2	1	1	1	1
Marasmus	1	1			1	1
Tetany	1	1			1	1
	22	33	5	9	17	24

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	60	71	43	49	17	22
Arthritis	3	3	1	1	2	2
Arthritis reactive	1	1			1	1
Back pain	15	16	12	12	3	4
Groin pain	1	1			1	1
Haemarthrosis	1	1			1	1
Joint range of motion decreased	6	7	3	3	3	4
Joint swelling	2	2	2	2		
Limb discomfort	6	13	5	10	1	3
Mobility decreased	3	6	1	4	2	2
Muscle spasms	7	10	3	4	4	6
Muscle tightness	2	3	2	3		
Muscle twitching	1	2	1	1		1
Muscular weakness	24	32	9	12	15	20
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort	3	4	2	3	1	1
Musculoskeletal stiffness	6	6	4	4	2	2
Myalgia	76	98	67	86	9	12
Myositis		2		1		1
Neck pain	7	8	3	3	4	5
Pain in extremity	37	49	30	40	7	9
Soft tissue atrophy	1	1			1	1
	263	337	189	239	74	98

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acoustic neuroma	1	1	1	1
Acute lymphocytic leukaemia	1	1	1	1
Brain neoplasm		1		1
Breast cancer	1	1	1	1
Lymphoma	1	1	1	1
	4	5	4	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness	4	9			4	9
Amnesia	2	2			2	2
Anaesthesia dolorosa	1	1			1	1
Aphasia	1	1			1	1
Apraxia		1				1
Autonomic nervous system imbalance	1	1			1	1
Autonomic neuropathy	1	1			1	1
Balance disorder	1	1			1	1
Brain compression		1				1
Brain stem haemorrhage	1	1			1	1
Brain stem infarction	1	1			1	1
Burning sensation	2	3	1	2	1	1
Cerebral congestion	1	1			1	1
Cerebral haemorrhage	5	6			5	6
Cerebral infarction	5	6			5	6
Cerebral venous sinus thrombosis	1	1			1	1
Cholinergic syndrome	1	1			1	1
Complex regional pain syndrome	2	3	1	1	1	2
Convulsions local	1	1			1	1
Decreased vibratory sense	2	2			2	2
Depressed level of consciousness	13	22	1	1	12	21
Disturbance in attention	1	1			1	1
Dizziness	88	126	58	74	30	52
Dizziness postural	5	8	4	6	1	2
Dysaesthesia	3	3	1	1	2	2
Dysgeusia	1	2	1	1		1
Dyskinesia	1	1			1	1
Dyslalia	1	1	1	1		
Dysstasia		2		1		1
Epilepsy	1	1			1	1
Facial paralysis	13	15			13	15
Guillain-Barre syndrome	7	7			7	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
145	189	66	96
11	16	8	11
		1	1
		2	2
		2	2
	1		
1	1		
52	69	33	39
1	1		
		1	1
		1	1
		1	1
		1	1
		1	1
		22	31
			1
	1	1	1
1	2	4	4
		1	1
1	1		
			1
1	1	21	27
			1
		1	1
		1	1
9	14	4	5
		1	2
1	2		
		1	1
		1	2
1	1		
	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	43	60	34	46	9	14
Reduced facial expression	1	1			1	1
Seizure	17	21			17	21
Sensory disturbance	5	8	4	6	1	2
Slow response to stimuli	1	1			1	1
Somnolence	10	15	7	9	3	6
Speech disorder	2	2	1	1	1	1
Subarachnoid haemorrhage	5	7			5	7
Sympathicotonia		1				1
Syncope	8	15			8	15
Taste disorder	1	1	1	1		
Tension headache		1				1
Tremor	16	26	7	9	9	17
Trigeminal nerve disorder	2	3			2	3
Trigeminal neuralgia	1	1	1	1		
Unresponsive to stimuli	1	2			1	2
Vagus nerve disorder		1				1
Vertebral artery dissection	2	2			2	2
Visual field defect	1	1	1	1		
Vlth nerve disorder		1				1
	682	938	348	462	334	476

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue	2	2	2	2
Product leakage	1	2	1	2
	3	4	3	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affective disorder		1		1		
Agitation	1	1	1	1		
Anxiety	7	8	2	3	5	5
Bradyphrenia	1	1			1	1
Confusional state	1	1	1	1		
Daydreaming	1	2	1	1		1
Delirium	1	1			1	1
Dysphoria	5	8	3	4	2	4
Eating disorder	2	2			2	2
Hallucination, visual	1	1			1	1
Illusion		1				1
Insomnia	2	2	2	2		
Listless	2	3	2	3		
Panic attack		1				1
Sleep disorder		1				1
Sleep disorder due to general medical condition, insomnia type	1	1			1	1
Somatic symptom disorder	1	2	1	2		
Speech sound disorder	1	1	1	1		
Stress	3	3	2	2	1	1
Tension	1	1	1	1		
Trance	1	1	1	1		
	32	43	18	23	14	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bilirubinuria	1	1			1	1
Calculus urinary		1		1		
Dysuria		1				1
Nephrotic syndrome	1	2			1	2
Pollakiuria	1	2			1	2
Urinary retention		2				2
Urine abnormality	1	1			1	1
	4	10		1	4	9

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostatitis	1	1	1	1
Prostatomegaly	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	3	3			3	3
Aphonia	1	1	1	1		
Apnoea		3				3
Apnoeic attack		1				1
Asthma	32	55	10	21	22	34
Bronchial obstruction		1				1
Bronchiectasis	1	1			1	1
Bronchospasm		1				1
Bronchostenosis	3	4			3	4
Choking	1	1			1	1
Choking sensation	1	1			1	1
Cough	136	207	56	76	80	131
Dry throat	2	2	2	2		
Dysphonia	17	25	9	10	8	15
Dyspnoea	124	189	54	68	70	121
Epistaxis	1	2			1	2
Grunting	1	1			1	1
Haemoptysis		1				1
Hyperventilation	14	19	5	6	9	13
Hypoventilation		1				1
Hypoxia	1	2			1	2
Interstitial lung disease	1	1			1	1
Irregular breathing	1	1			1	1
Laryngeal discomfort	4	7	2	4	2	3
Laryngeal obstruction		1				1
Laryngeal oedema	4	6			4	6
Laryngeal pain	1	1	1	1		
Laryngospasm	1	1			1	1
Larynx irritation	2	3	1	1	1	2
Lung infiltration		1				1
Nasal congestion	2	4			2	4
Nasal mucosal disorder		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal obstruction	3	5	1	1	2	4
Nasal pruritus		1				1
Obstructive airways disorder	2	2			2	2
Organising pneumonia		1				1
Oropharyngeal discomfort	114	181	60	80	54	101
Oropharyngeal pain	20	34	16	25	4	9
Pharyngeal disorder	1	1			1	1
Pharyngeal erythema	1	1	1	1		
Pharyngeal paraesthesia	3	3	2	2	1	1
Pharyngeal stenosis	2	2			2	2
Pharyngeal swelling	7	9	3	4	4	5
Pneumothorax	2	2			2	2
Productive cough	3	6	2	3	1	3
Prolonged expiration		1		1		
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism	1	1			1	1
Respiratory alkalosis	1	1	1	1		
Respiratory disorder	9	10	3	3	6	7
Respiratory distress	1	10		1	1	9
Respiratory symptom	3	6	1	1	2	5
Rhinorrhoea	15	22	11	14	4	8
Sneezing	3	5	1	2	2	3
Sputum discoloured	1	1	1	1		
Sputum retention	1	1	1	1		
Stridor	3	5	1	2	2	3
Suffocation feeling	1	2		1	1	1
Tachypnoea	6	10	4	6	2	4
Throat irritation	22	38	16	22	6	16
Throat tightness	19	27	9	11	10	16
Tonsillar disorder	1	1	1	1		
Tracheal stenosis	2	2			2	2
Upper airway obstruction	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vocal cord disorder	1	1			1	1
Wheezing	19	31	3	5	16	26
Yawning	4	5	2	3	2	2
	627	978	281	382	346	596

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute febrile neutrophilic dermatosis		1				1	
Angioedema	2	3			2	3	
Blister	1	1			1	1	
Capillaritis	1	1	1	1			
Cold sweat	32	44	16	20	16	24	
Cutaneous symptom		4		2		2	
Dermatitis	1	1	1	1			
Dermatitis allergic	3	6	3	4		2	
Dermatitis atopic	2	3	2	2		1	
Drug eruption	4	8	3	6	1	2	
Dry skin	2	2	2	2			
Eczema	4	9	4	7		2	
Erythema	177	250	122	154	55	96	
Erythema ab igne	1	1	1	1			
Erythema multiforme	2	2			2	2	
Haemorrhage subcutaneous	8	8			8	8	
Henoch-Schonlein purpura	1	1	1	1			
Hyperhidrosis	30	44	17	22	13	22	
Livedo reticularis	1	1	1	1			
Mucocutaneous disorder	1	1	1	1			
Neutrophilic dermatosis		1		1			
Night sweats		1		1			
Oculomucocutaneous syndrome	7	8			7	8	
Palmar erythema		1		1			
Papule	1	1	1	1			
Pigmentation disorder		1		1			
Piloerection	1	2			1	2	
Pruritus	210	306	136	189	74	117	
Purpura	2	2	2	2			
Rash	127	188	82	115	45	73	
Rash erythematous	9	11	6	7	3	4	
Rash papular		1		1			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic	1	1	1	1		
Skin disorder		1		1		
Skin fissures	1	1	1	1		
Skin plaque	1	1			1	1
Toxic skin eruption	4	4			4	4
Urticaria	149	218	105	145	44	73
	786	1,140	509	692	277	448

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of personal independence in daily activities		1				1
Sitting disability	1	1	1	1		
	1	2	1	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm	1	1			1	1
Aortic dissection	2	2			2	2
Blood pressure fluctuation	1	2	1	1		1
Circulatory collapse	4	4			4	4
Cyanosis	3	3	2	2	1	1
Deep vein thrombosis	2	2			2	2
Embolism venous	1	1			1	1
Flushing	22	36	12	18	10	18
Haemorrhage	1	1			1	1
Hot flush	29	46	20	27	9	19
Hyperaemia	1	1			1	1
Hypertension	18	26	6	6	12	20
Hypertensive emergency	2	2			2	2
Hypertensive urgency		1				1
Internal haemorrhage	14	14			14	14
Lymphoedema	1	1			1	1
Orthostatic hypotension		1				1
Pallor	17	24	6	9	11	15
Peripheral circulatory failure	1	1			1	1
Peripheral coldness	25	28	18	18	7	10
Phlebitis	1	1	1	1		
Post thrombotic syndrome	1	1			1	1
Raynaud's phenomenon	1	1	1	1		
Shock	2	4			2	4
Shock symptom		1				1
Thrombophlebitis superficial	1	1	1	1		
Thrombosis	3	3			3	3
Vasculitis	1	1	1	1		
Vasodilatation	2	2	2	2		
Vasospasm	1	1			1	1
	158	213	71	87	87	126

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**JORDAN**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Haematemesis		1				1
Mesenteric vein thrombosis		1				1
Tongue disorder		1		1		
		4		1		3

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1			1	1
Chills		1		1		
Condition aggravated		1				1
Fatigue		3		3		
Influenza like illness		1		1		
Injection site pain		1		1		
Pain		2		2		
Pyrexia		1		1		
Swelling		1				1
Swelling face		1		1		
Vaccination site pain		2		2		
	1	15		12	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		3		1		2
COVID-19 pneumonia		1				1
Gangrene		1				1
Influenza		1		1		
Pneumonia		1				1
		7		2		5

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Vaccination failure		1		1
		1		1

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
Weight decreased		1		1		
		2		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle spasms		1		1
Myalgia		3		3
Pain in extremity		3		3
		7		7

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia		1		1		
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Dizziness		1		1		
Dysgeusia		1		1		
Headache		1		1		
Loss of consciousness		1				1
Syncope		2				2
	2	9		4	2	5

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusional state	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1		1		
Cough		1		1		
Dyspnoea		1				1
Hypoxia		1				1
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1				1
Lung disorder		1				1
Obstructive airways disorder		1				1
Respiratory failure		1				1
Sputum retention		1				1
Tachypnoea		1				1
		11		2		9

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erythema		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred  
**KOREA, REPUBLIC OF (SOUTH KOREA)**

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint swelling	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**KUWAIT**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy		1		1
Splenomegaly		1		1
		2		2

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		2		2
Pain	1	1	1	1
Peripheral swelling		1		1
Polyp		1		1
Pyrexia		2		2
Swelling		1		1
Tenderness		2		2
Vaccination site pain		1		1
Vaccination site swelling		1		1
	1	12	1	12

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	2	1	2
	1	2	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
<i>Preferred Term</i>				
Lymphocyte percentage increased		1		1
Mean cell haemoglobin concentration increased		1		1
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
<i>Preferred Term</i>				
Musculoskeletal stiffness	1	1	1	1
Myalgia		1		1
Neck pain		1		1
Pain in extremity		1		1
	1	4	1	4

System Organ Class

Nervous system disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
<i>Preferred Term</i>				
Headache	1	2	1	2
	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LATVIA**

System Organ Class

**Blood and lymphatic system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		2		1		1
Lymphadenopathy		22		18		4
Lymph node pain		6		3		3
		30		22		8

System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Arrhythmia		2				2
Atrial fibrillation		1				1
Bradycardia		1				1
Bundle branch block left		1				1
Extrasystoles		1				1
Palpitations		3				3
Tachycardia		7		1		6
		17		1		16

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Ear discomfort		1				1
Ear pain		2		1		1
Hypoacusis		1		1		
Vertigo	1	4	1	4		
	1	9	1	6		3

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypothyroidism		1		1
		1		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1		1		
Blepharitis		1		1		
Conjunctival haemorrhage		1				1
Diplopia		1				1
Eye pain		12		12		
Lacrimation increased	1	2	1	1		1
Photophobia		3		2		1
Vision blurred		1				1
	1	22	1	17		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		5		5		
Abdominal pain lower		1		1		
Abdominal pain upper		2				2
Diarrhoea		6		6		
Dry mouth		2		1		1
Nausea		25		24		1
Oral discomfort		1		1		
Palatal swelling		1		1		
Paraesthesia oral		2				2
Stomatitis		1				1
Tongue spasm		1				1
Toothache		1		1		
Vomiting		7		6		1
		55		46		9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		25		21		4
Chest discomfort	1	1			1	1
Chest pain		2		2		
Chills		54		54		
Condition aggravated		2		1		1
Disease recurrence		2				2
Drug ineffective		3				3
Face oedema		1				1
Fatigue	1	70		62	1	8
Feeling hot		2		2		
Gait disturbance		2		2		
Generalised oedema		1				1
Illness		2		2		
Influenza like illness		1		1		
Malaise		3		3		
Oedema mucosal	1	1			1	1
Oedema peripheral		1				1
Pain	1	4	1	3		1
Peripheral swelling	1	1	1	1		
Pyrexia		81		66		15
Thirst		2		1		1
Vaccination site discolouration		1		1		
Vaccination site erythema		12		10		2
Vaccination site haematoma		1				1
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation	1	1	1	1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		2				2
Vaccination site oedema		8		6		2
Vaccination site pain	1	73	1	69		4
Vaccination site pruritus		4		3		1
Vaccination site rash		2				2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction		2		2		
Vaccination site swelling		1		1		
Vaccination site warmth		5		4		1
	7	375	4	319	3	56

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Bacille Calmette-Guerin scar reactivation		1		1		
		2		1		1

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	3	9		3	3	6
Herpes zoster		1				1
Nasopharyngitis		1		1		
	3	11		4	3	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy		2		1		1
Inappropriate schedule of product administration		1		1		
Off label use		2		2		
Product use issue		1		1		
Vaccination failure	3	3			3	3
	3	9		5	3	4

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1	1			
Blood pressure decreased		1	1			
Blood pressure increased		3	1		2	
Body temperature decreased		1	1			
Body temperature increased	2	49	2	48	1	
C-reactive protein increased		3		3		
Glomerular filtration rate decreased		1		1		
Heart rate increased		2		1	1	
Neutrophil count increased		1		1		
Pulse volume decreased		1		1		
SARS-CoV-2 test positive		1			1	
	2	64	2	59	5	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		7		7
Increased appetite		1		1
		8		8

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		51		47		4
Back pain		2		2		
Bone pain		2		2		
Joint range of motion decreased		1		1		
Joint stiffness		2		1		1
Muscle spasms		2		1		1
Muscular weakness		5		2		3
Musculoskeletal discomfort		2		2		
Musculoskeletal stiffness		2		1		1
Myalgia	1	58	1	54		4
Neck pain		3		2		1
Pain in extremity		8		6		2
Rhabdomyolysis		1				1
Somatic dysfunction		1				1
	1	140	1	121		19

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia	1	1			1	1
Burning sensation		4		1		3
Coordination abnormal		1		1		
Disturbance in attention		8		5		3
Dizziness	1	21		17	1	4
Dysgeusia		4		2		2
Facial paralysis		1				1
Facial paresis		2				2
Generalised tonic-clonic seizure		1				1
Headache		79		70		9
Head discomfort		1		1		
Hyperaesthesia		7		4		3
Hypoaesthesia		1				1
Loss of proprioception		1				1
Mental impairment		1				1
Migraine		2		1		1
Neuralgia		3				3
Paraesthesia		7		1		6
Peripheral sensory neuropathy		1				1
Presyncope		1				1
Restless legs syndrome		1		1		
Somnolence		9		7		2
Syncope		2				2
Transient ischaemic attack	1	1			1	1
Tunnel vision		1				1
Vertebrobasilar stroke	1	1			1	1
	4	162		111	4	51

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		2				2
Bradyphrenia		1		1		
Confusional state		1		1		
Depressed mood		1		1		
Depression		1		1		
Initial insomnia		3		3		
Insomnia		2		1		1
Sleep disorder		2		2		
Sleep disorder due to general medical condition, insomnia type		1		1		
		14		11		3

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Costovertebral angle tenderness		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Polymenorrhoea		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Asthma		2		1			1
Cough	1	8	1	8			
Dysphonia		2		2			
Dyspnoea		6		3			3
Dyspnoea exertional		2		2			
Epistaxis		1					1
Nasal congestion		2		2			
Nasal oedema		1		1			
Oropharyngeal pain		6		5			1
Pharyngeal oedema		1		1			
Respiratory distress		1					1
Rhinorrhoea	1	2		1	1		1
Throat irritation		4		4			
Upper respiratory tract congestion		1		1			
	2	39	1	31	1		8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		2		1		1
Dry skin		1		1		
Erythema		2		1		1
Hyperhidrosis		7		7		
Night sweats		1		1		
Pruritus		3		1		2
Purpura		2				2
Rash	1	4	1	3		1
Rash macular		1		1		
Rash pruritic		3		3		
Skin burning sensation		1				1
Skin tightness		1				1
Urticaria	1	1	1	1		
Vasculitic rash	1	1	1	1		
	3	30	3	21		9

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		3		2		1
Hypertension		3		2		1
Hypertensive crisis		2				2
Hypotension		1		1		
Peripheral coldness		2		1		1
		11		6		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LEBANON**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles		1				1
Tachycardia	2	2	2	2		
	2	3	2	2		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vision blurred	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper		1		1
Diarrhoea	1	1	1	1
Irritable bowel syndrome		1		1
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort		1		1		
Chills	3	6	3	5		1
Death	10	11			10	11
Drug ineffective	2	4			2	4
Fatigue	1	2	1	2		
Feeling cold	1	1	1	1		
Malaise		1		1		
Pain		1		1		
Pyrexia	2	6	2	5		1
Vaccination site pain		1		1		
	19	34	7	17	12	17

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient	1	1	1	1		
Anaphylactic reaction		1				1
Hypersensitivity		1				1
	1	3	1	1		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	7	14	1	4	6	10
Influenza		1		1		
Pyelonephritis	1	1			1	1
	8	16	1	5	7	11

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect route of product administration		2		2		
Vaccination failure	4	4			4	4
	4	6		2	4	4

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dehydration	1	1	1	1
	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain		2		2
Limb discomfort		1		1
Muscle twitching		1		1
Myalgia		2		2
Pain in extremity		2		2
	1	9	1	9

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident		1			1	
Dizziness		1		1		
Facial paralysis	1	1			1	1
Facial paresis		1				1
Headache	1	4	1	4		
Hypoesthesia	1	1	1	1		
Loss of consciousness	1	1			1	1
Paraesthesia		4		4		
Sciatica		1		1		
Speech disorder		1		1		
	4	16	2	12	2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Insomnia	1	1	1	1
Mood altered	1	1	1	1
Panic attack	1	1	1	1
	3	3	3	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia		1				1
Dyspnoea	1	2	1	2		
Lung disorder	1	1			1	1
Oropharyngeal pain		2		2		
Respiratory tract oedema		1				1
Rhinorrhoea	2	2	2	2		
Throat irritation	2	2	2	2		
Throat tightness	1	1			1	1
	7	12	5	8	2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic		1		1		
Erythema	1	1			1	1
Hyperhidrosis	1	1	1	1		
Pruritus	1	1			1	1
Rash		2				2
Urticaria		1		1		
	3	7	1	3	2	4

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1	1	1		
Hypertension	3	5	2	3	1	2
Hypotension	1	1	1	1		
	5	7	4	5	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LIECHTENSTEIN**

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term

	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LITHUANIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia		1				1
Lymphadenopathy	1	6	1	5		1
Lymph node pain		1				1
	1	8	1	5		3

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	2	4			2	4
Arrhythmia	1	1			1	1
Cardiogenic shock		1				1
Tachycardia		2		1		1
	3	8		1	3	7

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain	1	2	1	2		
Hypoacusis		1		1		
Tinnitus		2		1		1
	1	5	1	4		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye	1	1	1	1		
Eye disorder	1	1	1	1		
Eye irritation		1		1		
Eyelid function disorder		1				1
Eye pain	3	5	3	5		
Lacrimation increased	1	3	1	2		1
Visual impairment	1	1	1	1		
	7	13	7	11		2

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		3		2		1
Chronic gastritis		1		1		
Diarrhoea		6		4		2
Diverticulum		1		1		
Dyspepsia		1		1		
Dysphagia		1				1
Flatulence		1		1		
Hypoaesthesia oral		1				1
Lip swelling		1		1		
Nausea	5	13	4	9	1	4
Vomiting		6		2		4
	5	36	4	23	1	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	9	25	8	19	1	6
Axillary pain	3	5	3	4		1
Chest discomfort		1				1
Chest pain		1		1		
Chills	4	17	4	15		2
Condition aggravated		2				2
Death		3				3
Fatigue	1	6	1	5		1
Feeling abnormal		1		1		
Feeling drunk		1		1		
Feeling hot		2		1		1
Feeling of body temperature change	1	1	1	1		
Gait disturbance	1	1			1	1
Injected limb mobility decreased	1	1	1	1		
Local reaction		1				1
Malaise	1	3	1	1		2
Mucosal disorder	1	1	1	1		
Non-cardiac chest pain	1	1	1	1		
Pain		2		1		1
Peripheral swelling		4		3		1
Pyrexia	8	26	8	25		1
Sensation of foreign body		1				1
Swelling face		1		1		
Vaccination site erythema	3	10	3	9		1
Vaccination site induration	1	1	1	1		
Vaccination site inflammation		1		1		
Vaccination site pain	5	19	5	18		1
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling	4	9	4	8		1
Vaccination site warmth		3		2		1
	45	152	43	123	2	29

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction		2		2
Anaphylactic shock		1		1
Hypersensitivity		1		1
		4		4

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic sinusitis	1	1	1	1		
COVID-19	1	1	1	1		
COVID-19 pneumonia		1				1
Herpes simplex		1		1		
Lymph node abscess	9	9			9	9
Nasopharyngitis	3	3	3	3		
Peritonitis		1				1
Peritonsillar abscess	1	1			1	1
Pneumonia	1	1			1	1
	16	19	5	6	11	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1				1
Exposure during pregnancy		1		1		
Off label use		1		1		
Overdose		1		1		
Product preparation issue		1				1
Product use issue		1		1		
Underdose		1		1		
Vaccination complication		1		1		
Vaccination failure		1				1
		9		6		3

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal	1	1	1	1		
Blood pressure ambulatory increased	1	1	1	1		
Blood pressure decreased		2				2
Blood pressure increased		7		1		6
Body temperature increased	2	4	2	3		1
Heart rate increased	1	8	1	5		3
Heart rate irregular		1				1
Lymph node palpable		1				1
	5	25	5	11		14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	2	1	2
	1	2	1	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	14	4	13		1
Back pain		1		1		
Bone pain	3	5	3	5		
Facial asymmetry		1				1
Mobility decreased	1	1	1	1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Muscular weakness		2		2		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	4	19	4	17		2
Myositis		1		1		
Neck pain	1	3	1	3		
Pain in extremity	7	16	6	15	1	1
Polymyositis		1				1
Tendon pain		1		1		
	21	68	20	62	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Cognitive disorder		1				1
Convulsions local		1				1
Coordination abnormal		1				1
Depressed level of consciousness	1	1			1	1
Dizziness	2	13	1	9	1	4
Dysgeusia		1		1		
Epilepsy		1				1
Facial nerve disorder	1	1	1	1		
Facial paralysis	1	5			1	5
Headache	7	26	6	19	1	7
Head discomfort	1	1	1	1		
Hypoaesthesia	1	9	1	8		1
Loss of consciousness		4				4
Memory impairment		1		1		
Neuralgia		1				1
Paraesthesia	1	3	1	2		1
Paresis		1				1
Seizure		5				5
Slow response to stimuli	1	1	1	1		
Somnolence	1	4	1	4		
Syncope		6				6
Taste disorder		1				1
Tremor		5		3		2
	17	94	13	51	4	43

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1			1	1
Apathy		1		1		
Confusional state		1		1		
Disorientation		2				2
Insomnia	1	1	1	1		
Irritability		1				1
Stress		1		1		
	2	8	1	4	1	4

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary incontinence		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	3	4	3	4		
Dyspnoea		5		2		3
Pulmonary oedema		1				1
Rhinorrhoea	1	1	1	1		
Sneezing		1		1		
Tonsillar hypertrophy	1	1	1	1		
	5	13	5	9		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Erythema	2	3	2	2		1
Hyperhidrosis	1	2	1	2		
Pain of skin	1	1	1	1		
Pruritus		2		2		
Rash	1	1	1	1		
Rash maculo-papular	1	1	1	1		
Rash papular		1				1
Sensitive skin		1		1		
Skin mass		1				1
	6	14	6	11		3

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation		2		1		1
Deep vein thrombosis	1	1			1	1
Hot flush	1	1	1	1		
Hypertension		2		1		1
Hypertensive crisis		1				1
Hypotension		1				1
Pallor	1	1			1	1
Peripheral coldness		1		1		
Thrombosis	1	1			1	1
	4	11	1	4	3	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LUXEMBOURG**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	3	5	3	4		1
	3	5	3	4		1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome	1	1	1	1
Arrhythmia	1	2	1	2
Palpitations		3		3
Tachycardia	1	4	1	4
	3	10	3	10

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1			1	1
Vertigo	1	1	1	1		
	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia		1				1
Eyelid oedema	2	2	1	1	1	1
Eye movement disorder		1				1
Eye pain	1	1			1	1
	3	5	1	1	2	4

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper	1	2			1	2
Diarrhoea	1	7	1	1		6
Dry mouth		2				2
Nausea	3	11	1	1	2	10
Paraesthesia oral	1	1	1	1		
Rectal haemorrhage		1				1
Tongue ulceration		1				1
Vomiting		4				4
	6	30	3	3	3	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		3		1		2
Chest discomfort	1	3			1	3
Chest pain		2		1		1
Chills	3	16	3	3		13
Drug ineffective		1				1
Face oedema	1	2			1	2
Fatigue	4	28	2	3	2	25
Feeling abnormal		1				1
Feeling hot		1				1
General physical health deterioration		1				1
Hyperthermia	1	2	1	1		1
Injected limb mobility decreased		1				1
Injection site reaction	1	1	1	1		
Malaise	3	12	1	3	2	9
Pain		1				1
Peripheral swelling	2	3	1	2	1	1
Pyrexia	4	18	2	2	2	16
Swelling		1				1
Swelling face		2		1		1
Therapeutic response unexpected	1	1	1	1		
Vaccination site pain		3				3
Vaccination site reaction	16	23	16	16		7
	37	126	28	35	9	91

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	1	1	1	1		
Hypersensitivity		3				3
	1	4	1	1		3

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctivitis		1				1
COVID-19	1	2			1	2
Herpes zoster		1		1		
Influenza	1	6		2	1	4
Nasopharyngitis		1		1		
Oral herpes		1		1		
Pneumonia	1	1			1	1
Sepsis		1				1
Urinary tract infection	1	1	1	1		
	4	15	1	6	3	9

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chillblains	1	1	1	1		
Fall	1	2			1	2
Vaccination complication		4				4
	2	7	1	1	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Blood pressure increased		1		1
Haemoglobin decreased		1		1
Heart rate increased		1		1
Oxygen saturation decreased		1		1
Pulse abnormal		1		1
SARS-CoV-2 antibody test negative		1		1
		6		6

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		1			1	
Feeding disorder		1			1	
Hypernatraemia		1			1	
Tetany	1	1	1	1		
Vitamin B12 deficiency		1			1	
	1	5	1	1	4	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	16	4	4	1	12
Back pain		1		1		
Muscular weakness		1				1
Musculoskeletal stiffness	1	2			1	2
Myalgia	5	26	4	6	1	20
Neck pain	1	2		1	1	1
Pain in extremity	3	6	2	2	1	4
	15	54	10	14	5	40

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness		1				1
Cerebral haemorrhage	1	1			1	1
Dizziness	2	6			2	6
Dysaesthesia		1				1
Dysgeusia		1				1
Epilepsy	2	3			2	3
Formication		1				1
Headache	9	36	6	6	3	30
Hemiparaesthesia		1				1
Hypersomnia		1		1		
Hypoaesthesia	1	1			1	1
Loss of consciousness		2				2
Migraine		1				1
Paraesthesia		3				3
Paresis	1	1			1	1
Presyncope		1				1
Somnolence		1				1
Tremor	2	3	1	1	1	2
Vlth nerve paralysis	1	1			1	1
	19	66	7	8	12	58

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	2	1	1		1
Bradyphrenia		1				1
Insomnia		1				1
	1	4	1	1		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury		1		1
Urinary incontinence		1		1
		2		2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthmatic crisis		1		1
Cough		1		1
Dysphonia	1	2	1	2
Dyspnoea		5		5
Dyspnoea exertional		1		1
Epistaxis		1		1
Hypoxia		1		1
Laryngeal discomfort		1		1
Lung disorder		1		1
Oropharyngeal discomfort		1		1
Productive cough		1		1
Pulmonary embolism	3	3	3	3
Pulmonary pain		1		1
Respiratory failure		1		1
Throat tightness	1	1	1	1
Wheezing		2		2
	5	24	5	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic		1				1
Dermatitis bullous		1				1
Dry skin		1				1
Erythema nodosum		1				1
Hyperhidrosis		2				2
Pruritus	1	6	1	1		5
Rash		3				3
Skin haemorrhage		1				1
Urticaria	1	1	1	1		
	2	17	2	2		15

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	1	1			1	1
Haematoma	1	1	1	1		
Hot flush	1	1			1	1
Hypertension	3	7	1	1	2	6
Hypotension	1	5		1	1	4
Pallor		1				1
Peripheral coldness	1	1			1	1
	8	17	2	3	6	14

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**MACAO**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**MACEDONIA, THE FORMER YUGOSLAV**

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye oedema		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lip oedema		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Administration site pain		1		1
Asthenia		1		1
Malaise		4		4
Pyrexia		4		4
Vaccination site pain	1	1	1	1
	1	11	1	11

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity		1		1
		1		1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nasopharyngitis		1		1
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration		1		1
		1		1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Body temperature increased		3		3
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Myalgia	1	3	1	3
	2	4	2	4

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	2	4	2	4		
Loss of consciousness	1	1			1	1
	3	5	2	4	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rhinorrhoea		1		1
		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rash maculo-papular		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MALAYSIA**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Constipation	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Death		1				1
Fatigue	1	1	1	1		
Malaise		1		1		
No adverse event		1		1		
Pyrexia	1	1	1	1		
Vaccination site pain	1	2	1	2		
	4	8	4	7		1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal stiffness	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness		1		1		
Headache	2	2	2	2		
Hypoaesthesia	1	1	1	1		
Neuropathy peripheral		2				2
Seizure		1				1
	3	7	3	4		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hair texture abnormal	1	1	1	1		
Rash erythematous	1	1	1	1		
Rash papular	1	1	1	1		
Skin necrosis	1	1			1	1
Urticaria		1		1		
	4	5	3	4	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MALTA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	2	1	2		
Lymph node pain		1		1		
Normochromic normocytic anaemia		1		1		
Nucleated red cells		1		1		
Thrombocytopenia		1				1
	1	6	1	5		1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial fibrillation		1				1
Palpitations	3	5		1	3	4
Sinus tachycardia		1				1
Tachycardia		2				2
	3	9		1	3	8

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear swelling		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Goitre		1		1
		1		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye swelling	1	1			1	1
Ocular hyperaemia		1		1		
Periorbital swelling		1		1		
Retinal vein occlusion	1	1			1	1
Vision blurred	2	2			2	2
	4	6		2	4	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		2		
Defaecation urgency		1		1		
Diarrhoea		3		2		1
Dysphagia		1				1
Lip swelling	1	2		1	1	1
Nausea		4		3		1
Swollen tongue	1	1			1	1
Toothache	1	1	1	1		
Vomiting		3		2		1
	3	19	1	13	2	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Asthenia		1		1			
Chest discomfort	2	2			2	2	
Chest pain	2	2	1	1	1	1	
Chills	2	10	2	10			
Discomfort		1		1			
Drug ineffective		6				6	
Fatigue	4	16	4	14		2	
Feeling abnormal		1		1			
Feeling of body temperature change	1	1			1	1	
Gait disturbance		1		1			
Gait inability		1		1			
Hypothermia		1				1	
Influenza like illness		1		1			
Injection site pain		1		1			
Malaise		6		6			
Pain	2	9	2	9			
Peripheral swelling	1	1	1	1			
Pyrexia	5	23	5	21		2	
Swelling		1				1	
Swelling face	3	5	1	2	2	3	
Vaccination site discomfort		1		1			
Vaccination site erythema	1	1	1	1			
Vaccination site induration		1		1			
Vaccination site movement impairment		1		1			
Vaccination site pain	2	12	2	12			
Vaccination site pruritus	2	2	2	2			
Vaccination site rash	1	1	1	1			
Vaccination site urticaria		2		1		1	
	28	111	22	91	6	20	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	3	7			3	7
Hypersensitivity	4	7	1	3	3	4
	7	14	1	3	6	11

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis infective	1	1			1	1
COVID-19	1	9		1	1	8
COVID-19 pneumonia		2				2
Sepsis		1				1
Septic shock		1				1
	2	14		1	2	13

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	2	1	2		
Overdose		1		1		
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Vaccination failure	1	2			1	2
	2	7	1	5	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Activated partial thromboplastin time prolonged		1		1
Activated partial thromboplastin time ratio increased		1		1
Alanine aminotransferase increased		1		1
Basophil count increased		1		1
Blood alkaline phosphatase increased		1		1
Blood creatinine increased		1		1
Blood glucose increased		1		1
Blood magnesium decreased		1		1
Blood osmolarity increased		1		1
Blood phosphorus decreased		1		1
Blood urea increased		2		2
C-reactive protein increased		2		2
Eosinophil count decreased		1		1
Haematocrit decreased		2		2
Haemoglobin decreased		2		2
Heart rate increased	1	1	1	1
Immature granulocyte count increased		1		1
Lymphocyte count decreased		2		2
Mean cell haemoglobin concentration increased		1		1
Monocyte count decreased		1		1
Monocyte count increased		1		1
Neutrophil count increased		2		2
Oxygen saturation decreased		1		1
Platelet count decreased		1		1
Platelet count increased		1		1
Red blood cell count decreased		2		2
Red cell distribution width increased		1		1
Reticulocyte count increased		1		1
White blood cell count increased		1		1
	1	36	1	36

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dehydration		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	4	2	4		
Bone pain	1	2	1	2		
Limb discomfort		2		1		1
Mobility decreased		1		1		
Muscle spasms	1	1	1	1		
Muscle twitching		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	3	9	3	9		
Neck pain	2	3	1	2	1	1
Pain in extremity	2	9	2	7		2
	11	34	10	30	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness		1				1
Burning sensation	2	2	1	1	1	1
Cerebellar atrophy		1				1
Cerebral atrophy		2				2
Cerebrovascular accident	1	1			1	1
Dizziness		4		4		
Dysgeusia		2		1		1
Facial paralysis	2	5			2	5
Generalised tonic-clonic seizure		1				1
Headache	4	6	3	5	1	1
Hypoaesthesia		4		3		1
Lethargy	4	11	4	11		
Migraine		1		1		
Paraesthesia		5		5		
Parosmia		1		1		
Somnolence		3		3		
Syncope	1	3			1	3
Taste disorder	1	1	1	1		
Tremor	1	1			1	1
	16	55	9	36	7	19

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fear of injection		1		1
Insomnia		1		1
Panic reaction		1		1
Restlessness		1		1
		4		4

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		2				2
Bronchospasm		1				1
Cough		3		2		1
Dysphonia	2	3			2	3
Dyspnoea	1	4			1	4
Hypoxia		2				2
Oropharyngeal pain		1		1		
Pulmonary embolism	1	1			1	1
Respiratory depression		1				1
Respiratory distress		1				1
Tachypnoea		2				2
Throat tightness		1				1
Wheezing		2				2
	4	24		3	4	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	3	8	2	5	1	3
Hyperhidrosis		3		3		
Night sweats		1		1		
Pruritus	3	8	1	4	2	4
Rash	1	5	1	3		2
Rash erythematous		3		1		2
Rash pruritic	1	2			1	2
Urticaria	1	3	1	2		1
	9	33	5	19	4	14

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Injection		1		1
		1		1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis		1				1
Flushing	1	1	1	1		
Hot flush	1	3	1	3		
Hypertension	1	3	1	1		2
Peripheral coldness		1		1		
Poor peripheral circulation		1		1		
	3	10	3	7		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MEXICO**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia	1	1			1	1
Haemorrhagic disorder	9	10			9	10
Leukopenia		3				3
Lymphadenitis	1	2	1	2		
Lymphadenopathy	36	91	33	82	3	9
Lymph node pain		1		1		
Lymphopenia		2		1		1
Splenomegaly	1	1	1	1		
Thrombocytopenia	1	2			1	2
Thrombocytopenic purpura	2	3	1	2	1	1
	51	116	36	89	15	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Angina pectoris		1				1
Arrhythmia	4	8			4	8
Atrial fibrillation		2				2
Bradycardia	2	19			2	19
Cardio-respiratory arrest	2	2			2	2
Cardiovascular disorder	1	1	1	1		
Myocardial infarction	1	2			1	2
Palpitations	7	24	6	20	1	4
Pericardial disease	1	1	1	1		
Sinus tachycardia	2	4	1	2	1	2
Tachyarrhythmia		1		1		
Tachycardia	111	456	73	354	38	102
	132	523	82	379	50	144

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling		1		1		
Deafness		1				1
Deafness unilateral		2				2
Ear discomfort		5		5		
Ear disorder		1		1		
Ear pain	3	9	3	8		1
External ear inflammation		1		1		
Hypoacusis		3		3		
Tinnitus	4	14	2	11	2	3
Tympanic membrane disorder		1		1		
Vertigo	11	34	10	28	1	6
	18	72	15	59	3	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharitis	1	1	1	1		
Blepharospasm		1		1		
Blindness		1				1
Blindness transient		1				1
Conjunctival haemorrhage	3	5			3	5
Conjunctival hyperaemia	1	4		3	1	1
Diplopia	1	2	1	2		
Eye discharge	1	1	1	1		
Eye disorder	1	3	1	3		
Eye inflammation		1		1		
Eye irritation	4	14	4	14		
Eyelid oedema	3	8	1	6	2	2
Eyelid pain		1		1		
Eyelid ptosis	3	5	3	5		
Eyelid rash		1		1		
Eyelid sensory disorder		1		1		
Eyelids pruritus		1		1		
Eye movement disorder		1				1
Eye pain	6	21	5	20	1	1
Eye pruritus	1	4	1	4		
Eye swelling	1	3	1	2		1
Foreign body sensation in eyes		1		1		
Lacrimation increased	3	13	3	13		
Metamorphopsia		1		1		
Ocular discomfort	1	2	1	2		
Ocular hyperaemia	4	10	3	9	1	1
Periorbital oedema		1		1		
Photophobia	1	5	1	5		
Photopsia	2	6	1	4	1	2
Vision blurred	8	31	7	26	1	5
Visual impairment		1		1		
Xerophthalmia	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	46	152	35	130	11	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	4	2	3	1	1
Abdominal distension		2		2		
Abdominal pain	46	176	35	153	11	23
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	2	9	2	8		1
Abdominal symptom	1	1	1	1		
Abnormal faeces	2	5	1	3	1	2
Aphthous ulcer	2	2	2	2		
Bowel movement irregularity		1		1		
Colitis	1	2	1	2		
Diarrhoea	68	231	47	193	21	38
Diarrhoea haemorrhagic		1				1
Diverticulum intestinal	1	1			1	1
Dry mouth	7	22	5	15	2	7
Dyspepsia	1	2	1	2		
Dysphagia	1	17	1	13		4
Epigastric discomfort		1		1		
Faeces discoloured		1		1		
Frequent bowel movements		1		1		
Gastritis	2	4	2	4		
Gastrointestinal disorder		1				1
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal hypermotility	1	1	1	1		
Gastrointestinal hypomotility	1	1	1	1		
Gastrointestinal motility disorder	2	3	2	3		
Gastrooesophageal reflux disease	1	1	1	1		
Gingival bleeding	1	1	1	1		
Gingival pain	1	1	1	1		
Gingival swelling	1	1	1	1		
Glossodynia	1	1	1	1		
Haematochezia	9	19			9	19
Hypoaesthesia oral	4	15	3	12	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intussusception	9	13			9	13
Lip discolouration		1		1		
Lip disorder		2		2		
Lip oedema	3	7	3	7		
Lip pain	1	1	1	1		
Melaena	1	1			1	1
Mouth haemorrhage		1				1
Mouth swelling	1	1			1	1
Mucous stools		1		1		
Nausea	183	568	137	480	46	88
Noninfective gingivitis	1	1	1	1		
Odynophagia	20	62	15	52	5	10
Oral discomfort	1	1			1	1
Oral disorder	2	2	1	1	1	1
Oral dysaesthesia		1		1		
Paraesthesia oral	13	32	8	22	5	10
Parotid gland enlargement		1		1		
Salivary hypersecretion	1	2	1	1		1
Stomatitis	1	1	1	1		
Swollen tongue	2	2	2	2		
Tongue oedema		3		2		1
Toothache		2		2		
Vomiting	84	234	56	182	28	52
	484	1,470	339	1188	145	282

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Application site pain		1		1			
Asthenia	274	835	222	732	52	103	
Atrophy	1	1	1	1			
Axillary pain	3	7	3	7			
Chest discomfort	4	21	1	16	3	5	
Chest pain	22	94	15	75	7	19	
Chills	145	555	113	478	32	77	
Condition aggravated	2	5	1	2	1	3	
Crying	13	32	12	29	1	3	
Death	1	3			1	3	
Decreased activity		1		1			
Discharge		1		1			
Discomfort	14	47	11	42	3	5	
Disease recurrence	1	5		3	1	2	
Drug ineffective	5	30			5	30	
Face oedema	2	7	2	7			
Fatigue	192	641	157	566	35	75	
Feeling abnormal	2	7	2	5		2	
Feeling cold	2	7	1	6	1	1	
Feeling drunk	1	1	1	1			
Feeling hot	3	17	3	12		5	
Feeling of body temperature change		1		1			
Fibrosis	1	1	1	1			
Gait disturbance	2	6	2	6			
Generalised oedema	1	1	1	1			
General physical health deterioration	2	12	2	12			
General symptom	1	1			1	1	
Hunger		2		2			
Hyperpyrexia		1				1	
Hyperthermia	6	16	5	15	1	1	
Hypothermia	4	17			4	17	
Induration	61	165	54	152	7	13	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammation	42	149	36	134	6	15
Influenza like illness	1	3	1	3		
Injection site haemorrhage		1		1		
Injection site pain	1	1	1	1		
Irritability postvaccinal		3		3		
Localised oedema	2	3	2	3		
Local reaction	14	55	14	52		3
Malaise	35	106	28	93	7	13
Mass		1		1		
Mucosal dryness	2	2	2	2		
Nodule	66	184	59	167	7	17
Oedema	55	223	41	186	14	37
Oedema peripheral	8	17	7	16	1	1
Oral administration complication		1		1		
Pain	224	736	182	645	42	91
Peripheral swelling	3	4	2	2	1	2
Pyrexia	146	542	124	482	22	60
Screaming	1	1	1	1		
Secretion discharge		1		1		
Sensation of foreign body	9	18	1	6	8	12
Sudden infant death syndrome	1	1			1	1
Swelling	5	10	5	8		2
Swelling face	2	3	1	2	1	1
Temperature intolerance		2		2		
Temperature regulation disorder	1	1	1	1		
Tenderness		4		4		
Thirst		4		3		1
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort	5	7	5	7		
Vaccination site erythema	10	25	9	23	1	2
Vaccination site haematoma	2	2	2	2		
Vaccination site haemorrhage	1	2	1	1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hyperaesthesia	2	5	2	5		
Vaccination site hypersensitivity	11	37	11	37		
Vaccination site hypoaesthesia	1	3	1	3		
Vaccination site induration	10	35	9	30	1	5
Vaccination site inflammation	5	20	4	18	1	2
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site joint pain		1		1		
Vaccination site movement impairment	3	7	3	7		
Vaccination site nodule	4	17	3	15	1	2
Vaccination site oedema	5	18	4	15	1	3
Vaccination site pain	111	345	105	328	6	17
Vaccination site paraesthesia	1	4	1	4		
Vaccination site pruritus	3	7	3	6		1
Vaccination site rash	1	3	1	2		1
Vaccination site reaction	6	21	6	20		1
Vaccination site recall reaction	1	1	1	1		
Vaccination site swelling	5	6	5	6		
Vaccination site warmth	1	15	1	15		
	1,573	5,200	1297	4543	276	657

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deficiency of bile secretion		1				1
Hepatic function abnormal	1	1	1	1		
Hepatic pain		1		1		
Hyperbilirubinaemia		1				1
Jaundice	1	2			1	2
	2	6	1	2	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		7		6		1
Anaphylactic reaction	10	27			10	27
Anaphylactic shock	14	45			14	45
Anaphylactoid reaction		1				1
Drug hypersensitivity	2	3			2	3
Hypersensitivity	7	41	5	32	2	9
Sensitisation		2		2		
Type I hypersensitivity		1				1
	33	127	5	40	28	87

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	7	8	6	7	1	1
Asymptomatic COVID-19		1				1
Atypical pneumonia		1				1
Cellulitis	19	44			19	44
Conjunctivitis	4	12	4	12		
COVID-19	20	63	15	33	5	30
COVID-19 pneumonia	1	6			1	6
Cystitis	1	1	1	1		
Disseminated Bacillus Calmette-Guerin infection	7	12			7	12
Ear infection	1	3	1	3		
Gastroenteritis	1	2		1	1	1
Herpes zoster	1	2	1	2		
Influenza	2	5	2	5		
Lymphangitis		1				1
Measles	1	1			1	1
Meningitis		2				2
Myelitis		1				1
Nasal abscess	1	1			1	1
Nasopharyngitis	2	7	1	5	1	2
Oral candidiasis	1	2	1	2		
Oral herpes	1	1	1	1		
Otitis externa		1		1		
Otitis media	1	1	1	1		
Otitis media acute		1		1		
Parotitis		2		2		
Pharyngitis		1				1
Pneumonia	5	23			5	23
Pyelonephritis		1				1
Respiratory tract infection viral		1		1		
Rhinitis	1	3	1	3		
Sepsis	1	1			1	1
Septic shock	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sputum purulent		1				1
Suspected COVID-19	2	6		3	2	3
Sweating fever		1				1
Urinary tract infection	1	2	1	2		
Vaccination site abscess	1	2	1	2		
Vaccination site cellulitis	8	24	7	14	1	10
Vestibular neuronitis		1				1
	91	249	44	102	47	147

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burn oral cavity	1	1			1	1
Contusion	2	3	2	3		
Counterfeit product administered	4	4	4	4		
Expired product administered	1	2	1	2		
Exposure during pregnancy	1	3	1	3		
Exposure to SARS-CoV-2		1		1		
Exposure via breast milk		1		1		
Eye injury	3	19	1	14	2	5
Fall	4	6	2	3	2	3
Foreign body in throat		1				1
Hip fracture		1				1
Inappropriate schedule of product administration	4	10	4	10		
Incorrect route of product administration	1	1	1	1		
Joint injury		1		1		
Maternal exposure during pregnancy	5	14	5	14		
Off label use	4	12	4	12		
Overdose	1	1	1	1		
Palate injury		1		1		
Peroneal nerve injury		1				1
Poor quality product administered	2	2	2	2		
Product use issue	2	8	2	8		
Skeletal injury	1	1	1	1		
Skin injury	1	1	1	1		
Thermal burn	1	1			1	1
Thermal burns of eye	1	2			1	2
Toxicity to various agents	1	1			1	1
Traumatic lung injury		2		2		
Vaccination complication	2	2	1	1	1	1
Wrong product administered	2	2	2	2		
Wrong technique in product usage process	6	6	6	6		
	50	111	41	94	9	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased	1	1	1	1		
Antibody test abnormal	1	2	1	2		
Antibody test negative	2	3	2	3		
Aspartate aminotransferase increased	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased	2	3	2	3		
Blood pressure abnormal	1	3	1	3		
Blood pressure decreased	1	2			1	2
Blood pressure diastolic increased		1		1		
Blood pressure increased	22	50	13	31	9	19
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased	56	163	48	145	8	18
Coagulation time prolonged		1				1
C-reactive protein increased		1		1		
General physical condition abnormal		1				1
Heart rate abnormal		2		2		
Heart rate decreased		1		1		
Heart rate increased	4	14	4	13		1
Heart rate irregular		1				1
Immunology test abnormal	1	1	1	1		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Mean cell haemoglobin decreased	1	1	1	1		
Mean cell volume decreased	1	1	1	1		
Mean platelet volume decreased	1	1	1	1		
Monocyte count increased	1	1	1	1		
Muscle strength abnormal	1	1	1	1		
Neutrophil count increased	2	2	2	2		
Oxygen saturation abnormal	2	9	1	5	1	4
Oxygen saturation decreased	7	41	5	25	2	16
Platelet count decreased	1	1			1	1
Platelet count increased	3	3	3	3		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory rate increased		1		1		
SARS-CoV-2 antibody test negative		2		2		
SARS-CoV-2 test positive	1	3	1	1		2
Transaminases increased		2				2
Vascular test abnormal		1		1		
White blood cell count increased		1				1
	114	326	91	254	23	72

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	28	93	27	83	1	10
Dehydration	1	5	1	3		2
Diabetes mellitus	1	1			1	1
Diabetic ketoacidosis		1				1
Dyslipidaemia	1	1	1	1		
Electrolyte imbalance		1				1
Hyperglycaemia	3	4	2	2	1	2
Hypernatraemia		1				1
Hypoglycaemia		1				1
	34	108	31	89	3	19

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	163	616	135	547	28	69
Arthritis	1	1	1	1		
Axillary mass		1		1		
Back pain	12	34	10	31	2	3
Bone pain		2		1		1
Flank pain		1		1		
Groin pain	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Joint stiffness		1		1		
Joint swelling		1		1		
Limb discomfort	3	4	3	3		1
Masticatory pain		1		1		
Mobility decreased	2	16	2	16		
Muscle atrophy		1		1		
Muscle contracture		2		2		
Muscle fatigue	2	3	2	3		
Muscle rigidity		1		1		
Muscle spasms	3	11	3	10		1
Muscle tightness	1	2	1	2		
Muscular weakness	10	26	3	15	7	11
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	188	720	154	640	34	80
Myalgia intercostal	1	1	1	1		
Myopathy	1	1	1	1		
Neck pain	9	24	9	24		
Pain in extremity	39	83	37	78	2	5
Pain in jaw		2		1		1
Sacroiliitis		1				1
Synovial cyst	2	2	2	2		
Systemic lupus erythematosus		1				1
	441	1,564	368	1390	73	174

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

*System Organ Class*

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Diffuse large B-cell lymphoma	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		7		6		1
Akathisia		1		1		
Allodynia		2		2		
Amnesia	1	1			1	1
Anosmia	9	27	8	24	1	3
Aphasia		2		2		
Asterixis	1	1			1	1
Ataxia		1		1		
Aura		1				1
Axonal neuropathy		1				1
Balance disorder	3	5	2	3	1	2
Brain oedema		1				1
Brain stem ischaemia	1	2			1	2
Burning sensation	4	7	3	3	1	4
Cerebral haematoma		1				1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	3	3			3	3
Clonic convulsion		1				1
Demyelinating polyneuropathy	1	1			1	1
Demyelination		3				3
Depressed level of consciousness	2	7			2	7
Diplegia		1				1
Disturbance in attention	1	2	1	2		
Dizziness	198	712	143	582	55	130
Dizziness postural		1		1		
Dysaesthesia		5		4		1
Dysarthria	1	3	1	3		
Dysgeusia	12	29	11	25	1	4
Dyskinesia	1	1	1	1		
Dyslalia	1	1			1	1
Dysstasia		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dystonia	2	2			2	2
Encephalitis post immunisation		1				1
Epilepsy	1	2			1	2
Facial nerve disorder		2		2		
Facial paralysis	8	29			8	29
Facial paresis	1	3	1	3		
Facial spasm	1	1	1	1		
Febrile convulsion	11	31	8	22	3	9
Generalised tonic-clonic seizure	3	8			3	8
Glabellar reflex abnormal		1		1		
Guillain-Barre syndrome	7	9			7	9
Headache	355	1,193	282	1034	73	159
Head discomfort		2		2		
Hemiparaesthesia	4	8			4	8
Hemiparesis	3	11			3	11
Hemiplegia		2				2
Hyperaesthesia	2	7	2	7		
Hyperreflexia	1	1	1	1		
Hypersomnia	1	2	1	2		
Hypoaesthesia	9	40	7	29	2	11
Hypokinesia	2	9	2	8		1
Hyposmia	1	2	1	2		
Hypotonia	2	3	2	3		
Intracranial aneurysm	1	1			1	1
Ischaemic stroke	1	1			1	1
Lateropulsion		1				1
Lethargy	1	3		1	1	2
Loss of consciousness	4	19			4	19
Migraine	1	1	1	1		
Mononeuropathy		2				2
Monoparesis	2	3	1	1	1	2
Monoplegia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Motor dysfunction		1		1		
Movement disorder	3	7	1	4	2	3
Muscle contractions involuntary	1	5		3	1	2
Muscle spasticity		1				1
Myelitis transverse		1				1
Myoclonic epilepsy	1	1			1	1
Myoclonus		1		1		
Narcolepsy	1	1			1	1
Nerve degeneration		1				1
Nervous system disorder	1	2			1	2
Neuralgia	1	1	1	1		
Neuritis	2	5	2	3		2
Neuropathy peripheral		2				2
Nystagmus		1		1		
Paraesthesia	42	133	28	100	14	33
Paraesthesia mucosal	1	1			1	1
Paralysis	5	26			5	26
Paraparesis	2	2			2	2
Paresis	2	2	2	2		
Parosmia		1		1		
Patient elopement		1		1		
Peripheral motor neuropathy		1				1
Petit mal epilepsy		1				1
Presyncope	1	4	1	2		2
Radiculitis brachial	1	1	1	1		
Radiculopathy		2				2
Reflexes abnormal	1	1	1	1		
Ruptured cerebral aneurysm		1				1
Sciatica		1				1
Sciatic nerve neuropathy		1				1
Seizure	17	69			17	69
Sensory disturbance		1		1		

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss	1	3	1	2		1
Slow response to stimuli		2		2		
Slow speech	1	1	1	1		
Somnolence	6	23	5	21	1	2
Speech disorder	1	2	1	2		
Subarachnoid haemorrhage	1	2			1	2
Syncope	15	80			15	80
Taste disorder	1	1	1	1		
Tension headache		1		1		
Tongue paralysis	1	1			1	1
Tremor	10	24	8	22	2	2
	782	2,654	534	1956	248	698

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product colour issue	1	1	1	1
Product complaint	1	1	1	1
Product supply issue		1		1
Suspected counterfeit product	4	4	4	4
	6	7	6	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect lability		1		1		
Aggression	2	2	2	2		
Agitation		1		1		
Anxiety	16	43	9	30	7	13
Confusional state		4		3		1
Conversion disorder	1	2	1	2		
Delirium	1	1			1	1
Disorientation	1	8		6	1	2
Eating disorder	1	1	1	1		
Feeling of despair	1	3	1	3		
Hallucination, visual	1	3			1	3
Insomnia	2	5	1	4	1	1
Irritability	39	112	26	91	13	21
Laziness	1	1	1	1		
Near death experience		1				1
Nervousness	1	6	1	5		1
Panic attack	1	1	1	1		
Persistent depressive disorder		1		1		
Restlessness		1		1		
Sleep disorder	1	1			1	1
Sleep inertia		1				1
Stress	1	1	1	1		
	70	200	45	154	25	46

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choluria	1	2			1	2
End stage renal disease	1	1			1	1
Urinary incontinence		2		2		
	2	5		2	2	3

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1		1		
Dysmenorrhoea		1		1		
Genital paraesthesia	1	1	1	1		
Genital tract inflammation		1		1		
Menstrual disorder		1		1		
Metrorrhagia		1		1		
Pelvic discomfort	1	1			1	1
Pelvic pain		2		2		
Vaginal haemorrhage		1		1		
	2	10	1	9	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	2	2	2	2		
Asthma	1	2	1	2		
Asthmatic crisis		2				2
Bronchial disorder		2		2		
Bronchospasm	28	73	14	38	14	35
Catarrh	1	1	1	1		
Choking	1	1			1	1
Choking sensation		1				1
Cough	81	316	61	267	20	49
Dry throat	1	2	1	1		1
Dysphonia	4	8	2	6	2	2
Dyspnoea	112	617	78	466	34	151
Dyspnoea at rest		1				1
Dyspnoea exertional	1	6	1	6		
Epiglottic oedema		2				2
Epistaxis	3	9	1	6	2	3
Haemoptysis		1		1		
Hypoventilation	1	2			1	2
Hypoxia	1	1			1	1
Laryngeal inflammation		1				1
Laryngeal obstruction		1				1
Laryngeal oedema	3	7			3	7
Laryngospasm	1	4	1	2		2
Larynx irritation		1				1
Lung disorder	1	1	1	1		
Nasal congestion	3	17	3	17		
Nasal obstruction	1	2	1	2		
Nasal pruritus	1	2	1	2		
Obstructive airways disorder		1				1
Oropharyngeal discomfort	1	10		5	1	5
Oropharyngeal pain	76	340	61	304	15	36
Painful respiration		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal disorder	1	3	1	3		
Pharyngeal erythema	1	1	1	1		
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation		2				2
Pharyngeal oedema		5				5
Pharyngeal paraesthesia	2	5	1	2	1	3
Pharyngeal ulceration	1	1	1	1		
Pleural effusion		1		1		
Pneumonitis		1		1		
Productive cough	2	3	1	2	1	1
Pulmonary oedema		1				1
Pulmonary pain	1	1	1	1		
Rales		1		1		
Respiratory arrest	2	2			2	2
Respiratory disorder	2	3	1	2	1	1
Respiratory distress	105	605			105	605
Respiratory failure	2	3			2	3
Rhinalgia		1		1		
Rhinorrhoea	64	276	60	256	4	20
Sneezing	1	2	1	2		
Sputum discoloured		1		1		
Stridor	1	2			1	2
Suffocation feeling		3		2		1
Tachypnoea	6	13	1	5	5	8
Throat irritation	1	14	1	12		2
Throat tightness	2	3	1	2	1	1
Upper-airway cough syndrome		1		1		
Upper airway obstruction		1				1
Wheezing	3	6		2	3	4
	521	2,400	301	1432	220	968

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	2	2	2	2		
Angioedema	2	10			2	10
Blister	2	4	1	2	1	2
Cold sweat		1		1		
Dermatitis allergic	2	2	2	2		
Dermatosis		2		2		
Ecchymosis	2	3	1	2	1	1
Erythema	60	192	46	165	14	27
Erythema multiforme		1				1
Hyperhidrosis	13	47	5	32	8	15
Livedo reticularis	2	3	2	3		
Mechanical urticaria		1		1		
Nail discolouration		1		1		
Night sweats	1	2		1	1	1
Pain of skin	1	3	1	3		
Palmar erythema		1		1		
Papule	1	2	1	2		
Petechiae	2	5	1	2	1	3
Photosensitivity reaction		1		1		
Pigmentation disorder		1		1		
Prurigo		2		2		
Pruritus	67	187	50	150	17	37
Purpura		3		2		1
Rash	49	173	37	131	12	42
Rash erythematous		2		1		1
Rash macular	2	3	2	2		1
Rash maculo-papular	2	5	1	4	1	1
Scab		1				1
Sensitive skin	205	575	168	505	37	70
Skin burning sensation	1	2	1	2		
Skin discolouration	1	2	1	2		
Skin disorder		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin exfoliation		1		1		
Skin haemorrhage		1		1		
Skin lesion	1	3	1	3		
Skin mass	1	1	1	1		
Skin reaction	1	1			1	1
Skin sensitisation		2		2		
Skin swelling		1		1		
Stasis dermatitis	1	1	1	1		
Stevens-Johnson syndrome	3	5			3	5
Toxic epidermal necrolysis	1	1			1	1
Urticaria	9	15	7	13	2	2
	434	1,272	332	1049	102	223

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fasting	1	1	1	1		
Loss of personal independence in daily activities		2		1		1
	1	3	1	2		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis	2	5	1	4	1	1
Embolism	2	2			2	2
Flushing	1	10		8	1	2
Haematoma	2	2	2	2		
Haemorrhage	22	26			22	26
Hot flush	1	4	1	4		
Hyperaemia	3	7	3	6		1
Hypertension	27	104	12	60	15	44
Hypertensive crisis	11	69			11	69
Hypertensive emergency	1	2			1	2
Hypotension	9	25	4	13	5	12
Hypovolaemic shock	20	31			20	31
Pallor	1	9	1	7		2
Peripheral coldness	3	8	2	7	1	1
Peripheral vascular disorder	1	1			1	1
Raynaud's phenomenon	1	2	1	2		
Shock	1	4			1	4
Thrombosis	3	3			3	3
Vasodilatation		1		1		
	111	315	27	114	84	201

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MONACO**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Drug ineffective		1		1
		1		1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
		1		1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Speech disorder		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**NETHERLANDS**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	1	1	1		
Coagulopathy	1	1	1	1		
Coombs negative haemolytic anaemia	1	1			1	1
Immune thrombocytopenia		1				1
Increased tendency to bruise		1		1		
Leukopenia		1				1
Lymphadenopathy	35	79	34	78	1	1
Lymph node pain	5	6	5	6		
Pancytopenia	1	1			1	1
Splenic infarction	1	1			1	1
Thrombocytopenia	4	4			4	4
	49	97	41	87	8	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute cardiac event	1	1					1	1
Acute coronary syndrome		1						1
Acute myocardial infarction	5	7					5	7
Angina pectoris	5	8					5	8
Angina unstable		1						1
Aortic valve stenosis	1	3					1	3
Arrhythmia	10	17					10	17
Atrial fibrillation	6	24	1	1			6	24
Atrial flutter	1	2				1	1	1
Atrioventricular block complete	1	1					1	1
Bradycardia		4						4
Bundle branch block right		1				1		
Cardiac arrest	6	16					6	16
Cardiac asthma	5	6					5	6
Cardiac disorder	3	5			1	1	2	4
Cardiac failure	8	29					8	29
Cardiac failure acute	2	4					2	4
Cardiac failure congestive		1						1
Cardiac ventricular thrombosis		1						1
Cardiogenic shock	1	3					1	3
Cardiopulmonary failure		1						1
Coronary artery disease	1	1					1	1
Dilatation atrial		1						1
Extrasystoles	1	2			1	2		
Left ventricular dysfunction		1						1
Left ventricular failure	1	1					1	1
Left ventricular hypertrophy	1	1					1	1
Myocardial infarction	10	20					10	20
Palpitations	12	34			10	26	2	8
Pericarditis	1	3					1	3
Right ventricular failure	1	2					1	2
Sinus bradycardia	1	1					1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sinus tachycardia	1	3			1	3		
Supraventricular tachycardia		2				1		1
Tachycardia	1	11			1	7		4
Ventricular fibrillation	2	3					2	3
	88	222	1	1	14	42	74	180

System Organ Class

**Congenital, familial and genetic disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Haemophilia		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Auricular swelling		1				1			
Deafness	1	1					1	1	
Deafness neurosensory		1							1
Deafness transitory	1	1					1	1	
Deafness unilateral	2	4				1	2	3	
Ear discomfort	1	1			1	1			
Ear pain	1	5			1	5			
Hyperacusis		1				1			
Hypoacusis		1				1			
Meniere's disease	1	5					1	5	
Paraesthesia ear		1				1			
Sudden hearing loss	3	7					3	7	
Tinnitus	4	10	1	1	3	9	1	1	
Vertigo	2	14			1	12	1	2	
	16	53	1	1	6	32	10	21	

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal disorder		1		1
Pituitary apoplexy		1		1
Secondary adrenocortical insufficiency	1	1	1	1
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accommodation disorder		1				1		
Amaurosis fugax	1	1			1	1		
Blindness	4	7	1	1			4	7
Blindness unilateral	2	3					2	3
Conjunctival haemorrhage		2						2
Conjunctival oedema		1						1
Dark circles under eyes		1				1		
Diplopia	8	10			7	8	1	2
Dry eye	1	2			1	2		
Endocrine ophthalmopathy	1	1					1	1
Eye disorder	1	2			1	2		
Eye haematoma	1	1					1	1
Eye haemorrhage	3	3					3	3
Eyelid ptosis	1	1			1	1		
Eye movement disorder	1	1			1	1		
Eye pain	2	3			1	2	1	1
Eye pruritus	1	3			1	3		
Eye swelling	3	5			3	4		1
Eye symptom	1	1			1	1		
Gaze palsy		1						1
Hypotony of eye	1	1					1	1
Iridocyclitis	1	1					1	1
Lacrimation increased	1	2			1	2		
Macular degeneration		1						1
Night blindness		1				1		
Ocular discomfort		1				1		
Ocular hyperaemia		2				1		1
Ocular myasthenia	1	1					1	1
Optic nerve infarction	1	1					1	1
Oscillopsia	1	1			1	1		
Periorbital oedema	1	1			1	1		
Periorbital swelling		1				1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Photophobia	1	1			1	1		
Pupillary disorder		1				1		
Retinal artery occlusion	1	1					1	1
Retinal detachment	1	1					1	1
Retinal vein occlusion	2	2					2	2
Swelling of eyelid	2	5			2	4		1
Vision blurred	4	9			4	9		
Visual impairment	8	13			4	5	4	8
	57	97	1	1	32	55	25	42

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	12	3	10		2
Abdominal pain	12	14	10	12	2	2
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	2	11	2	11		
Abnormal faeces		1				1
Acute abdomen		1				1
Anal sphincter hypertonia		1		1		
Aphthous ulcer		1		1		
Constipation		3		2		1
Crohn's disease	1	1			1	1
Diarrhoea	18	42	16	39	2	3
Dry mouth		2		2		
Dyspepsia	1	1	1	1		
Dysphagia	4	19	1	5	3	14
Enterocolitis		1				1
Eructation		1		1		
Faeces discoloured	1	2	1	2		
Gastric haemorrhage	1	1			1	1
Gastrointestinal disorder		1		1		
Gastrointestinal haemorrhage	1	6			1	6
Gastrointestinal obstruction		1				1
Gastrointestinal pain		1		1		
Gingival discomfort	1	1	1	1		
Glossodynia		1		1		
Haematemesis		1				1
Haematochezia	1	1			1	1
Haemorrhoids		1		1		
Hiatus hernia		1				1
Hyperaesthesia teeth		1		1		
Hypoaesthesia oral		3		2		1
Intestinal haemorrhage	1	2			1	2
Intestinal ischaemia	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intestinal obstruction	1	1			1	1
Lip blister		1		1		
Lip swelling	2	4	1	2	1	2
Melaena		1				1
Mesenteric artery thrombosis		1				1
Mouth swelling	2	3	1	1	1	2
Nausea	183	437	170	398	13	39
Odynophagia	1	1	1	1		
Oral discomfort	1	1	1	1		
Oral mucosal blistering	1	3		2	1	1
Oral mucosal erythema	1	1			1	1
Oral pain	1	1	1	1		
Oral pruritus		1				1
Paraesthesia oral	5	17	4	15	1	2
Rectal haemorrhage	2	3			2	3
Rectal prolapse		1				1
Retching		3		1		2
Salivary gland pain		1		1		
Salivary hypersecretion		1				1
Small intestinal obstruction		1				1
Stiff tongue	1	1	1	1		
Stomatitis	1	1	1	1		
Swollen tongue	1	10	1	4		6
Thrombosis mesenteric vessel		1				1
Tongue disorder		4		2		2
Tongue oedema		1				1
Toothache		1		1		
Uvulitis		1		1		
Vomiting	17	53	12	33	5	20
	269	694	230	563	39	131

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	5	14	4	9	1	5
Axillary pain	3	15	3	15		
Brain death	1	1			1	1
Cardiac death	1	3			1	3
Chest discomfort	8	15	6	11	2	4
Chest pain	18	37	11	25	7	12
Chills	216	526	210	504	6	22
Condition aggravated	5	12	1	3	4	9
Death	7	34			7	34
Discomfort	3	5	2	4	1	1
Disease recurrence	5	7			5	7
Drug ineffective	6	11			6	11
Extensive swelling of vaccinated limb	110	286	109	285	1	1
Face oedema	1	1			1	1
Facial pain	1	2		1	1	1
Fatigue	360	791	338	736	22	55
Feeling abnormal	7	14	5	12	2	2
Feeling cold	1	9	1	8		1
Feeling drunk		2		2		
Feeling hot	4	15	3	12	1	3
Feeling jittery	1	3	1	3		
Feeling of body temperature change	1	1	1	1		
Gait disturbance	5	11	3	8	2	3
Gait inability	4	4	2	2	2	2
General physical health deterioration	7	15	1	4	6	11
Hernia pain		1		1		
Hyperpyrexia	33	71			33	71
Hypothermia	2	4			2	4
Ill-defined disorder	1	1			1	1
Illness		1				1
Inflammation	4	5	2	3	2	2
Influenza like illness	1	6	1	5		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injected limb mobility decreased	2	4	2	4		
Injection site discomfort		1		1		
Injection site erythema	1	6	1	6		
Injection site haematoma		1		1		
Injection site induration		1		1		
Injection site inflammation	5	10	5	10		
Injection site pain	8	20	8	20		
Injection site pruritus	3	6	3	6		
Injection site swelling	4	9	4	9		
Injection site warmth	4	9	4	9		
Loss of control of legs	1	1			1	1
Malaise	366	835	325	732	41	103
Mucosal dryness	1	1	1	1		
Multiple organ dysfunction syndrome	1	2			1	2
Oedema	2	5	1	3	1	2
Oedema peripheral	4	5	1	2	3	3
Pain	30	44	28	39	2	5
Peripheral swelling	2	9	1	6	1	3
Prolapse		1		1		
Puncture site pain		1		1		
Pyrexia	205	434	181	364	24	70
Sensation of foreign body	1	2			1	2
Sudden cardiac death	1	4			1	4
Sudden death	5	14			5	14
Swelling	6	12	6	12		
Swelling face	3	14	1	8	2	6
Symptom recurrence	1	1			1	1
Thirst	1	1	1	1		
Thirst decreased		1				1
Vaccination site bruising	17	35	17	35		
Vaccination site discomfort	4	9	4	9		
Vaccination site erythema	116	305	115	304	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haematoma	23	59	23	59		
Vaccination site haemorrhage		1		1		
Vaccination site induration	9	21	9	21		
Vaccination site inflammation	82	207	82	207		
Vaccination site movement impairment	2	2	2	2		
Vaccination site pain	292	668	291	665	1	3
Vaccination site pallor	1	1			1	1
Vaccination site papule		1		1		
Vaccination site pruritus	54	125	54	125		
Vaccination site rash		3		3		
Vaccination site reaction	3	6	3	6		
Vaccination site swelling	149	368	147	366	2	2
Vaccination site urticaria		1		1		
Vaccination site warmth	131	338	131	338		
Vascular stent thrombosis	1	1			1	1
	2,362	5,528	2155	5034	207	494

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis		1				1
Hepatic failure	1	2			1	2
Hepatitis	1	1			1	1
Hepatitis acute	1	1			1	1
Hepatitis cholestatic		1				1
Jaundice	2	4	1	1	1	3
	5	10	1	1	4	9

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous					
			Serious		Nonserious		Serious			
			I	C	I	C	I	C		
Allergy to vaccine	1	2		1	1	1			1	
Anamnestic reaction	1	1						1	1	
Anaphylactic reaction	3	15						3	15	
Anaphylactic shock	1	4						1	4	
Decreased immune responsiveness		1								1
Drug hypersensitivity		1								1
Food allergy		1				1				
Haemophagocytic lymphohistiocytosis	1	1						1	1	
Hypersensitivity	6	20			4	10		2	10	
Immune system disorder		1								1
	13	47		1	5	12		8	35	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	1	1			1	1
Appendicitis	1	1			1	1
Bacterial infection	1	1			1	1
Bronchitis		1				1
Candida infection		1				1
COVID-19	9	28	2	8	7	20
COVID-19 pneumonia	1	2			1	2
Cystitis	4	8	2	4	2	4
Dacryocystitis	1	1			1	1
Encephalitis enteroviral		1				1
Endocarditis		1				1
Erysipelas		4				4
Escherichia urinary tract infection	1	1			1	1
Gastroenteritis		1				1
Hepatitis C		1				1
Herpes ophthalmic	1	3			1	3
Herpes virus infection		1		1		
Herpes zoster	2	8		5	2	3
Herpes zoster reactivation		1				1
Infection	1	4			1	4
Infection susceptibility increased		1				1
Joint abscess	1	1			1	1
Kidney infection	1	1			1	1
Laryngitis		1		1		
Localised infection	1	1			1	1
Lymphangitis		2				2
Nasopharyngitis	5	14	5	13		1
Oophoritis	1	1			1	1
Ophthalmic herpes zoster	1	1			1	1
Oral bacterial infection		1				1
Oral herpes	2	2	2	2		
Pneumonia	15	28			15	28

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia bacterial	1	1			1	1
Pyelonephritis	1	1			1	1
Respiratory tract infection		2				2
Respiratory tract infection viral	1	1			1	1
Rhinitis		2		2		
Sepsis	1	2			1	2
Sialoadenitis		2				2
Soft tissue infection		1				1
Suspected COVID-19		2		1		1
Tinea versicolour		1		1		
Tonsillitis		2		2		
Urinary tract infection	3	7	1	3	2	4
Urosepsis	1	4			1	4
Vestibular neuronitis		1				1
Viral infection	1	2			1	2
Wound infection		1				1
	59	156	12	43	47	113

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Chest injury	2	2					2	2
Chillblains	3	3			3	3		
Circumstance or information capable of leading to medication error		1				1		
Concussion		1						1
Contusion	5	5			3	3	2	2
Exposure during pregnancy		2				2		
Exposure to SARS-CoV-2		1				1		
Exposure via breast milk		1				1		
Facial bones fracture	1	1					1	1
Fall	12	26	1	1	4	10	8	16
Fracture		1						1
Hand fracture		1						1
Head injury	2	2					2	2
Hip fracture	1	2					1	2
Inappropriate schedule of product administration	6	9			6	9		
Incorrect dose administered		1				1		
Incorrect route of product administration		1				1		
Intentional product use issue	1	1			1	1		
Limb injury	1	2				1	1	1
Maternal exposure during pregnancy	3	3			1	1	2	2
Muscle strain	3	6			2	5	1	1
Occupational exposure to product		1				1		
Off label use	6	8			6	8		
Pelvic fracture	1	1					1	1
Poor quality product administered	1	1			1	1		
Post concussion syndrome		1				1		
Product label confusion		1				1		
Product preparation error	1	2			1	2		
Product storage error	1	1			1	1		
Scrotal injury		1				1		
Subdural haematoma	2	2					2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Traumatic haematoma	1	1					1	1
Upper limb fracture		1						1
Vaccination failure	1	2					1	2
Wound		1				1		
Wound haemorrhage	1	1			1	1		
Wrist fracture		1						1
	55	98	1	1	30	58	25	40

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time shortened		1		1		
Alanine aminotransferase decreased		1		1		
Alanine aminotransferase increased	1	1	1	1		
Amylase increased	1	1	1	1		
Aspartate aminotransferase increased	2	2	2	2		
Bacterial test positive	1	1			1	1
Basophil count decreased	1	1	1	1		
Blood alcohol decreased	1	1	1	1		
Blood alkaline phosphatase increased	2	2	2	2		
Blood bicarbonate decreased	1	2	1	2		
Blood bilirubin increased	2	4	2	4		
Blood calcium decreased	1	1	1	1		
Blood cholesterol abnormal	1	1	1	1		
Blood cholesterol increased	1	2	1	2		
Blood creatine phosphokinase increased	1	1	1	1		
Blood creatinine increased	1	2	1	2		
Blood glucose decreased	1	3	1	3		
Blood glucose fluctuation		1		1		
Blood glucose increased	2	6	2	5		1
Blood lactate dehydrogenase increased	1	1	1	1		
Blood lactic acid increased		1		1		
Blood potassium decreased	2	2	2	2		
Blood pressure abnormal	1	1	1	1		
Blood pressure decreased	1	6		1	1	5
Blood pressure increased	6	11	4	7	2	4
Blood pressure systolic increased	1	2		1	1	1
Blood sodium decreased	2	2	2	2		
Blood urea abnormal	1	1	1	1		
Blood urea increased	2	3	2	3		
Blood uric acid increased		1		1		
Body temperature decreased		3		1		2
Body temperature increased	11	59	9	54	2	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
C-reactive protein increased	7	11
Electrocardiogram ST segment abnormal		1
Eosinophil count decreased	1	2
Fibrin D dimer increased	2	2
Gamma-glutamyltransferase increased	2	3
Glomerular filtration rate decreased	1	4
Haematocrit decreased	4	4
Haematocrit increased		1
Haemoglobin abnormal	1	1
Haemoglobin decreased	8	9
Heart rate abnormal	1	1
Heart rate decreased	2	4
Heart rate increased	5	14
Heart rate irregular		1
Inflammatory marker increased		1
International normalised ratio fluctuation	1	1
International normalised ratio increased	2	2
Lymphocyte count decreased	2	2
Mean cell volume increased	1	1
Neutrophil count decreased	1	1
Neutrophil count increased	2	2
Oxygen saturation abnormal	2	3
Oxygen saturation decreased	4	20
Platelet count decreased	4	5
Platelet count increased	1	1
Prothrombin time ratio increased	1	1
Pulmonary arterial pressure increased	1	1
Red blood cell count decreased	3	3
Respiratory rate decreased		2
Respiratory rate increased	1	5
SARS-CoV-2 antibody test positive		1
SARS-CoV-2 test positive	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
6	8	1	3
			1
1	2		
1	1	1	1
2	3		
1	4		
4	4		
	1		
1	1		
5	6	3	3
1	1		
2	3		1
4	7	1	7
	1		
			1
		1	1
		2	2
1	1	1	1
1	1		
		1	1
2	2		
1	1	1	2
1	1	3	19
3	4	1	1
1	1		
1	1		
		1	1
3	3		
	2		
	2	1	3
	1		
		1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Serum ferritin abnormal	1	1			1	1
Troponin increased	1	2		1	1	1
Urine output decreased		1		1		
Weight decreased		6		4		2
Weight increased		1		1		
White blood cell count decreased	1	1	1	1		
White blood cell count increased	2	2	2	2		
	114	254	86	180	28	74

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal loss of weight	1	1	1	1		
Cachexia	1	3			1	3
Decreased appetite	5	21	3	15	2	6
Dehydration	2	5		1	2	4
Diabetes mellitus inadequate control	1	2			1	2
Electrolyte imbalance		1				1
Feeding disorder	2	3	1	2	1	1
Fluid intake reduced	1	3		1	1	2
Fluid retention	1	3		1	1	2
Glucose tolerance impaired		1		1		
Hyperglycaemia		1				1
Hyperkalaemia	1	1			1	1
Hypernatraemia		2				2
Hypertriglyceridaemia	1	1			1	1
Hypoglycaemia		3		1		2
Hypokalaemia		1				1
Hyponatraemia		1		1		
Hypophagia		6		1		5
Metabolic acidosis		1		1		
Type 1 diabetes mellitus	1	1			1	1
Underweight		1		1		
	17	62	5	27	12	35

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	161	375	155	362	6	13
Arthritis	2	3	1	1	1	2
Back pain	4	9	3	8	1	1
Flank pain	1	1	1	1		
Haemarthrosis	1	1			1	1
Hand deformity		1				1
Joint stiffness	1	1	1	1		
Limb discomfort	4	7	2	5	2	2
Mobility decreased	1	3	1	2		1
Muscle disorder	1	1	1	1		
Muscle rigidity	1	1	1	1		
Muscle spasms	3	9	2	8	1	1
Muscle tightness		1		1		
Muscle twitching	1	3	1	2		1
Muscular weakness	6	12	3	7	3	5
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder	1	2		1	1	1
Musculoskeletal pain	16	17	16	17		
Musculoskeletal stiffness	5	8	5	8		
Myalgia	375	816	365	794	10	22
Neck pain	5	7	3	5	2	2
Pain in extremity	26	63	24	58	2	5
Pain in jaw	4	5	3	4	1	1
Rheumatoid arthritis	1	2			1	2
Soft tissue swelling	1	1			1	1
Spinal osteoarthritis	1	1	1	1		
Torticollis		1		1		
	623	1,353	589	1290	34	63

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Myelodysplastic syndrome		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ageusia	2	6			2	6		
Allodynia		1				1		
Altered state of consciousness		1						1
Amnesia	2	2					2	2
Anosmia	1	5			1	5		
Apallic syndrome	1	2					1	2
Aphasia	6	14			1	3	5	11
Apraxia	1	1					1	1
Ataxia	1	2					1	2
Autonomic nervous system imbalance		2						2
Balance disorder	2	9			1	6	1	3
Basilar artery thrombosis	1	2					1	2
Bradykinesia	1	1			1	1		
Burning sensation	2	4			2	4		
Carotid arteriosclerosis	1	1					1	1
Carotid artery thrombosis	1	1					1	1
Cerebellar haematoma	1	1					1	1
Cerebellar infarction	1	1					1	1
Cerebellar ischaemia	1	1					1	1
Cerebral amyloid angiopathy	1	1					1	1
Cerebral haemorrhage	7	11					7	11
Cerebral infarction	15	23					15	23
Cerebral ischaemia	1	2					1	2
Cerebral thrombosis	4	4					4	4
Cerebral venous sinus thrombosis	1	1					1	1
Cerebrovascular accident	8	28	1	1			8	28
Cerebrovascular disorder		1						1
Cervical radiculopathy	1	1			1	1		
Chorea		1						1
Cognitive disorder		1						1
Coma hepatic		1						1
Consciousness fluctuating		1						1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Coordination abnormal	3	5
Dementia		1
Dementia Alzheimer's type		1
Depressed level of consciousness	5	15
Disturbance in attention		4
Dizziness	36	118
Dysarthria	4	10
Dysgeusia	2	9
Dysgraphia	2	2
Dysstasia	1	2
Encephalitis autoimmune	1	1
Epilepsy	17	34
Facial neuralgia	1	1
Facial paralysis	10	14
Facial paresis	3	4
Febrile convulsion	2	2
Generalised tonic-clonic seizure	1	6
Guillain-Barre syndrome	1	1
Headache	389	850
Head discomfort		3
Hemianaesthesia		1
Hemiparesis	4	10
Hemiplegia	2	4
Hyperaesthesia	1	3
Hypersomnia		3
Hypoaesthesia	2	8
Hypokinesia	1	1
Intention tremor	1	1
Intracranial pressure increased	1	1
Ischaemic cerebral infarction	14	23
Ischaemic stroke	1	2
IVth nerve paralysis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	2
					1
					1
				5	15
			4		
		28	104	8	14
			3	4	7
		2	9		
		1	1	1	1
			1	1	1
				1	1
				17	34
		1	1		
				10	14
		1	2	2	2
		2	2		
				1	6
				1	1
		378	825	11	25
			2		1
					1
				4	10
				2	4
			2	1	1
			3		
		2	7		1
		1	1		
				1	1
				1	1
				14	23
				1	2
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lacunar infarction	1	1
Lethargy		1
Loss of consciousness	12	30
Memory impairment		3
Mental impairment	3	4
Migraine	3	5
Monoparesis	2	2
Monoplegia	1	1
Movement disorder	4	4
Multiple sclerosis	1	2
Muscle contractions involuntary	1	1
Myelopathy	1	1
Myoclonus	1	1
Neuralgia	2	3
Neuritis		1
Neurologic neglect syndrome	1	1
Neuropathy peripheral	5	5
Nystagmus		1
Optic neuritis		1
Paraesthesia	11	34
Paralysis	3	4
Parkinson's disease	2	2
Parosmia		1
Peroneal nerve palsy		2
Poor quality sleep		1
Posterior reversible encephalopathy syndrome	1	1
Postictal state		1
Presyncope	5	14
Quadriplegia	1	1
Reduced facial expression	1	1
Resting tremor		1
Restless legs syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
			1	12	29
			3		
				3	4
		3	4		1
				2	2
				1	1
		2	2	2	2
				1	2
		1	1		
				1	1
		1	1		
		2	3		
					1
				1	1
				5	5
			1		
					1
		10	32	1	2
				3	4
				2	2
			1		
			1		1
			1		
				1	1
		4	11	1	3
				1	1
				1	1
			1		
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Sciatica		1							1
Seizure	6	10					6		10
Sensory disturbance	1	1			1	1			
Slow speech	1	1			1	1			
Somnolence	2	13				5	2		8
Speech disorder	6	8			1	2	5		6
Spinal cord compression	1	1					1		1
Spinal epidural haemorrhage	1	1					1		1
Spinal meningeal cyst	1	1					1		1
Status epilepticus	1	3					1		3
Stiff person syndrome	1	1					1		1
Syncope	48	86	1	1			48		86
Taste disorder	1	3			1	3			
Thrombotic cerebral infarction	1	1					1		1
Thunderclap headache		1							1
Transient aphasia	1	1					1		1
Transient ischaemic attack	38	48	1	1			38		48
Tremor	5	13			3	11	2		2
Unresponsive to stimuli	2	8					2		8
	748	1,608	3	3	457	1086	291		522

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed	2	2	2	2
Abortion spontaneous	9	11	9	11
Anembryonic gestation	2	2	2	2
	13	15	13	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product packaging quantity issue		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1			1	1
Abnormal dreams		1		1		
Affect lability	1	1	1	1		
Agitation	1	1	1	1		
Anxiety	6	9	6	8		1
Apathy		2		1		1
Bradyphrenia	2	3	2	2		1
Catatonia		2		1		1
Confusional state	14	22	4	9	10	13
Conversion disorder		1				1
Delirium	12	23			12	23
Delirium febrile		1				1
Delusion		1		1		
Depressed mood	2	4	2	4		
Depression	1	6		4	1	2
Derealisation		1		1		
Disorganised speech		1		1		
Disorientation	2	2	1	1	1	1
Dissociation		1		1		
Emotional disorder	1	1			1	1
Emotional distress	1	1	1	1		
Emotional poverty	1	1			1	1
Fear	1	2		1	1	1
Hallucination	2	4			2	4
Hallucination, visual	1	1			1	1
Imperception	1	1			1	1
Insomnia	2	2	2	2		
Listless	3	4	3	4		
Mood altered	1	2	1	2		
Mutism	1	2			1	2
Nightmare		1		1		
Panic attack	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Personality disorder		1		1		
Psychotic symptom		2				2
Restlessness	1	6		5	1	1
Sleep disorder	1	1	1	1		
Somnambulism		2		2		
Suicidal ideation		1				1
Suspiciousness		1		1		
Thinking abnormal		1		1		
	60	121	26	60	34	61

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Azotaemia		2				2
Cystitis noninfective	1	1			1	1
Glomerulonephritis minimal lesion		1				1
Incontinence	1	3			1	3
Nephrolithiasis	2	3			2	3
Nephrotic syndrome		2				2
Oliguria		1		1		
Pollakiuria	1	1	1	1		
Polyuria		1		1		
Renal disorder	1	2	1	2		
Renal failure	1	3			1	3
Renal impairment	1	3			1	3
Renal infarct	1	1			1	1
Urinary incontinence	2	3	1	2	1	1
Urinary retention	1	5			1	5
	13	33	3	7	10	26

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorder female		1		1		
Erectile dysfunction		1				1
Genital paraesthesia		1		1		
Pelvic pain	2	2	2	2		
Postmenopausal haemorrhage	1	2			1	2
Vulvovaginal pain	1	1	1	1		
	4	8	3	5	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute respiratory failure		1						1
Aphonia		3				1		2
Aspiration		1						1
Asthma		3						3
Bronchospasm		1						1
Choking		1						1
Choking sensation		2						2
Chronic obstructive pulmonary disease	1	4			1	1		3
Cough	2	18			2	15		3
Diaphragmalgia		1				1		
Dysphonia	2	4					2	4
Dyspnoea	37	112		1	14	51	23	61
Dyspnoea at rest	2	2					2	2
Dyspnoea exertional	3	5			1	2	2	3
Epistaxis	9	11			3	4	6	7
Haemoptysis	2	2			1	1	1	1
Hyperventilation	3	6			2	3	1	3
Hypoxia	6	14					6	14
Increased upper airway secretion		1						1
Interstitial lung disease		1						1
Lung disorder	1	6			1	2		4
Nasal congestion	2	3			1	2	1	1
Oropharyngeal blistering	1	1					1	1
Oropharyngeal discomfort		2				2		
Oropharyngeal pain	6	24			6	23		1
Painful respiration	1	2			1	2		
Pharyngeal erythema	1	1					1	1
Pharyngeal oedema		1						1
Pharyngeal paraesthesia	1	2					1	2
Pharyngeal swelling	6	13			3	4	3	9
Pleural effusion	2	3					2	3
Pneumonia aspiration	2	10					2	10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Productive cough	1	2				1	1	1	1
Pulmonary embolism	30	35					30	35	
Pulmonary haemorrhage		1							1
Pulmonary hypertension	1	1					1	1	
Pulmonary infarction	3	3					3	3	
Pulmonary mass	1	1					1	1	
Pulmonary oedema	1	2					1	2	
Pulmonary pain	1	3			1	3			
Respiration abnormal		1							1
Respiratory disorder		3				2			1
Respiratory failure	4	9					4	9	
Respiratory tract irritation	2	2			2	2			
Respiratory tract oedema		1							1
Rhinorrhoea	3	4			3	4			
Sneezing	1	3			1	3			
Snoring		1				1			
Sputum increased		1				1			
Stridor	2	3					2	3	
Tachypnoea	2	4			2	3			1
Throat tightness	2	5			1	2	1	3	
Wheezing		1				1			
	144	347		1	46	137	98	210	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne	1	1			1	1		
Angioedema	7	14					7	14
Blister	1	2				1	1	1
Cold sweat	4	8			3	5	1	3
Dandruff		1				1		
Dermatitis	1	1			1	1		
Dermatitis allergic	1	1			1	1		
Dermatitis bullous	1	2					1	2
Ecchymosis	1	2					1	2
Eczema	1	1			1	1		
Erythema	10	34			8	27	2	7
Erythema nodosum	1	1					1	1
Hyperhidrosis	5	25			4	21	1	4
Hypersensitivity vasculitis	2	2					2	2
Ingrowing nail		1				1		
Livedo reticularis		1						1
Night sweats	1	1			1	1		
Pain of skin	2	5			2	5		
Panniculitis	1	1					1	1
Pemphigoid		1						1
Petechiae	4	4			4	4		
Piloerection	1	1			1	1		
Pruritus	5	22		1	4	19	1	3
Rash	6	17		1	5	12	1	5
Rash erythematous	2	9			2	9		
Rash macular		1				1		
Rash maculo-papular		1				1		
Rash papular		4				4		
Rash pruritic	1	2				1	1	1
Rash vesicular		1				1		
Sensitive skin	1	2			1	2		
Skin burning sensation	1	3			1	3		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin discolouration	4	6			2	4	2	2
Skin induration	1	1			1	1		
Skin swelling	1	1			1	1		
Skin warm		1				1		
Toxic skin eruption	1	1					1	1
Trichodynia		1				1		
Urticaria	5	20			4	15	1	5
	73	203		2	48	147	25	56

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		2		1		1
Loss of personal independence in daily activities		3		2		1
		5		3		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aneurysm		1						1
Aortic dissection	1	1					1	1
Arterial thrombosis		1						1
Circulatory collapse	1	5					1	5
Cyanosis		2						2
Deep vein thrombosis	21	27					21	27
Embolism	1	1					1	1
Flushing		4				4		
Giant cell arteritis	1	2					1	2
Haematoma	2	2			1	1	1	1
Haemodynamic instability	1	1					1	1
Haemorrhage	1	2					1	2
Hot flush	2	5			1	4	1	1
Hypertension	15	31			7	15	8	16
Hypertensive crisis		1						1
Hypertensive urgency	1	1					1	1
Hypotension	8	19	1	1	3	7	5	12
Hypovolaemic shock		1						1
Infarction	1	1					1	1
Pallor	2	14			1	7	1	7
Peripheral coldness		8				6		2
Raynaud's phenomenon		1				1		
Shock		2						2
Thrombophlebitis	4	6			3	4	1	2
Thrombophlebitis superficial	1	1					1	1
Thrombosis	16	21					16	21
Vasculitis	3	3			3	3		
	82	164	1	1	19	52	63	112

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**NEW ZEALAND**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Drug ineffective		1		1
Influenza like illness	1	1	1	1
Reactogenicity event	1	1	1	1
	2	3	2	3

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypersensitivity	5	5	5	5
	5	5	5	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Asymptomatic COVID-19		1		1
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Exposure to SARS-CoV-2		1		1
		1		1

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia	1	3	1	3
	1	3	1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chest discomfort		1		1
Chills		1		1
Fatigue		1		1
		3		3

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		2		2
		2		2

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Pain in extremity		1		1
		2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Dizziness		1		1
Headache		1		1
Poor quality sleep		1		1
		3		3

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Disorientation		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**NORWAY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilia	1	1			1	1
Immune thrombocytopenia	1	1			1	1
Increased tendency to bruise	1	1			1	1
Leukocytosis		2		1		1
Lymphadenitis	2	2	1	1	1	1
Lymphadenopathy		4		3		1
Neutropenia		1				1
Pancytopenia	1	1			1	1
Thrombocytopenia	4	5			4	5
	10	18	1	5	9	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Acute myocardial infarction		5				5
Angina pectoris		2				2
Arrhythmia	1	2			1	2
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	1	4			1	4
Atrial flutter		1				1
Atrioventricular block first degree		1				1
Bradycardia		5				5
Cardiac arrest	1	3			1	3
Cardiac failure		4				4
Cardiac fibrillation	1	1			1	1
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1				1
Coronary artery occlusion		1				1
Extrasystoles	1	1			1	1
Intracardiac thrombus		1				1
Left ventricular failure		1				1
Myocardial infarction	1	2			1	2
Palpitations	3	6	2	3	1	3
Pericardial effusion		2				2
Pericardial haemorrhage		1				1
Pericarditis	4	6			4	6
Supraventricular extrasystoles		1				1
Tachycardia	2	9	2	5		4
Ventricular tachycardia		1				1
	15	64	4	8	11	56

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory disorder	1	1	1	1		
Ear discomfort	1	3	1	3		
Ear pain		2		2		
Ear swelling		1		1		
Vertigo	2	3		1	2	2
Vertigo positional		1				1
	4	11	2	8	2	3

System Organ Class

**Endocrine disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Basedow's disease		1		1
Hyperthyroidism		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm		1		1		
Blindness	1	1			1	1
Diplopia	1	3		1	1	2
Eye haemorrhage		2				2
Eye pain		1		1		
Iridocyclitis	2	2			2	2
Myopia	1	1			1	1
Ocular hyperaemia		2		1		1
Orbital oedema		1				1
Photophobia		3		2		1
Pupil fixed		2				2
Swelling of eyelid	1	2	1	1		1
Vision blurred	2	3			2	3
Visual impairment	2	4	1	2	1	2
	10	28	2	9	8	19

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal discomfort		2		2			
Abdominal pain	2	14		8	2		6
Abdominal pain upper	4	14		4	4		10
Abdominal wall haemorrhage		1					1
Anal incontinence		1					1
Constipation		2		1			1
Defaecation disorder		1					1
Diarrhoea	4	31	1	18	3		13
Dry mouth		6		5			1
Duodenitis		1					1
Dysphagia	1	7	1	2			5
Faeces discoloured		2		1			1
Flatulence		1		1			
Gastric disorder		1					1
Gastric haemorrhage	1	1			1		1
Gastritis		1		1			
Gastrointestinal haemorrhage		2					2
Gastrointestinal necrosis		1					1
Haematemesis	1	2			1		2
Hypoaesthesia oral	2	5	1	3	1		2
Intestinal ischaemia		1					1
Lip pruritus		1					1
Melaena		1					1
Mesenteric artery embolism		1					1
Mouth haemorrhage	1	1	1	1			
Mouth swelling		1					1
Nausea	16	79	9	52	7		27
Oral pruritus		2					2
Paraesthesia oral	1	2		1	1		1
Rectal haemorrhage	1	2			1		2
Retching	1	7		3	1		4
Vomiting	3	43	1	16	2		27

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	38	237	14	119	24	118

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event		1		1		
Adverse reaction		1		1		
Asthenia	5	15	2	6	3	9
Axillary pain		2		1		1
Chest discomfort	1	3	1	2		1
Chest pain	8	20	4	6	4	14
Chills	6	33	3	20	3	13
Concomitant disease aggravated		2				2
Condition aggravated	3	7	1	2	2	5
Death	2	29			2	29
Decreased activity		1		1		
Discomfort	2	6	1	4	1	2
Disease recurrence	1	6		1	1	5
Drug ineffective	2	2			2	2
Drug interaction	3	4	3	3		1
Face oedema		1				1
Fatigue	22	112	15	82	7	30
Feeling abnormal	1	5	1	4		1
Feeling cold		3		3		
Feeling drunk		1		1		
Feeling hot	2	9	1	6	1	3
Feeling of body temperature change		1		1		
Foaming at mouth		1		1		
Gait disturbance	1	2	1	1		1
General physical health deterioration	15	68	5	17	10	51
General symptom		1				1
Hyperpyrexia		1				1
Hypothermia		1				1
Illness	1	1	1	1		
Inflammation		1				1
Influenza like illness	2	10	1	6	1	4
Injection site muscle weakness		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain		1		1		
Irritability postvaccinal		1				1
Local reaction		1				1
Malaise	5	40	4	29	1	11
Moaning	1	1			1	1
Oedema peripheral		5		2		3
Pain	6	19	4	13	2	6
Peripheral swelling	3	6	2	3	1	3
Pyrexia	22	107	12	61	10	46
Secretion discharge		2				2
Sudden cardiac death		1				1
Sudden death		8				8
Swelling	1	1			1	1
Swelling face	2	5	1	2	1	3
Tenderness		2		2		
Terminal state		1				1
Therapeutic product effect decreased	1	1	1	1		
Thirst		2		1		1
Vaccination site erythema		9		8		1
Vaccination site hypoaesthesia		1		1		
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	3	35	2	28	1	7
Vaccination site paraesthesia		2		2		
Vaccination site pruritus		4		3		1
Vaccination site rash		1		1		
Vaccination site reaction		3		2		1
Vaccination site swelling		6		3		3
Vaccination site warmth		3		2		1
	122	620	66	337	56	283

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cholecystitis		1		1
Hepatic cyst	1	1	1	1
	1	2	1	2

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		2				2
Anaphylactic reaction	5	13			5	13
Hypersensitivity	1	7		2	1	5
Immune-mediated adverse reaction	1	1			1	1
	7	23		2	7	21

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis	2	2			2	2
Arthritis bacterial		1				1
Bacterial sepsis		1				1
Bronchitis		1		1		
Conjunctivitis		1		1		
COVID-19	5	5	1	1	4	4
Diverticulitis		1				1
Erysipelas	2	3			2	3
Gastroenteritis		1				1
Herpes simplex reactivation	1	1	1	1		
Infection		8		1		7
Infective exacerbation of chronic obstructive airways disease		1				1
Influenza		2		2		
Lower respiratory tract infection		1				1
Lymphangitis	1	1			1	1
Nasopharyngitis		2		1		1
Neuroborreliosis		1				1
Ophthalmic herpes zoster	1	2			1	2
Pneumonia	5	25			5	25
Pneumonia bacterial	1	1			1	1
Pyelonephritis		1				1
Respiratory tract infection		1				1
Sepsis		4				4
Staphylococcal sepsis	1	1			1	1
Urinary tract infection		6		5		1
Urosepsis	1	1			1	1
Vaccine breakthrough infection	1	1			1	1
	21	76	2	13	19	63

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriovenous fistula thrombosis	2	2			2	2
Concussion	1	2			1	2
Contusion	1	1			1	1
Exposure during pregnancy		2		2		
Fall	5	23	1	5	4	18
Femoral neck fracture		2				2
Femur fracture		1				1
Fracture		1				1
Frostbite		1				1
Head injury		2				2
Inappropriate schedule of product administration	2	3	2	3		
Incorrect dose administered		5		5		
Incorrect route of product administration		4		4		
Intentional product use issue	1	1	1	1		
Intercepted product preparation error		1		1		
Maternal exposure during pregnancy		1		1		
Multiple fractures		1				1
Off label use	2	2	2	2		
Poor quality product administered		6		6		
Product administered at inappropriate site		1		1		
Product preparation error		2		2		
Product preparation issue		8		8		
Skin laceration		1				1
Subdural haematoma	1	1			1	1
Subdural haemorrhage	1	1			1	1
Tooth avulsion		1				1
Transfusion reaction	1	1	1	1		
Vaccination failure	2	2			2	2
Wrong technique in product usage process		1		1		
	19	80	7	43	12	37

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Antinuclear antibody increased	1	1	1	1		
Anti-thyroid antibody	1	1	1	1		
Bacterial test positive		1		1		
Blood glucose decreased		1		1		
Blood glucose fluctuation		3		3		
Blood glucose increased	1	2	1	2		
Blood pressure decreased	2	12		2	2	10
Blood pressure diastolic decreased		1		1		
Blood pressure increased		2		1		1
Blood pressure systolic decreased	1	1			1	1
Blood pressure systolic increased	2	2			2	2
Body temperature decreased		1		1		
Body temperature fluctuation	1	1			1	1
Body temperature increased	1	2		1	1	1
Breath sounds abnormal		1				1
C-reactive protein increased	10	30	3	8	7	22
Grip strength decreased	1	2			1	2
Haemoglobin decreased	1	3			1	3
Heart rate decreased		1				1
Heart rate increased	3	14		4	3	10
Heart rate irregular		2		1		1
Inflammatory marker increased	1	1			1	1
International normalised ratio increased		2				2
N-terminal prohormone brain natriuretic peptide increased	1	2			1	2
Oxygen saturation decreased	3	19	1	2	2	17
Red blood cell sedimentation rate increased	1	1	1	1		
Respiratory rate decreased		1		1		
Respiratory rate increased	1	11	1	5		6
Salmonella test positive	1	1			1	1
Troponin increased		1				1
Weight decreased		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count increased	2	3	2	2		1
	35	127	11	40	24	87

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	15	1	7		8
Dehydration	1	3		1	1	2
Diabetes mellitus inadequate control	1	1			1	1
Electrolyte imbalance	1	1			1	1
Food refusal		1				1
Hyperglycaemia	1	2	1	1		1
Hyperkalaemia		1				1
Hypernatraemia		1				1
Hyponatraemia	2	2			2	2
Hypophagia	1	4			1	4
Marasmus		1				1
	8	32	2	9	6	23

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	11	24	9	20	2	4
Arthritis		2		1		1
Arthritis reactive		1				1
Axillary mass		1				1
Back pain	3	14	2	8	1	6
Bone pain	1	2	1	1		1
Joint swelling		1		1		
Limb discomfort	1	3		2	1	1
Mobility decreased		1		1		
Muscle rigidity		1				1
Muscle spasms	1	5		1	1	4
Muscle twitching		1		1		
Muscular weakness	4	6	1	1	3	5
Musculoskeletal stiffness	1	8		5	1	3
Myalgia	10	44	6	33	4	11
Neck pain		7		5		2
Pain in extremity	5	15	4	12	1	3
Tendon pain		1		1		
	37	137	23	93	14	44

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastases to peritoneum		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness		7				7
Amnesia		2		1		1
Apallic syndrome		1				1
Aphasia	3	5			3	5
Autonomic nervous system imbalance		1				1
Balance disorder	1	7		2	1	5
Brain stem stroke		1				1
Burning sensation		1				1
Carotid arteriosclerosis		1		1		
Carotid artery occlusion	1	1			1	1
Cerebellar infarction	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	5	10			5	10
Cerebral infarction	5	9			5	9
Cerebral thrombosis	2	3			2	3
Cerebrovascular accident	4	22			4	22
Cerebrovascular disorder		1				1
Cognitive disorder		3		1		2
Coma		1				1
Coordination abnormal	2	3	1	1	1	2
Dementia		2				2
Dementia Alzheimer's type		1				1
Demyelinating polyneuropathy	1	1			1	1
Depressed level of consciousness	2	7			2	7
Disturbance in attention		2		2		
Dizziness	19	55	6	27	13	28
Drooling		1		1		
Dysarthria	3	7	2	2	1	5
Dysgeusia	1	4	1	3		1
Dyskinesia		1				1
Embolic cerebral infarction		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Epilepsy		5				5	
Facial paralysis		4				4	
Facial paresis	3	9	1	3	2	6	
Generalised tonic-clonic seizure		1				1	
Guillain-Barre syndrome	1	1			1	1	
Headache	24	91	12	67	12	24	
Hemianopia	1	1			1	1	
Hemiparesis	2	5			2	5	
Hemiplegia	2	4			2	4	
Hyperaesthesia	1	2			1	2	
Hypersomnia		1		1			
Hypoaesthesia	1	9	1	7		2	
Hypogeusia		1		1			
Hypokinesia		2		1		1	
Hyposmia	1	1	1	1			
Ischaemic stroke	2	3			2	3	
Lethargy	2	7		3	2	4	
Loss of consciousness	3	13			3	13	
Memory impairment	2	3	2	3			
Mental impairment	1	1			1	1	
Migraine	1	3	1	2		1	
Monoparesis		1				1	
Monoplegia	1	1			1	1	
Motor dysfunction		1		1			
Muscle contractions involuntary	1	1	1	1			
Muscle spasticity	1	1			1	1	
Neuropathy peripheral		2				2	
Nystagmus	1	1			1	1	
Paraesthesia	1	7	1	3		4	
Paralysis		1				1	
Paresis	1	1	1	1			
Parosmia	1	1	1	1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Postictal state		1		1		
Presyncope	3	9	1	2	2	7
Psychomotor hyperactivity		2		1		1
Seizure		1				1
Somnolence	1	17		9	1	8
Speech disorder		5		2		3
Status epilepticus		1				1
Status migrainosus		1				1
Syncope	9	33			9	33
Thrombotic stroke		1				1
Transient ischaemic attack	3	5			3	5
Tremor	2	8	1	3	1	5
Unresponsive to stimuli	1	4			1	4
Vlth nerve paralysis	1	1			1	1
	126	438	34	155	92	283

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product temperature excursion issue	1	7	1	7
	1	7	1	7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		1				1
Abnormal dreams		1		1		
Aggression	1	1	1	1		
Agitation		1				1
Anxiety		3		1		2
Apathy		2				2
Communication disorder		1		1		
Confusional state	5	31	1	10	4	21
Delirium	2	5			2	5
Depressed mood		1		1		
Disorientation	1	1			1	1
Fear of death	1	1	1	1		
Hallucination		6				6
Hallucination, auditory		2				2
Hallucinations, mixed	1	1			1	1
Hallucination, visual		1				1
Insomnia	1	1	1	1		
Listless		1		1		
Mania		1				1
Middle insomnia		1		1		
Nightmare	1	1	1	1		
Panic attack	1	1	1	1		
Personality change		1				1
Restlessness	1	13		5	1	8
Sleep disorder	1	2		1	1	1
Time perception altered	1	1	1	1		
	17	82	7	28	10	54

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	2			1	2
Chronic kidney disease		1				1
Glomerulonephritis chronic		1				1
Glomerulonephritis minimal lesion		1				1
Incontinence	1	1			1	1
Kidney fibrosis		1				1
Nephrolithiasis	1	1			1	1
Renal failure	2	2			2	2
Renal impairment		1				1
Tubulointerstitial nephritis		1				1
Urinary incontinence		2		1		1
Urinary retention		2				2
	5	16		1	5	15

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast enlargement		1		1
Breast pain		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apnoea		3				3
Apnoeic attack		1				1
Aspiration		1				1
Asthma		1				1
Atelectasis		1				1
Chronic obstructive pulmonary disease	1	6			1	6
Cough	4	20	1	11	3	9
Cystic lung disease		1		1		
Dysphonia		4		4		
Dyspnoea	18	67	6	18	12	49
Dyspnoea at rest		1				1
Emphysema		1		1		
Epistaxis		1		1		
Haemothorax		1				1
Hypercapnia	1	1			1	1
Hyperventilation		7		4		3
Hypoxia		4				4
Increased bronchial secretion	1	3		1	1	2
Increased viscosity of upper respiratory secretion	1	1	1	1		
Interstitial lung disease		1				1
Intranasal hypoaesthesia		1		1		
Intranasal paraesthesia		1		1		
Lung consolidation	1	1			1	1
Lung opacity	1	3			1	3
Mediastinal haemorrhage		1				1
Nasal congestion		4		4		
Nasal pruritus		1				1
Obstructive airways disorder		2				2
Oropharyngeal pain	2	11	1	7	1	4
Oropharyngeal swelling	1	1			1	1
Paranasal sinus discomfort		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia	1	1			1	1
Pharyngeal swelling	1	3		1	1	2
Pleural effusion		2				2
Pleurisy		1				1
Pneumonia aspiration	1	3			1	3
Pneumonitis	1	2			1	2
Productive cough		5				5
Pulmonary congestion	1	1			1	1
Pulmonary embolism	6	13			6	13
Pulmonary necrosis		1				1
Pulmonary oedema		1				1
Pulmonary thrombosis	1	1			1	1
Rales		4		2		2
Respiration abnormal		1				1
Respiratory acidosis	1	1			1	1
Respiratory alkalosis		1				1
Respiratory arrest		4				4
Respiratory disorder		1				1
Respiratory failure	4	10			4	10
Respiratory tract congestion		1				1
Rhinorrhoea		6		6		
Sneezing		1		1		
Snoring	1	1			1	1
Sputum increased		1		1		
Stridor	1	2			1	2
Tachypnoea		3		1		2
Throat clearing		1		1		
Throat irritation		2				2
Throat tightness	1	3			1	3
Wheezing	2	3			2	3
	53	233	9	69	44	164

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		3				3
Cold sweat		13		4		9
Decubitus ulcer		1		1		
Dermatitis allergic		1				1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry skin		1		1		
Eczema		1				1
Erythema	2	11	1	7	1	4
Exfoliative rash	1	1			1	1
Haemorrhage subcutaneous	1	2			1	2
Hyperhidrosis	1	6	1	6		
Livedo reticularis		1		1		
Night sweats		1		1		
Pain of skin	1	2	1	1		1
Petechiae	3	5	1	1	2	4
Pruritus	3	15		4	3	11
Rash	1	11		7	1	4
Rash erythematous	1	3		2	1	1
Rash pruritic	2	5		2	2	3
Skin haemorrhage	1	2	1	2		
Urticaria	2	9		1	2	8
	20	95	5	41	15	54

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	7	1	2		5
Immobile		1				1
Loss of personal independence in daily activities	2	2			2	2
	3	10	1	2	2	8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Arterial haemorrhage		1				1
Circulatory collapse	2	4			2	4
Cyanosis		2				2
Deep vein thrombosis	5	6			5	6
Flushing	2	4	1	3	1	1
Giant cell arteritis	1	1			1	1
Haematoma		2				2
Haemorrhage		3				3
Hot flush		1		1		
Hypertension	1	6		4	1	2
Hypotension	2	17	1	1	1	16
Inferior vena caval occlusion	1	1			1	1
Malignant hypertension		2				2
Orthostatic hypotension	1	2		1	1	1
Pallor		11		3		8
Peripheral coldness		3		2		1
Shock		1				1
Thrombophlebitis	3	3	2	2	1	1
Thrombophlebitis superficial	3	3	1	1	2	2
Thrombosis		1				1
	21	76	5	19	16	57

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**OMAN**

*System Organ Class*

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Gastritis		1		1
		2		2

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Pain		1		1
Pyrexia		1		1
Therapeutic response unexpected		1		1
		4		4

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
		1		1

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product supply issue		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PANAMA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	1	1	1	1		
Flatulence		1		1		
Hypoaesthesia oral	1	1			1	1
Lip dry	1	1	1	1		
	3	4	2	3	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		4		4		
Chills		1		1		
Fatigue	1	1	1	1		
Gait disturbance	1	1			1	1
Local reaction	1	2	1	2		
Pyrexia	1	1			1	1
Vaccination site pain	3	4	2	3	1	1
Vaccination site reaction		1		1		
	7	15	4	12	3	3

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2	2	2		
Anaphylactic reaction		1				1
Hypersensitivity	1	2	1	2		
	3	5	3	4		1

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration		1		1
Overdose		1		1
		2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	1	1	1	1		
Hemiparesis	1	1			1	1
Hypotonia		1		1		
Hypotonic-hyporesponsive episode		2		1		1
Paraesthesia	1	1			1	1
Syncope		3				3
	3	9	1	3	2	6

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state	1	1	1	1
Irritability		1		1
	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry throat	1	1	1	1		
Dyspnoea	1	1			1	1
Pulmonary pain	1	1			1	1
	3	3	1	1	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		1		1		
Rash erythematous		1				1
Rash pruritic		7				7
		9		1		8

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pallor		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PERU**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort	1	1	1	1
Diarrhoea	1	1	1	1
	2	2	2	2

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	1	1	1		
Discomfort	2	2	2	2		
Drug ineffective	1	1			1	1
Fatigue	1	1	1	1		
Pain	1	1	1	1		
Pyrexia	7	7	7	7		
Vaccination site pain	1	2	1	2		
	14	15	13	14	1	1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	2	1	1	1	1
	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	2	2	2	2
Off label use	2	2	2	2
Product use issue	2	2	2	2
	6	6	6	6

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Heart rate increased	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Pain in extremity	2	2	2	2
	4	4	4	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	4	5	4	5
	4	5	4	5

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1	1	1		
Epistaxis	1	1			1	1
Nasal dryness	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
	4	4	3	3	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hyperhidrosis	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**POLAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Coagulopathy		2		1		1
Haemorrhagic diathesis	1	1			1	1
Lymphadenopathy	9	61	3	25	6	36
Lymph node pain	5	40	1	10	4	30
Thrombocytopenia	1	1			1	1
	16	106	4	36	12	70

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	3			1	3
Arrhythmia	3	9			3	9
Atrial fibrillation	1	3			1	3
Atrial flutter	1	2			1	2
Bradyarrhythmia		1				1
Bradycardia		2				2
Cardiac arrest	5	11			5	11
Cardiogenic shock		2				2
Cardiovascular disorder	1	3	1	1		2
Coronary artery thrombosis		1				1
Extrasystoles		1				1
Myocardial hypoxia		2				2
Myocardial infarction		2				2
Myocarditis		1				1
Palpitations	1	8		2	1	6
Supraventricular extrasystoles	1	1			1	1
Tachyarrhythmia		1				1
Tachycardia	4	29	1	4	3	25
Ventricular extrasystoles		1				1
	18	83	2	7	16	76

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		2				2
Deafness unilateral		1				1
Ear pain		1		1		
Ear swelling		1				1
Hyperacusis		1		1		
Tinnitus	2	6	1	5	1	1
Vertigo		6		1		5
	2	18	1	8	1	10

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Goitre		1		1
Thyroiditis		1		1
Thyroid pain		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival hyperaemia		3		1		2
Conjunctival pallor		1				1
Eye disorder		1		1		
Eyelid oedema		1				1
Eyelids pruritus		1				1
Eye pain	1	11		2	1	9
Eye pruritus		1				1
Hypoaesthesia eye		2				2
Iritis		1		1		
Lacrimation increased		7				7
Lagophthalmos	1	1	1	1		
Ocular hyperaemia		1				1
Photophobia		3		2		1
Vision blurred		1		1		
Visual acuity reduced		1				1
Visual impairment	1	5	1	2		3
	3	41	2	11	1	30

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	4	18	1	9	3	9
Abdominal pain lower		2		1		1
Abdominal pain upper		4		2		2
Anal incontinence	2	4		1	2	3
Aphthous ulcer		1		1		
Defaecation urgency		1		1		
Diarrhoea	11	35	8	20	3	15
Dry mouth	1	3	1	2		1
Dysphagia		3				3
Epigastric discomfort	1	1			1	1
Faeces soft	1	1			1	1
Flatulence	1	2		1	1	1
Gastrointestinal disorder	1	2	1	1		1
Gastrointestinal haemorrhage		1				1
Gingival swelling	1	1	1	1		
Haematemesis		2				2
Hyperaesthesia teeth		1		1		
Hypoaesthesia oral	1	9	1	3		6
Lip blister		1				1
Lip pruritus		1				1
Lip swelling		3		1		2
Melaena		1				1
Nausea	6	61	2	37	4	24
Pancreatitis acute	1	2			1	2
Paraesthesia oral		1				1
Retching		1		1		
Swollen tongue		4		1		3
Tongue oedema		1				1
Toothache		2		1		1
Vomiting	5	36	3	15	2	21
	37	206	18	100	19	106

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse reaction	1	1	1	1		
Asthenia	24	152	13	85	11	67
Axillary pain	1	6	1	6		
Cardiac death		1				1
Chest discomfort		6		5		1
Chest pain		9		1		8
Chills	11	95	6	59	5	36
Condition aggravated	2	2	1	1	1	1
Crying		1		1		
Death	4	17			4	17
Decreased activity		1		1		
Discomfort		2		2		
Disease progression		1				1
Disease recurrence		2				2
Drug ineffective	18	54			18	54
Exercise tolerance decreased	1	2	1	2		
Extensive swelling of vaccinated limb		1		1		
Face oedema		2				2
Fatigue	9	35	7	30	2	5
Feeling abnormal	1	11		10	1	1
Feeling cold	3	19	1	10	2	9
Feeling hot	2	13	2	10		3
Feeling of relaxation		1				1
Gait disturbance		4		3		1
Gait inability	1	1			1	1
General physical health deterioration		1				1
Hyperpyrexia	2	2			2	2
Hypothermia		1				1
Illness		1		1		
Inflammation		4		3		1
Influenza like illness	1	10	1	9		1
Injection site erythema		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain	1	6	1	6		
Injection site swelling		2		2		
Localised oedema		1				1
Malaise	5	62	1	47	4	15
Oedema	1	5		2	1	3
Oedema peripheral	1	4	1	1		3
Pain		12		9		3
Peripheral swelling	3	5	1	2	2	3
Pyrexia	35	230	19	118	16	112
Sensation of foreign body		1				1
Sluggishness	1	1			1	1
Sudden cardiac death	1	1			1	1
Sudden death	1	2			1	2
Swelling	1	6	1	4		2
Swelling face	1	3			1	3
Temperature intolerance		1		1		
Therapeutic response unexpected	1	3	1	3		
Thirst		2		2		
Vaccination site abscess sterile		2				2
Vaccination site discomfort		1				1
Vaccination site erythema	3	21	3	15		6
Vaccination site extravasation		3		2		1
Vaccination site hypersensitivity		2		1		1
Vaccination site induration		3		3		
Vaccination site inflammation		1		1		
Vaccination site macule		1		1		
Vaccination site movement impairment		3		3		
Vaccination site oedema	2	6	1	3	1	3
Vaccination site pain	9	116	7	103	2	13
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	2	11	2	11		
Vaccination site rash		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	2	59		13	2	46
Vaccination site scab		1		1		
Vaccination site swelling	1	19	1	16		3
Vaccination site vesicles		1		1		
Vaccination site warmth		6		5		1
	152	1,064	73	619	79	445

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient		2		2		
Allergy to vaccine		2				2
Anaphylactic reaction		13				13
Anaphylactic shock	1	12			1	12
Drug hypersensitivity	1	2			1	2
Hypersensitivity		25		3		22
Reaction to excipient		1		1		
	2	57		6	2	51

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	5	8		1	5	7
COVID-19	27	78	1	9	26	69
COVID-19 pneumonia		1				1
Cystitis		1		1		
Erysipelas	1	1			1	1
Herpes virus infection		3		3		
Herpes zoster		1		1		
Infection		3		2		1
Influenza		1		1		
Labyrinthitis	1	2			1	2
Nasopharyngitis	1	3	1	3		
Oral candidiasis		1		1		
Oral herpes	1	2	1	2		
Parotitis		1		1		
Pneumonia	2	8			2	8
Pneumonia viral	2	2			2	2
Pulpitis dental		1		1		
Respiratory tract infection		1				1
Rhinitis		3				3
Sepsis		1				1
Sinusitis		1		1		
Suspected COVID-19		2		1		1
Vaccination site infection		1		1		
Vestibular neuronitis	1	1	1	1		
Viral infection		1		1		
	41	128	4	31	37	97

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brachial plexus injury		1				1
Circumstance or information capable of leading to medication error		1		1		
Contusion	1	7	1	1		6
Exposure during pregnancy	1	4	1	4		
Exposure via breast milk	1	8	1	8		
Fall	3	5			3	5
Head injury	1	1			1	1
Inappropriate schedule of product administration	1	6	1	6		
Incorrect dose administered		1		1		
Incorrect route of product administration	2	6	2	6		
Joint injury		1				1
Maternal exposure during pregnancy		2		2		
Muscle injury		1				1
Off label use	2	15	2	14		1
Poor quality product administered		4		4		
Product administered at inappropriate site		1		1		
Product label confusion		2		2		
Product preparation error		1		1		
Product use issue	1	11	1	10		1
Vaccination complication		2		2		
Vaccination failure	7	13			7	13
	20	93	9	63	11	30

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Alanine aminotransferase increased		2				2	
Antibody test abnormal		10		10			
Aspartate aminotransferase increased		2				2	
Basophil count decreased		1		1			
Blood creatine phosphokinase increased		3		1		2	
Blood glucose increased	1	2			1	2	
Blood pressure abnormal		3		1		2	
Blood pressure decreased	4	23	2	5	2	18	
Blood pressure diastolic increased		1				1	
Blood pressure increased	8	26	2	4	6	22	
Blood smear test abnormal		1		1			
Blood thyroid stimulating hormone decreased		1				1	
Blood urine present		1		1			
Body temperature decreased		1		1			
Body temperature fluctuation		1		1			
Body temperature increased	1	10		5	1	5	
Bone density decreased	1	1	1	1			
Breath sounds abnormal		1				1	
C-reactive protein increased	1	4	1	2		2	
Eosinophil count decreased		1		1			
Fibrin D dimer increased		1				1	
Grip strength decreased		1		1			
Heart rate abnormal	1	1	1	1			
Heart rate increased	3	12	1	5	2	7	
International normalised ratio increased	1	1	1	1			
Lymphocyte count decreased		1		1			
Monocyte count decreased		1		1			
Neutrophil count increased		1		1			
Oxygen saturation decreased	3	14	1	3	2	11	
PCO2 abnormal	1	1			1	1	
Prostatic specific antigen increased		1				1	
Protein urine present		2		2			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 antibody test negative		1				1
SARS-CoV-2 antibody test positive	1	1	1	1		
SARS-CoV-2 test positive		2		1		1
Transaminases increased		1				1
White blood cell count increased		1				1
	26	138	11	53	15	85

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	13		6	2	7
Electrolyte imbalance		1		1		
Metabolic acidosis		1				1
Type 2 diabetes mellitus	1	1			1	1
	3	16		7	3	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	7	81	4	49	3	32
Arthritis		1		1		
Arthropathy		2		2		
Axillary mass		1		1		
Back pain	2	15	2	13		2
Bone pain	2	17		10	2	7
Bursitis		1		1		
Cervical spinal stenosis		1				1
Decreased nasolabial fold		1		1		
Intervertebral disc protrusion		1				1
Joint effusion		1		1		
Joint range of motion decreased		2		2		
Joint stiffness		1		1		
Joint swelling		4		1		3
Limb discomfort		1		1		
Mobility decreased	1	1			1	1
Muscle spasms		2		2		
Muscle tightness		2		2		
Muscular weakness		6		2		4
Musculoskeletal chest pain		1		1		
Musculoskeletal pain	1	3		1	1	2
Musculoskeletal stiffness		4		4		
Myalgia	18	127	12	78	6	49
Neck pain		10		6		4
Pain in extremity	11	78	9	60	2	18
Pain in jaw		1		1		
Psoriatic arthropathy	1	1			1	1
Rhabdomyolysis		1				1
Spinal pain		4		2		2
Synovial disorder		1		1		
Systemic lupus erythematosus		1				1
	43	373	27	244	16	129

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

*System Organ Class*

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Bladder cancer		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		9		7		2
Altered state of consciousness	1	3			1	3
Anosmia	1	11	1	9		2
Aphasia	1	3		1	1	2
Balance disorder	1	3		2	1	1
Brain oedema		1				1
Brain stem stroke	1	1			1	1
Brain stem syndrome		1				1
Burning sensation		3		3		
Cerebral haematoma		2				2
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	5			1	5
Chorea		1		1		
Cognitive disorder		1		1		
Coma		1				1
Depressed level of consciousness		2				2
Disturbance in attention	1	7	1	5		2
Dizziness	5	47	2	23	3	24
Dysarthria	1	2			1	2
Dysgeusia		7		2		5
Dysstasia		1		1		
Encephalopathy		2				2
Facial paralysis	3	12			3	12
Febrile convulsion		8				8
Formication		1				1
Generalised tonic-clonic seizure		1				1
Guillain-Barre syndrome		1				1
Haemorrhagic stroke		1				1
Headache	14	140	9	91	5	49
Head discomfort		2		2		
Hemiparesis		1				1
Hyperaesthesia	2	7	2	3		4

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	3	33	2	14	1	19
Hypotonia		3				3
Hypotonic-hyporesponsive episode	2	25		4	2	21
Ischaemic stroke	1	1			1	1
Lethargy	1	2		1	1	1
Loss of consciousness	4	28			4	28
Memory impairment	2	4	1	3	1	1
Migraine		2		2		
Monoparesis		1				1
Movement disorder	1	3	1	2		1
Multiple sclerosis relapse		1				1
Neuritis cranial		1				1
Neuropathy peripheral	1	1			1	1
Optic neuritis		1				1
Paraesthesia	4	15	3	8	1	7
Paralysis		2				2
Paraparesis		3				3
Paresis		2		1		1
Parosmia	1	4	1	2		2
Poor quality sleep		1		1		
Presyncope	1	8		2	1	6
Radicular pain		1		1		
Radiculitis brachial		1		1		
Sciatica	1	2		1	1	1
Seizure	3	24			3	24
Sensory disturbance		3				3
Sinus headache		1				1
Somnolence	1	12		8	1	4
Speech disorder	2	9		3	2	6
Spinal cord compression		1				1
Stupor	1	1			1	1
Syncope	4	28			4	28

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		5		4		1
Tension headache		1		1		
Transient ischaemic attack		1				1
Tremor	1	7	1	4		3
Trigeminal nerve disorder		1		1		
Trigeminal neuralgia		2		1		1
Trigeminal neuritis		1				1
Ulnar nerve palsy		1		1		
Visual field defect		2		2		
	67	533	24	219	43	314

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Needle issue		1		1
Product contamination physical		1		1
Product temperature excursion issue		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1				1
Anxiety		6		4		2
Confusional state	1	7		3	1	4
Delirium	1	2			1	2
Disorientation	1	2			1	2
Distractibility		1		1		
Eating disorder		1		1		
Hallucination, olfactory	1	1			1	1
Helplessness		1				1
Initial insomnia		1		1		
Insomnia		10		10		
Mental disorder		1		1		
Middle insomnia		1		1		
Mood altered		1		1		
Mutism		1		1		
Nervousness	1	2		1	1	1
Nightmare		1		1		
Restlessness		1				1
Sleep disorder	1	1			1	1
Stress		1				1
	6	43		26	6	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	2			1	2
Anuria		5				5
Bladder disorder		1		1		
Chromaturia	1	1			1	1
Haematuria		2		1		1
Hydronephrosis		1				1
Myoglobinuria	1	1			1	1
Oliguria		1		1		
Renal failure	1	2			1	2
Renal pain		1		1		
Urinary incontinence	1	3			1	3
Urinary tract inflammation		1				1
	5	21		4	5	17

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Breast enlargement		1		1		
Breast pain		2		1		1
Prostatitis		1				1
Suppressed lactation		2		1		1
		7		4		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic respiratory symptom		2				2
Apnoea	1	2			1	2
Asphyxia		1				1
Asthma		8				8
Asthmatic crisis		1				1
Bronchial oedema		1				1
Choking		1				1
Choking sensation		1				1
Cough	6	18	2	7	4	11
Dysphonia		3		3		
Dyspnoea	10	42	3	10	7	32
Dyspnoea at rest		1				1
Dyspnoea exertional	1	1			1	1
Emphysema	1	1	1	1		
Epistaxis		2		2		
Haemoptysis	1	1	1	1		
Hypopnoea	1	2			1	2
Hypoxia		1				1
Increased upper airway secretion		1		1		
Irregular breathing		1				1
Laryngeal oedema		1				1
Laryngospasm		8				8
Lung disorder	1	2	1	2		
Lung opacity	1	1	1	1		
Nasal congestion		2		1		1
Oropharyngeal pain	1	6	1	4		2
Painful respiration		1		1		
Pharyngeal hypoaesthesia		2				2
Pharyngeal swelling		2		1		1
Pleural effusion		1		1		
Pulmonary calcification	1	1	1	1		
Pulmonary congestion	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary mass	1	1	1	1		
Pulmonary oedema		3				3
Pulmonary pain	1	1			1	1
Respiration abnormal		1		1		
Respiratory arrest		2				2
Respiratory disorder	1	2			1	2
Respiratory failure	2	5			2	5
Respiratory tract oedema		1				1
Rhinorrhoea		10		8		2
Tachypnoea		3				3
Throat irritation		1		1		
Throat tightness		2		1		1
Tonsillar hypertrophy		1		1		
Tracheal oedema		1				1
	31	153	12	50	19	103

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	12			1	12
Blister		1				1
Cold sweat		1				1
Dermatitis allergic		1				1
Ecchymosis		1				1
Erythema	2	12		3	2	9
Erythema multiforme		3				3
Haemorrhage subcutaneous		1				1
Hyperhidrosis	3	23	1	14	2	9
Lividity		4				4
Macule	1	1			1	1
Night sweats		1		1		
Pain of skin	1	3		2	1	1
Petechiae		4		1		3
Pruritus	2	9		4	2	5
Rash	3	15	1	4	2	11
Rash erythematous	1	3		1	1	2
Rash macular		1		1		
Rash morbilliform		1				1
Rash papular		3		1		2
Rash pruritic		1		1		
Rash rubelliform		2				2
Rash vesicular	2	2			2	2
Skin exfoliation		1				1
Skin hypertrophy		1		1		
Skin lesion		1				1
Skin mass		1		1		
Urticaria	2	12	1	3	1	9
Yellow skin		1				1
	18	122	3	38	15	84

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illiteracy		1				1
Walking disability		2		1		1
		3		1		2

System Organ Class

**SOC Not Yet Coded**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angiopathy		1				1
Aortic aneurysm rupture		1				1
Arteriosclerosis	1	2	1	1		1
Bleeding varicose vein	1	1			1	1
Blood pressure fluctuation		2				2
Circulatory collapse	1	1			1	1
Cyanosis		4				4
Essential hypertension	1	1			1	1
Flushing		3		2		1
Haematoma		1		1		
Hot flush		4		3		1
Hypertension	3	7	1	2	2	5
Hypotension		5		1		4
Pallor	1	10		1	1	9
Peripheral coldness		3		2		1
Phlebitis	1	1	1	1		
Shock	1	1			1	1
Shock symptom		1				1
Subclavian vein thrombosis		1				1
Thrombophlebitis	1	1	1	1		
Thrombosis	3	8			3	8
Vein disorder		1		1		
Venous thrombosis	1	1			1	1
	15	61	4	16	11	45

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PORTUGAL**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1		1		
Granulomatous lymphadenitis		1				1
Leukaemoid reaction		1				1
Leukocytosis	1	1			1	1
Lymphadenitis	4	11	3	4	1	7
Lymphadenopathy	63	240	16	42	47	198
Lymph node pain		3				3
Myelosuppression		1				1
Neutrophilia	1	1			1	1
Pancytopenia		1				1
Thrombocytopenia		1				1
Thrombotic microangiopathy		1				1
	69	263	19	47	50	216

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	2	4			2	4
Angina pectoris		1				1
Arrhythmia		6				6
Atrial fibrillation	2	2			2	2
Atrioventricular block complete		2				2
Bradycardia	1	9			1	9
Cardiac disorder		1				1
Cardiac failure		1				1
Cardio-respiratory arrest	2	4			2	4
Extrasystoles		2		1		1
Myocardial infarction		1				1
Myocarditis		2				2
Palpitations	7	21	2	5	5	16
Pericardial effusion	1	1			1	1
Pericarditis		1				1
Postural orthostatic tachycardia syndrome		1				1
Sinus tachycardia		2				2
Tachyarrhythmia		3				3
Tachycardia	11	64	4	13	7	51
Ventricular extrasystoles		1				1
	26	129	6	19	20	110

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autophony		1				1
Deafness		1				1
Deafness neurosensory	1	1			1	1
Deafness transitory		1				1
Deafness unilateral	1	2			1	2
Ear pain	1	5	1	1		4
Hypoacusis		3				3
Sudden hearing loss		2				2
Tinnitus	2	6		1	2	5
Vertigo	3	19	1	3	2	16
Vertigo positional		1				1
	8	42	2	5	6	37

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypothyroidism		1		1
Thyroid mass	1	1	1	1
	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia		1				1
Blindness	2	2			2	2
Blindness unilateral		1				1
Choroiditis		1				1
Conjunctival haemorrhage		1				1
Conjunctival irritation		1				1
Corneal degeneration		1				1
Corneal opacity		1				1
Diplopia	1	1	1	1		
Dry eye		1		1		
Episcleritis		1				1
Exophthalmos		1				1
Eye disorder		2		1		1
Eye irritation	1	5	1	4		1
Eyelid myokymia		1				1
Eyelid oedema		4				4
Eyelid sensory disorder		1		1		
Eye movement disorder		1				1
Eye pain		3		3		
Eye paraesthesia		1				1
Eye pruritus		1				1
Eye swelling		1				1
Lacrimation increased		1				1
Ocular discomfort		2		2		
Ocular hyperaemia		2				2
Photophobia		6		2		4
Retinal haemorrhage		1				1
Vision blurred	3	8	2	4	1	4
Visual acuity reduced		1		1		
Visual impairment	1	3			1	3
Vitreous floaters	1	1			1	1
	9	58	4	20	5	38

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	9	1	3		6
Abdominal distension		1				1
Abdominal pain	9	28	3	4	6	24
Abdominal pain lower		1				1
Abdominal pain upper	3	15	1	5	2	10
Abnormal faeces		1				1
Aphthous ulcer	1	4	1	1		3
Cheilitis	1	1	1	1		
Constipation	1	1			1	1
Crohn's disease		1				1
Diarrhoea	28	90	8	17	20	73
Dry mouth	1	9	1	3		6
Dyspepsia	3	5	1	1	2	4
Dysphagia	2	11	1	1	1	10
Eructation		2		2		
Faeces soft		1				1
Flatulence		3		1		2
Functional gastrointestinal disorder		3				3
Gastric disorder		1				1
Gastrointestinal pain		1				1
Glossodynia	1	2	1	2		
Hypoaesthesia oral	2	15	2	5		10
Lip oedema	1	13	1	1		12
Lip pruritus		1				1
Lip swelling		3				3
Nausea	74	259	28	54	46	205
Odynophagia	2	19	1	5	1	14
Oedema mouth		3				3
Oesophageal disorder		1				1
Oesophageal pain		1				1
Oral discomfort	1	1	1	1		
Oral disorder		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oral pain		1					1
Palatal disorder	1	1			1		1
Pancreatitis		1					1
Paraesthesia oral	4	22	3	5	1		17
Salivary hypersecretion	1	2	1	2			
Stiff tongue		1					1
Stomatitis		3		2			1
Terminal ileitis		1					1
Tongue coated		1					1
Tongue discomfort		2					2
Tongue disorder	1	2		1	1		1
Tongue dry	1	3	1	1			2
Tongue eruption		2					2
Tongue oedema	5	17	3	3	2		14
Tongue pruritus		1					1
Tongue rough	1	1	1	1			
Trichoglossia		1		1			
Upper gastrointestinal haemorrhage	1	1			1		1
Vomiting	21	76	5	9	16		67
	167	646	66	132	101		514

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site bruise		1		1		
Asthenia	18	149	6	22	12	127
Axillary pain	6	35	3	10	3	25
Chest discomfort		14		4		10
Chest pain	9	31	2	3	7	28
Chills	52	220	14	39	38	181
Condition aggravated	2	9	1	3	1	6
Crying		2		1		1
Death	3	8			3	8
Discomfort	2	5			2	5
Disease recurrence		1				1
Drug ineffective	15	72			15	72
Drug interaction	1	2			1	2
Face oedema	5	24	2	4	3	20
Fatigue	69	233	14	43	55	190
Feeling abnormal		2		1		1
Feeling cold	4	16	2	3	2	13
Feeling hot	7	30	6	9	1	21
Feeling of body temperature change		1				1
Gait disturbance		2		1		1
Gait inability	1	4		2	1	2
General symptom		1				1
Hyperthermia	1	14		4	1	10
Hypothermia	1	3			1	3
Illness		1		1		
Inflammation		4				4
Influenza like illness		2		1		1
Injected limb mobility decreased		2		1		1
Injection site erythema		1		1		
Injection site pain	1	4	1	4		
Injection site warmth		1		1		
Localised oedema	1	7		1	1	6

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	19	112	10	28	9	84
Nodule	1	1	1	1		
Non-cardiac chest pain	1	1	1	1		
Oedema	3	9	1	2	2	7
Oedema mucosal		1				1
Oedema peripheral	7	16	1	4	6	12
Pain	24	70	10	18	14	52
Peripheral swelling	3	6	1	1	2	5
Puncture site haematoma		1				1
Pyrexia	83	502	18	87	65	415
Sensation of foreign body	1	2	1	1		1
Sudden cardiac death	1	1			1	1
Swelling	3	12	2	2	1	10
Swelling face		1				1
Systemic inflammatory response syndrome	1	1			1	1
Vaccination site discolouration		1				1
Vaccination site discomfort	2	4	2	2		2
Vaccination site eczema		2		1		1
Vaccination site erythema	26	72	12	25	14	47
Vaccination site haematoma	5	6	3	3	2	3
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration	3	14	3	5		9
Vaccination site inflammation	3	15	1	2	2	13
Vaccination site injury		1				1
Vaccination site joint inflammation	1	1			1	1
Vaccination site joint movement impairment	3	3			3	3
Vaccination site joint pain	1	1			1	1
Vaccination site lymphadenopathy		2				2
Vaccination site movement impairment	4	6	1	1	3	5
Vaccination site nodule		1		1		
Vaccination site oedema	33	81	10	25	23	56

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	167	512	81	213	86	299
Vaccination site paraesthesia	1	3	1	2		1
Vaccination site pruritus	8	31	5	9	3	22
Vaccination site rash	4	6	2	2	2	4
Vaccination site reaction	3	8	3	4		4
Vaccination site swelling	5	32	2	7	3	25
Vaccination site urticaria		1				1
Vaccination site warmth	4	23	3	10	1	13
	619	2,465	227	619	392	1846

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cholangitis	1	1	1	1
Cholestasis	1	1	1	1
Drug-induced liver injury	1	1	1	1
Hepatitis	1	1	1	1
Jaundice	1	1	1	1
	5	5	5	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		3				3
Anaphylactic reaction	5	22			5	22
Anaphylactic shock		2				2
Anaphylactoid reaction		2				2
Drug hypersensitivity		1				1
Hypersensitivity		13		4		9
	5	43		4	5	39

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adenopathy syphilitic	1	2			1	2
Asymptomatic COVID-19	11	29		2	11	27
Bacterial infection		1				1
COVID-19	25	149	6	32	19	117
COVID-19 pneumonia	1	4			1	4
Escherichia bacteraemia	1	1			1	1
Gonorrhoea		1				1
Herpes zoster		1				1
Impetigo	1	1			1	1
Influenza	2	6			2	6
Mastitis	1	2			1	2
Meningitis viral	1	1			1	1
Myelitis		1				1
Nasopharyngitis		1				1
Ophthalmic herpes simplex		1				1
Oral candidiasis	1	2			1	2
Oral herpes		2				2
Pharyngitis		1				1
Pneumonia	1	2			1	2
Pyelonephritis		1				1
Respiratory tract infection	1	1			1	1
Rhinitis		2		1		1
Sepsis	1	1			1	1
Sinusitis		2		2		
Tonsillitis		1				1
Tonsillitis bacterial		1				1
Tooth abscess	1	1	1	1		
Urinary tract infection	1	6			1	6
Urinary tract infection bacterial		1				1
Vaccination site abscess		1		1		
Varicella		1				1
	50	227	7	39	43	188

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chillblains		1		1		
Contraindicated product administered	1	1	1	1		
Contusion	1	1			1	1
Exposure during pregnancy	2	7	1	6	1	1
Exposure to SARS-CoV-2		1				1
Exposure via breast milk	3	10	3	10		
Fall	1	4		2	1	2
Head injury		1				1
Inappropriate schedule of product administration		7		6		1
Incorrect dose administered	2	2	2	2		
Incorrect route of product administration	1	20	1	20		
Maternal exposure during pregnancy		5		5		
Occupational exposure to SARS-CoV-2		1		1		
Off label use	2	14	2	14		
Overdose	8	23	8	22		1
Patella fracture	1	1			1	1
Procedural haemorrhage		1				1
Procedural nausea		1				1
Product administered at inappropriate site	1	2	1	2		
Product use issue	2	12	2	12		
Scar		1		1		
Vaccination complication		4		1		3
Vaccination failure	16	57			16	57
Wound		1		1		
	41	178	21	107	20	71

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amylase increased		1				1
Blood glucose fluctuation		1		1		
Blood glucose increased		1				1
Blood pressure decreased	1	2			1	2
Blood pressure diastolic decreased		1		1		
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased	2	9		1	2	8
Blood pressure systolic increased		1		1		
Blood thyroid stimulating hormone increased		1				1
Body temperature abnormal		1				1
Body temperature decreased		1				1
Body temperature increased		6		1		5
Computerised tomogram thorax abnormal		1		1		
Fibrin D dimer increased	2	2	2	2		
Heart rate decreased		1				1
Heart rate increased		5		1		4
Inspiratory capacity decreased		2				2
International normalised ratio decreased	1	1	1	1		
International normalised ratio increased	1	1			1	1
Lipase increased		1				1
Lymph node palpable		2		1		1
Magnetic resonance imaging brain abnormal		1		1		
Monocyte count increased	1	1	1	1		
Oxygen saturation decreased	4	12			4	12
Platelet count increased	1	1	1	1		
PO2 decreased	1	1			1	1
SARS-CoV-2 test positive		11		1		10
Thyroid function test abnormal		1		1		
Transaminases increased		1				1
Weight decreased		1		1		
	15	72	5	17	10	55

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis	1	1			1	1
Decreased appetite	7	34	1	4	6	30
Food refusal	1	1			1	1
Hyperglycaemia		5		1		4
Hyperlactacidaemia	1	1			1	1
Hypoglycaemia		3				3
Hypokalaemia		3				3
Polydipsia	1	5			1	5
	11	53	1	5	10	48

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	49	194	7	18	42	176
Arthritis		1				1
Arthritis reactive		1				1
Axillary mass		1				1
Back pain	2	21	1	2	1	19
Bone pain		2		1		1
Facial asymmetry		1				1
Groin pain		1				1
Joint range of motion decreased	2	5	1	1	1	4
Joint swelling	1	2			1	2
Limb discomfort	2	4	2	2		2
Limb mass		1		1		
Mobility decreased	6	8	3	3	3	5
Muscle fatigue	2	5	1	2	1	3
Muscle rigidity		1				1
Muscle spasms		3		1		2
Muscle tightness		1				1
Muscle twitching		1				1
Muscular weakness	3	15	1	2	2	13
Musculoskeletal discomfort		1				1
Musculoskeletal disorder	2	2			2	2
Musculoskeletal stiffness		6		1		5
Myalgia	137	709	38	140	99	569
Myalgia intercostal		1				1
Neck mass		1		1		
Neck pain	5	12	2	4	3	8
Osteitis		1				1
Pain in extremity	21	66	7	16	14	50
Pain in jaw		1				1
Rhabdomyolysis		1				1
Soft tissue haemorrhage		1		1		
Spinal pain	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Synovial cyst	2	9			2	9
Tenosynovitis		1		1		
Trismus		1				1
	235	1,082	63	197	172	885

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphoproliferative disorder	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		3		1		2
Allodynia	1	1			1	1
Altered state of consciousness	1	2			1	2
Amnesia		1		1		
Anosmia		6		3		3
Aphasia	1	1			1	1
Aura	1	1	1	1		
Autonomic nervous system imbalance		1				1
Balance disorder		5				5
Burning sensation	3	7	1	1	2	6
Cerebral venous sinus thrombosis	1	2			1	2
Cerebrovascular accident	6	8			6	8
Cholinergic syndrome		1				1
Conus medullaris syndrome	1	1			1	1
Depressed level of consciousness		1				1
Disturbance in attention	1	1			1	1
Dizziness	32	140	16	30	16	110
Dizziness postural		2				2
Drooling		1		1		
Dysarthria		5		1		4
Dysgeusia	11	24	10	14	1	10
Dyskinesia		1				1
Dyslexia		1				1
Dysstasia		1				1
Embolic stroke	1	1			1	1
Extrapyramidal disorder		1				1
Facial nerve disorder		1				1
Facial paralysis	2	10			2	10
Facial paresis		2				2
Facial spasm		2		1		1
Febrile convulsion		1				1
Generalised tonic-clonic seizure		3				3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhagic transformation stroke	1	1			1	1
Headache	131	615	50	137	81	478
Head discomfort	1	3	1	1		2
Hemianaesthesia		1				1
Hemidysaesthesia		1				1
Hemiparaesthesia	1	2			1	2
Hemiparesis	1	1			1	1
Hemiplegia	1	1			1	1
Hydrocephalus	1	1			1	1
Hyperaesthesia		2				2
Hypoaesthesia	6	19	4	8	2	11
Hyposmia		1				1
Hypotonic-hyporesponsive episode		1				1
Infant irritability		1		1		
Intercostal neuralgia		2				2
Ischaemic stroke	2	3			2	3
Lacunar stroke	2	2			2	2
Lethargy		3				3
Loss of consciousness	1	3			1	3
Migraine	2	9	1	3	1	6
Motor dysfunction	1	4			1	4
Movement disorder	3	4	2	2	1	2
Muscle contractions involuntary	1	3	1	1		2
Myoclonus		3				3
Neuralgia		1				1
Neuropathy peripheral	1	2			1	2
Nystagmus		4				4
Paraesthesia	27	90	15	28	12	62
Paralysis		2				2
Poor quality sleep		2				2
Presyncope	11	40	7	10	4	30
Sciatica		1				1

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	2	8			2	8
Sensory disturbance		1				1
Sensory loss		7		2		5
Somnolence	23	67	11	28	12	39
Speech disorder	2	3		1	2	2
Status epilepticus	1	1			1	1
Stroke in evolution		1				1
Syncope	7	28			7	28
Taste disorder		10		3		7
Tension headache		1				1
Tonic clonic movements		1				1
Transient ischaemic attack	1	1			1	1
Tremor	3	46	2	9	1	37
Trigeminal palsy		1				1
	295	1,242	122	288	173	954

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	2	1	2
	1	2	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	1	2			1	2
Anxiety	4	12	4	7		5
Apathy	1	1			1	1
Bradyphrenia		2				2
Confusional state		2				2
Depressed mood		1				1
Disorientation	3	3	1	1	2	2
Hallucination		1				1
Insomnia	5	26	3	8	2	18
Libido decreased		1		1		
Mental fatigue	1	1			1	1
Mood altered		1				1
Nervousness		2				2
Phonophobia		1				1
Restlessness	1	1	1	1		
Sleep disorder	1	5			1	5
	17	62	9	18	8	44

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	2	2			2	2
Bladder disorder	1	1			1	1
Chronic kidney disease	1	1			1	1
Dysuria	1	1			1	1
Haemoglobinuria	1	1			1	1
Leukocyturia		1		1		
Oliguria	2	2	1	1	1	1
Proteinuria		1		1		
Renal colic		1				1
Renal tubular necrosis		1				1
	8	12	1	3	7	9

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea	1	1	1	1		
Breast discomfort	1	1			1	1
Breast pain		5		2		3
Breast swelling	1	2		1	1	1
Gynaecomastia	1	1			1	1
Menstrual disorder	1	1	1	1		
Metrorrhagia		1				1
Nipple disorder	1	1	1	1		
Perineal pain		1				1
Suppressed lactation		1		1		
Vaginal haemorrhage	1	2			1	2
Vulvovaginal burning sensation	1	2	1	1		1
Vulvovaginal swelling		1				1
	8	20	4	8	4	12

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	1	1			1	1
Aphonia	1	1			1	1
Apnoea	1	1			1	1
Atelectasis		1		1		
Bradypnoea	1	1			1	1
Bronchospasm	1	7			1	7
Choking sensation		1				1
Cough	13	53	2	9	11	44
Dry throat		1				1
Dysphonia	3	10		3	3	7
Dyspnoea	15	47		7	15	40
Dyspnoea at rest	1	3			1	3
Dyspnoea exertional	2	2			2	2
Epistaxis	3	8	2	4	1	4
Haemoptysis		1				1
Hyperventilation		1				1
Hypopnoea	1	1			1	1
Laryngeal oedema		13				13
Lung infiltration	1	1			1	1
Nasal congestion	1	6		1	1	5
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction		2		1		1
Nasal oedema	1	1	1	1		
Oropharyngeal discomfort	6	18	4	7	2	11
Oropharyngeal oedema		2		1		1
Oropharyngeal pain	6	16	2	5	4	11
Orthopnoea	1	1			1	1
Painful respiration		1				1
Pharyngeal cyst	2	2			2	2
Pharyngeal erythema		1				1
Pharyngeal hypoaesthesia	2	3	1	1	1	2

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal inflammation		2		1		1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	1	5			1	5
Pharyngeal swelling	1	1			1	1
Pleuritic pain		2				2
Pneumonia aspiration	1	2			1	2
Productive cough		4		1		3
Pulmonary embolism	4	4			4	4
Respiratory disorder		1				1
Respiratory distress	1	3			1	3
Respiratory failure	1	1			1	1
Respiratory tract congestion		1				1
Rhinalgia	1	1	1	1		
Rhinorrhoea	2	23	2	8		15
Sneezing	2	3	1	1	1	2
Tachypnoea	1	3			1	3
Throat irritation	1	15	1	7		8
Throat tightness	2	9		1	2	8
Tonsillar hypertrophy		1				1
Tonsillar inflammation	1	1	1	1		
Upper-airway cough syndrome		1				1
Wheezing	3	5		1	3	4
	85	298	18	65	67	233

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1				1
Angioedema	1	11			1	11
Circumoral oedema		1				1
Cold sweat		4				4
Cutaneous vasculitis		1				1
Dermatitis allergic		1				1
Dermatitis exfoliative	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Dry skin	1	1			1	1
Ecchymosis	1	1			1	1
Eczema		2				2
Erythema	2	33	1	9	1	24
Erythema nodosum	1	1			1	1
Hyperhidrosis	6	29	3	5	3	24
Macule		1				1
Night sweats		3				3
Palmar-plantar erythrodysesthesia syndrome		1				1
Petechiae		2				2
Piloerection		4				4
Pityriasis rosea		2				2
Pruritus	5	47	3	9	2	38
Purpura	1	4			1	4
Rash	15	73	5	17	10	56
Rash erythematous	1	5	1	3		2
Rash macular	5	13		1	5	12
Rash maculo-papular	1	7		2	1	5
Rash papular		4		2		2
Rash pruritic	4	10	2	5	2	5
Rash vesicular	1	1			1	1
Sensitive skin		2		1		1
Skin burning sensation		2				2
Skin exfoliation	1	2			1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion		2				2
Skin reaction	1	2			1	2
Skin warm	2	7		1	2	6
Urticaria	2	18	1	3	1	15
Urticaria cholinergic		2		2		
Urticaria papular		1				1
	53	303	16	60	37	243

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aborted pregnancy		1				1
Bedridden		2				2
Impaired work ability		2		1		1
Loss of personal independence in daily activities	2	5		1	2	4
	2	10		2	2	8

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Axillary lymphadenectomy	1	1	1	1
	1	1	1	1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis	1	1	1	1		
Blood pressure fluctuation	1	1			1	1
Cyanosis		2				2
Deep vein thrombosis	3	3			3	3
Diastolic hypertension		1				1
Embolism		1				1
Embolism venous	2	2			2	2
Flushing	6	18	3	5	3	13
Haematoma	1	4		1	1	3
Hot flush		4				4
Hyperaemia		1				1
Hypertension	10	39	4	4	6	35
Hypertensive crisis		5				5
Hypoperfusion		1				1
Hypotension	3	26		1	3	25
Lymphoedema		1				1
Pallor		13		2		11
Peripheral artery occlusion	1	1			1	1
Peripheral artery stenosis	1	1			1	1
Peripheral coldness	1	5			1	5
Phlebitis		1				1
Shock	1	1			1	1
Takayasu's arteritis		1				1
Thrombophlebitis	2	3			2	3
Thrombosis	2	2			2	2
Vasculitis	1	2			1	2
	36	140	8	14	28	126

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PUERTO RICO**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis		1		1
Lymphadenopathy	1	6	1	6
	1	7	1	7

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		1		1		
Sinus arrhythmia		1				1
Tachycardia		3		3		
		5		4		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Photophobia		1		1
		1		1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort		4		4
Abdominal pain		2		2
Diarrhoea		3		3
Dry mouth		1		1
Dyspepsia		1		1
Flatulence		1		1
Gingival bleeding		1		1
Nausea		6		6
Oral discomfort		1		1
		20		20

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Axillary pain		1		1		
Chest discomfort		1		1		
Chest pain		1		1		
Chills		7		7		
Death	1	1			1	1
Discomfort		1		1		
Facial pain		1		1		
Fatigue	1	15	1	15		
Feeling cold	1	1			1	1
Gait disturbance		1		1		
Illness		1				1
Inflammation		1		1		
Injection site discomfort		1		1		
Injection site pruritus		1		1		
Injection site swelling		1		1		
Injection site warmth		1		1		
Malaise		1		1		
Nodule		1		1		
Pain		6		6		
Peripheral swelling		1		1		
Pyrexia	1	16	1	16		
Swelling		1		1		
Swelling face		1		1		
Thirst		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling	1	5	1	5		
	6	81	4	78	2	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1		1		
Pneumonia		1				1
Urinary tract infection		1				1
		3		1		2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration	1	3	1	3
Maternal exposure during pregnancy		1		1
Off label use	1	2	1	2
Poor quality product administered		10		10
Product administered at inappropriate site		1		1
	2	17	2	17

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Antibody test abnormal		1		1		
Antinuclear antibody positive		1		1		
Blood pressure increased		1		1		
Blood test abnormal		1		1		
Heart rate decreased		1				1
Heart rate increased		1		1		
Red blood cell sedimentation rate increased		1		1		
		7		6		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dehydration		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		8		8
Back pain		1		1
Bone disorder		1		1
Bone pain		1		1
Joint range of motion decreased		1		1
Joint swelling		1		1
Limb discomfort		1		1
Muscle spasms		2		2
Muscle twitching		1		1
Musculoskeletal stiffness		1		1
Myalgia		10		10
Neck pain		2		2
Pain in extremity	1	7	1	7
	1	37	1	37

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Burning sensation		3		3		
Cerebrovascular accident		1				1
Dizziness		3		3		
Dysgeusia		1		1		
Dyskinesia		1				1
Facial paralysis	1	3			1	3
Headache	1	22	1	22		
Head discomfort		1		1		
Hypoaesthesia	1	6	1	6		
Migraine		1				1
Movement disorder		1		1		
Neuralgia		1		1		
Paraesthesia		3		3		
Somnolence		1		1		
Speech disorder		1		1		
Taste disorder		2		2		
	3	52	2	46	1	6

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Depression		1		1
Insomnia	1	1	1	1
Stress		1		1
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia		1		1		
Dyspnoea		2		1		1
Productive cough		1		1		
Rhinorrhoea		1		1		
		5		4		1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		1		1		
Hyperhidrosis	1	1			1	1
Night sweats		1				1
Pruritus	1	2	1	2		
Rash	2	4	2	4		
	4	9	3	7	1	2

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Loss of personal independence in daily activities		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	1	1			1	1
Flushing		2		2		
Haematoma		1		1		
Hypertension	1	3		2	1	1
Thrombosis	1	1			1	1
	3	8		5	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**QATAR**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	2	1	1		1
	1	2	1	1		1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ocular hyperaemia		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia		2		2		
Nausea		1				1
		3		2		1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	2		1	1	1
Drug ineffective	1	1			1	1
Feeling cold		1		1		
Feeling hot		1				1
Gait disturbance	1	1	1	1		
Pyrexia	1	2	1	1		1
	4	8	2	4	2	4

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	3		1	2	2
Herpes zoster		2		2		
Rhinovirus infection		1				1
	2	6		3	2	3

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy	1	1	1	1		
Overdose		1		1		
Product preparation error		1		1		
Product use issue	1	1	1	1		
Vaccination failure	1	1			1	1
	3	5	2	4	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1		1		
C-reactive protein increased		1				1
Heart rate decreased	1	1	1	1		
Heart rate increased		1		1		
Inflammatory marker increased		1				1
Neutrophil count increased		1				1
Platelet count increased		1				1
Red blood cell sedimentation rate increased		1				1
White blood cell count increased		1				1
	1	9	1	3		6

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Starvation	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	1	1			1	1
Myalgia		1		1		
Neck pain	1	1			1	1
Pain in extremity	1	1			1	1
	3	4		1	3	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention	1	1	1	1		
Dizziness		2				2
Dysgeusia		1		1		
Facial paralysis		1				1
Headache	1	2	1	2		
Muscle spasticity	1	1			1	1
Neuralgia		1		1		
Presyncope		1				1
Syncope		1				1
	3	11	2	5	1	6

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state	1	1	1	1
Depressed mood	1	1	1	1
Middle insomnia	1	1	1	1
Mood altered		1		1
Sleep disorder	1	1	1	1
	4	5	4	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cough		1		1
Dyspnoea		1		1
		2		2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	2	1	1		1
Hyperhidrosis		1				1
Rash		1				1
	1	4	1	1		3

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypertension	1	1	1	1
Hypotension	1	1	1	1
Peripheral coldness		1		1
	2	3	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ROMANIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	4	8	2	4	2	4
Lymphadenopathy	11	36	5	20	6	16
Lymph node pain		1		1		
Lymphopenia		1				1
Paratracheal lymphadenopathy		1				1
	15	47	7	25	8	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Angina pectoris		3				3
Arrhythmia	2	5			2	5
Atrial fibrillation		1				1
Atrioventricular block		1				1
Cardiac arrest		1				1
Cardiac fibrillation		1				1
Cardio-respiratory arrest		1				1
Myocardial infarction	1	1			1	1
Myocardial ischaemia		1				1
Palpitations	7	12	1	1	6	11
Pericarditis		1				1
Sinus tachycardia		2				2
Supraventricular tachycardia	1	2			1	2
Tachyarrhythmia	1	1			1	1
Tachycardia	5	28	1	9	4	19
Ventricular extrasystoles		1		1		
	17	63	2	11	15	52

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear discomfort		1		1		
Ear pain		2		1		1
Hypoacusis	4	4			4	4
Paraesthesia ear		1		1		
Tinnitus	3	4		1	3	3
Vertigo	9	26	2	6	7	20
Vestibular disorder		1		1		
	16	39	2	11	14	28

System Organ Class

**Endocrine disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Goitre		1				1
Hypothyroidism		1				1
Thyroiditis subacute		1		1		
		3		1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angle closure glaucoma		1				1
Blepharitis		1				1
Cataract	1	1			1	1
Diplopia	3	4	1	1	2	3
Eye haemorrhage	2	2			2	2
Eyelid oedema		2		1		1
Eyelid ptosis		2		1		1
Eye pain	1	2			1	2
Eye pruritus		1		1		
Hypoaesthesia eye	1	1			1	1
Metamorphopsia		1				1
Ocular discomfort	3	3	2	2	1	1
Ocular hyperaemia		1		1		
Photophobia		1				1
Vision blurred	2	3			2	3
Visual acuity reduced		1				1
Visual impairment	3	5	1	1	2	4
	16	32	4	8	12	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	4	9	1	3	3	6
Abdominal pain upper		2		1		1
Diarrhoea	5	16	3	6	2	10
Dry mouth	1	3			1	3
Dysphagia	1	4		1	1	3
Eructation		1				1
Faeces soft		1				1
Flatulence	1	1			1	1
Hypoaesthesia oral	2	4			2	4
Lip dry	1	1			1	1
Lip oedema		6		2		4
Lip swelling		1				1
Mouth swelling	1	1			1	1
Nausea	23	70	9	31	14	39
Odynophagia		1		1		
Oedematous pancreatitis		1				1
Oral pigmentation	1	1	1	1		
Paraesthesia oral		1		1		
Rectal haemorrhage		1				1
Stomatitis	2	2			2	2
Swollen tongue	1	1			1	1
Teething	1	1			1	1
Tongue disorder		1		1		
Tongue oedema		1				1
Tongue spasm		1				1
Vomiting	5	24	2	8	3	16
	50	157	16	56	34	101

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain	2	3	2	2		1
Administration site reaction	4	4	4	4		
Administration site swelling	1	1	1	1		
Adverse event		1		1		
Adverse reaction		1		1		
Asthenia	16	42	13	30	3	12
Axillary pain	2	5		3	2	2
Chest discomfort	4	7	2	4	2	3
Chest pain	4	14		3	4	11
Chills	44	119	20	60	24	59
Condition aggravated	1	4		1	1	3
Crying		1		1		
Death	6	9			6	9
Discomfort	1	2	1	2		
Disease recurrence	1	2			1	2
Drug ineffective	32	90			32	90
Extensive swelling of vaccinated limb		1				1
Face oedema		2				2
Facial pain	1	2		1	1	1
Fatigue	34	88	21	63	13	25
Feeling abnormal	2	5	2	3		2
Feeling cold	2	5		2	2	3
Feeling hot	2	5		2	2	3
Foaming at mouth		1				1
Gait disturbance	1	2			1	2
General physical health deterioration		3		3		
Hyperpyrexia		1				1
Hyperthermia		1		1		
Illness		1				1
Inflammation		2		2		
Influenza like illness	5	8	5	8		
Injected limb mobility decreased		4		4		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Localised oedema		1
Local reaction	1	1
Malaise	11	32
Mucosal dryness		1
No adverse event		2
Oedema	1	3
Oedema peripheral	1	3
Pain	3	16
Peripheral swelling		2
Pyrexia	48	148
Swelling		2
Swelling face	1	1
Systemic inflammatory response syndrome		1
Thirst	3	4
Vaccination site discolouration		1
Vaccination site discomfort		3
Vaccination site erythema	4	26
Vaccination site granuloma	1	1
Vaccination site induration	2	5
Vaccination site inflammation		3
Vaccination site joint movement impairment		3
Vaccination site lymphadenopathy		2
Vaccination site macule	1	1
Vaccination site movement impairment	3	7
Vaccination site nodule		2
Vaccination site oedema		3
Vaccination site pain	39	146
Vaccination site papule	1	1
Vaccination site paraesthesia		2
Vaccination site pruritus	2	4
Vaccination site reaction	19	25
Vaccination site swelling	4	7

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
2	14	9	18
			1
	2		
1	2		1
		1	3
1	13	2	3
	1		1
23	82	25	66
	2		
		1	1
			1
		3	4
	1		
	3		
4	23		3
1	1		
2	4		1
	2		1
	1		2
	2		
1	1		
1	4	2	3
	2		
	3		
28	112	11	34
1	1		
	1		1
2	4		
19	25		
4	7		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria		1		1		
Vaccination site warmth		1		1		
	310	897	162	518	148	379

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Hepatitis		1		1
Hepatocellular injury		1		1
		2		2

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Anaphylactic reaction	4	9			4	9
Anaphylactic shock	2	5			2	5
Anaphylactoid reaction	1	2			1	2
Autoimmune disorder	1	1			1	1
Hypersensitivity	19	24	17	20	2	4
	27	42	17	21	10	21

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		2				2
Bronchitis	1	1			1	1
Coronavirus infection		1				1
COVID-19	120	182	4	10	116	172
Herpes zoster		2		1		1
Influenza		1		1		
Nasal vestibulitis		1				1
Pharyngitis		1		1		
Pneumonia		1				1
Sialoadenitis	1	1			1	1
Suspected COVID-19	1	5		1	1	4
Sweating fever	1	1			1	1
Toxocariasis	1	1			1	1
Viral infection	1	1			1	1
	126	201	4	14	122	187

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Burn of internal organs		1				1	
Circumstance or information capable of leading to medication error		3		3			
Contusion		1		1			
Exposure during pregnancy	1	2	1	2			
Exposure to SARS-CoV-2	1	1	1	1			
Exposure via breast milk		1		1			
Inappropriate schedule of product administration	1	2	1	2			
Incomplete course of vaccination	1	1	1	1			
Incorrect route of product administration	1	8	1	5		3	
Intercepted medication error		1		1			
Limb injury		1				1	
Maternal exposure during pregnancy	1	3	1	3			
Medication error		3		3			
Off label use	1	4	1	4			
Overdose		1		1			
Product preparation error	1	13	1	13			
Product preparation issue	3	9	3	9			
Product use issue		2		2			
Underdose	2	3	2	3			
Vaccination failure	7	15			7	15	
Wrong product administered		2		2			
Wrong technique in product usage process	3	17	3	17			
	23	94	16	74	7	20	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood fibrinogen increased	1	1	1	1		
Blood glucose decreased	1	1			1	1
Blood glucose increased	1	1			1	1
Blood pressure abnormal	1	3	1	2		1
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure increased	3	10	1	4	2	6
Blood pressure systolic increased		3		1		2
Blood uric acid increased	1	1	1	1		
Body temperature abnormal		3		3		
Body temperature increased	1	2		1	1	1
Gastric pH decreased		1		1		
General physical condition abnormal		2		2		
Heart rate abnormal		1		1		
Heart rate decreased	1	2			1	2
Heart rate increased	8	19	1	2	7	17
Herpes virus test	1	1	1	1		
High density lipoprotein decreased	1	1	1	1		
Laboratory test abnormal	1	2	1	2		
Lipase increased		1		1		
Listeria test positive	1	1	1	1		
Lymph node palpable	1	1	1	1		
Mean cell haemoglobin increased		1		1		
Nitrite urine present	1	1	1	1		
Oxygen saturation abnormal	1	1			1	1
Oxygen saturation decreased	2	5		1	2	4
Protein urine present	1	1	1	1		
Pulse abnormal	1	4	1	2		2
Pulse volume decreased		2		2		
Red blood cells urine positive	1	1	1	1		
SARS-CoV-2 antibody test negative		7		7		
SARS-CoV-2 antibody test positive	2	9	2	9		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive		9		3		6
Toxoplasma serology positive	1	1	1	1		
Transaminases increased		1		1		
Urine ketone body present	1	1	1	1		
Weight decreased		1				1
Weight increased		1				1
White blood cells urine positive	1	1	1	1		
	35	106	19	58	16	48

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	6	10	3	4	3	6
Dehydration		1				1
Diabetes mellitus	1	1			1	1
Hyperglycaemia		3		1		2
Hyperkalaemia		2				2
Hypocalcaemia		1				1
Metabolic acidosis		1				1
Type 2 diabetes mellitus	1	1			1	1
	8	20	3	5	5	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	14	57	9	34	5	23
Back disorder		1		1		
Back pain	6	10		3	6	7
Bone pain	4	11		4	4	7
Jaw disorder		1				1
Joint ankylosis		1				1
Joint stiffness		1				1
Mobility decreased	1	2		1	1	1
Muscle contracture	1	2		1	1	1
Muscle rigidity	1	1			1	1
Muscle spasms		1				1
Muscle swelling		1		1		
Muscular weakness	2	6	2	5		1
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness	1	1			1	1
Myalgia	47	137	25	74	22	63
Neck pain		1		1		
Pain in extremity	15	48	6	37	9	11
Rheumatic disorder		1		1		
Spinal pain	1	2		1	1	1
Tendon pain	1	1			1	1
	94	287	42	164	52	123

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acoustic neuroma	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	6	1	4		2
Anosmia	1	4		2	1	2
Balance disorder	2	4	1	1	1	3
Burning sensation	1	4		1	1	3
Cerebral small vessel ischaemic disease		1				1
Cerebrovascular accident	3	5			3	5
Coma		2				2
Dementia	1	1			1	1
Depressed level of consciousness		1				1
Disturbance in attention	1	4		1	1	3
Dizziness	24	60	7	26	17	34
Dysgeusia	1	2			1	2
Dysstasia	1	1			1	1
Facial neuralgia		1				1
Facial paralysis	2	10			2	10
Facial paresis	3	5	2	2	1	3
Guillain-Barre syndrome	1	1			1	1
Headache	65	172	33	98	32	74
Head discomfort	2	2			2	2
Hemianaesthesia	1	1			1	1
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	1			1	1
Horner's syndrome		1				1
Hyperaesthesia		1		1		
Hypoaesthesia	13	23	2	8	11	15
Hypokinesia		1		1		
Hypotonia		1				1
Hypoxic-ischaemic encephalopathy		1				1
Intracranial pressure increased		1				1
Lethargy		2		2		
Loss of consciousness	5	8			5	8
Memory impairment		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Migraine		3		1		2	
Monoplegia	1	2			1	2	
Movement disorder		1				1	
Muscle contractions involuntary		2		1		1	
Myoclonus		2				2	
Nervous system disorder		3		3			
Neuralgia		1				1	
Neurological symptom		3				3	
Neuronal neuropathy	1	1			1	1	
Neuropathy peripheral	1	2			1	2	
Nystagmus		1		1			
Optic neuritis	1	1			1	1	
Paraesthesia	9	34	1	12	8	22	
Paralysis		1				1	
Paraplegia		1				1	
Parkinson's disease	1	1			1	1	
Parosmia	2	3		1	2	2	
Presyncope	1	6		4	1	2	
Seizure		3				3	
Sensory loss		1		1			
Somnolence	14	34	6	18	8	16	
Speech disorder		1				1	
Syncope	16	36			16	36	
Taste disorder	2	3	1	2	1	1	
Tremor	3	8		2	3	6	
Visual field defect		1				1	
	182	484	54	193	128	291	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product quality issue		1		1
Syringe issue		1		1
		2		2

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1			1	
Anxiety		13		4	9	
Confusional state		1		1		
Disorientation	1	1			1	
Emotional distress		1		1		
Fear		1		1		
Insomnia	2	7		2	2	
Mental status changes	1	1			1	
Panic attack	1	3	1	3		
Sleep disorder	1	1			1	
Stress		1		1		
	6	31	1	13	5	
					18	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nephropathy		1		1
Pollakiuria	1	1	1	1
Polyuria	2	3	2	3
Renal pain		3		3
Urinary incontinence	1	1	1	1
	4	9	4	9

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1			1	
Amenorrhoea	1	1	1	1		
Breast inflammation	2	2			2	2
Breast pain	1	4		1	1	3
Menstrual disorder		1				1
Menstruation irregular	1	1			1	1
Pelvic pain	1	1			1	1
Suppressed lactation		1		1		
	6	12	1	3	5	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		2				2
Aphonia		1		1		
Apnoea	1	1			1	1
Asphyxia	1	2			1	2
Asthma		1				1
Asthmatic crisis		1				1
Bronchospasm	2	6	1	2	1	4
Cough	2	12	1	6	1	6
Dysphonia		2		2		
Dyspnoea	10	22	1	3	9	19
Dyspnoea exertional	1	1			1	1
Epiglottic oedema		1				1
Epistaxis		1		1		
Laryngeal oedema		2				2
Laryngospasm		1				1
Lung disorder		1		1		
Nasal congestion	1	1			1	1
Nasal discomfort		2		2		
Nasal dryness	1	3		1	1	2
Nasal oedema		1				1
Obstructive airways disorder		1				1
Oropharyngeal discomfort		2				2
Oropharyngeal pain	4	4			4	4
Pleurisy		1				1
Productive cough		1				1
Rales		1				1
Respiration abnormal		1				1
Respiratory disorder		2		1		1
Respiratory distress		3				3
Respiratory failure		1				1
Rhinalgia		1				1
Rhinorrhoea	4	5	3	4	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stridor		1		1		
Suffocation feeling	2	4	1	1	1	3
Tachypnoea		1				1
Throat tightness		1		1		
Use of accessory respiratory muscles		1		1		
Wheezing		2		1		1
	29	97	7	29	22	68

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	5			1	5
Blister		1				1
Circumoral oedema		1				1
Cold sweat		4		2		2
Dermatitis allergic	2	5	1	1	1	4
Drug eruption		2				2
Erythema		22		13		9
Erythema nodosum		2		1		1
Hyperhidrosis	5	20		7	5	13
Lividity	1	1			1	1
Night sweats	2	2	1	1	1	1
Pain of skin	2	2			2	2
Petechiae	1	1			1	1
Photosensitivity reaction	1	1			1	1
Pruritus	1	12	1	6		6
Rash	2	15	1	10	1	5
Rash erythematous		4				4
Rash pruritic		4		2		2
Rash vesicular		1				1
Scar pain		1		1		
Skin burning sensation	1	1			1	1
Skin discolouration	1	2	1	2		
Skin hypertrophy	1	1			1	1
Skin irritation		2				2
Skin plaque		1				1
Urticaria	3	16	1	6	2	10
Urticaria papular		1		1		
	24	130	6	53	18	77

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immobile	1	1			1	1
Impaired work ability		1				1
Loss of personal independence in daily activities	1	2	1	2		
Sitting disability		1				1
Walking disability		1		1		
	2	6	1	3	1	3

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	3			1	3
Cyanosis		3		1		2
Deep vein thrombosis	2	3			2	3
Flushing		1		1		
Hot flush		1		1		
Hyperaemia		1				1
Hypertension	23	48	4	8	19	40
Hypertensive crisis	1	2			1	2
Hypotension	1	7		1	1	6
Infarction		1				1
Pallor	2	4		1	2	3
Peripheral arterial occlusive disease		1				1
Peripheral coldness		2		1		1
Raynaud's phenomenon		1				1
Shock		1				1
Systolic hypertension		1				1
Thrombosis	1	1			1	1
	31	81	4	14	27	67

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SAUDI ARABIA**

System Organ Class

**Blood and lymphatic system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		1				1
Lymphadenopathy		4		4		
		5		4		1

System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cardiac arrest		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1	1			
Abdominal pain upper		1			1	
Mouth ulceration		1	1			
Nausea		1	1			
Vomiting		3			3	
		7	3		4	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		2		
Axillary pain	1	1	1	1		
Chills		2		2		
Fatigue		7		6		1
Feeling hot	1	1	1	1		
Gait disturbance		2		1		1
Gait inability		1				1
Malaise	1	2	1	2		
Pain	1	6	1	5		1
Pyrexia	1	7	1	6		1
Temperature intolerance	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain	1	6	1	6		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
	7	41	7	36		5

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	3	1	3
Herpes zoster		1		1
Nasopharyngitis		1		1
Vaginal infection		1		1
	1	6	1	6

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Accidental overdose		1		1
Inappropriate schedule of product administration		1		1
Product preparation issue		1		1
		3		3

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased		1	1			
Heart rate decreased		1			1	
Red blood cell sedimentation rate increased		1	1			
		3	2		1	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		3		3		
Mastication disorder		1		1		
Mobility decreased		4		3		1
Musculoskeletal stiffness		1		1		
Myalgia	1	7	1	6		1
Pain in extremity		4		2		2
Pain in jaw		1		1		
	1	21	1	17		4

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphoma	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carotid artery stenosis		1				1
Dizziness		2		1		1
Dysstasia		1				1
Headache	1	6	1	6		
Movement disorder		1		1		
Sciatica		2		2		
Seizure	1	2			1	2
Somnolence		1		1		
Syncope		3				3
Tremor	1	1	1	1		
	3	20	2	12	1	8

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sleep disorder	1	1	1	1
	1	1	1	1

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pollakiuria		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation irregular	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain		1		1		
Pulmonary embolism	1	1			1	1
Rhinorrhoea		1		1		
	1	3		2	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis		4		3		1
Night sweats	1	1	1	1		
Pain of skin		1		1		
	1	6	1	5		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Sitting disability		1		1
		1		1

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	1	1	1	1		
Hypotension		1				1
Peripheral coldness		2		2		
	1	4	1	3		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**SERBIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		1				1
Lymphadenopathy		3		2		1
		4		2		2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	1	1			1	1
Palpitations		1		1		
Tachycardia		2				2
	1	4		1	1	3

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Huntington's disease		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Deafness unilateral		1				1
Tinnitus		1		1		
Vertigo		1		1		
		4		2		2

System Organ Class

**Eye disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm		1				1
Eyelid oedema		1		1		
Eyelid ptosis		1				1
Eye pain	1	1	1	1		
Lacrimation increased		1		1		
Swelling of eyelid		1		1		
Vision blurred		2		1		1
	1	8	1	5		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Diarrhoea		2		2		
Dry mouth		1		1		
Haematemesis		1				1
Hypoaesthesia oral		2		1		1
Lip disorder	1	1	1	1		
Lip pruritus		1		1		
Lip swelling		1		1		
Nausea	3	19	3	16		3
Oedema mouth		1		1		
Pancreatitis acute		1				1
Paraesthesia oral		1		1		
Swollen tongue		1		1		
Tongue oedema		1				1
Vomiting		4		3		1
	5	38	5	30		8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	9	1	8	1	1
Axillary pain		2		1		1
Chest discomfort		1		1		
Chest pain		3		1		2
Chills	1	11	1	9		2
Disease recurrence	1	1	1	1		
Drug ineffective	1	3			1	3
Face oedema		1				1
Fatigue	3	10	3	9		1
Feeling abnormal		1		1		
Feeling cold		2		2		
Feeling hot	1	2	1	2		
Influenza like illness		2		2		
Localised oedema		1		1		
Malaise	4	20	4	17		3
No adverse event		3		3		
Oedema mucosal		1				1
Oedema peripheral	1	2	1	2		
Pain		3		2		1
Peripheral swelling		1				1
Pyrexia	3	38	2	33	1	5
Swelling		2		1		1
Vaccination site erythema		4		4		
Vaccination site haematoma		1				1
Vaccination site induration		1		1		
Vaccination site oedema		2		2		
Vaccination site pain		16		16		
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
	17	146	14	122	3	24

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactoid reaction		1				1
Hypersensitivity		3		2		1
		4		2		2

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess		1				1
Conjunctivitis		1		1		
COVID-19	4	10	4	8		2
COVID-19 pneumonia		1				1
Herpes zoster		1		1		
Nasopharyngitis		1		1		
Pneumonia		1		1		
	4	16	4	12		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy		1		1		
Fall		2		1		1
Inappropriate schedule of product administration	1	2	1	2		
Maternal exposure during pregnancy		1		1		
Off label use	1	1	1	1		
Overdose	1	1			1	1
Vaccination complication		5		5		
Vaccination failure		1				1
Wrong product administered		1		1		
	3	15	2	12	1	3

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood lactate dehydrogenase increased		1				1
Blood pressure increased		2		1		1
Body temperature increased	3	14	3	13		1
C-reactive protein increased	1	2	1	1		1
Fibrin D dimer increased	1	1	1	1		
Heart rate increased	1	1	1	1		
Inflammatory marker increased		1		1		
Intraocular pressure increased		1				1
Monocyte count increased		1		1		
Oxygen saturation decreased		1				1
Red blood cell count increased	1	1	1	1		
Red blood cell sedimentation rate increased		1				1
SARS-CoV-2 antibody test negative		1		1		
SARS-CoV-2 test positive		3		1		2
	7	31	7	22		9

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		12		11		1
Back pain	1	2		1	1	1
Bone pain		2		2		
Joint stiffness		2		1		1
Muscular weakness		2		2		
Musculoskeletal stiffness		1		1		
Myalgia	2	15	2	14		1
Myositis		1				1
Neck pain		1				1
Pain in extremity	3	12	3	12		
Pain in jaw		1		1		
	6	51	5	45	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	3	1	2		1
Anosmia	1	2	1	2		
Balance disorder		1				1
Burning sensation	1	1	1	1		
Dizziness	2	6	2	5		1
Dysgeusia		1				1
Facial paralysis		1				1
Facial paresis		1				1
Headache	5	24	4	21	1	3
Hyperaesthesia	1	1	1	1		
Hypoaesthesia		1		1		
Ischaemic stroke		1				1
Loss of consciousness		1				1
Movement disorder		1		1		
Paraesthesia		2		2		
Somnolence	1	3	1	2		1
Syncope	2	4			2	4
Tremor	1	2	1	2		
	15	56	12	40	3	16

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply issue		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		2		2		
Confusional state		1		1		
Fear	1	1			1	1
Fear of death		1		1		
Insomnia	1	2	1	1		1
Nervousness		1				1
Sleep disorder		1		1		
	2	9	1	6	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asphyxia		2				2
Bronchospasm		2		1		1
Cough	1	3	1	1		2
Dyspnoea		3				3
Hypopnoea		1				1
Nasal congestion		2		1		1
Oropharyngeal pain	1	2	1	2		
Pulmonary pain		2		1		1
Rhinorrhoea		1				1
Sneezing		1				1
Wheezing		1				1
	2	20	2	6		14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		8		7		1
Hyperhidrosis	1	4	1	3		1
Pruritus	1	2	1	2		
Rash	1	3	1	2		1
Rash macular		2				2
Skin burning sensation	1	2	1	1		1
Skin reaction		1				1
Urticaria		4		4		
	4	26	4	19		7

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematoma		1		1		
Hypertension	1	8		2	1	6
Pallor		2		2		
Phlebitis		1				1
Superficial vein prominence	1	1	1	1		
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
	4	15	1	6	3	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SINGAPORE**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bicytopenia	1	1			1	1
Eosinophilia	1	1			1	1
Lymphadenopathy	1	1	1	1		
	3	3	1	1	2	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles	1	1			1	1
Myocardial infarction	1	1			1	1
Palpitations	8	10	1	1	7	9
Postural orthostatic tachycardia syndrome	1	1			1	1
Sinus tachycardia	1	1			1	1
Tachycardia	4	4			4	4
	16	18	1	1	15	17

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness neurosensory	1	1			1	1
Dysacusis		1		1		
Vertigo	1	1	1	1		
	2	3	1	2	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hyperthyroidism	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm	1	1	1	1		
Diplopia	1	1			1	1
Dry eye	1	1			1	1
Eye disorder	1	1			1	1
Eye movement disorder	3	3			3	3
Eye pruritus	2	2	1	1	1	1
Eye swelling	1	2		1	1	1
Lacrimation increased	1	1			1	1
Periorbital swelling	5	6	1	1	4	5
Swelling of eyelid	1	1			1	1
Vision blurred	2	2			2	2
Visual impairment	1	1			1	1
	20	22	3	4	17	18

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	4	5			4	5
Abdominal tenderness	1	1			1	1
Diarrhoea	3	5		1	3	4
Dry mouth	1	1	1	1		
Dysphagia	2	2			2	2
Enlarged uvula	2	4			2	4
Gastroesophageal reflux disease	1	1			1	1
Lip swelling	2	4	1	1	1	3
Nausea	10	11	5	5	5	6
Odynophagia	1	1			1	1
Palatal oedema	2	2			2	2
Swollen tongue	1	1			1	1
Vomiting	8	9	2	2	6	7
	38	47	9	10	29	37

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	2	1	1	1	1
Chest discomfort	11	12	2	2	9	10
Chest pain	3	3			3	3
Chills	5	7		2	5	5
Disease progression	1	1	1	1		
Disease recurrence	1	1			1	1
Fatigue	5	5	4	4	1	1
Gait disturbance	1	1			1	1
Hunger	1	1	1	1		
Influenza like illness	1	1	1	1		
Injection site pruritus	1	1	1	1		
Injection site swelling		1		1		
Malaise	1	2			1	2
Oedema peripheral	1	1	1	1		
Pain	2	2	1	1	1	1
Peripheral swelling	1	1			1	1
Pyrexia	9	10	3	4	6	6
Secretion discharge	1	1	1	1		
Sensation of foreign body	5	5			5	5
Swelling face	1	1			1	1
Vaccination site erythema	1	2	1	2		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site mass		1		1		
Vaccination site pain	2	4		2	2	2
Vaccination site paraesthesia	1	1			1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	1			1	1
Vaccination site reaction		1		1		
Vaccination site urticaria	1	1			1	1
	61	72	19	28	42	44

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatitis	1	1	1	1
	1	1	1	1

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	15	17			15	17
Anaphylactic shock		5				5
Hypersensitivity	2	3		1	2	2
	18	26		1	18	25

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cellulitis	1	1			1	1
Gianotti-Crosti syndrome		1		1		
Respiratory tract infection	1	1			1	1
Vestibular neuronitis	1	1			1	1
	3	4		1	3	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	2	2			2	2
Femoral neck fracture	1	1			1	1
Maternal exposure during pregnancy		1		1		
Nerve injury	1	1			1	1
Poor quality product administered	1	3	1	3		
Skin abrasion	1	1			1	1
Vaccination complication	1	1			1	1
	7	10	1	4	6	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Alanine aminotransferase increased	1	1	1	1
Aspartate aminotransferase increased	1	1	1	1
Blood alkaline phosphatase increased	1	1	1	1
Blood bilirubin increased	1	1	1	1
Blood pressure decreased	1	1	1	1
Blood pressure increased	3	3	3	3
Blood pressure systolic increased	3	3	3	3
Body temperature increased	1	1	1	1
Breath sounds abnormal	1	1	1	1
Complement factor C3 increased	1	1	1	1
Haematocrit increased	1	1	1	1
Haemoglobin increased	1	1	1	1
Heart rate increased	2	3	2	3
Oxygen saturation decreased	2	2	2	2
Pupillary light reflex tests abnormal	1	1	1	1
Respiratory rate decreased	1	1	1	1
Respiratory rate increased	1	1	1	1
Transaminases increased	2	2	2	2
Troponin increased	1	1	1	1
	26	27	26	27

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Decreased appetite	1	1	1	1
Dehydration	1	1	1	1
Feeding disorder	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2			2	2
Arthritis	1	1			1	1
Facial asymmetry	1	1			1	1
Muscular weakness	2	2			2	2
Musculoskeletal stiffness	1	1			1	1
Myalgia	3	3	2	2	1	1
Neck pain	1	1			1	1
Pain in extremity	4	4	3	3	1	1
Rheumatoid arthritis	1	1			1	1
Tenosynovitis	1	1			1	1
	17	17	5	5	12	12

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fibroma		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	19	20	5	5	14	15
Drooling	1	1			1	1
Dyskinesia	4	4			4	4
Dysstasia	1	1			1	1
Facial paralysis	3	3			3	3
Generalised tonic-clonic seizure	2	2			2	2
Headache	6	7	4	5	2	2
Head discomfort		1		1		
Hypoaesthesia	6	6	1	1	5	5
Migraine	1	1			1	1
Optic neuritis	1	1			1	1
Parosmia	2	2	2	2		
Petit mal epilepsy	1	1			1	1
Radiculopathy	1	1			1	1
Seizure	4	4			4	4
Sensory disturbance	1	1			1	1
Somnolence	2	2			2	2
Status epilepticus	1	1			1	1
Syncope	5	5			5	5
Taste disorder		1		1		
Tongue biting	1	1			1	1
Tonic clonic movements	1	1			1	1
Tonic convulsion	1	1			1	1
Toxic neuropathy	1	1			1	1
Unresponsive to stimuli	3	3			3	3
Vlth nerve paralysis	1	1			1	1
	69	73	12	15	57	58

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute psychosis	1	1	1	1
Confusional state	2	2	2	2
Mental status changes	1	1	1	1
Tic	1	1	1	1
	5	5	5	5

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	1	1	1
Haematuria	1	1	1	1
Proteinuria	1	1	1	1
Renal impairment	1	1	1	1
	4	4	4	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	2	2			2	2
Cough	2	4			2	4
Dysphonia	7	9	1	1	6	8
Dyspnoea	20	22	1	1	19	21
Dyspnoea exertional	2	2	1	1	1	1
Laryngeal oedema	1	1			1	1
Oropharyngeal pain	2	2			2	2
Pharyngeal mass	1	1	1	1		
Pharyngeal swelling	2	2			2	2
Pneumonia aspiration	1	1			1	1
Pulmonary embolism	1	1			1	1
Rhinorrhoea	1	1			1	1
Throat irritation	4	4	2	2	2	2
Throat tightness	8	9	1	1	7	8
Upper respiratory tract congestion	1	1	1	1		
Wheezing	4	4	1	1	3	3
	59	66	9	9	50	57

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Acute generalised exanthematous pustulosis	1	1			1	1
Angioedema	4	7			4	7
Cold sweat	1	1			1	1
Dermatitis bullous	1	1			1	1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Erythema	2	2			2	2
Erythema multiforme	1	1			1	1
Hand dermatitis	1	1	1	1		
Hyperhidrosis	2	2	1	1	1	1
Pruritus	4	5			4	5
Rash	13	16	3	6	10	10
Rash erythematous	1	1	1	1		
Rash macular	2	4			2	4
Rash maculo-papular	1	2		1	1	1
Rash papular	1	1			1	1
Rash pruritic	1	1			1	1
Skin lesion		1		1		
Urticaria	10	13	1	2	9	11
	47	62	7	14	40	48

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	1	1			1	1
Flushing	3	3			3	3
Hypertension	4	5			4	5
Hypotension	6	6			6	6
Pallor	1	1			1	1
Peripheral coldness	1	1	1	1		
	16	17	1	1	15	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SLOVAKIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis	1	1	1	1
Lymphadenopathy	5	13	5	13
Lymph node pain	1	1	1	1
	7	15	7	15

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Atrial fibrillation		1				1
Bradycardia		1				1
Cardiac discomfort	1	1	1	1		
Cardiac failure		1				1
Cardiac fibrillation		1				1
Myocardial ischaemia		1				1
Palpitations	1	7	1	7		
Sinus tachycardia		2				2
Tachycardia	4	10	4	7		3
	6	26	6	15		11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Sudden hearing loss	2	2			2	2
Tinnitus	4	5	4	5		
Vertigo	5	14	4	13	1	1
	12	22	8	18	4	4

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia		1		1		
Eye allergy		1		1		
Eye irritation	2	3	2	3		
Eyelid rash		1		1		
Eye oedema		3		1		2
Eye pain	1	2	1	2		
Eye pruritus	1	2	1	2		
Lacrimation increased	1	1	1	1		
Mydriasis		1		1		
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Photophobia		2		2		
Vision blurred	3	3	3	3		
Visual impairment	1	1			1	1
	9	23	8	20	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	1		1
Abdominal pain	1	2	1	1		1
Abdominal pain upper	1	2	1	2		
Diarrhoea	3	8	2	6	1	2
Dry mouth	1	3	1	2		1
Dysphagia	1	1	1	1		
Enlarged uvula	1	1	1	1		
Flatulence		1		1		
Lip oedema		1		1		
Nausea	12	31	12	28		3
Oral discomfort		1		1		
Pancreatitis acute	1	1			1	1
Paraesthesia oral		3		2		1
Retching	2	2	2	2		
Tongue discolouration	1	1	1	1		
Tongue dry	1	1			1	1
Vomiting	3	8	2	5	1	3
	29	69	25	55	4	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	16	39	14	33	2	6
Axillary pain	1	4	1	4		
Chest discomfort	1	4		3	1	1
Chest pain	2	2	2	2		
Chills	27	79	27	73		6
Condition aggravated	1	1	1	1		
Drug ineffective	5	7			5	7
Face oedema	1	3	1	2		1
Fatigue	18	46	18	46		
Feeling abnormal		1		1		
Feeling hot	3	8	3	8		
Feeling of body temperature change		1		1		
Gait disturbance		1		1		
Inflammation		1		1		
Influenza like illness		2		2		
Malaise	6	16	6	15		1
No adverse event		1		1		
Oedema		1		1		
Oedema peripheral		1		1		
Pain	2	8	2	8		
Peripheral swelling	2	2	2	2		
Pyrexia	24	62	24	59		3
Thirst	2	2	2	2		
Tissue infiltration		1		1		
Vaccination site bruising	1	1	1	1		
Vaccination site dermatitis		1		1		
Vaccination site erythema	4	8	4	8		
Vaccination site hypersensitivity		1		1		
Vaccination site induration	2	3	2	3		
Vaccination site inflammation	1	1	1	1		
Vaccination site joint movement impairment		1		1		
Vaccination site movement impairment		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	7	12	7	12		
Vaccination site pain	24	69	24	68		1
Vaccination site pruritus	2	3	2	3		
Vaccination site swelling	1	2	1	1		1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	1	1	1		
	154	398	146	371	8	27

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		2				2
Hypersensitivity		2		1		1
		4		1		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1				1
Conjunctivitis		2		1		1
COVID-19	6	13		3	6	10
Erysipelas		1				1
Lymphangitis	1	1			1	1
Rash pustular		1		1		
Rhinitis		2		2		
Viral infection	1	1			1	1
	8	22		7	8	15

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brachial plexus injury	1	1			1	1
Brain contusion		1				1
Fall	1	2	1	1		1
Incorrect dose administered		1		1		
Maternal exposure during pregnancy		2		2		
Medication error		1		1		
Product administered at inappropriate site		2		2		
Product administration error	1	1			1	1
Vaccination failure	1	2			1	2
	4	13	1	7	3	6

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased	2	2	2	2		
Blood pressure decreased	3	8		2	3	6
Blood pressure increased	8	20	3	7	5	13
Body temperature fluctuation	1	1	1	1		
Body temperature increased	20	33	18	29	2	4
Heart rate decreased		1		1		
Heart rate increased	2	4	2	4		
SARS-CoV-2 antibody test positive		1				1
SARS-CoV-2 test positive		2		1		1
Tryptase decreased		1		1		
	36	73	26	48	10	25

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	3	5	3	5		
Dehydration	2	2	1	1	1	1
Insulin resistance		1				1
	5	8	4	6	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	15	33	15	32		1
Back pain	2	4	2	4		
Bone pain	2	2	2	2		
Limb discomfort		1		1		
Muscular weakness	1	2		1	1	1
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	16	46	16	46		
Neck pain	2	2	2	2		
Pain in extremity	20	49	20	49		
Synovitis		1		1		
Tendonitis	1	1	1	1		
	61	144	60	142	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness	1	2			1	2
Amnesia	1	1			1	1
Aphasia	2	2	1	1	1	1
Balance disorder	1	1	1	1		
Burning sensation		3		3		
Cerebral ischaemia	1	1			1	1
Cervicobrachial syndrome	1	1			1	1
Dizziness	8	20	7	16	1	4
Dysaesthesia		1		1		
Dysarthria	1	1	1	1		
Dyskinesia	1	1	1	1		
Epilepsy	1	1			1	1
Facial paresis		1				1
Headache	23	67	23	66		1
Head discomfort	1	3	1	3		
Hypoaesthesia		1		1		
Loss of consciousness	1	3			1	3
Migraine		1		1		
Movement disorder	1	2	1	2		
Paraesthesia	7	19	7	14		5
Presyncope	2	7	2	4		3
Somnolence	2	5	1	4	1	1
Speech disorder	1	1			1	1
Syncope	3	11			3	11
Tension headache	1	2	1	2		
Tonic convulsion		1				1
Tremor		1				1
	60	160	47	121	13	39

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		1		1		
Disorientation	1	1	1	1		
Insomnia	1	3	1	3		
Restlessness		2				2
	2	7	2	5		2

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Micturition urgency		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asphyxia	1	1			1	1
Cough	2	8	2	8		
Dry throat		1		1		
Dyspnoea	3	9	2	6	1	3
Oropharyngeal pain	1	2	1	2		
Rhinalgia	1	1	1	1		
Tachypnoea		1				1
Throat irritation		2		2		
Throat tightness		1		1		
Wheezing	1	1			1	1
	9	27	6	21	3	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Cold sweat		1		1		
Cutaneous vasculitis		1		1		
Dermatitis allergic		1		1		
Erythema	1	6	1	5		1
Hyperhidrosis	2	9	2	6		3
Pain of skin		1		1		
Petechiae		1		1		
Pruritus	1	4	1	3		1
Rash	2	5	2	5		
Rash papular		1		1		
Rash pruritic		2		2		
Rash vesicular	1	1	1	1		
Urticaria		1				1
	7	36	7	28		8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary vein thrombosis		1				1
Cyanosis	1	1			1	1
Flushing	1	1	1	1		
Hot flush	2	7	2	5		2
Hypertension		4		3		1
Hypertensive crisis		1				1
Pallor	1	3	1	2		1
Peripheral coldness		3		3		
Subclavian vein stenosis	1	1			1	1
Subclavian vein thrombosis		1				1
Thrombosis	1	2			1	2
Venous thrombosis limb	1	2			1	2
	8	27	4	14	4	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SLOVENIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		1		1		
Lymphadenopathy		5		5		
Neutropenia		1				1
Thrombocytopenia		2				2
		9		6		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Angina pectoris		1				1
Arrhythmia	1	1			1	1
Atrial fibrillation	1	3			1	3
Atrial tachycardia		1				1
Bradycardia	3	3			3	3
Cardiac arrest		1				1
Cardiac failure	1	1			1	1
Cardiac failure congestive	1	1			1	1
Cardiac tamponade		1				1
Cardiopulmonary failure	1	2			1	2
Extrasystoles	1	1			1	1
Myocardial infarction		2				2
Myocardial rupture		1				1
Sinus tachycardia		1				1
Tachycardia	1	3		2	1	1
Ventricular extrasystoles	1	2		1	1	1
	12	27		3	12	24

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain		1				1
Vertigo	4	11	2	5	2	6
	4	12	2	5	2	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune thyroiditis		1		1
		1		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral		1				1
Eyelid disorder		1		1		
Eyelid oedema		1		1		
Eye pruritus		1		1		
Miosis		1				1
		5		3		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Abdominal pain upper	1	1	1	1		
Diarrhoea	2	7	1	6	1	1
Gastrointestinal haemorrhage	1	1			1	1
Lip oedema	1	1			1	1
Lip swelling		1		1		
Nausea	1	8	1	5		3
Paraesthesia oral	1	3		1	1	2
Swollen tongue		2		2		
Tongue movement disturbance		1		1		
Tongue pruritus		2		2		
Vomiting		4		2		2
	7	36	3	26	4	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	4	1	3		1
Axillary pain		1				1
Chest discomfort	2	4		1	2	3
Chest pain	3	7	1	3	2	4
Chills		7		7		
Death		1				1
Disease recurrence		1				1
Drug ineffective	1	2			1	2
Fatigue	3	25	1	20	2	5
Feeling abnormal	1	1	1	1		
Feeling cold	1	1	1	1		
Feeling hot	1	3		1	1	2
Gait disturbance		1				1
Gait inability	1	1			1	1
General physical health deterioration		1				1
Malaise		19		12		7
Oedema peripheral	1	2			1	2
Pain		2		2		
Pyrexia		11		9		2
Sensation of foreign body	1	1			1	1
Sudden cardiac death	2	2			2	2
Sudden death		2				2
Vaccination site erythema		10		10		
Vaccination site oedema		4		4		
Vaccination site pain	7	51	5	46	2	5
Vaccination site pruritus		3		3		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	1	1			1	1
	27	170	11	125	16	45

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Hypersensitivity		1		1		
		2		1		1

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic bacteriuria		1				1
COVID-19		4				4
COVID-19 pneumonia		1				1
Infection		1				1
Lower respiratory tract infection	1	1			1	1
Nasopharyngitis		2		2		
Oral herpes		1				1
Pneumonia		2				2
Sinusitis		1		1		
Suspected COVID-19	1	1			1	1
	2	15		3	2	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy	1	1	1	1		
Fall	2	3	1	1	1	2
Head injury	1	1	1	1		
Inappropriate schedule of product administration	1	3	1	3		
Off label use	1	3	1	3		
Vaccination failure		2				2
	6	13	5	9	1	4

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1		1		
Body temperature increased	1	12		10	1	2
Oxygen saturation decreased		3				3
Protein total increased		1		1		
Total lung capacity decreased	1	1			1	1
White blood cell count increased		1		1		
	2	19		13	2	6

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diabetes mellitus	1	1	1	1
Hypokalaemia		1		1
	1	2	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		6		6		
Bone pain		1		1		
Muscular weakness	1	1	1	1		
Myalgia		12		10		2
Neck pain		1		1		
Pain in extremity		2		1		1
	1	23	1	20		3

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
B-cell lymphoma		1		1
B-cell type acute leukaemia		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	2			1	2
Aura		1		1		
Basilar artery thrombosis		1				1
Cerebral haemorrhage	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident		1				1
Coordination abnormal		1				1
Dementia		1				1
Dizziness	1	6		3	1	3
Dysarthria	1	1			1	1
Dysgeusia		2		2		
Epilepsy	1	3			1	3
Facial paralysis		1				1
Guillain-Barre syndrome		2				2
Headache	2	24	1	20	1	4
Hypoaesthesia		2		1		1
Hyposmia		2		2		
Ischaemic cerebral infarction		1				1
Ischaemic stroke	1	1			1	1
Loss of consciousness	3	11			3	11
Migraine		2		1		1
Migraine with aura		1				1
Monoparesis	1	1			1	1
Neurological symptom		1		1		
Paraesthesia		7		4		3
Paresis		1				1
Presyncope	1	1	1	1		
Quadriparesis		1				1
Seizure		1				1
Sensory disturbance		2		1		1
Somnolence	1	8		5	1	3
Speech disorder		2		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		5				5
Tongue biting		1				1
Transient ischaemic attack		1				1
Unresponsive to stimuli	1	3			1	3
Vertebral artery thrombosis		1				1
	15	104	2	43	13	61

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	1	2	1	1		1
Insomnia		3		3		
Irritability	1	1			1	1
Mood altered	1	1			1	1
Nightmare		1		1		
Restlessness		1		1		
Soliloquy	1	1	1	1		
Thinking abnormal		1		1		
	4	11	2	8	2	3

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Uterine spasm		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchial disorder		1				1
Cough		1				1
Dyspnoea	2	7		1	2	6
Hyperventilation		1				1
Oropharyngeal pain		1		1		
Pharyngeal erythema		1		1		
Pneumothorax spontaneous	1	1			1	1
Pulmonary embolism	1	3			1	3
Pulmonary oedema	1	1			1	1
Suffocation feeling		1				1
Throat tightness		1		1		
Wheezing		1				1
	5	20		4	5	16

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		1				1
Erythema		2		1		1
Night sweats		1				1
Pityriasis rosea		1		1		
Rash	1	2	1	2		
Rash pruritic		2		2		
Skin burning sensation		1		1		
Skin disorder		1				1
Urticaria		1				1
	1	12	1	7		5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Bedridden		1		1
Walking disability	1	1	1	1
	1	2	1	2

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse	2	3			2	3
Deep vein thrombosis	1	2			1	2
Hot flush	1	1			1	1
Hypertension	1	5			1	5
Hypotension		1				1
Peripheral coldness		1		1		
Superficial vein prominence	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
	7	15		1	7	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SPAIN**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	2	2			2	2
Atypical haemolytic uraemic syndrome	1	1			1	1
Autoimmune haemolytic anaemia	1	1			1	1
Coombs positive haemolytic anaemia	1	1			1	1
Haemorrhagic diathesis		1				1
Hyperfibrinogenaemia		1				1
Immune thrombocytopenia	4	6			4	6
Leukocytosis	1	2	1	1		1
Leukopenia		1				1
Lymphadenitis	7	15	4	6	3	9
Lymphadenopathy	27	141	9	50	18	91
Lymph node pain		1				1
Lymphocytosis	1	1	1	1		
Lymphopenia		3		3		
Neutropenia		1				1
Neutrophilia	1	2		1	1	1
Normochromic normocytic anaemia		1		1		
Pancytopenia	1	2			1	2
Spontaneous haematoma		1				1
Thrombocytopenia	7	8			7	8
Thrombotic microangiopathy		1				1
Thrombotic thrombocytopenic purpura		1				1
	54	194	15	63	39	131

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute myocardial infarction	4	7			4	7
Angina pectoris		2				2
Aortic valve calcification	1	1			1	1
Arrhythmia	2	4			2	4
Atrial fibrillation	4	10			4	10
Atrioventricular block first degree		1		1		
Bradycardia		9				9
Bundle branch block left	1	1			1	1
Bundle branch block right	1	1			1	1
Cardiac arrest	1	3			1	3
Cardiac disorder	1	2	1	1		1
Cardiac failure	8	16			8	16
Cardiac failure acute	2	7			2	7
Cardiac failure congestive	2	2			2	2
Cardiac tamponade		1				1
Cardiomegaly	2	2			2	2
Cardio-respiratory arrest	3	13			3	13
Cardio-respiratory distress		1				1
Dilatation atrial	1	1			1	1
Dilatation ventricular	1	1			1	1
Extrasystoles	1	2			1	2
Hyperdynamic left ventricle		1				1
Myocardial infarction	1	2			1	2
Myocardial ischaemia	1	2			1	2
Myocardial rupture	1	1			1	1
Myocarditis		3				3
Palpitations	6	24	2	5	4	19
Pericardial haemorrhage	1	1			1	1
Pericarditis	3	9			3	9
Pleuropericarditis		1				1
Sinus arrest		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus bradycardia		1		1		
Sinus tachycardia	6	9		1		
Supraventricular extrasystoles	1	1		1	6	8
Supraventricular tachycardia	1	2			1	1
Tachyarrhythmia		1				1
Tachycardia	15	74	6	16	9	58
Tachycardia paroxysmal		1				1
Tricuspid valve incompetence	1	1			1	1
Ventricular dysfunction	1	1			1	1
Ventricular enlargement	1	1			1	1
Ventricular extrasystoles		1				1
Ventricular fibrillation	1	1			1	1
	76	227	9	25	67	202

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Macroglossia	1	1	1	1
Myoclonic dystonia		2		2
	1	3	1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Deafness unilateral		2				2
Ear discomfort		1				1
Ear pain	2	8	1	2	1	6
Hypoacusis		7				7
Meniere's disease	1	1			1	1
Misophonia		1				1
Neurosensory hypoacusis		1				1
Tinnitus	3	15	1	5	2	10
Vertigo	2	20		5	2	15
Vertigo positional	1	1			1	1
	9	58	2	12	7	46

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal mass		1		1		
Autoimmune hypothyroidism	1	1			1	1
Goitre		1		1		
Hyperthyroidism		1				1
Hypothyroidism		1				1
Silent thyroiditis	1	1			1	1
	2	6		2	2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amaurosis fugax	2	2			2	2
Anisometropia	1	1	1	1		
Asthenopia	1	3			1	3
Blepharitis	1	2	1	2		
Blepharospasm	1	2		1	1	1
Blindness transient		1				1
Blindness unilateral	1	1			1	1
Chorioretinopathy		1				1
Conjunctival haemorrhage	3	8			3	8
Conjunctival hyperaemia	2	2			2	2
Diplopia	4	8	2	2	2	6
Dry eye	1	2		1	1	1
Dyschromatopsia	1	1			1	1
Episcleritis		1				1
Eye discharge	1	1			1	1
Eye haemorrhage	1	1			1	1
Eyelid oedema	1	6		1	1	5
Eye pain	2	8		2	2	6
Eye pruritus	1	5		2	1	3
Eye swelling		1				1
Floppy eyelid syndrome		1				1
Foreign body sensation in eyes	1	3	1	3		
Gaze palsy		1				1
Giant papillary conjunctivitis		1				1
Hypoaesthesia eye	1	1			1	1
Iridocyclitis	1	1			1	1
Keratitis	2	2			2	2
Lacrimation increased		5		1		4
Macular oedema		1				1
Miosis		1				1
Ocular dysmetria	1	1	1	1		
Ocular hyperaemia		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital oedema		1		1		
Periorbital pain		1				1
Periorbital swelling		1		1		
Photophobia	1	7	1	2		5
Photopsia	1	2	1	2		
Retinal artery occlusion	2	2			2	2
Retinal vein occlusion		1				1
Retinal vein thrombosis	1	1			1	1
Scleritis		1				1
Sudden visual loss	1	1			1	1
Vision blurred	2	16		3	2	13
Visual acuity reduced		1				1
Visual impairment	1	3			1	3
Vitreous detachment		2				2
Vitreous floaters		1				1
	39	118	8	26	31	92

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	7		5	1	2
Abdominal distension	1	3	1	3		
Abdominal mass	1	1	1	1		
Abdominal pain	12	30	11	16	1	14
Abdominal pain lower	1	4	1	3		1
Abdominal pain upper	1	12		7	1	5
Abdominal symptom		1		1		
Abnormal faeces		1		1		
Anal incontinence	1	2	1	1		1
Anal sphincter atony		3				3
Angular cheilitis		1		1		
Aphthous ulcer	1	7	1	4		3
Atrophic glossitis		1				1
Cheilitis		4				4
Colitis	1	1	1	1		
Colitis ulcerative		1				1
Constipation	5	8	3	5	2	3
Dental caries		1		1		
Diarrhoea	44	136	36	75	8	61
Diarrhoea haemorrhagic		2				2
Dry mouth	2	8		1	2	7
Duodenal ulcer haemorrhage		1				1
Dyspepsia	2	3	1	1	1	2
Dysphagia	6	17	2	4	4	13
Epigastric discomfort		1				1
Faeces discoloured		1				1
Faeces soft	1	2	1	2		
Flatulence	2	4	2	3		1
Gastric disorder	1	2	1	1		1
Gastritis	2	2	1	1	1	1
Gastrointestinal disorder	2	2	2	2		
Gastrointestinal haemorrhage	2	3			2	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastroesophageal reflux disease		2		1		1
Gingival bleeding	2	3	1	1	1	2
Gingival discolouration		1		1		
Gingival swelling	1	1			1	1
Glossitis		4				4
Glossodynia		1				1
Haematochezia		1				1
Hiatus hernia	2	3		1	2	2
Hypoaesthesia oral	3	9	1	3	2	6
Ileus paralytic	1	2			1	2
Inflammatory bowel disease	1	2			1	2
Intestinal ischaemia		2				2
Intestinal obstruction	1	3			1	3
Lip blister		1		1		
Lip erythema		1				1
Lip oedema	1	12		2	1	10
Lip pruritus		5		3		2
Lip swelling	3	8	1	1	2	7
Melaena	1	3			1	3
Mouth swelling		2				2
Mouth ulceration		1				1
Nausea	51	176	48	106	3	70
Noninfective gingivitis		1				1
Odynophagia	3	19	3	5		14
Oedema mouth	1	3		1	1	2
Oral discomfort	1	2	1	2		
Oral disorder		1				1
Oral dysaesthesia		1				1
Oral mucosal blistering		1		1		
Oral pain		2		2		
Oral pruritus	1	4	1	1		3
Palatal oedema	1	13			1	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palatal swelling	1	3	1	1		2
Pancreatitis chronic	1	1			1	1
Paraesthesia oral	1	20	1	3		17
Parotid gland enlargement	2	2	2	2		
Proctalgia		1		1		
Proctitis		1				1
Rectal discharge		1				1
Rectal haemorrhage	2	6			2	6
Rectal tenesmus		1				1
Salivary hypersecretion	1	1			1	1
Stomatitis		5		4		1
Swollen tongue	2	8			2	8
Tongue coated		1				1
Tongue discomfort		1		1		
Tongue disorder	1	1	1	1		
Tongue eruption		2		2		
Tongue erythema		1				1
Tongue oedema		12		1		11
Tongue pruritus	1	6	1	2		4
Tongue ulceration		1		1		
Upper gastrointestinal haemorrhage	1	1			1	1
Uvulitis	1	2			1	2
Volvulus		1				1
Vomiting	43	128	34	63	9	65
	220	769	162	354	58	415

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	45	134	29	61	16	73
Axillary pain	3	16	3	10		6
Chest discomfort	2	22	1	4	1	18
Chest pain	8	39	3	8	5	31
Chills	28	123	24	72	4	51
Concomitant disease aggravated	1	4			1	4
Condition aggravated	5	22	2	4	3	18
Death	1	7			1	7
Discomfort	6	18	3	10	3	8
Disease recurrence	4	8	1	1	3	7
Drowning		2				2
Drug ineffective	7	53			7	53
Drug interaction		2		1		1
Extensive swelling of vaccinated limb	2	3	2	3		
Face oedema	3	15			3	15
Facial pain		2		1		1
Fatigue	42	142	31	79	11	63
Feeling abnormal	2	8	2	4		4
Feeling cold		8		2		6
Feeling drunk		1		1		
Feeling hot	6	20	6	12		8
Gait disturbance	2	14		3	2	11
Gait inability	3	8		2	3	6
Generalised oedema		2				2
General physical health deterioration	3	10	2	4	1	6
Hyperpyrexia		1				1
Hyperthermia		1				1
Hypothermia	4	8			4	8
Ill-defined disorder	1	1			1	1
Induration		2		1		1
Inflammation	4	11	3	6	1	5
Influenza like illness		5		4		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site erythema		2		2		
Injection site haematoma		1		1		
Injection site inflammation		1		1		
Injection site pain		1		1		
Injection site paraesthesia		1		1		
Localised oedema	1	2			1	2
Local reaction	2	5		1	2	4
Malaise	65	208	55	124	10	84
Mass		2				2
Mucosal dryness		1				1
Multiple organ dysfunction syndrome		5				5
Necrosis		1				1
No adverse event	1	1	1	1		
Nodule		1		1		
Oedema		7		5		2
Oedema peripheral	5	16	2	3	3	13
Pain	13	38	10	23	3	15
Peripheral swelling	2	8	2	4		4
Pyrexia	201	575	170	330	31	245
Sensation of foreign body	1	5			1	5
Sense of oppression		2				2
Shoulder injury related to vaccine administration		1		1		
Sudden cardiac death	1	1			1	1
Sudden death	4	16			4	16
Swelling	1	4	1	3		1
Swelling face	2	6	2	2		4
Systemic inflammatory response syndrome		1				1
Temperature intolerance	1	1	1	1		
Temperature regulation disorder	4	28	3	14	1	14
Tenderness		2		1		1
Thirst	1	1	1	1		
Vaccination site discomfort	2	5	1	3	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erosion		1		1		
Vaccination site erythema	5	17	5	10		7
Vaccination site haematoma	2	7	1	1	1	6
Vaccination site haemorrhage		1		1		
Vaccination site hyperaesthesia	1	2	1	1		1
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site hypoaesthesia	3	5	1	2	2	3
Vaccination site induration	3	8	3	6		2
Vaccination site inflammation	21	41	19	31	2	10
Vaccination site joint erythema	5	15	4	9	1	6
Vaccination site joint inflammation	1	3	1	1		2
Vaccination site joint movement impairment		1				1
Vaccination site joint swelling	1	2	1	2		
Vaccination site lymphadenopathy	4	22	2	8	2	14
Vaccination site movement impairment	4	6	4	5		1
Vaccination site oedema	2	5	2	2		3
Vaccination site pain	74	196	66	136	8	60
Vaccination site paraesthesia	2	7	1	2	1	5
Vaccination site pruritus	4	13	4	7		6
Vaccination site rash	4	5	3	3	1	2
Vaccination site reaction	1	5	1	3		2
Vaccination site swelling	3	10	1	5	2	5
Vaccination site warmth	3	9	3	4		5
	633	2,043	485	1058	148	985

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure	1	1			1	1
Autoimmune hepatitis	1	2			1	2
Biliary colic		2				2
Biliary cyst	1	1	1	1		
Cholestasis	1	1			1	1
Gallbladder enlargement		1				1
Granulomatous liver disease		1				1
Hepatic cyst	1	2	1	2		
Hepatic failure		1				1
Hepatic steatosis	1	1			1	1
Hepatitis	1	2			1	2
Hepatitis acute	2	5			2	5
Hepatitis cholestatic	1	1			1	1
Hepatomegaly		1				1
Hypertransaminasaemia		4		1		3
Portal vein thrombosis	1	1			1	1
	11	27	2	4	9	23

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema		2				2
Allergic reaction to excipient		1				1
Allergy to vaccine	1	9		1	1	8
Anaphylactic reaction	5	49			5	49
Anaphylactic shock		6				6
Bacille Calmette-Guerin scar reactivation		1		1		
Drug hypersensitivity		2				2
Food allergy		1				1
Haemophagocytic lymphohistiocytosis		1				1
Hypersensitivity	5	29	2	4	3	25
Immune system disorder		1				1
Immunisation reaction		1		1		
Reaction to excipient		1				1
Type IV hypersensitivity reaction		1				1
	11	105	2	7	9	98

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Appendicitis	1	3					1	3
Asymptomatic COVID-19	7	23			2	5	5	18
Bacteraemia	1	1					1	1
Bacterial disease carrier		1						1
Bronchitis		1						1
Bronchitis bacterial		1						1
Cellulitis	2	9					2	9
Cellulitis staphylococcal		1						1
Citrobacter infection		1						1
Clostridium difficile colitis		1						1
COVID-19	27	99			15	27	12	72
COVID-19 pneumonia	2	12					2	12
Ear infection		1						1
Eczema herpeticum		1						1
Encephalitis	1	5					1	5
Enterococcal infection	1	1					1	1
Epiglottitis		1						1
Epstein-Barr virus infection reactivation		1						1
Escherichia infection	1	2					1	2
Fungal skin infection		1						1
Gastroenteritis	4	6			3	4	1	2
Genital herpes		1				1		
Gingivitis		2				2		
Herpes ophthalmic	1	3					1	3
Herpes simplex	1	3			1	1		2
Herpes virus infection	1	2			1	1		1
Herpes zoster	19	56	1	1	3	9	16	47
Herpes zoster cutaneous disseminated	1	2					1	2
Herpes zoster oticus		1						1
Herpes zoster reactivation		3						3
Infection	1	2			1	1		1
Infectious mononucleosis		1						1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Infective exacerbation of bronchiectasis	1	1
Influenza	1	6
Labyrinthitis		1
Large intestine infection	1	1
Laryngitis		1
Localised infection		1
Lower respiratory tract infection		1
Lymphangitis		3
Meningitis herpes	1	1
Morganella infection	1	1
Myelitis		1
Nasal herpes		1
Nasopharyngitis	1	3
Ophthalmic herpes zoster		2
Oral candidiasis	1	4
Oral herpes	3	10
Parotitis		2
Periorbital abscess		1
Persistent generalised lymphadenopathy	1	1
Pertussis		2
Pharyngitis		1
Pharyngotonsillitis	1	2
Pneumonia	4	14
Post viral fatigue syndrome		1
Pulmonary sepsis	1	1
Pustule		1
Pyelonephritis	1	1
Respiratory tract infection	3	6
Rhinitis	4	6
Sepsis		2
Septic arthritis staphylococcal	1	1
Septic shock	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2		4
					1
				1	1
					1
					1
					1
					3
				1	1
				1	1
					1
					1
		1	3		
					2
		1	3		1
		1	4	2	6
					2
					1
				1	1
					2
					1
				1	2
				4	14
					1
				1	1
					1
				1	1
				3	6
		4	5		1
					2
				1	1
				2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Severe acute respiratory syndrome		1							1
Sialoadenitis	1	1					1		1
Sinusitis	1	2			1	2			
Staphylococcal infection	1	1					1		1
Subcutaneous abscess		1							1
Superinfection bacterial		1							1
Suspected COVID-19	1	1					1		1
Tonsillitis		2							2
Tuberculosis		1							1
Upper respiratory tract infection		1							1
Urinary tract infection	3	14				3	3		11
Urinary tract infection bacterial		1							1
Urinary tract infection pseudomonal	1	1					1		1
Urosepsis	1	1					1		1
Vaccination site abscess		1							1
Vaccination site cellulitis		2							2
Vestibular neuronitis	1	1					1		1
Viral keratouveitis	1	1					1		1
Viral rash		1							1
Vulvovaginal candidiasis	1	1					1		1
	111	366	1	1	35	73	76		293

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alcohol poisoning		1				1
Brachial plexus injury		1				1
Chest injury		1				1
Conjunctival laceration		1		1		
Contusion	2	5		2	2	3
Craniocerebral injury	2	6			2	6
Exposure during pregnancy		2		1		1
Exposure via breast milk	1	7	1	5		2
Face injury		1				1
Facial bones fracture	1	2			1	2
Fall	4	18		7	4	11
Femur fracture	1	1			1	1
Foreign body in throat		1				1
Fracture		1				1
Head injury	2	4		1	2	3
Inappropriate schedule of product administration	3	10	3	10		
Incorrect dose administered	2	4	2	4		
Incorrect route of product administration	3	7	3	7		
Injury	2	2	1	1	1	1
Jaw fracture		1				1
Joint injury	1	2			1	2
Ligament sprain		1		1		
Maternal exposure during pregnancy	1	5	1	4		1
Maternal exposure timing unspecified	1	1	1	1		
Medication error		1		1		
Off label use	2	13	2	13		
Overdose	4	9	4	9		
Patella fracture	1	1			1	1
Periorbital haematoma		1				1
Poor quality product administered	5	5	5	5		
Product preparation error	5	5	5	5		
Product preparation issue		4		4		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue		8		8		
Rib fracture	1	1			1	1
Skeletal injury		1				1
Spinal cord injury		1				1
Subcutaneous haematoma	1	1			1	1
Tongue injury		1		1		
Tooth avulsion		1				1
Toxicity to various agents		1				1
Underdose		5		5		
Upper limb fracture	1	2		1	1	1
Vaccination complication		4		1		3
Vaccination failure	11	24			11	24
Vasoplegia syndrome	1	1			1	1
Wound	1	1			1	1
Wrong technique in product usage process	1	2	1	2		
	60	178	29	100	31	78

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged	1	1			1	1
Activated partial thromboplastin time shortened	1	1	1	1		
Antibody test abnormal		1		1		
Antipsychotic drug level increased		1				1
Autoantibody negative		1				1
Bacterial test	1	1			1	1
Base excess decreased	1	1	1	1		
Blood bicarbonate decreased	1	1			1	1
Blood bicarbonate increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood chloride decreased		1		1		
Blood creatinine increased	1	1	1	1		
Blood fibrinogen decreased	1	1	1	1		
Blood fibrinogen increased	1	2	1	2		
Blood gases abnormal	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased		2		1		1
Blood iron decreased		1		1		
Blood lactate dehydrogenase increased	2	2	1	1	1	1
Blood pressure abnormal	2	4	1	2	1	2
Blood pressure decreased		2		1		1
Blood pressure diastolic decreased		1				1
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased	2	14	1	9	1	5
Blood pressure systolic increased	1	2	1	2		
Blood sodium decreased		1		1		
Blood thyroid stimulating hormone increased		1		1		
Blood urea increased	1	1			1	1
Body temperature decreased	1	2		1	1	1
Body temperature increased		2		2		
Breath sounds abnormal		1				1
Cardiothoracic ratio increased	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carotid bruit		2				2
Corneal reflex decreased		1				1
C-reactive protein increased	1	4	1	4		
Cytomegalovirus test positive	1	1			1	1
Electrocardiogram normal	1	1			1	1
Electrocardiogram QRS complex prolonged		1				1
Electrocardiogram QRS complex shortened		2				2
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram ST-T change		1				1
Electrocardiogram T wave inversion		1				1
Epstein-Barr virus antibody positive	1	1			1	1
Fibrin D dimer increased	4	7	1	1	3	6
Fibrinolysis	1	1			1	1
Foetal heart rate abnormal		1				1
Gamma-glutamyltransferase increased		1		1		
Glomerular filtration rate decreased	1	1	1	1		
Haematocrit decreased		1		1		
Haemoglobin decreased	1	4	1	3		1
Haemoglobin increased	1	1	1	1		
Heart rate decreased	1	1			1	1
Heart rate increased	1	5		2	1	3
Heart rate irregular	1	1			1	1
Hepatic enzyme abnormal	1	1			1	1
Hepatitis B virus test positive	1	1	1	1		
Lipase decreased	1	1	1	1		
Liver function test abnormal	1	1			1	1
Lymphocyte count decreased	1	1	1	1		
Lymphocyte count increased	1	1	1	1		
Lymphocyte percentage decreased		1		1		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Neutrophil count increased	2	4	2	4		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neutrophil percentage increased		1
N-terminal prohormone brain natriuretic peptide increased	1	1
Oxygen saturation decreased	5	17
PCO2 decreased	1	1
Platelet count decreased	1	1
Platelet count increased		1
PO2 decreased	3	3
Positron emission tomogram	1	1
Prothrombin level decreased	1	1
Prothrombin time prolonged	2	3
Pulse abnormal		2
Red blood cell sedimentation rate increased		2
Respiratory rate decreased	1	1
SARS-CoV-2 antibody test negative		2
SARS-CoV-2 antibody test positive		4
SARS-CoV-2 test positive	2	7
Serology negative		1
Serum ferritin abnormal		1
Thyroxine decreased		1
Transaminases increased		1
Transferrin abnormal		1
Troponin I increased	1	1
Troponin T increased	1	2
Urinary sediment abnormal		1
Urinary sediment present		1
Urine output decreased		1
Vitamin B12 decreased		1
Vitamin D decreased		1
White blood cell count decreased		1
White blood cell count increased		2
X-ray abnormal	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	1
1	2	4	15
1	1		
		1	1
	1		
3	3		
		1	1
		1	1
1	2	1	1
			2
	2		
		1	1
	2		
	3		1
2	6		1
	1		
	1		
	1		
			1
	1		
		1	1
		1	2
	1		
	1		
	1		
	1		
			1
	2		
		1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	68	173	31	90	37	83

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia		1				1
Cell death	1	1			1	1
Decreased appetite	4	14	2	4	2	10
Dehydration		3		2		1
Diabetes mellitus		2				2
Diabetes mellitus inadequate control	1	2			1	2
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		2				2
Electrolyte imbalance		1				1
Fluid overload	1	1			1	1
Folate deficiency		1		1		
Hypercholesterolaemia	1	1	1	1		
Hyperglycaemia	4	9		1	4	8
Hyperkalaemia	1	1			1	1
Hypernatraemia		3		1		2
Hypocalcaemia	1	2		1	1	1
Hypoglycaemia	1	6		1	1	5
Hypokalaemia		1				1
Hyponatraemia	2	3			2	3
Hypophosphataemia		1		1		
Insulin resistance		1		1		
Iron deficiency		1		1		
Malnutrition		1		1		
Vitamin D deficiency		1		1		
	17	60	3	17	14	43

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	47	129	38	78	9	51
Arthritis	1	2			1	2
Arthritis allergic		1				1
Arthritis reactive	1	2			1	2
Back pain	4	23	4	13		10
Bursitis		2				2
Costochondritis		1				1
Decreased nasolabial fold		1				1
Fibromyalgia	1	1			1	1
Groin pain		1				1
Haematoma muscle	2	3			2	3
Immobilisation syndrome	1	1	1	1		
Jaw disorder		1		1		
Joint contracture		2		2		
Joint range of motion decreased		2				2
Joint swelling		1				1
Joint warmth		1				1
Limb discomfort	2	4	1	2	1	2
Mobility decreased	3	13	1	4	2	9
Muscle contracture		5		4		1
Muscle fatigue		1		1		
Muscle rigidity	1	2			1	2
Muscle spasms	1	8	1	5		3
Muscle tightness	1	4		1	1	3
Muscular weakness	1	15	1	7		8
Musculoskeletal chest pain		2		2		
Musculoskeletal discomfort		4				4
Musculoskeletal disorder	1	1			1	1
Musculoskeletal pain	6	36	2	10	4	26
Musculoskeletal stiffness		6		2		4
Myalgia	91	258	77	154	14	104
Myositis	1	4			1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck mass		1		1		
Neck pain	2	15	1	5	1	10
Nuchal rigidity		4				4
Osteoarthritis	1	1	1	1		
Pain in extremity	18	64	12	38	6	26
Pain in jaw		1		1		
Periarthritis		2				2
Polyarthritis		1				1
Psoriatic arthropathy		1				1
Rotator cuff syndrome	2	2			2	2
Scoliosis	1	1			1	1
SLE arthritis		1				1
Spinal osteoarthritis	1	1			1	1
Spinal pain		2				2
Systemic lupus erythematosus		1				1
Tendon disorder		1				1
Tendonitis	1	2	1	1		1
Tenosynovitis		1				1
	191	639	141	334	50	305

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute leukaemia		1				1
Chronic lymphocytic leukaemia	1	1			1	1
Kaposi's sarcoma AIDS related		1				1
Lipoma	1	1	1	1		
Neoplasm	1	2	1	2		
	3	6	2	3	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acoustic neuritis		1				1
Ageusia	5	11	3	3	2	8
Allodynia		1		1		
Amnesia	1	8		4	1	4
Anosmia	4	9	3	3	1	6
Aphasia	2	8		1	2	7
Ataxia	1	1			1	1
Autoimmune demyelinating disease		1				1
Axonal neuropathy	1	1	1	1		
Balance disorder	5	16	2	6	3	10
Basal ganglia stroke	1	1			1	1
Basilar artery thrombosis	1	1			1	1
Bradykinesia		2		1		1
Brain oedema		1				1
Burning sensation		3				3
Burning sensation mucosal		1		1		
Cerebellar infarction	1	1			1	1
Cerebellar syndrome		1				1
Cerebral disorder		1				1
Cerebral haematoma	2	3			2	3
Cerebral haemorrhage	6	6			6	6
Cerebral infarction	2	2			2	2
Cerebral ischaemia	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebral venous thrombosis	2	3			2	3
Cerebrovascular accident	4	9			4	9
Cerebrovascular disorder	1	1			1	1
Cervicobrachial syndrome	1	2	1	1		1
Circadian rhythm sleep disorder	1	1			1	1
Cognitive disorder	3	4		1	3	3
Coordination abnormal	1	2		1	1	1
Demyelination	1	2			1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Depressed level of consciousness	3	22
Disturbance in attention		7
Dizziness	45	174
Dizziness postural	2	3
Dysaesthesia		8
Dysarthria	2	7
Dysgeusia	1	11
Dyskinesia		1
Dyslexia	1	1
Dysstasia		1
Dystonia		1
Embolic stroke	2	2
Encephalopathy	1	2
Epilepsy	4	7
Essential tremor	1	2
Extensor plantar response		1
Extrapyramidal disorder		1
Facial neuralgia	1	1
Facial paralysis	11	48
Facial paresis	2	4
Febrile convulsion	1	5
Formication	1	5
Fumbling		1
Generalised tonic-clonic seizure	2	7
Guillain-Barre syndrome	4	6
Haemorrhage intracranial	1	1
Haemorrhagic stroke	1	2
Headache	143	434
Head discomfort	1	1
Hemianaesthesia		1
Hemidysaesthesia		1
Hemihyperaesthesia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		3	22
	1		6
32	80	13	94
1	2	1	1
	1		7
	3	2	4
	5	1	6
			1
		1	1
	1		
			1
		2	2
		1	2
		4	7
1	1		1
	1		
			1
1	1		
		11	48
	1	2	3
		1	5
	2	1	3
			1
		2	7
		4	6
		1	1
		1	2
116	236	27	198
		1	1
			1
			1
		1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparaesthesia	1	7			1	7
Hemiparesis	1	4			1	4
Hemiplegia	2	4			2	4
Hyperaesthesia	2	4	2	2		2
Hypersomnia		1				1
Hypertensive encephalopathy	1	1			1	1
Hypoaesthesia	7	34	3	10	4	24
Hypokinesia	2	2	1	1	1	1
Hyporeflexia		2		1		1
Hyporesponsive to stimuli		1				1
Hypotonia		1		1		
Incoherent	1	2			1	2
Infant irritability		1				1
Intraventricular haemorrhage	1	1			1	1
Ischaemic cerebral infarction		1				1
Ischaemic stroke	10	19			10	19
Lacunar stroke		1				1
Lethargy	1	1			1	1
Leukoencephalopathy		1				1
Loss of consciousness	4	26			4	26
Memory impairment		1				1
Meningism		1				1
Meningoradiculitis	1	1			1	1
Mental impairment	1	6			1	6
Migraine	1	9		2	1	7
Migraine with aura	1	3	1	1		2
Migraine without aura	1	1			1	1
Mononeuropathy		1				1
Monoparesis	2	2			2	2
Monoplegia	1	3			1	3
Movement disorder		3		1		2
Multiple sclerosis		1				1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle contractions involuntary	1	5	1	3		2
Myoclonus		1				1
Nervous system disorder	1	2			1	2
Neuralgia	1	5	1	2		3
Neuralgic amyotrophy	3	3			3	3
Neuropathy peripheral	2	5			2	5
Oculofacial paralysis	1	1			1	1
Optic neuritis		1				1
Paraesthesia	23	107	6	26	17	81
Paraesthesia mucosal		1				1
Paraparesis		2				2
Paresis		1		1		
Parosmia	1	1			1	1
Partial seizures		2				2
Peripheral paralysis		1				1
Peripheral sensory neuropathy	1	1			1	1
Petit mal epilepsy		6				6
Poor quality sleep		1				1
Presyncope	7	25	3	6	4	19
Psychomotor hyperactivity		4		1		3
Restless legs syndrome		1				1
Seizure	4	12			4	12
Sensory disturbance		2				2
Sensory loss	3	9	1	4	2	5
Slow speech	1	3	1	1		2
Somnolence	3	24	3	14		10
Spasmodic dysphonia		1		1		
Speech disorder	1	4		1	1	3
Status epilepticus		1				1
Stupor		1				1
Subarachnoid haemorrhage	1	1			1	1
Syncope	15	75			15	75

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tension headache	2	7	2	4		3
Thalamic infarction	1	1			1	1
Thunderclap headache		1				1
Tonic clonic movements		1				1
Transient global amnesia		1				1
Transient ischaemic attack	4	8			4	8
Tremor		14		3		11
Trigeminal neuralgia		2				2
Tunnel vision		1				1
Vestibular migraine	1	1			1	1
White matter lesion	2	2	1	1	1	1
	399	1,369	187	446	212	923

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed	1	2	1	2
Abortion spontaneous		3		3
Cephalhaematoma	1	1	1	1
	2	6	2	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute psychosis	1	1			1	1
Agitation	5	6	1	1	4	5
Anxiety	2	8	1	7	1	1
Apathy	1	1			1	1
Bradyphrenia	3	8	2	4	1	4
Bruxism		1		1		
Confusional state	4	15	1	4	3	11
Delirium	3	3			3	3
Delirium febrile		1				1
Delusion	1	1			1	1
Depressed mood	1	3	1	3		
Disorganised speech		1				1
Disorientation	5	13	1	5	4	8
Eating disorder		1		1		
Euphoric mood		3		1		2
Gastrointestinal somatic symptom disorder	1	1	1	1		
Hallucination	3	4			3	4
Hallucination, auditory	1	1			1	1
Hallucinations, mixed	1	1			1	1
Hallucination, visual	1	2			1	2
Hypersexuality		1				1
Insomnia	4	9	3	5	1	4
Mental disorder		1				1
Middle insomnia		1		1		
Mood altered		1				1
Nervousness	2	7		3	2	4
Panic reaction		1				1
Persistent depressive disorder		1				1
Phonophobia		1				1
Psychotic disorder	1	1	1	1		
Restlessness	2	5		2	2	3
Suicide attempt		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tic		3				
	42	108	12	40	30	68

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	6			1	6
Anuria	1	1			1	1
Bladder spasm		2				2
Bladder sphincter atony		2				2
Chromaturia		1		1		
Chronic kidney disease	2	2			2	2
Dysuria	3	6	2	3	1	3
Haematuria	2	3		1	2	2
Micturition urgency	1	2			1	2
Pollakiuria	1	1			1	1
Polyuria	1	1			1	1
Prerenal failure	1	1			1	1
Renal cyst	1	2	1	2		
Renal failure	3	5			3	5
Renal impairment	1	3			1	3
Urinary incontinence	1	1	1	1		
Urinary retention		2				2
	19	41	4	8	15	33

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain	1	1	1	1		
Amenorrhoea	1	1			1	1
Breast haematoma	1	1			1	1
Breast mass		1		1		
Breast oedema		1				1
Dysmenorrhoea		1		1		
Galactorrhoea		1				1
Genital blister		1		1		
Genital ulceration		1				1
Menometrorrhagia		1				1
Menorrhagia		1				1
Menstruation delayed		2				2
Metrorrhagia	1	8			1	8
Ovarian cyst		1				1
Pelvic pain		1		1		
Penile discomfort		1		1		
Polymenorrhoea	1	1	1	1		
Testicular pain	1	1	1	1		
Uterine haemorrhage		2				2
Vaginal discharge		1		1		
Vaginal haemorrhage		2		1		1
Vulval ulceration		1				1
	6	32	3	10	3	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	1	1			1	1
Acute respiratory distress syndrome		1				1
Acute respiratory failure	5	12			5	12
Allergic cough		1		1		
Aphonia	1	7	1	2		5
Apnoea		1				1
Asphyxia		3				3
Aspiration		1				1
Asthma		4		1		3
Asthmatic crisis		2				2
Atelectasis	1	3	1	1		2
Bronchial hyperreactivity		2				2
Bronchiectasis		1				1
Bronchospasm	3	18			3	18
Catarrh	1	2	1	1		1
Choking		2				2
Choking sensation	1	7		1	1	6
Chronic obstructive pulmonary disease	1	1			1	1
Chronic respiratory failure		2				2
Cough	9	47	8	20	1	27
Diaphragmalgia	1	1			1	1
Dry throat		2		1		1
Dysphonia	4	9	2	2	2	7
Dyspnoea	24	117	8	14	16	103
Dyspnoea at rest		1				1
Dyspnoea exertional	2	11	1	3	1	8
Epistaxis	3	5	2	2	1	3
Haemoptysis	1	2			1	2
Hyperventilation		1				1
Hypoxia	1	13			1	13
Increased bronchial secretion		1				1
Interstitial lung disease		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Laryngeal disorder		1					1
Laryngeal erythema		1					1
Laryngeal oedema	2	14			2		14
Laryngeal pain		1					1
Laryngospasm		2		1			1
Larynx irritation		1					1
Lung disorder		2					2
Lung infiltration		3		2			1
Nasal congestion	5	14	5	9			5
Nasal disorder	1	1	1	1			
Nasal pruritus		1					1
Oropharyngeal discomfort	1	6		1	1		5
Oropharyngeal oedema		3					3
Oropharyngeal pain	5	14	2	7	3		7
Orthopnoea	1	1			1		1
Pharyngeal erythema		3					3
Pharyngeal hypoesthesia		1					1
Pharyngeal inflammation	2	3	1	1	1		2
Pharyngeal oedema	1	4	1	1			3
Pharyngeal swelling	2	4			2		4
Pleural effusion	1	5		1	1		4
Pleuritic pain	1	3	1	1			2
Pneumonia aspiration	2	4			2		4
Pneumonitis	1	2			1		2
Pneumothorax	1	1			1		1
Productive cough	2	4	1	2	1		2
Pulmonary embolism	29	39			29		39
Pulmonary haemorrhage	1	1			1		1
Pulmonary hypertension	1	1			1		1
Pulmonary infarction	2	3			2		3
Pulmonary thrombosis	2	3			2		3
Rales	1	1			1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Respiration abnormal		1					1
Respiratory acidosis	1	2			1		2
Respiratory arrest		2					2
Respiratory disorder	2	4	1	1	1		3
Respiratory distress	6	23			6		23
Respiratory failure	4	11			4		11
Rhinalgia		1		1			
Rhinorrhoea	4	11	4	8			3
Sneezing	2	2	2	2			
Stridor		1					1
Suffocation feeling		2					2
Tachypnoea		7		2			5
Throat irritation	2	19	1	6	1		13
Throat tightness	1	5	1	1			4
Wheezing	3	9	3	3			6
Yawning		1		1			
	148	531	48	101	100		430

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute generalised exanthematous pustulosis		1				1	
Alopecia	1	1			1	1	
Androgenetic alopecia	1	1			1	1	
Angioedema	5	35			5	35	
Blister	1	3	1	1		2	
Butterfly rash		1		1			
Circumoral swelling		1		1			
Cold sweat	1	4	1	2		2	
Dermatitis allergic	3	7			3	7	
Dermatitis atopic	1	1			1	1	
Dermatitis bullous		3				3	
Dermatitis contact		1				1	
Drug eruption	1	1	1	1			
Dry skin	1	1			1	1	
Ecchymosis		1				1	
Eczema		2		1		1	
Epidermal necrosis		1				1	
Erythema	12	57	10	24	2	33	
Erythema multiforme		1				1	
Erythema nodosum		1				1	
Hyperhidrosis	3	17	2	5	1	12	
Hypersensitivity vasculitis	2	2			2	2	
Idiopathic angioedema		1				1	
Lichen planus		1				1	
Lividity		1				1	
Mechanical urticaria		1				1	
Neutrophilic dermatosis	1	1			1	1	
Night sweats	2	5	1	2	1	3	
Panniculitis		1				1	
Papule		2		1		1	
Pernio-like erythema		2		1		1	
Petechiae	3	8	1	3	2	5	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pigmentation disorder		1		1			
Pityriasis rosea	1	4		1	1	4	
Pruritus	21	85	13	26	8	59	
Psoriasis		1				1	
Purpura		1				1	
Rash	15	64	10	19	5	45	
Rash erythematous	1	8			1	8	
Rash macular	1	2		1	1	1	
Rash maculo-papular	1	4		1	1	3	
Rash papular	3	5			3	5	
Rash pruritic	3	10		1	3	9	
Rash vesicular	1	1	1	1			
Scab	1	1	1	1			
Skin exfoliation		2				2	
Skin lesion		6		2		4	
Skin necrosis		2				2	
Skin odour abnormal		1				1	
Skin reaction	1	4	1	2		2	
Skin tightness		1		1			
Skin ulcer	2	4	2	3		1	
Systemic lupus erythematosus rash	1	1	1	1			
Toxic skin eruption	1	2			1	2	
Urticaria	25	63	19	25	6	38	
	116	439	65	128	51	311	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	2			1	2
Loss of personal independence in daily activities	1	2		1	1	1
	2	4		1	2	3

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion induced		1		1
Limb immobilisation		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Aortic dissection		1				1	
Circulatory collapse	1	1			1	1	
Cyanosis	1	5	1	2		3	
Deep vein thrombosis	11	16			11	16	
Embolism		1				1	
Essential hypertension		1				1	
Flushing		5		2		3	
Giant cell arteritis	1	1			1	1	
Haematoma	5	9	3	5	2	4	
Haemorrhage		3				3	
Hot flush		3		1		2	
Hyperaemia		1		1			
Hypertension	14	54	5	13	9	41	
Hypertensive crisis	4	27			4	27	
Hypertensive emergency	1	1			1	1	
Hypertensive urgency	1	3			1	3	
Hypotension	8	33	1	8	7	25	
Hypovolaemic shock		1				1	
Ischaemia	1	1			1	1	
Neurogenic shock		1				1	
Orthostatic hypotension		1				1	
Pallor		7		2		5	
Peripheral artery thrombosis		1				1	
Peripheral coldness	3	6	3	3		3	
Peripheral embolism	1	1			1	1	
Peripheral ischaemia		2				2	
Peripheral venous disease	1	1			1	1	
Phlebitis	1	2		1	1	1	
Phlebitis superficial	1	2	1	1		1	
Poor peripheral circulation	2	2	2	2			
Post thrombotic syndrome	1	1			1	1	
Raynaud's phenomenon		5				5	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock		1				1
Thrombophlebitis	4	4	1	1	3	3
Thrombophlebitis superficial	6	7	1	1	5	6
Thrombosis	2	2			2	2
Vasculitis	2	3			2	3
Venous thrombosis limb	4	5			4	5
	76	221	18	43	58	178

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SWAZILAND**

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death		1				1
Influenza like illness		1		1		
Pyrexia		1		1		
		3		2		1

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Nasopharyngitis		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspnoea		1		1
		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		1			1	
Dermatitis allergic		1		1		
Skin swelling		1		1		
		3		2	1	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SWEDEN**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	1			1	1
Coagulopathy	1	1			1	1
Haemolytic anaemia	1	2			1	2
Immune thrombocytopenia	1	2			1	2
Leukocytosis		1				1
Leukopenia	2	2			2	2
Lymphadenitis		1				1
Lymphadenopathy	3	24	1	14	2	10
Lymphadenopathy mediastinal		1		1		
Lymph node pain		9		7		2
Myelosuppression		1				1
Pancytopenia	2	2			2	2
Spleen disorder	1	1			1	1
Spontaneous haematoma	1	1			1	1
Thrombocytopenia	14	14			14	14
Thrombocytopenic purpura	1	1			1	1
	28	64	1	22	27	42

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute left ventricular failure		1				1
Acute myocardial infarction	4	8			4	8
Angina pectoris	2	4			2	4
Arrhythmia	1	5			1	5
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	5	10			5	10
Atrial flutter	1	2			1	2
Atrial thrombosis		1				1
Atrioventricular block complete		2				2
Bradycardia	1	1			1	1
Bundle branch block left	1	2	1	1		1
Bundle branch block right		1				1
Cardiac arrest	10	20			10	20
Cardiac discomfort	2	2			2	2
Cardiac disorder	1	4			1	4
Cardiac failure	5	15			5	15
Cardiac failure acute		2				2
Cardiac failure chronic		1				1
Cardiac fibrillation		1				1
Cardiac flutter		1				1
Cardiogenic shock	1	2			1	2
Cardiopulmonary failure		1				1
Cardiovascular disorder	1	1			1	1
Coronary artery occlusion	1	1			1	1
Coronary artery stenosis		1				1
Cor pulmonale acute		1				1
Extrasystoles	1	3			1	3
Left ventricular hypertrophy		1				1
Myocardial fibrosis		1				1
Myocardial infarction	3	13			3	13
Myocardial ischaemia		3				3
Myocardial rupture		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocarditis	3	4			3	4
Palpitations	5	33		7	5	26
Pericardial effusion		3				3
Pericardial haemorrhage		1				1
Pericarditis		1				1
Sinus tachycardia		1				1
Supraventricular extrasystoles		1				1
Supraventricular tachycardia		1				1
Tachycardia	1	17		5	1	12
Ventricular fibrillation	2	2			2	2
Ventricular hypokinesia	1	1			1	1
Ventricular tachycardia		1				1
	52	179	1	13	51	166

System Organ Class

**Congenital, familial and genetic disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Atrial septal defect		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral		2				2
Ear discomfort		2				2
Ear pain	1	3			1	3
Ear swelling	1	1			1	1
Hyperacusis		1				1
Hypoacusis		7				7
Paraesthesia ear		1				1
Sudden hearing loss		1				1
Tinnitus	3	16			3	16
Vertigo	1	5		2	1	3
Vertigo positional		1		1		
	6	40		3	6	37

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenocortical insufficiency acute		1				1
Basedow's disease		1				1
Goitre	1	2			1	2
Hyperparathyroidism primary		1		1		
	1	5		1	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1				1
Asthenopia		4				4
Blepharospasm		1				1
Blindness	1	3			1	3
Blindness transient		1				1
Diplopia	1	1	1	1		
Eye disorder		3				3
Eye haemorrhage	2	2			2	2
Eye inflammation		1				1
Eye irritation		3				3
Eye pain		9		1		8
Eye pruritus		2				2
Eye swelling		2				2
Lacrimation increased		1				1
Myopia		1				1
Ocular discomfort		3		1		2
Periorbital discomfort		1				1
Periorbital oedema		3				3
Periorbital pain		2		1		1
Periorbital swelling		2		1		1
Photophobia		4				4
Retinal artery occlusion	1	1			1	1
Retinal haemorrhage	1	1			1	1
Retinal vein occlusion	1	1			1	1
Sudden visual loss	1	1			1	1
Vision blurred	1	8		1	1	7
Visual impairment	3	10		1	3	9
	12	72	1	7	11	65

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	5	1	2		3
Abdominal distension	1	3	1	1		2
Abdominal pain	4	21	1	9	3	12
Abdominal pain lower		2				2
Abdominal pain upper	1	9	1	4		5
Abdominal symptom		1				1
Abdominal wall haemorrhage	1	1			1	1
Ascites		1				1
Chronic gastritis		1				1
Coeliac artery stenosis		1				1
Constipation		2		2		
Diarrhoea	7	49	3	27	4	22
Diverticulum		1		1		
Dry mouth	1	3			1	3
Dyspepsia		1		1		
Dysphagia	6	15	1	4	5	11
Flatulence		1		1		
Gastric disorder	1	2		1	1	1
Gastric haemorrhage	1	1			1	1
Gastritis		1		1		
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal pain	1	1	1	1		
Glossodynia		1		1		
Haematemesis	2	4			2	4
Haematochezia		1				1
Hypoaesthesia oral		14		4		10
Infrequent bowel movements		1		1		
Intestinal haemorrhage	1	3			1	3
Intestinal ischaemia	1	3			1	3
Lip pruritus	1	2			1	2
Lip swelling		8		2		6
Lip ulceration	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loose tooth	1	1			1	1
Mesenteric artery embolism		1				1
Mouth swelling		1				1
Mouth ulceration	1	1	1	1		
Nausea	17	113	5	53	12	60
Oesophageal ulcer haemorrhage	1	1			1	1
Oral discomfort		3				3
Oral mucosal blistering	1	2			1	2
Oral pain		1		1		
Oral pruritus	1	7	1	4		3
Palatal swelling		1				1
Paraesthesia oral	1	12		5	1	7
Retroperitoneal haemorrhage	1	1			1	1
Stomatitis		1				1
Swollen tongue	2	12		1	2	11
Tongue discomfort		2		1		1
Tongue movement disturbance		1				1
Tongue pruritus	1	4			1	4
Upper gastrointestinal haemorrhage		1				1
Vomiting	16	65	4	16	12	49
	75	392	21	146	54	246

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	10	42	3	16	7	26
Axillary pain	1	11		7	1	4
Cardiac death	1	1			1	1
Catheter site haemorrhage		1		1		
Chest discomfort	4	19	2	9	2	10
Chest pain	9	32	1	9	8	23
Chills	12	103	2	53	10	50
Chronic fatigue syndrome	1	1			1	1
Concomitant disease aggravated		1				1
Condition aggravated	8	20	1	4	7	16
Crepitations		2		1		1
Crying		1		1		
Death	3	42			3	42
Discomfort	3	9		3	3	6
Disease recurrence	5	12	1	3	4	9
Drug ineffective	1	10			1	10
Energy increased	1	1			1	1
Facial discomfort	1	1	1	1		
Facial pain		3				3
Fatigue	34	214	12	112	22	102
Feeling abnormal	2	15	1	6	1	9
Feeling cold	6	20	2	13	4	7
Feeling drunk		1		1		
Feeling hot	3	26	2	12	1	14
Feeling of body temperature change		3				3
Gait disturbance	1	4		1	1	3
Gait inability		1				1
Generalised oedema		2				2
General physical health deterioration	9	45	2	10	7	35
Hypothermia		3				3
Illness	2	5		1	2	4
Inflammation	1	3			1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	2	11	1	6	1	5
Injected limb mobility decreased		1		1		
Local reaction		1		1		
Malaise	7	56	3	31	4	25
Mass		1				1
Nodule		1		1		
Oedema peripheral	1	2	1	1		1
Pain	18	83	7	37	11	46
Peripheral swelling	12	22	1	5	11	17
Physical deconditioning		2		1		1
Pyrexia	41	275	13	135	28	140
Screaming	1	1	1	1		
Sensation of foreign body		1				1
Sense of oppression		1				1
Sluggishness	1	1			1	1
Sudden death	2	6			2	6
Swelling	1	9	1	4		5
Swelling face	2	14	1	5	1	9
Systemic inflammatory response syndrome		1				1
Temperature regulation disorder		1		1		
Tenderness	2	3		1	2	2
Vaccination site bruising	1	2	1	1		1
Vaccination site discolouration		1				1
Vaccination site discomfort		1				1
Vaccination site erythema	3	34	1	21	2	13
Vaccination site haematoma		2				2
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		2		2		
Vaccination site induration	1	5	1	4		1
Vaccination site joint movement impairment		3		3		
Vaccination site lymphadenopathy		1				1
Vaccination site mass		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment	1	7	1	6		1
Vaccination site nodule		1		1		
Vaccination site pain	14	133	12	106	2	27
Vaccination site paraesthesia		1		1		
Vaccination site phlebitis		1		1		
Vaccination site pruritus		10		7		3
Vaccination site rash		1				1
Vaccination site reaction		4		2		2
Vaccination site swelling	5	41	4	28	1	13
Vaccination site thrombosis		1				1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	11	1	10		1
	234	1,412	80	691	154	721

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Biliary colic	1	1	1	1
Biliary dilatation	1	1	1	1
Biliary tract disorder		1		1
Cholecystitis		1		1
Gallbladder disorder		1		1
Gallbladder oedema		1		1
Hepatitis acute		1		1
Jaundice		1		1
Liver disorder		2		2
	2	10	2	10

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		3		1		2
Anaphylactic reaction	6	26			6	26
Anaphylactic shock	1	3			1	3
Anaphylactoid reaction	1	1			1	1
Graft versus host disease		1				1
Hypersensitivity	3	38		4	3	34
Immunisation reaction		1				1
Lung transplant rejection		1				1
	11	74		5	11	69

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection	1	1			1	1
Atypical pneumonia	1	1			1	1
Bronchitis		1				1
Clostridium difficile colitis	1	1			1	1
COVID-19	10	46	3	23	7	23
COVID-19 pneumonia		1				1
Device related infection		1				1
Diverticulitis		1				1
Encephalitis	1	2			1	2
Erysipelas	4	6			4	6
Escherichia infection		1				1
Escherichia sepsis		1				1
Escherichia urinary tract infection		1				1
Furuncle		1				1
Gastroenteritis	1	1			1	1
Herpes ophthalmic	1	1			1	1
Herpes simplex	1	1			1	1
Herpes zoster	5	14		3	5	11
Infection	4	12		1	4	11
Meningitis		1				1
Meningitis herpes		1				1
Myelitis		2				2
Nasopharyngitis	6	13	2	5	4	8
Ophthalmic herpes zoster		1				1
Oral herpes		3		2		1
Oral viral infection		1				1
Pharyngitis		1		1		
Pneumonia	2	14			2	14
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pneumonia streptococcal		1				1
Post viral fatigue syndrome		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinitis		2		2		
Sepsis	1	7			1	7
Septic shock	1	2			1	2
Streptococcal bacteraemia		1				1
Suspected COVID-19		2		1		1
Upper respiratory tract infection		3				3
Urinary tract infection	3	10	1	5	2	5
Urosepsis		3				3
Vaccination site infection		1				1
	43	166	6	44	37	122

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain herniation	1	1			1	1
Circumstance or information capable of leading to medication error		29		29		
Concussion	1	1	1	1		
Contusion	2	2			2	2
Face injury		1				1
Fall	8	16	2	3	6	13
Femoral neck fracture		1				1
Head injury	2	4	1	2	1	2
Heat stroke		1				1
Hip fracture		1				1
Inappropriate schedule of product administration	3	3	3	3		
Incorrect route of product administration	2	9	2	9		
Limb injury	1	1			1	1
Off label use	3	4	3	4		
Overdose		2		2		
Poor quality product administered		37		37		
Postoperative wound complication		1				1
Product administered at inappropriate site	1	2	1	2		
Product preparation issue		4		4		
Product storage error		1		1		
Product use issue		1		1		
Rib fracture	1	1			1	1
Scapula fracture	1	1			1	1
Skin wound	1	1			1	1
Subdural haematoma	2	2			2	2
Tracheal haemorrhage		1				1
Underdose		5		5		
Vaccination failure	5	7			5	7
Wound	1	2		1	1	1
Wound necrosis		1				1
	35	143	13	104	22	39

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatinine increased	3	4	1	2	2	2
Blood fibrinogen decreased	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased		3		1		2
Blood lactate dehydrogenase increased	1	1			1	1
Blood phosphorus decreased		1		1		
Blood potassium increased	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure decreased	2	14	1	3	1	11
Blood pressure diastolic decreased		1		1		
Blood pressure increased	2	8		2	2	6
Blood pressure systolic increased		2		1		1
Body temperature decreased		2				2
Body temperature increased	2	5	1	3	1	2
Brain scan abnormal		1				1
Breath sounds abnormal		1				1
Cardiac murmur	1	1			1	1
C-reactive protein abnormal		1		1		
C-reactive protein increased	5	12	2	6	3	6
Electrocardiogram ST segment elevation	2	2			2	2
Electrocardiogram T wave inversion		1				1
Gamma-glutamyltransferase increased		1				1
Glomerular filtration rate decreased	2	2	1	1	1	1
Haemoglobin decreased		2				2
Heart rate decreased		3		2		1
Heart rate increased	2	21		4	2	17
Heart rate irregular		4		3		1
Hepatic enzyme increased	1	1			1	1
International normalised ratio increased	1	1			1	1
Oxygen saturation abnormal		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	3	23		4	3	19
Platelet count decreased	1	1			1	1
Procalcitonin increased	2	2			2	2
Pulse abnormal		3		2		1
Pulse pressure decreased		1		1		
Red blood cell sedimentation rate increased		1				1
Respiratory rate increased		8		1		7
Skin turgor decreased		1				1
Transaminases increased		1				1
Troponin increased	1	1	1	1		
Urine output decreased		2				2
Weight decreased		2		1		1
White blood cell count increased	1	2	1	2		
White blood cells urine positive		1		1		
	34	151	8	45	26	106

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia		1				1
Decreased appetite	3	17	1	7	2	10
Dehydration	3	7	1	2	2	5
Feeding disorder	2	2	1	1	1	1
Fluid intake reduced		1				1
Fluid retention	1	2			1	2
Food refusal		1				1
Gout		1				1
Hypercalcaemia		1				1
Hyperglycaemia		1				1
Hypernatraemia		1				1
Hypoalbuminaemia		1		1		
Hypoglycaemia		4				4
Hypokalaemia	1	2			1	2
Hypophagia		2				2
Lactic acidosis		1				1
Metabolic acidosis	1	1			1	1
Metabolic disorder	1	2	1	1		1
	12	48	4	12	8	36

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	51	1	25	4	26
Arthritis	1	6		2	1	4
Back pain	5	23	1	12	4	11
Bone disorder		1		1		
Bursitis	1	1			1	1
Fibromyalgia		1				1
Flank pain		1		1		
Jaw disorder		1				1
Joint lock		1				1
Joint range of motion decreased	1	2		1	1	1
Joint stiffness	1	4		2	1	2
Joint swelling		2		1		1
Limb discomfort		2		1		1
Mobility decreased		2		1		1
Muscle fatigue		1				1
Muscle spasms	5	14	3	5	2	9
Muscle tightness		1				1
Muscle twitching		5				5
Muscular weakness	8	27		4	8	23
Musculoskeletal chest pain		2				2
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness	2	25		8	2	17
Myalgia	14	100	3	48	11	52
Neck pain	3	18		9	3	9
Pain in extremity	19	123	9	80	10	43
Pain in jaw		3		1		2
Periarthritis	1	1			1	1
Polyarthritis	1	1			1	1
Polymyalgia rheumatica		1				1
Spinal pain		1		1		
Systemic lupus erythematosus	1	1			1	1
Tenosynovitis		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	68	424	17	203	51	221

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastasis	1	1	1	1
Neoplasm progression		1		1
	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		6		3		3
Akinesia		1				1
Allodynia		1		1		
Altered state of consciousness	2	2			2	2
Amnesia	2	5			2	5
Anosmia		7		3		4
Aphasia	1	3			1	3
Areflexia		1				1
Autonomic nervous system imbalance		1				1
Balance disorder	7	12	1	1	6	11
Basilar artery thrombosis	1	1			1	1
Brain injury		1				1
Brain stem syndrome		1				1
Burning sensation		1				1
Central pain syndrome		1				1
Cerebellar haemorrhage	1	1			1	1
Cerebellar syndrome		1				1
Cerebral artery embolism	1	2			1	2
Cerebral atrophy		1				1
Cerebral haemorrhage	5	8			5	8
Cerebral infarction	3	5			3	5
Cerebral microangiopathy	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident	9	21			9	21
Cerebrovascular disorder		1				1
Cognitive disorder	1	2			1	2
Coordination abnormal	1	3			1	3
Cranial nerve disorder		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	3	19			3	19
Disturbance in attention	2	7		2	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	22	111	3	33	19	78
Dizziness exertional	1	1			1	1
Dysaesthesia	1	1	1	1		
Dysarthria	1	7		1	1	6
Dysgeusia	1	8		2	1	6
Dysstasia		3				3
Dystonia	1	1			1	1
Embolic cerebral infarction	1	1			1	1
Encephalopathy		1				1
Epilepsy	3	5			3	5
Facial neuralgia		1				1
Facial paralysis	2	15			2	15
Facial paresis	4	17			4	17
Formication		4		1		3
Generalised tonic-clonic seizure	1	1			1	1
Guillain-Barre syndrome		1				1
Haemorrhage intracranial	1	1			1	1
Headache	29	229	11	131	18	98
Head discomfort	1	10		4	1	6
Hemiparaesthesia		1				1
Hemiparesis	3	8			3	8
Horner's syndrome	1	1			1	1
Hyperaesthesia		1		1		
Hypersomnia	1	3		1	1	2
Hypoaesthesia	9	73	2	19	7	54
Hypokinesia		2				2
Intention tremor		1				1
Ischaemic stroke	6	8			6	8
Lethargy	2	3	1	1	1	2
Loss of consciousness	6	16			6	16
Memory impairment	1	7		2	1	5
Meningism	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	3	12		5	3	7
Monoparesis	1	1			1	1
Monoplegia		1				1
Motor dysfunction		1				1
Multiple sclerosis	1	3			1	3
Muscle contractions involuntary		1				1
Muscle tone disorder		1				1
Neuralgia	1	3	1	2		1
Neurological symptom		1				1
Neuropathy peripheral		2				2
Paraesthesia	4	45	2	13	2	32
Paralysis		1				1
Paresis		1				1
Parkinson's disease	1	1			1	1
Parosmia	1	3			1	3
Peripheral motor neuropathy		1				1
Peripheral sensory neuropathy		1				1
Petit mal epilepsy		2				2
Polyneuropathy	1	1			1	1
Poor quality sleep	1	2	1	1		1
Post stroke epilepsy	1	1			1	1
Presyncope	1	5		1	1	4
Reduced facial expression		1				1
Restless legs syndrome		2				2
Sciatica		2		1		1
Seizure	4	11			4	11
Seizure like phenomena		2				2
Sensory disturbance		2		1		1
Sleep paralysis	1	2	1	1		1
Slow speech		1				1
Somnolence	1	10	1	4		6
Speech disorder	2	4	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Status epilepticus	1	1			1	1
Subarachnoid haemorrhage	2	4			2	4
Syncope	7	27			7	27
Taste disorder		3				3
Transient ischaemic attack	6	9			6	9
Tremor	1	13	1	2		11
Trigeminal nerve paresis	1	1			1	1
Unresponsive to stimuli	1	3			1	3
Vascular dementia		1				1
Visual field defect	1	4			1	4
	183	856	27	240	156	616

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product colour issue		36		36
		36		36

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		3		1		2
Abnormal dreams	1	1	1	1		
Aggression		1				1
Agitation	1	2			1	2
Anxiety	2	14		5	2	9
Apathy	1	2			1	2
Confusional state	3	18	1	1	2	17
Delirium	1	1			1	1
Delusional disorder, unspecified type		1				1
Depressed mood		4		1		3
Depression	1	2		1	1	1
Derealisation		1				1
Disorganised speech		1				1
Disorientation		1				1
Dissociation		1				1
Eating disorder	1	1			1	1
Fear of death	1	1			1	1
Feeling of despair		1				1
Hallucination		4				4
Hallucination, auditory		1				1
Hallucination, visual	1	3			1	3
Helplessness	1	1			1	1
Hypersomnia-bulimia syndrome		1				1
Initial insomnia		1				1
Insomnia	1	9		4	1	5
Laziness		1		1		
Mental fatigue	1	8		1	1	7
Nervousness		2		1		1
Nightmare	1	4	1	1		3
Panic attack		2				2
Panic reaction		2				2
Psychotic disorder	2	3			2	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Reading disorder		1				1
Sleep disorder	2	5			2	5
Sleep talking		1				1
Stress	1	2	1	2		
	22	107	4	20	18	87

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	2	5			2	5
Haematuria	1	1			1	1
Incontinence		1		1		
Nephrolithiasis	1	1			1	1
Renal failure	1	2			1	2
Renal haemorrhage	1	1			1	1
Renal impairment		1				1
Renal infarct		1				1
Renal pain		3		2		1
Renal tubular necrosis	1	1			1	1
Urinary incontinence		1				1
Urinary retention		1				1
	7	19		3	7	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		1		1		
Breast pain	1	1			1	1
Metrorrhagia		1				1
Penile haemorrhage	1	1			1	1
Uterine inflammation		1		1		
Vaginal haemorrhage		1				1
	2	6		2	2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apnoea		2				2
Aspiration	1	1			1	1
Asthma		1				1
Atelectasis		1				1
Bronchial haemorrhage		1				1
Bronchospasm		1				1
Chronic obstructive pulmonary disease		5				5
Chronic respiratory failure		1				1
Cough	7	34	2	16	5	18
Dysphonia	2	10		5	2	5
Dyspnoea	22	111	2	20	20	91
Dyspnoea exertional	2	4			2	4
Epistaxis	4	7		3	4	4
Haemoptysis	1	2			1	2
Hiccups		1				1
Hydrothorax		1				1
Hyperventilation		3				3
Hypopnoea		1				1
Hypoxia		1				1
Idiopathic pulmonary fibrosis		1				1
Increased upper airway secretion		2		2		
Irregular breathing		1		1		
Laryngeal oedema		1				1
Lung disorder	1	2			1	2
Lung infiltration	1	1			1	1
Nasal congestion	1	12	1	5		7
Obstructive airways disorder	1	3			1	3
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	3	23		15	3	8
Oropharyngeal spasm		1				1
Painful respiration	1	2	1	2		
Pharyngeal disorder		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pharyngeal erythema		2		1			1
Pharyngeal hypoaesthesia		3					3
Pharyngeal mass	1	1			1		1
Pharyngeal oedema	1	1			1		1
Pharyngeal paraesthesia		2					2
Pharyngeal swelling	3	16		4	3		12
Pleural effusion	1	5		1	1		4
Pleurisy		1					1
Pneumonia aspiration	2	3			2		3
Productive cough	2	5			2		5
Pulmonary artery thrombosis		1					1
Pulmonary embolism	34	49			34		49
Pulmonary hypertension	1	1			1		1
Pulmonary infarction	1	1			1		1
Pulmonary oedema	1	9			1		9
Pulmonary pain		3		1			2
Pulmonary thrombosis	1	2			1		2
Respiration abnormal		1					1
Respiratory arrest	1	5			1		5
Respiratory disorder	1	1			1		1
Respiratory distress	2	15			2		15
Respiratory failure	2	3			2		3
Rhinalgia		2		1			1
Rhinorrhoea	5	18	1	14	4		4
Sinus congestion		1		1			
Sinus disorder		1		1			
Sneezing		1		1			
Tachypnoea	1	5		2	1		3
Throat irritation	2	13		4	2		9
Throat tightness		6		1			5
Upper respiratory tract congestion		1		1			
Wheezing	3	10	1	3	2		7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	112	427	8	106	104	321

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Angioedema	1	6			1	6
Blister		2		1		1
Cold sweat	2	11		3	2	8
Decubitus ulcer		1		1		
Dermatitis		2		1		1
Drug eruption		2		1		1
Dry skin		1		1		
Eczema		2		1		1
Erythema	7	34	4	18	3	16
Haemorrhage subcutaneous	1	1			1	1
Hyperhidrosis	1	15	1	6		9
Livedo reticularis		1		1		
Nail discolouration		1				1
Night sweats		1		1		
Pain of skin	1	4		2	1	2
Pemphigoid		2				2
Petechiae	4	5	1	1	3	4
Pruritus	7	33	2	11	5	22
Psoriasis		1		1		
Purpura		1				1
Rash	4	20	1	8	3	12
Rash erythematous		7		1		6
Rash macular	1	2	1	2		
Rash maculo-papular		1				1
Rash pruritic		4		2		2
Skin burning sensation		1				1
Skin discolouration	1	5		2	1	3
Skin disorder	1	1			1	1
Skin reaction		1		1		
Skin tightness	1	1			1	1
Skin ulcer	1	4			1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin warm		1		1		
Solar dermatitis	1	1		1	1	1
Stevens-Johnson syndrome		1				1
Toxic epidermal necrolysis		1				1
Urticaria	6	39	1	14	5	25
	40	217	11	82	29	135

System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	3		2	1	1
Loss of personal independence in daily activities	1	2		1	1	1
	2	5		3	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm rupture		1				1
Aortic arteriosclerosis	1	2		1	1	1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		2				2
Blood pressure fluctuation		1				1
Circulatory collapse	1	6			1	6
Cyanosis	1	4	1	2		2
Deep vein thrombosis	16	23			16	23
Embolism	1	3			1	3
Embolism arterial	1	1			1	1
Flushing		3				3
Haematoma	2	6			2	6
Haemorrhage	4	5			4	5
Hot flush		3		1		2
Hypertension	5	17	1	4	4	13
Hypoperfusion	1	1			1	1
Hypotension	7	23	1	4	6	19
Lymphoedema		1				1
Orthostatic hypotension		1				1
Pallor	1	8	1	4		4
Peripheral coldness		4		1		3
Peripheral embolism	1	1			1	1
Phlebitis	1	1			1	1
Thrombophlebitis	4	5	1	1	3	4
Thrombophlebitis superficial	1	1			1	1
Thrombosis	7	12			7	12
Vasculitis		1				1
Vasodilatation	1	1	1	1		
Venous thrombosis		1				1
	57	139	6	19	51	120

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SWITZERLAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Eosinophilia		1		1		
Immune thrombocytopenia		1				1
Lymphadenopathy	3	4		1	3	3
Lymph node pain	1	1			1	1
Lymphopenia		1				1
Monocytosis		1		1		
Neutrophilia		1				1
Sickle cell anaemia with crisis	1	1			1	1
Thrombocytopenia	1	2			1	2
	6	14		3	6	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Angina pectoris		1				1
Arrhythmia	2	4			2	4
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	4	4			4	4
Cardiac arrest	1	2			1	2
Cardiac failure	3	5			3	5
Cardiac failure acute	2	2			2	2
Cardiac failure chronic		1				1
Cardiac failure congestive	1	1			1	1
Cardiac fibrillation		1				1
Cardio-respiratory arrest		1				1
Cardiovascular disorder	2	2			2	2
Myocardial infarction	1	1			1	1
Palpitations	2	4			2	4
Pericardial effusion	1	1			1	1
Sinus tachycardia	1	1			1	1
Stress cardiomyopathy	1	1			1	1
Tachycardia	8	15	1	2	7	13
Ventricular fibrillation		1				1
	30	51	1	2	29	49

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral		1				1
Ear pain		1				1
Ear pruritus	1	1			1	1
Meniere's disease	1	1			1	1
Sudden hearing loss		1				1
Tinnitus		1				1
Vertigo	2	4	1	1	1	3
Vertigo positional		1				1
	4	11	1	1	3	10

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness transient		1				1
Diplopia	1	1			1	1
Eye haemorrhage	1	1			1	1
Eyelid oedema		2				2
Eyelids pruritus		1		1		
Eye pain	1	1	1	1		
Photophobia	1	1			1	1
Swelling of eyelid	1	1			1	1
Visual impairment	2	3			2	3
	7	12	1	2	6	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2	1	1	1	1
Abdominal pain	3	6		1	3	5
Abdominal pain lower		1				1
Anal haemorrhage		1		1		
Aphthous ulcer	1	1			1	1
Ascites		1				1
Cheilitis		1		1		
Diarrhoea	7	12	1	3	6	9
Gastric disorder		1				1
Gastritis	1	1			1	1
Gastrointestinal disorder	2	3	2	2		1
Gastrooesophageal reflux disease	2	2			2	2
Haematemesis	1	1			1	1
Hypoaesthesia oral	2	2	1	1	1	1
Lip oedema		1				1
Lip swelling	1	1			1	1
Nausea	10	22	3	6	7	16
Odynophagia		1				1
Oesophageal perforation		1				1
Pancreatitis		1				1
Paraesthesia oral	2	3	1	1	1	2
Salivary hypersecretion		1				1
Swollen tongue		1				1
Tongue oedema		1				1
Vomiting	8	21		3	8	18
	42	89	9	20	33	69

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	11	16	2	3	9	13
Atrophy		1				1
Chest discomfort	3	5			3	5
Chest pain	3	4			3	4
Chills	9	20	1	4	8	16
Condition aggravated	2	2			2	2
Death	1	6			1	6
Discomfort	1	2	1	1		1
Disease recurrence	3	3			3	3
Drug ineffective	3	7			3	7
Drug interaction		1		1		
Fatigue	18	24	7	11	11	13
Feeling cold	1	3	1	3		
Feeling hot	2	4		1	2	3
Gait disturbance		4		1		3
General physical health deterioration	3	8	2	3	1	5
Hyperthermia		1		1		
Inflammation		3				3
Influenza like illness	2	4	2	2		2
Malaise	9	21	1	4	8	17
Oedema peripheral	1	3		1	1	2
Pain	6	8	1	3	5	5
Performance status decreased	1	1			1	1
Peripheral swelling		1				1
Pyrexia	24	49	7	12	17	37
Sense of oppression		2				2
Sudden death	2	4			2	4
Swelling face	1	2	1	2		
Therapeutic response unexpected		2		2		
Vaccination site erythema	1	6		3	1	3
Vaccination site haematoma		1				1
Vaccination site induration		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site lymphadenopathy	1	1			1	1
Vaccination site oedema		1		1		
Vaccination site pain	7	15	3	8	4	7
Vaccination site pruritus		2		1		1
Vaccination site rash		1		1		
Vaccination site reaction	1	1			1	1
Vaccination site swelling	1	2			1	2
Vaccination site urticaria		1				1
Vaccination site warmth		2		1		1
	117	245	29	70	88	175

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cholecystitis acute	1	1	1	1
Cholestasis	1	2	1	2
Hepatic cirrhosis		1		1
Hepatocellular injury	1	1	1	1
Liver disorder	1	1	1	1
Liver injury		1		1
	4	7	4	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	3	14			3	14
Anaphylactic shock		1				1
Haemophagocytic lymphohistiocytosis	1	1			1	1
Hypersensitivity	11	22	3	4	8	18
Type I hypersensitivity		1				1
Type II hypersensitivity	1	1			1	1
	16	40	3	4	13	36

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Appendicitis		1				1
Asymptomatic COVID-19	1	1	1	1		
Conjunctivitis bacterial		1				1
COVID-19	8	20		1	8	19
COVID-19 pneumonia	1	1			1	1
Cystitis	1	1			1	1
Encephalitis		1				1
Erysipelas	2	2			2	2
Erysipeloid		1				1
Genital herpes	1	1			1	1
Herpes zoster	13	18			13	18
Infection		1		1		
Influenza	1	1			1	1
Myelitis	1	1			1	1
Nasopharyngitis	1	1			1	1
Ophthalmic herpes zoster	2	2			2	2
Oral herpes	1	1			1	1
Parotitis	1	1			1	1
Pneumonia	2	4			2	4
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Rash pustular		1				1
Respiratory tract infection		1				1
Rhinitis		1		1		
Sepsis		2				2
Septic shock		1				1
Urinary tract infection	1	2			1	2
Urinary tract infection bacterial		1				1
Varicella zoster virus infection	1	1			1	1
Viral infection	1	1	1	1		
	39	74	2	5	37	69

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Craniocerebral injury	1	1			1	1
Exposure during pregnancy	1	1			1	1
Fall	4	6	1	1	3	5
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	4	7	4	6		1
Joint dislocation	1	1			1	1
Off label use	1	1	1	1		
Road traffic accident	1	1			1	1
Scratch	1	2	1	2		
Skull fracture	1	1			1	1
Subdural haematoma	1	1			1	1
Tendon rupture	1	1			1	1
Underdose		2		2		
Vaccination failure	4	4			4	4
Wrong product administered		1		1		
Wrong technique in product usage process		1		1		
	22	32	8	15	14	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Anti-myelin-associated glycoprotein antibodies positive		1				1
Blood alkaline phosphatase increased		1		1		
Blood glucose increased		1		1		
Blood pressure decreased		2		1		1
Blood pressure increased	2	5		1	2	4
Body temperature increased		1		1		
C-reactive protein increased	1	4	1	1		3
CSF test abnormal		1				1
Heart rate decreased		1				1
Heart rate increased		1				1
NIH stroke scale score decreased	1	1			1	1
Oxygen saturation decreased	1	3			1	3
Peak expiratory flow rate decreased	1	1			1	1
Platelet count increased		1		1		
SARS-CoV-2 antibody test negative		1		1		
Tumour marker increased	2	2	2	2		
Weight decreased	1	1	1	1		
	9	29	4	12	5	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	3		1	1	2
Dehydration	1	2			1	2
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Feeding disorder	1	2	1	1		1
Fluid overload	1	1			1	1
Gout		1				1
Hyperglycaemia		1				1
Metabolic syndrome		1				1
	4	13	1	2	3	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	7	11	3	3	4	8
Back pain	1	3		2	1	1
Bone formation increased		1		1		
Bone pain	1	1	1	1		
Joint range of motion decreased		1				1
Joint swelling		1				1
Mobility decreased	1	1	1	1		
Muscle disorder		1				1
Muscle spasms		3				3
Muscular weakness	1	2			1	2
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness		1				1
Myalgia	11	20	4	7	7	13
Neck pain		1				1
Pain in extremity	9	11	3	5	6	6
Rheumatoid arthritis		2				2
Tendon pain	1	1	1	1		
	33	62	14	22	19	40

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Meningioma	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Altered state of consciousness		1				1
Amnesia	1	2	1	2		
Aphasia		4				4
Brain hypoxia		1				1
Central nervous system lesion		1				1
Cerebral infarction		1				1
Cerebrovascular accident	1	4			1	4
Coma		2				2
Dementia		1				1
Disturbance in attention	2	4		1	2	3
Dizziness	9	23	1	5	8	18
Dysaesthesia	1	2			1	2
Dysarthria	1	2			1	2
Dysgeusia		2		2		
Embolic stroke		1				1
Encephalopathy		1				1
Epilepsy	1	6			1	6
Facial paralysis		2				2
Facial paresis	4	4			4	4
Generalised tonic-clonic seizure		2				2
Haemorrhagic stroke		1				1
Headache	16	33	4	12	12	21
Hemiplegia		1				1
Hypoglycaemic coma		1				1
Ischaemic cerebral infarction	1	3			1	3
Lethargy		1		1		
Loss of consciousness	2	3			2	3
Migraine	1	1	1	1		
Monoplegia	1	1			1	1
Nervous system disorder		1				1
Neuralgia	3	3			3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgic amyotrophy	2	2			2	2
Paraesthesia	3	7	1	2	2	5
Pleocytosis		1				1
Polyneuropathy		1				1
Presyncope	4	7			4	7
Sedation	1	1			1	1
Seizure		1				1
Sensory disturbance	2	3			2	3
Somnolence		4				4
Speech disorder		1				1
Spinal cord ischaemia	1	1			1	1
Syncope	6	8			6	8
Transient ischaemic attack		2				2
Tremor		3				3
Trigeminal neuralgia	1	1			1	1
Vascular encephalopathy		1				1
White matter lesion		1		1		
	64	161	8	28	56	133

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute stress disorder		2				2
Agitation		1				1
Confusional state	1	3			1	3
Delirium	2	4			2	4
Depressed mood	1	1	1	1		
Disorientation		2				2
Dissociative disorder		1				1
Enuresis	1	1			1	1
Hallucination, visual	1	1			1	1
Illusion		1		1		
Immunisation anxiety related reaction	2	2			2	2
Insomnia	1	2	1	2		
Middle insomnia		1		1		
Paranoia		1				1
Sleep disorder		1		1		
	9	24	2	6	7	18

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	2	3	2	3
Glomerulonephritis minimal lesion		1		1
Renal failure		2		2
Renal impairment	1	1	1	1
Urinary incontinence		1		1
Urogenital haemorrhage		1		1
	3	9	3	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Breast haematoma	1	1	1	1
Breast pain	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	1	2			1	2
Apnoea	1	1			1	1
Asthma		3				3
Chronic obstructive pulmonary disease		2				2
Cough	3	7		2	3	5
Dysphonia		1		1		
Dyspnoea	9	19	2	4	7	15
Epistaxis		1		1		
Hyperventilation	2	4			2	4
Lung disorder	1	1			1	1
Obstructive airways disorder		1				1
Oropharyngeal oedema	1	1			1	1
Oropharyngeal pain		2		1		1
Pharyngeal paraesthesia	1	1			1	1
Pleural effusion	1	2		1	1	1
Pulmonary embolism	5	5			5	5
Pulmonary fibrosis	1	1			1	1
Pulmonary oedema	1	1			1	1
Respiratory depression		1				1
Respiratory distress	1	2			1	2
Respiratory failure	1	3			1	3
Respiratory paralysis		1				1
Tachypnoea	1	2			1	2
Throat irritation	1	1			1	1
Throat tightness	1	2			1	2
	32	67	2	10	30	57

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia	1	1			1	1
Angioedema	4	9			4	9
Blister		1		1		
Cold sweat	1	1			1	1
Dermatitis allergic		1		1		
Drug eruption	1	1			1	1
Erythema	3	8	1	2	2	6
Erythema annulare	1	1			1	1
Hair growth abnormal		1		1		
Hyperhidrosis	1	4			1	4
Pruritus	4	15		4	4	11
Purpura	1	1			1	1
Rash	5	12	4	6	1	6
Rash erythematous		2				2
Rash maculo-papular	1	2		1	1	1
Rash papular	1	1			1	1
Rash pruritic	1	1			1	1
Skin disorder	1	1			1	1
Skin lesion		1				1
Skin reaction	1	1			1	1
Urticaria	2	6		1	2	5
	29	71	5	17	24	54

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Impaired work ability	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Axillary lymphadenectomy	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		1				1
Circulatory collapse	3	3			3	3
Deep vein thrombosis	2	3			2	3
Embolism		1				1
Flushing		2				2
Hypertension	8	18		2	8	16
Hypertensive crisis		2				2
Hypertensive emergency		1				1
Hypotension	5	7		1	5	6
Lymphangiectasia	1	1			1	1
Pallor	1	2			1	2
Peripheral coldness		2				2
Peripheral vascular disorder		1				1
	20	44		3	20	41

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**TUNISIA**

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	2	2	2	2
Chills	1	1	1	1
Fatigue	2	2	2	2
Influenza like illness	1	1	1	1
Injection site pain	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	2	2	2	2
	10	10	10	10

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint range of motion decreased	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
	4	4	4	4

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	2	2	2	2
Dysgeusia	1	1	1	1
Headache	1	1	1	1
Paraesthesia	1	1	1	1
	5	5	5	5

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hypertension	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**TURKEY**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea	1	1	1	1
Toothache	2	2	2	2
Vomiting	1	1	1	1
	4	4	4	4

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	2	2	2		
Chills	1	1	1	1		
Drug ineffective	1	1			1	1
Fatigue	2	2	2	2		
Malaise	1	1	1	1		
Pyrexia	3	3	3	3		
Swelling face	1	1	1	1		
Vaccination site pain	4	4	4	4		
	15	15	14	14	1	1

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	4	4	3	3	1	1
Herpes zoster	1	1	1	1		
Meningitis	1	1			1	1
	6	6	4	4	2	2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Accidental overdose	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1
Incorrect dose administered	1	1	1	1
Maternal exposure during pregnancy	1	1	1	1
Off label use	1	1	1	1
Overdose	1	1	1	1
Product preparation error	2	2	2	2
	8	8	8	8

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Pain in extremity	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Invasive ductal breast carcinoma	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	2	2	2	2
Headache	5	5	5	5
	7	7	7	7

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Dyspnoea	1	1	1	1
Oropharyngeal pain	1	1	1	1
Tonsillar hypertrophy	1	1	1	1
	4	4	4	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Dry skin	1	1	1	1
Erythema	2	2	2	2
Pruritus	1	1	1	1
Urticaria	1	1	1	1
	5	5	5	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**TURKS AND CAICOS ISLANDS**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Nodule		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia		1		1
		1		1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Generalised tonic-clonic seizure		1		1
Haemorrhagic stroke	1	1	1	1
Seizure		1		1
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**UKRAINE**

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED ARAB EMIRATES**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Erythropenia		1				1	
Lymphadenopathy	1	2	1	2			
Lymph node pain	1	1	1	1			
	2	4	2	3			1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypoacusis		1		1
		1		1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral	1	1			1	1
Ocular vascular disorder	1	1			1	1
Vision blurred		2		2		
	2	4		2	2	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	4	1	4		
Nausea	1	6	1	5		1
Rectal haemorrhage		1				1
Vomiting		2		2		
	2	13	2	11		2

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chest discomfort		1		1		
Chest pain	1	2			1	2
Chills	2	3	2	3		
Death		1				1
Drug ineffective	1	7			1	7
Fatigue	3	7	3	7		
Feeling abnormal		2		2		
Gait disturbance		1		1		
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Pain	1	3	1	3		
Pyrexia	4	11	4	11		
Sudden death		1				1
Swelling		1				1
Vaccination site pain	3	7	3	7		
	16	50	14	38	2	12

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Babesiosis		1				1
COVID-19	3	10	2	2	1	8
Lyme disease		1				1
Nasopharyngitis		1		1		
Ophthalmic herpes zoster	1	1			1	1
Pneumonia	1	1			1	1
Suspected COVID-19	1	1			1	1
	6	16	2	3	4	13

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head injury	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Maternal exposure timing unspecified		1		1		
Off label use		1		1		
Product use issue		1		1		
Vaccination failure	1	1			1	1
	3	6	1	4	2	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
SARS-CoV-2 antibody test negative		3		3		
		4		3		1

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System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Arthralgia		2		2
Back pain	1	3	1	3
Bone pain	1	1	1	1
Fibromyalgia		1		1
Muscle fatigue		1		1
Myalgia	2	2	2	2
Pain in extremity	1	1	1	1
	5	11	5	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressed level of consciousness		1				1
Dizziness		4		3		1
Dysgeusia	2	2	2	2		
Facial paralysis	1	2			1	2
Headache	3	7	3	6		1
Hypoaesthesia		1				1
Loss of consciousness	1	1			1	1
Neuralgia		1		1		
Neurotoxicity		1				1
Paraesthesia		1		1		
Sciatica		2		2		
Sleep deficit		1		1		
Somnolence		1		1		
Tremor	1	1	1	1		
	8	26	6	18	2	8

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Depressed mood		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erectile dysfunction		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1		1		
Dyspnoea		2		1		1
Hypoxia		1				1
Respiratory tract irritation		1		1		
Tachypnoea		1		1		
		6		4		2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	1	1	1		
Pruritus		1		1		
Rash	1	3	1	2		1
Skin irritation		1		1		
Urticaria		1				1
	2	7	2	5		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		2		1		1
Thrombosis	2	2			2	2
	2	4		1	2	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**UNITED KINGDOM**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal lymphadenopathy	1	2					1	2
Acquired haemophilia		1						1
Anaemia	8	22				2	8	20
Anaemia megaloblastic	1	1					1	1
Anaemia vitamin B12 deficiency	1	2			1	1		1
Anisocytosis		2						2
Antiphospholipid syndrome	1	2					1	2
Autoimmune anaemia	1	1					1	1
Autoimmune haemolytic anaemia	2	3					2	3
Autoimmune neutropenia	2	2					2	2
Coagulopathy	3	8				1	3	7
Deficiency anaemia	1	1			1	1		
Disseminated intravascular coagulation	1	1					1	1
Eosinophilia		1				1		
Evans syndrome	1	1					1	1
Granulomatous lymphadenitis		2						2
Haemolysis	1	2					1	2
Haemolytic anaemia		1						1
Haemorrhagic diathesis	1	2					1	2
Hypercoagulation	1	1					1	1
Immune thrombocytopenia	18	37					18	37
Increased tendency to bruise	2	8				4	2	4
Intravascular haemolysis		1						1
Iron deficiency anaemia	1	3			1	1		2
Leukopenia	2	2					2	2
Lymphadenitis	26	54			8	19	18	35
Lymphadenopathy	931	2,327	1	4	319	802	612	1525
Lymphatic disorder	1	2					1	1
Lymph node pain	188	468		1	37	129	151	339
Lymphocytosis	2	3					2	3
Lymphopenia	1	4					2	2
Mast cell activation syndrome		4						4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Mastocytosis		1						1
Monocytosis		1			1			
Myelosuppression		1						1
Neutropenia	7	23					7	23
Neutrophilia		1						1
Pancytopenia	1	3					1	3
Platelet anisocytosis		1						1
Platelet disorder	1	1					1	1
Polychromasia	1	2					1	2
Pseudolymphoma		1						1
Spleen atrophy		1						1
Splenomegaly	1	3					1	3
Thrombocytopenia	41	64					41	64
Thrombocytosis		2				1		1
Thrombotic microangiopathy	1	1					1	1
Thrombotic thrombocytopenic purpura	4	5					4	5
White blood cell disorder	2	2					2	2
	1,257	3,084	1	5	367	966	890	2118

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute cardiac event		3						3
Acute coronary syndrome	4	4					4	4
Acute myocardial infarction	5	19					5	19
Angina pectoris	18	40					18	40
Angina unstable		1						1
Arrhythmia	8	30					8	30
Arrhythmia supraventricular	1	7				1	1	6
Arteriosclerosis coronary artery		1						1
Arteriospasm coronary		1						1
Atrial fibrillation	30	108	1	1			30	108
Atrial flutter	2	5					2	5
Atrial tachycardia		3				1		2
Atrioventricular block	3	3					3	3
Atrioventricular block complete	2	2					2	2
Bradycardia	6	27					6	27
Bundle branch block	1	1					1	1
Bundle branch block right		3				1		2
Cardiac arrest	8	61					8	61
Cardiac discomfort	1	3				1	1	2
Cardiac disorder	2	10			1	2	1	8
Cardiac failure	6	20					6	20
Cardiac failure acute	2	2					2	2
Cardiac failure chronic	1	1					1	1
Cardiac failure congestive		4						4
Cardiac flutter	13	48					13	48
Cardiac valve disease		1						1
Cardiogenic shock	1	2					1	2
Cardiomegaly		1				1		
Cardiomyopathy	1	1					1	1
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		1						1
Cardiovascular disorder	1	3					1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Congestive cardiomyopathy		1						1
Coronary artery disease	2	6					2	6
Coronary artery occlusion		1						1
Coronary artery stenosis		1						1
Coronary artery thrombosis	1	1					1	1
Cor pulmonale		1						1
Extrasystoles	5	23				3	5	20
Hypertensive heart disease		3						3
Left ventricular dysfunction	2	3					2	3
Left ventricular failure		2						2
Microvascular coronary artery disease	1	2					1	2
Mitral valve incompetence	1	1					1	1
Mitral valve prolapse		1						1
Myocardial fibrosis		1						1
Myocardial haemorrhage		1						1
Myocardial infarction	33	86					33	86
Myocardial ischaemia		10						10
Myocardial oedema		2						2
Myocarditis	4	15					4	15
Palpitations	189	696		1	58	181	131	515
Paroxysmal arrhythmia		1						1
Pericardial effusion	2	6					2	6
Pericardial haemorrhage	1	2					1	2
Pericarditis	3	15					3	15
Postural orthostatic tachycardia syndrome	1	7				1	1	6
Pulseless electrical activity		3						3
Right ventricular enlargement		1				1		
Right ventricular failure		1						1
Sinus arrest	2	2					2	2
Sinus bradycardia		1						1
Sinus node dysfunction		1						1
Sinus tachycardia	2	25			1	10	1	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Stress cardiomyopathy	1	2					1	2
Supraventricular extrasystoles	1	1					1	1
Supraventricular tachycardia	5	20			2	5	3	15
Tachycardia	69	360	1	1	28	106	41	254
Ventricular arrhythmia		2						2
Ventricular extrasystoles	1	11				1	1	10
Ventricular fibrillation		6						6
Ventricular hypertrophy	1	2					1	2
Ventricular tachycardia	3	4					3	4
	446	1,747	2	3	90	315	356	1432

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Amegakaryocytic thrombocytopenia		1		1
Congenital cystic lung		1		1
Congenital multiplex arthrogryposis	1	1	1	1
Dysmorphism		1		1
Ehlers-Danlos syndrome		1		1
Familial hemiplegic migraine		1		1
Familial periodic paralysis		1		1
Foetal malformation	1	1	1	1
Gastroschisis	1	1	1	1
Haemophilia		1		1
Heart disease congenital		2		2
Hereditary neuropathy with liability to pressure palsies	1	1	1	1
Hypertrophic cardiomyopathy		1		1
Retinitis pigmentosa		1		1
	4	15	4	15

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute vestibular syndrome		1				1		
Auditory disorder	2	6				1	2	5
Auricular swelling		4						4
Deafness	32	68					32	68
Deafness bilateral	1	2					1	2
Deafness neurosensory	4	11					4	11
Deafness transitory	1	2					1	2
Deafness unilateral	10	17					10	17
Ear canal erythema	1	1			1	1		
Ear congestion	1	4				1	1	3
Ear discomfort	11	44			3	16	8	28
Ear disorder	3	11			1	5	2	6
Ear haemorrhage	2	3					2	3
Ear pain	89	287			27	81	62	206
Ear pruritus		8				3		5
Ear swelling	6	15			1	2	5	13
Eustachian tube disorder		1						1
Eustachian tube dysfunction		2						2
Excessive cerumen production	2	2					2	2
External ear inflammation		1						1
External ear pain	1	4			1	3		1
Hyperacusis	10	29			3	9	7	20
Hypoacusis	21	43			9	17	12	26
Inner ear disorder	2	4					2	4
Inner ear inflammation		1						1
Meniere's disease	4	8					4	8
Middle ear effusion		1						1
Middle ear inflammation		1						1
Misophonia	1	1					1	1
Motion sickness	11	26			4	10	7	16
Otorrhoea		1				1		
Sudden hearing loss	4	12					4	12

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tinnitus	157	347			31	70	126	277
Tympanic membrane hyperaemia	1	1					1	1
Vertigo	141	383		1	28	65	113	318
Vertigo labyrinthine	1	3					1	3
Vertigo positional	12	29			2	3	10	26
Vestibular disorder	1	3				1	1	2
	532	1,387		1	111	290	421	1097

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Addison's disease		1				1
Adrenocortical insufficiency acute	3	8			3	8
Anovulatory cycle		1				1
Basedow's disease	1	1			1	1
Goitre	3	5	1	2	2	3
Hyperthyroidism	5	8			5	8
Hypothyroidism	6	10			6	10
Premature menarche	1	1	1	1		
Thyroid disorder	1	1			1	1
Thyroiditis subacute		1		1		
Thyroid pain		1				1
	20	38	2	4	18	34

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal sensation in eye	4	13			2	6	2	7
Age-related macular degeneration		1						1
Amblyopia	1	2				1	1	1
Asthenopia	19	67			8	19	11	48
Autoimmune uveitis		1						1
Binocular eye movement disorder		1						1
Blepharitis	1	4				1	1	3
Blepharospasm	6	17			3	3	3	14
Blindness	18	39					18	39
Blindness transient	1	8					1	8
Blindness unilateral	4	7					4	7
Cataract	1	1					1	1
Central vision loss	1	2					1	2
Chalazion	1	2					1	2
Charles Bonnet syndrome		1						1
Chorioretinopathy	1	1					1	1
Choroidal neovascularisation		3						3
Chromatopsia	1	1			1	1		
Conjunctival haemorrhage	6	17					6	17
Conjunctival hyperaemia	1	2					1	2
Conjunctival oedema	1	2					1	2
Corneal disorder		1						1
Corneal erosion		1						1
Cyanopsia		1						1
Dark circles under eyes	1	1					1	1
Diabetic eye disease		1				1		
Diplopia	27	61			10	18	17	43
Dry eye	7	41			1	15	6	26
Dyschromatopsia	1	1			1	1		
Eczema eyelids	1	3			1	3		
Episcleritis	1	4				1	1	3
Erythema of eyelid	1	4				1	1	3

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\* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythroptosis		2
Exophthalmos		1
Exposure keratitis		1
Extraocular muscle disorder	1	1
Extraocular muscle paresis		1
Eye allergy	1	2
Eye colour change		1
Eye discharge	2	9
Eye disorder	6	25
Eye haematoma		1
Eye haemorrhage	4	11
Eye inflammation	3	10
Eye irritation	14	47
Eyelid bleeding	1	1
Eyelid cyst		1
Eyelid disorder		4
Eyelid exfoliation		1
Eyelid function disorder	1	4
Eyelid irritation		2
Eyelid margin crusting		1
Eyelid oedema	1	4
Eyelid pain		7
Eyelid ptosis	5	15
Eyelid rash	2	5
Eyelids pruritus	2	7
Eye movement disorder	2	10
Eye oedema	3	5
Eye pain	98	364
Eye paraesthesia		1
Eye pruritus	26	89
Eye swelling	47	170
Eye symptom	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
					1
			1		
				1	1
					1
		1	1		1
					1
		1	1	1	8
		1	8	5	17
					1
				4	11
		2	3	1	7
		3	10	11	37
				1	1
					1
			2		2
					1
			1	1	3
			1		1
			1		
			2	1	2
			2		5
		2	9	3	6
		2	2		3
			2	2	5
			1	2	9
		2	3	1	2
		31	91	67	273
			1		
	2	14	36	12	53
	2	23	50	24	120
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye ulcer	1	1
Foreign body sensation in eyes	5	16
Glaucoma	2	4
Halo vision		1
Hypoaesthesia eye	1	5
Iridocyclitis		6
Iritis	1	3
Keratitis		3
Lacrimal disorder		1
Lacrimation increased	12	70
Lagophthalmos	1	2
Limbal swelling	1	1
Macular degeneration	1	2
Macular hole	1	1
Macular oedema	1	2
Macular rupture	1	1
Maculopathy	1	2
Metamorphopsia	3	9
Miosis		2
Mydriasis	2	4
Ocular discomfort	8	20
Ocular hyperaemia	29	86
Ocular hypertension		1
Ocular myasthenia	1	1
Ocular sarcoidosis		1
Ocular vascular disorder	1	1
Ophthalmoplegia	1	3
Optic ischaemic neuropathy	1	1
Optic nerve disorder		1
Optic neuropathy		1
Orbital oedema	1	1
Oscillopsia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		3	5	2	11
				2	4
					1
			1	1	4
					6
			1	1	2
			2		1
					1
		5	18	7	52
		1	1		1
				1	1
				1	2
				1	1
				1	2
				1	1
			1	3	8
					2
		1	1	1	3
		4	10	4	10
		17	30	12	56
					1
				1	1
					1
				1	1
					1
				1	1
			1		

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\* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Papilloedema		2
Parophthalmia	1	1
Periorbital oedema		8
Periorbital pain	2	3
Periorbital swelling	13	48
Photophobia	37	154
Photopsia	12	38
Pupil fixed	1	1
Pupillary disorder		1
Pupillary reflex impaired	1	2
Pupils unequal	1	3
Retinal aneurysm	1	1
Retinal artery occlusion	1	2
Retinal artery thrombosis		1
Retinal detachment	1	1
Retinal disorder	1	1
Retinal exudates	2	2
Retinal fovea disorder	1	1
Retinal haemorrhage		2
Retinal tear	1	1
Retinal toxicity		1
Retinal vasculitis	1	1
Retinal vein occlusion	5	8
Retinal vein thrombosis	1	1
Retinopathy	1	1
Scintillating scotoma	1	1
Scleral discolouration		4
Scleritis	1	2
Strabismus	2	2
Sudden visual loss	1	2
Swelling of eyelid	20	55
Ulcerative keratitis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
			1		7
			1	2	2
		5	12	8	36
		9	37	28	117
		5	10	7	28
				1	1
					1
		1	1		1
				1	3
				1	1
				1	2
					1
				1	1
		1	1		
				2	2
				1	1
					2
				1	1
					1
				1	1
				5	8
				1	1
				1	1
				1	1
			2		2
				1	2
		1	1	1	1
				1	2
		6	17	14	38
					4

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Uveitis	1	10					1	10
Vision blurred	97	323			26	89	71	234
Visual acuity reduced	5	9			1	2	4	7
Visual brightness		1				1		
Visual impairment	53	141			18	44	35	97
Visual snow syndrome	1	1					1	1
Vitreous detachment	5	10					5	10
Vitreous floaters	4	16				6	4	10
Vitreous haemorrhage	2	2					2	2
	679	2,237		4	214	597	465	1640

\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions	1	2					1	2
Abdominal discomfort	62	231	1	3	27	68	35	163
Abdominal distension	38	108			15	37	23	71
Abdominal mass	1	1					1	1
Abdominal migraine	1	1					1	1
Abdominal pain	129	434		2	39	129	90	305
Abdominal pain lower	10	33			3	8	7	25
Abdominal pain upper	173	656		1	63	175	110	481
Abdominal rigidity		6				2		4
Abdominal symptom		1						1
Abdominal tenderness	3	8			1	3	2	5
Abnormal faeces	3	9			2	5	1	4
Acute abdomen	2	4					2	4
Aerophagia		2				1		1
Anal fissure		1						1
Anal haemorrhage	2	7					2	7
Anal incontinence	1	9		1		2	1	7
Anal pruritus	1	2				1	1	1
Anal sphincter atony		1						1
Angina bullosa haemorrhagica	1	1					1	1
Angular cheilitis	1	1					1	1
Anorectal discomfort	1	2			1	1		1
Anorectal swelling		1						1
Aphthous ulcer	6	14			3	4	3	10
Aptyalism	1	1			1	1		
Ascites		3						3
Bowel movement irregularity		3				1		2
Breath odour	3	11			2	6	1	5
Change of bowel habit	2	2			1	1	1	1
Chapped lips	2	7			1	3	1	4
Cheilitis	2	8			2	5		3
Chronic gastritis	1	1					1	1

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\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Coeliac disease	1	5
Colitis	7	12
Colitis ischaemic	1	1
Colitis microscopic	1	2
Colitis ulcerative	10	20
Constipation	28	80
Crohn's disease	4	16
Cyclic vomiting syndrome		1
Defaecation urgency	2	8
Dental caries	1	1
Dental discomfort		1
Diarrhoea	439	1,711
Diarrhoea haemorrhagic	4	11
Discoloured vomit	1	5
Diverticulum		1
Diverticulum intestinal	1	1
Dry mouth	39	184
Duodenal ulcer haemorrhage	1	1
Duodenal ulcer perforation		1
Duodenogastric reflux	1	2
Dyschezia	1	3
Dyspepsia	30	97
Dysphagia	41	129
Enlarged uvula	1	7
Enteritis	2	4
Epigastric discomfort	1	8
Eructation	4	20
Faecaloma		2
Faeces discoloured	2	17
Faeces hard	2	2
Faeces pale		4
Faeces soft	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
		1	1	6	11
				1	1
				1	2
1	1			10	20
		8	16	20	64
				4	16
					1
				2	8
				1	1
					1
2	7	182	477	257	1234
				4	11
			2	1	3
			1		
				1	1
	1	20	65	19	119
				1	1
					1
		1	1		1
		1	2		1
		11	29	19	68
		14	39	27	90
		1	3		4
			1	2	3
			2	1	6
			3	4	17
					2
			8	2	9
				2	2
			2		2
				1	2

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\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Flatulence	21	69
Food poisoning	1	3
Frequent bowel movements	3	19
Functional gastrointestinal disorder	2	3
Gastric antral vascular ectasia	1	2
Gastric dilatation		3
Gastric disorder	5	15
Gastric haemorrhage		2
Gastric ulcer	1	2
Gastric varices haemorrhage		1
Gastritis	4	16
Gastrointestinal disorder	6	12
Gastrointestinal haemorrhage	2	5
Gastrointestinal motility disorder		1
Gastrointestinal pain	15	46
Gastrointestinal sounds abnormal	4	13
Gastrointestinal wall thickening		1
Gastrooesophageal reflux disease	9	39
Gingival bleeding	6	11
Gingival blister	1	2
Gingival discomfort	1	3
Gingival disorder		4
Gingival erythema		1
Gingival pain	9	38
Gingival pruritus	1	1
Gingival swelling	4	9
Gingivitis ulcerative		2
Glossitis		5
Glossodynia	28	84
Haematemesis	2	18
Haematochezia	5	21
Haemoperitoneum	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	19	14	50
				1	3
		1	3	2	16
				2	3
				1	2
					3
		1	6	4	9
					2
				1	2
					1
			2	4	14
		1	5	5	7
				2	5
			1		
		4	6	11	40
		2	3	2	10
			1		
		3	5	6	34
		3	4	3	7
		1	2		
			1	1	2
			2		2
					1
		3	8	6	30
				1	1
		1	2	3	7
					2
			3		2
		14	36	14	48
				2	18
				5	21
				1	1

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemorrhoids	2	10
Hyperaesthesia teeth	2	5
Hyperchlorhydria		6
Hypoaesthesia oral	37	171
Hypoaesthesia teeth		1
Ileus paralytic	1	1
Impaired gastric emptying	1	2
Infantile vomiting		1
Inflammatory bowel disease	1	1
Internal hernia	1	1
Intestinal haemorrhage	1	1
Intestinal infarction	1	1
Intestinal ischaemia	1	3
Intestinal mass		1
Intestinal obstruction	3	6
Intestinal perforation	1	2
Intestinal pseudo-obstruction		1
Irritable bowel syndrome	5	30
Lip blister	3	12
Lip discolouration		1
Lip disorder		6
Lip dry	8	25
Lip erythema		4
Lip exfoliation		3
Lip haemorrhage		1
Lip oedema		3
Lip pain	8	29
Lip pruritus	3	5
Lip scab		1
Lip swelling	68	270
Lip ulceration	2	4
Mallory-Weiss syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	10
		2	2		3
			1		5
		24	78	13	93
			1		
				1	1
				1	2
					1
				1	1
				1	1
				1	1
				1	3
					1
				3	6
				1	2
					1
		2	4	3	26
		2	2	1	10
					1
			4		2
		3	11	5	14
			2		2
			1		2
					1
					3
		2	13	6	16
		2	4	1	1
					1
	1	35	88	33	182
		2	2		2
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Melaena	1	6
Mesenteric vein thrombosis	3	3
Mouth cyst	1	3
Mouth haemorrhage	5	7
Mouth swelling	9	41
Mouth ulceration	35	114
Mucous stools	3	4
Nausea	1,314	5,000
Noninfective gingivitis	1	3
Noninfective sialoadenitis	1	1
Obstructive pancreatitis	1	2
Odynophagia	7	23
Oedema mouth	1	4
Oesophageal discomfort		1
Oesophageal pain	1	4
Oesophageal spasm		2
Oesophageal stenosis		1
Oesophageal varices haemorrhage		1
Oesophagitis	1	1
Oral blood blister	1	5
Oral discharge		1
Oral discomfort	5	32
Oral disorder	5	10
Oral dysaesthesia		1
Oral lichen planus	2	2
Oral mucosa erosion		1
Oral mucosal blistering	4	16
Oral mucosal discolouration		1
Oral mucosal eruption	3	5
Oral mucosal erythema	2	4
Oral mucosal exfoliation	3	6
Oral mucosal roughening	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
				3	3
			2	1	1
		2	3	3	4
		3	11	6	30
		11	36	24	78
				3	4
	21	606	1675	708	3325
				1	3
				1	1
				1	2
		3	9	4	14
			1	1	3
			1		
			2	1	2
			1		1
					1
		1	1		
		1	3		2
			1		
		2	10	3	22
			3	5	7
					1
				2	2
			1		
		4	10		6
					1
		2	3	1	2
		1	1	1	3
		1	3	2	3
				1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oral pain	17	64
Oral papule		1
Oral pruritus	5	13
Oral purpura	1	1
Overflow diarrhoea		1
Palatal oedema		2
Palatal swelling		3
Palatal ulcer		1
Pancreatic disorder		1
Pancreatitis		3
Pancreatitis acute	2	4
Pancreatitis necrotising		1
Paraesthesia oral	117	477
Parotid gland enlargement	1	3
Peptic ulcer haemorrhage	1	2
Plicated tongue		2
Pouchitis		1
Proctalgia	2	6
Proctitis	1	1
Proctitis ulcerative		1
Pylorospasm		1
Rectal discharge		1
Rectal haemorrhage	9	29
Rectal spasm		1
Reflux gastritis	1	3
Regurgitation		1
Retching	7	54
Retroperitoneal haemorrhage		1
Salivary duct obstruction		1
Salivary gland disorder		1
Salivary gland enlargement	2	4
Salivary gland pain	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	21	7	43
					1
		2	5	3	8
				1	1
			1		
					2
					3
					1
					1
					3
				2	4
					1
	1	81	238	36	239
			1	1	2
				1	2
			1		1
					1
		1	3	1	3
		1	1		
					1
			1		
				9	29
			1		
			2	1	1
					1
		5	20	2	34
					1
					1
				2	4
				2	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Salivary hypersecretion	3	20
Scalloped tongue	1	1
Small intestinal haemorrhage		3
Small intestinal obstruction	1	2
Steatorrhoea	1	2
Stiff tongue	1	2
Stomatitis	10	27
Submaxillary gland enlargement	1	2
Swollen tongue	49	232
Teething		3
Tongue blistering	4	8
Tongue coated	1	5
Tongue cyst	1	1
Tongue discolouration	5	10
Tongue discomfort	8	20
Tongue disorder	6	27
Tongue dry		6
Tongue eruption	1	6
Tongue erythema	1	4
Tongue haemorrhage	1	1
Tongue movement disturbance	1	3
Tongue oedema	2	13
Tongue pruritus	3	8
Tongue rough		1
Tongue spasm	1	2
Tongue ulceration	5	14
Toothache	17	42
Tooth disorder		1
Tooth erosion	1	1
Upper gastrointestinal haemorrhage		2
Uvulitis	1	1
Vomiting	370	1,434

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8	2	12
				1	1
					3
				1	2
		1	1		1
		1	1		1
	1	5	11	5	16
		1	2		
		21	69	28	163
			2		1
		1	2	3	6
	1	1	3		2
				1	1
		2	5	3	5
		4	7	4	13
		2	6	4	21
			3		3
		1	2		4
			2	1	2
		1	1		
			1	1	2
		1	2	1	11
		1	2	2	6
			1		
				1	2
		2	6	3	8
		4	11	13	31
			1		
		1	1		
					2
		1	1		
1	5	122	399	248	1035

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vomiting projectile	8	29			3	6	5	23
	3,436	12,922	5	46	1429	4056	2007	8866

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site discomfort	1	1			1	1		
Administration site joint movement impairment		2						2
Adverse drug reaction	9	34			3	21	6	13
Adverse event	1	1			1	1		
Adverse reaction				1				
Alcohol interaction		2						2
Apparent death		1						1
Application site vesicles	1	1					1	1
Asthenia	239	958		2	77	284	162	674
Axillary pain	309	664			70	202	239	462
Chest discomfort	120	501		1	47	141	73	360
Chest pain	225	773		3	56	164	169	609
Chills	1,040	3,968	4	21	470	1393	570	2575
Chronic fatigue syndrome	17	32	1	1		1	17	31
Condition aggravated	94	280	1	1	27	64	67	216
Crying	7	37			2	9	5	28
Cyst	2	3			1	1	1	2
Death	14	106					14	106
Decreased activity	2	2			1	1	1	1
Discharge		2						2
Discomfort	46	151		1	16	57	30	94
Disease progression	1	3					1	3
Disease recurrence	71	225	1	1	3	23	68	202
Drug ineffective	115	589	2	2			115	589
Drug interaction	4	9				3	4	6
Drug withdrawal syndrome		1						1
Energy increased	3	4			1	1	2	3
Exercise tolerance decreased	7	10			3	3	4	7
Extensive swelling of vaccinated limb	3	9			1	6	2	3
Eye complication associated with device		1						1
Face oedema	3	12			1	4	2	8
Facial discomfort	1	11			1	4		7

\* I=Interval, C=Cumulative

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Facial pain	32	118
Fatigue	2,180	7,924
Feeling abnormal	225	745
Feeling cold	170	663
Feeling drunk	10	41
Feeling hot	155	631
Feeling jittery	4	18
Feeling of body temperature change	57	193
Feeling of relaxation	1	1
Foaming at mouth	1	1
Gait disturbance	82	238
Gait inability	23	85
Generalised oedema	2	2
General physical health deterioration	5	13
Glassy eyes		1
Hangover	4	25
Hunger	2	8
Hyperpyrexia		4
Hyperthermia		4
Hypothermia	4	22
Illness	216	659
Immediate post-injection reaction		1
Impaired healing	1	2
Impaired self-care		1
Implant site pain		1
Inadequate analgesia	1	1
Induration	1	5
Inflammation	39	108
Inflammatory pain	1	3
Influenza like illness	301	1,122
Inhibitory drug interaction		1
Injected limb mobility decreased	4	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	36	22	82
15	81	918	2569	1262	5355
1	3	80	242	145	503
1	4	66	234	104	429
		5	13	5	28
		86	303	69	328
		2	5	2	13
		20	68	37	125
				1	1
				1	1
	1	11	44	71	194
	1	5	14	18	71
		1	1	1	1
		1	3	4	10
					1
		1	5	3	20
		2	5		3
					4
					4
				4	22
1	2	84	182	132	477
			1		
				1	2
			1		
					1
				1	1
		1	2		3
		17	37	22	71
		1	2		1
	4	115	381	186	741
					1
		2	5	2	8

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site erythema	9	17
Injection site joint movement impairment		1
Injection site mass	2	3
Injection site muscle weakness	1	1
Injection site oedema	1	1
Injection site pain	33	61
Injection site pruritus	2	4
Injection site rash		1
Injection site reaction		3
Injection site swelling	9	12
Injection site urticaria		1
Injection site warmth	1	3
Injury associated with device		1
Localised oedema	3	10
Local reaction	7	24
Loss of control of legs	2	7
Malaise	695	2,773
Mass	7	19
Moaning		3
Mucosal haemorrhage		2
Multiple organ dysfunction syndrome	1	5
No adverse event	3	8
Nodule	6	11
Non-cardiac chest pain		4
No reaction on previous exposure to drug	2	2
Oedema	8	16
Oedema peripheral	11	33
Pain	994	3,073
Peripheral swelling	346	954
Physical deconditioning		1
Polyp	1	1
Potentiating drug interaction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	15	2	2
					1
			1	2	2
				1	1
		1	1		
		28	41	5	20
		1	3	1	1
					1
			2		1
		7	10	2	2
					1
			1	1	2
			1		
		3	4		6
		6	11	1	13
				2	7
3	10	278	901	417	1872
		1	4	6	15
					3
					2
				1	5
		3	8		
		2	4	4	7
			1		3
		2	2		
		3	5	5	11
		3	10	8	23
2	10	431	1171	563	1902
1	3	112	299	234	655
					1
				1	1
				1	1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pre-existing condition improved	1	4
Prolapse	1	1
Puncture site bruise	1	2
Puncture site discharge		1
Puncture site swelling	1	1
Pyrexia	1,355	5,548
Screaming	2	4
Secretion discharge	1	5
Sensation of blood flow		2
Sensation of foreign body	9	27
Sensitivity to weather change	1	2
Serositis	1	2
Shoulder injury related to vaccine administration		3
Sluggishness	3	12
Sudden death	4	21
Suprapubic pain		1
Swelling	327	759
Swelling face	94	346
Symptom recurrence	1	2
Systemic inflammatory response syndrome		2
Temperature intolerance	8	13
Temperature regulation disorder	3	11
Tenderness	71	163
Therapeutic product effect delayed	1	1
Therapeutic product effect increased		1
Therapeutic product ineffective		1
Therapeutic response unexpected	15	27
Thirst	35	120
Treatment noncompliance		1
Ulcer	1	5
Vaccination site bruising	36	110
Vaccination site calcification	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	1
				1	1
				1	2
					1
		1	1		
4	22	645	1974	710	3574
		1	2	1	2
		1	1		4
					2
		4	6	5	21
				1	2
				1	2
					3
		1	4	2	8
				4	21
			1		
		128	307	199	452
	1	33	91	61	255
			1	1	1
					2
		1	1	7	12
		1	4	2	7
	3	49	102	22	61
				1	1
					1
					1
		10	17	5	10
		12	38	23	82
					1
			1	1	4
		20	54	16	56
				1	1

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site coldness	1	2
Vaccination site cyst		1
Vaccination site discharge		1
Vaccination site discolouration	1	11
Vaccination site discomfort	19	76
Vaccination site dryness		2
Vaccination site eczema	1	1
Vaccination site erythema	183	652
Vaccination site haematoma		2
Vaccination site haemorrhage	6	23
Vaccination site hyperaesthesia		5
Vaccination site hypersensitivity	2	4
Vaccination site hypoaesthesia	3	23
Vaccination site induration	24	72
Vaccination site inflammation	23	62
Vaccination site irritation	3	8
Vaccination site joint discomfort	1	2
Vaccination site joint erythema	3	4
Vaccination site joint movement impairment		16
Vaccination site joint pain	1	13
Vaccination site joint swelling	1	2
Vaccination site joint warmth	1	1
Vaccination site lymphadenopathy	7	24
Vaccination site macule		2
Vaccination site mass	72	241
Vaccination site movement impairment	26	87
Vaccination site necrosis	1	3
Vaccination site nodule		1
Vaccination site oedema	3	12
Vaccination site pain	793	2,980
Vaccination site papule		1
Vaccination site paraesthesia	3	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
					1
		1	5		6
		11	42	8	34
			1		1
		1	1		
		117	360	66	292
					2
		2	5	4	18
			2		3
		2	2		2
		1	10	2	13
		17	45	7	27
		17	36	6	26
		1	3	2	5
		1	2		
		2	2	1	2
			7		9
		1	6		7
		1	1		1
		1	1		
		1	9	6	15
			2		
	1	35	112	37	129
		9	37	17	50
				1	3
					1
		2	4	1	8
1	9	465	1446	328	1534
					1
		2	15	1	16

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pruritus	75	248			55	147	20	101
Vaccination site rash	37	130			21	63	16	67
Vaccination site reaction	10	54			3	24	7	30
Vaccination site scab		3						3
Vaccination site scar		2				1		1
Vaccination site swelling	193	714			118	348	75	366
Vaccination site ulcer		1						1
Vaccination site urticaria	3	16			2	10	1	6
Vaccination site vesicles	4	11			2	3	2	8
Vaccination site warmth	71	327			46	162	25	165
Vascular stent thrombosis	1	1					1	1
Visceral pain		1				1		
Withdrawal syndrome	1	3			1	2		1
	11,547	41,178	38	189	4943	14557	6604	26621

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct stone		1				1
Biliary colic		1				1
Cholangitis	1	1			1	1
Cholelithiasis	2	3			2	3
Congestive hepatopathy		1				1
Drug-induced liver injury	1	2			1	2
Gallbladder disorder	1	1			1	1
Hepatic artery embolism		1				1
Hepatic cirrhosis		1				1
Hepatic failure		1				1
Hepatic function abnormal		1				1
Hepatic lesion		1				1
Hepatic pain	2	9	1	1	1	8
Hepatitis	3	6			3	6
Hepatomegaly	1	1			1	1
Immune-mediated hepatic disorder	1	1			1	1
Jaundice	4	8		1	4	7
Liver injury	2	5			2	5
Liver tenderness	1	1			1	1
Portal vein thrombosis	1	1			1	1
Primary biliary cholangitis		1				1
	20	48	1	2	19	46

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 \* AE=Adverse Event  
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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	2	5	1	1	1	4
Allergic reaction to excipient		4				4
Allergy to arthropod bite	1	1	1	1		
Allergy to arthropod sting	1	1			1	1
Allergy to vaccine	7	51	4	24	3	27
Anaphylactic reaction	34	268			34	268
Anaphylactic shock	4	19			4	19
Anaphylactoid reaction	2	14			2	14
Anaphylactoid shock	1	3			1	3
Atopy		1				1
Autoimmune disorder	4	15			4	15
Bacille Calmette-Guerin scar reactivation	2	7		3	2	4
Contrast media reaction		1				1
Decreased immune responsiveness		2				2
Drug hypersensitivity	3	16		3	3	13
Food allergy	2	6		1	2	5
Graft versus host disease	1	1			1	1
Hypersensitivity	65	283	22	74	43	209
Immune-mediated adverse reaction		2		1		1
Immune system disorder	5	15	1	1	4	14
Immunisation reaction	1	1			1	1
Immunodeficiency		3				3
Immunodeficiency common variable	1	1			1	1
Kidney transplant rejection	1	1			1	1
Multiple allergies		1				1
Oral allergy syndrome		1				1
Reaction to colouring	1	1			1	1
Reaction to excipient	1	4		1	1	3
Reaction to preservatives		3				3
Rubber sensitivity		1				1
Sarcoidosis	3	9			3	9
Seasonal allergy	6	12	3	5	3	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensitisation	1	2			1	2
Serum sickness		1				1
Serum sickness-like reaction		2				2
Systemic immune activation	1	2			1	2
Type I hypersensitivity		1				1
Type III immune complex mediated reaction	1	1			1	1
Type IV hypersensitivity reaction	2	6	1	1	1	5
	153	768	33	116	120	652

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal infection	1	1					1	1
Abscess	3	8				2	3	6
Abscess jaw		1						1
Abscess oral	1	3			1	1		2
Acarodermatitis	1	1					1	1
Acne pustular		2				1		1
African trypanosomiasis	1	2					1	2
Appendicitis	3	8					3	8
Appendicitis perforated	2	2					2	2
Arthritis bacterial		1						1
Arthritis viral	1	2				1	1	1
Asymptomatic COVID-19	7	19				2	7	17
Bacterial diarrhoea		1						1
Bacterial infection	1	2					1	2
Biliary sepsis		1						1
Blister infected		1				1		
Breast abscess		1						1
Breast cellulitis	1	1					1	1
Bronchitis		5				1		4
Bronchopulmonary aspergillosis		1						1
Candida infection	3	7				2	3	5
Cavernous sinus thrombosis	1	1					1	1
Cellulitis	31	98					31	98
Cholecystitis infective		1						1
Clostridium difficile colitis		1						1
Clostridium difficile infection		1						1
Conjunctivitis	5	23			4	6	1	17
Conjunctivitis bacterial		2						2
Conjunctivitis viral	1	1			1	1		
Coronavirus infection	1	3				1	1	2
COVID-19	139	592	2	3	40	119	99	473
COVID-19 pneumonia	5	27					5	27

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Creutzfeldt-Jakob disease	1	2
Cystitis	9	21
Cytomegalovirus infection reactivation		1
Dermatitis infected		3
Device related infection	1	1
Disseminated varicella zoster virus infection		1
Diverticulitis	1	4
Dysentery		1
Ear infection	16	29
Ear infection bacterial		1
Eczema herpeticum	1	2
Encephalitis	5	8
Encephalitis viral	2	2
Epididymitis		2
Epiglottitis	2	2
Epstein-Barr virus infection		2
External ear cellulitis		1
Eye abscess		1
Eye infection	3	8
Folliculitis		4
Fungal infection	1	1
Fungal skin infection		1
Furuncle	3	12
Gastroenteritis	3	16
Gastroenteritis norovirus	1	1
Gastroenteritis rotavirus	1	1
Gastroenteritis viral		6
Genital herpes	3	6
Gingival abscess		1
Gingivitis	1	3
Gonorrhoea		1
Hepatitis A	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		2	5	7	16
					1
			1		2
				1	1
					1
				1	4
					1
		3	8	13	21
					1
				1	2
				5	8
				2	2
					2
				2	2
					2
					1
					1
				3	8
			2		2
				1	1
					1
			2	3	10
		1	2	2	14
				1	1
			2		4
		1	2	2	4
					1
			2	1	1
					1
				1	1

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hepatitis viral	2	3
Herpes ophthalmic		2
Herpes simplex	3	8
Herpes simplex encephalitis		1
Herpes simplex reactivation	1	2
Herpes virus infection	1	6
Herpes zoster	67	346
Herpes zoster meningoencephalitis	1	1
Herpes zoster oticus	1	4
Herpes zoster reactivation	1	5
Hordeolum	1	5
Impetigo		1
Infected dermal cyst		1
Infected skin ulcer		1
Infection	33	75
Infectious mononucleosis	1	3
Infectious pleural effusion		1
Influenza	175	530
Injection site cellulitis	1	1
Injection site pustule	1	1
Kidney infection	4	9
Labyrinthitis	14	37
Laryngitis		3
Localised infection	3	16
Lower respiratory tract infection	27	91
Lower respiratory tract infection viral		1
Lymphangitis	2	4
Lymph gland infection	4	6
Lymph node abscess		1
Mastitis	8	17
Measles	2	2
Meningitis	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					2
		1	3	2	5
					1
		1	1		1
		1	1		5
		4	101	63	245
				1	1
				1	4
				1	5
			1	1	4
					1
					1
		10	20	23	55
				1	3
					1
1	4	59	143	116	387
				1	1
				1	1
				4	9
		3	5	11	32
					3
			3	3	13
				27	91
					1
				2	4
		1	2	3	4
					1
				8	17
				2	2
				2	4

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Meningitis aseptic		1
Meningitis bacterial		1
Meningitis pneumococcal		1
Meningitis viral	1	2
Mumps	1	3
Myelitis	1	3
Nasal herpes	1	2
Nasopharyngitis	96	289
Necrotising fasciitis	1	2
Neutropenic sepsis		2
Ophthalmic herpes zoster	1	7
Oral candidiasis	4	14
Oral herpes	19	70
Orchitis		3
Otitis externa		1
Parainfluenzae viral laryngotracheobronchitis	1	1
Parotitis		5
Periorbital cellulitis	1	2
Peritonitis		1
Pharyngeal pustule	1	1
Pharyngitis	3	9
Pharyngitis streptococcal		3
Pneumonia	14	54
Pneumonia bacterial		1
Pneumonia fungal		1
Pneumonia staphylococcal		1
Post viral fatigue syndrome	15	36
Prion disease		1
Prostatic abscess	1	1
Pulmonary sepsis		1
Pulmonary tuberculosis	1	1
Pulpitis dental		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
				1	2
				1	3
				1	3
		1	2		
	1	43	107	53	182
				1	2
					2
				1	7
		1	4	3	10
	1	8	27	11	43
					3
					1
				1	1
			2		3
				1	2
					1
		1	1		
			3	3	6
					3
				14	54
					1
					1
					1
1	1		1	15	35
					1
				1	1
					1
				1	1
					1

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pustule	1	4
Pyelonephritis		1
Q fever	1	7
Rash pustular	1	3
Rectal abscess	1	1
Relapsing fever	1	1
Respiratory tract infection	2	4
Rhinitis	4	22
Scarlet fever	1	1
Secondary transmission	1	1
Sepsis	10	28
Sepsis syndrome		1
Septic pulmonary embolism		1
Septic shock	2	3
Severe acute respiratory syndrome	1	1
Sialoadenitis	1	2
Sinusitis	10	31
Skin infection	6	9
Soft tissue infection		1
Sputum purulent		1
Staphylococcal abscess	1	1
Staphylococcal infection	1	3
Staphylococcal sepsis	1	1
Streptococcal abscess	1	1
Subcutaneous abscess		2
Suspected COVID-19	80	394
Sweating fever	10	54
Systemic candida		1
Tonsillitis	8	20
Tonsillitis bacterial	1	3
Tooth abscess		1
Tooth infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		3
					1
				1	7
				1	3
				1	1
				1	1
				2	4
		1	10	3	12
				1	1
				1	1
				10	28
					1
					1
				2	3
				1	1
				1	2
		1	4	9	27
		3	5	3	4
					1
					1
		1	1		
				1	3
				1	1
				1	1
			1		1
		41	145	39	249
				10	54
					1
1	1	2	4	6	16
				1	3
					1
				1	1

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tracheitis	2	3			1	1	1	2
Upper respiratory tract infection	4	7			2	3	2	4
Urinary tract infection	19	76	1	1	4	10	15	66
Urinary tract infection bacterial		1						1
Urosepsis		2						2
Vaccination site abscess	2	5			2	3		2
Vaccination site cellulitis	2	26			1	7	1	19
Vaccination site infection	7	25			3	7	4	18
Vaccination site pustule	1	1					1	1
Vaccine breakthrough infection	17	17					17	17
Varicella	4	6			1	2	3	4
Varicella zoster virus infection		1						1
Vestibular neuronitis	2	8					2	8
Viral infection	8	16			1	5	7	11
Viral labyrinthitis	2	5				3	2	2
Viral pericarditis		1						1
Viral pharyngitis		4						4
Viral rash	2	11			1	4	1	7
Viral tonsillitis		1						1
Viral upper respiratory tract infection		1						1
Virologic failure		1						1
Vulval abscess		1						1
Vulvovaginal candidiasis	3	9			1	2	2	7
Wound infection	1	1					1	1
	1,003	3,509	6	12	254	809	749	2700

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Accident		1				1			
Accidental exposure to product		3				2			1
Accidental overdose		18				18			
Airway burns		1							1
Alcohol poisoning		1							1
Ankle fracture	2	2					2		2
Arthropod bite	1	2			1	1			1
Arthropod sting	1	1			1	1			
Atypical femur fracture		1							1
Back injury	1	1					1		1
Bite		1							1
Bone contusion		1				1			
Brachial plexus injury	1	1					1		1
Burn oesophageal		1							1
Burn oral cavity		1							1
Burns second degree	1	3			1	2			1
Chest crushing	2	3					2		3
Chest injury	2	3					2		3
Chillblains	24	29			20	21	4		8
Circumstance or information capable of leading to medication error		5				5			
Clavicle fracture	1	2					1		2
Concussion		1				1			
Contraindicated product administered		2				1			1
Contraindicated product prescribed	1	1			1	1			
Contusion	108	232		2	40	88	68		144
Corneal abrasion		1							1
Decreased embryo viability	1	1					1		1
Delayed recovery from anaesthesia	2	2			1	1	1		1
Dose calculation error		1				1			
Electric shock	1	4				2	1		2
Epicondylitis	2	4			1	1	1		3

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Expired product administered	3	7
Exposure during pregnancy	14	33
Exposure to extreme temperature	1	1
Exposure to SARS-CoV-2		3
Exposure via breast milk	39	101
Eye contusion	2	10
Eye injury		2
Face crushing		1
Face injury	2	4
Failed in vitro fertilisation	1	1
Fall	48	152
Femoral neck fracture	1	2
Femur fracture		1
Foetal exposure during pregnancy	2	2
Foreign body in gastrointestinal tract	1	1
Foreign body in mouth	1	1
Fracture		1
Fractured skull depressed		1
Gastrointestinal stoma complication		1
Hand fracture		1
Head injury	8	36
Heart injury	1	7
Heat illness		1
Heat oedema	1	4
Heat stroke		2
Hip fracture		2
Humerus fracture	1	1
Hyphaema		1
Inappropriate schedule of product administration	388	496
Incision site pain	1	3
Incomplete course of vaccination		1
Incorrect dose administered	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	2	2
1	1	9	27	5	6
			1	1	1
			1		2
		26	75	13	26
	1	2	5		5
					2
			1	2	3
				1	1
		13	41	35	111
				1	2
					1
		1	1	1	1
				1	1
				1	1
					1
					1
		1	12	7	24
				1	7
					1
			1	1	3
			1		1
					2
				1	1
					1
1	1	375	480	13	16
			1	1	3
		3	7	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incorrect route of product administration	6	45
Infusion related reaction	1	3
Injection related reaction	5	20
Injury	4	5
Injury corneal		1
Intentional product misuse		1
Intentional product use issue		1
Joint dislocation		1
Joint injury	3	7
Ligament sprain	1	5
Limb crushing injury	1	1
Limb injury	10	19
Lower limb fracture		2
Maternal exposure before pregnancy	1	2
Maternal exposure during breast feeding	9	15
Maternal exposure during pregnancy	24	91
Maternal exposure timing unspecified	1	3
Medication error	1	6
Meniscus injury		1
Mouth injury		1
Multiple injuries		1
Muscle injury		3
Muscle rupture	1	3
Muscle strain	6	15
Nail avulsion		1
Nasal injury		1
Neck injury		1
Nerve injury	7	19
Occupational exposure to product		2
Occupational exposure to SARS-CoV-2		1
Off label use	443	947
Overdose	6	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	44		1
				1	3
		1	5	4	15
				4	5
					1
			1		
			1		
					1
		1	3	2	4
				1	5
				1	1
		2	4	8	15
					2
				1	2
		3	6	6	9
3	3	14	63	10	28
		1	3		
			3	1	3
			1		
					1
					1
			1		2
				1	3
		1	2	5	13
			1		
					1
					1
		3	6	4	13
			2		
			1		
1	1	421	901	22	46
		6	23		1

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Paternal exposure before pregnancy	1	1
Periorbital haematoma		1
Poisoning	1	3
Poor quality product administered	5	89
Post laminectomy syndrome		1
Post lumbar puncture syndrome		1
Postoperative ileus		1
Post procedural complication		3
Post procedural constipation	1	1
Procedural dizziness	2	4
Procedural nausea		3
Product administered at inappropriate site	6	25
Product administered to patient of inappropriate age	7	30
Product administration error	1	2
Product dose omission issue		2
Product label confusion		1
Product preparation error	3	10
Product preparation issue		3
Product storage error	1	8
Product use issue	58	478
Reaction to previous exposure to any vaccine		1
Rectal injury	1	1
Retinal injury	2	2
Rib fracture		1
Road traffic accident	2	4
Scar	2	5
Scratch	1	7
Sedation complication	1	1
Skin abrasion	2	8
Skin injury		1
Skin laceration		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	3
		5	89		
					1
					1
					1
					3
		1	1		
		1	1	1	3
					3
		6	21		4
		7	28		2
			1	1	1
			1		1
			1		
		3	10		
			3		
		1	8		
		50	448	8	30
					1
				1	1
				2	2
					1
		1	1	1	3
		1	1	1	4
			2	1	5
				1	1
		2	4		4
			1		
			2		3

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skull fracture		1
Soft tissue injury	1	1
Spinal column injury		1
Spinal fracture	2	2
Splenic rupture	2	2
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage		1
Subcutaneous haematoma	1	1
Subdural haematoma	1	2
Subdural haemorrhage	1	1
Sunburn	1	3
Superficial injury of eye		1
Synovial rupture		1
Tendon injury	1	5
Thermal burn	5	9
Thermal burns of eye	1	5
Tongue injury		1
Tooth fracture	1	2
Toxicity to various agents	1	2
Traumatic haemorrhage		1
Traumatic intracranial haemorrhage		1
Ulnar nerve injury		4
Underdose	1	12
Upper limb fracture	1	6
Vaccination complication	9	24
Vaccination error		1
Vaccination failure	3	8
Vascular injury	2	3
Venous injury	3	3
Vth nerve injury		1
Wound	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
				2	2
				2	2
					1
			1		
					1
		1	1		
				1	2
				1	1
		1	1		2
					1
			1		
				1	5
		2	3	3	6
				1	5
					1
				1	2
	1			1	2
					1
					1
		1	12		
				1	6
		4	9	5	15
			1		
		1	1	2	7
				2	3
				3	3
					1
			2	2	4

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Wound complication		2				1			1
Wound haemorrhage		1							1
Wound secretion	1	2					1		2
Wrist fracture		1							1
Wrong product administered	5	6			4	5	1		1
Wrong technique in product usage process		5				4			1
	1,342	3,299	6	10	1048	2542	294		757

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Activated partial thromboplastin time prolonged	5	5					5	5
Activated partial thromboplastin time shortened	2	2					2	2
Alanine aminotransferase increased	5	14				2	5	12
Ammonia abnormal		1				1		
Amylase increased	1	1			1	1		
Analgesic drug level		1						1
Antibody test positive		1				1		
Anticoagulation drug level below therapeutic	1	1					1	1
Anticoagulation drug level increased		1						1
Anti-thyroid antibody positive	1	1					1	1
Aspartate aminotransferase increased		2						2
Bleeding time abnormal		1						1
Blood albumin decreased		1						1
Blood alkaline phosphatase increased	1	4				1	1	3
Blood cholesterol increased	2	4					2	4
Blood count abnormal	3	3					3	3
Blood creatine phosphokinase increased	1	4				1	1	3
Blood creatinine increased		2				1		1
Blood electrolytes increased		1				1		
Blood fibrinogen decreased	1	1					1	1
Blood folate decreased	1	1			1	1		
Blood glucose	1	2					1	2
Blood glucose abnormal		5				2		3
Blood glucose decreased	6	20				5	6	15
Blood glucose fluctuation	3	15			1	4	2	11
Blood glucose increased	13	66			1	19	12	47
Blood growth hormone abnormal	1	2			1	2		
Blood heavy metal increased		1				1		
Blood immunoglobulin E increased	1	1					1	1
Blood immunoglobulin G increased		1				1		
Blood immunoglobulin M abnormal	1	1					1	1
Blood immunoglobulin M increased		1				1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood iron decreased	1	1
Blood iron increased	2	2
Blood ketone body increased		1
Blood ketone body present		1
Blood lactate dehydrogenase increased		1
Blood lactic acid increased	1	5
Blood luteinising hormone abnormal		1
Blood magnesium decreased		1
Blood oestrogen increased		1
Blood pH	1	2
Blood pH increased	1	4
Blood phosphorus decreased	1	2
Blood potassium abnormal		1
Blood potassium decreased	1	6
Blood potassium increased	2	2
Blood pressure abnormal	3	7
Blood pressure decreased	14	47
Blood pressure diastolic decreased	1	2
Blood pressure diastolic increased		3
Blood pressure increased	47	195
Blood pressure orthostatic abnormal		1
Blood pressure orthostatic decreased		1
Blood pressure systolic decreased	1	4
Blood pressure systolic increased		6
Blood prolactin increased		1
Blood sodium decreased	2	6
Blood test abnormal	5	8
Blood testosterone increased		1
Blood thrombin	1	1
Blood thyroid stimulating hormone increased		2
Blood urea increased		2
Blood urine		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	1	1
					1
					1
					1
		1	2		3
			1		
			1		
					1
				1	2
		1	2		2
				1	2
					1
		1	2		4
		1	1	1	1
		2	4	1	3
		5	13	9	34
		1	2		
					3
		15	76	32	119
					1
					1
				1	4
			3		3
			1		
		1	2	1	4
				5	8
			1		
				1	1
			1		1
			1		1
					2

\* I=Interval, C=Cumulative  
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood urine present	6	17
Blood viscosity increased		1
Body temperature	17	25
Body temperature abnormal	20	67
Body temperature decreased	7	34
Body temperature fluctuation	11	32
Body temperature increased	82	260
Breath sounds abnormal	1	2
Cardiac murmur	3	6
Cells in urine	1	1
Central venous pressure abnormal	1	1
Chest X-ray abnormal		1
Clostridium test positive	1	1
Clot retraction		1
Coagulation time prolonged		2
Coma scale abnormal		3
Corneal reflex decreased	1	2
Coronavirus test positive		1
Cortisol decreased		2
C-reactive protein abnormal	1	1
C-reactive protein increased	11	27
Culture negative		1
Drug level decreased		1
Drug level fluctuating	1	1
Electrocardiogram abnormal	3	6
Electrocardiogram change		1
Electrocardiogram ST segment abnormal		1
Electrocardiogram ST segment elevation		3
Eosinophil count increased	1	3
Epinephrine increased		1
Faecal calprotectin		1
Faecal calprotectin increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5	4	12
			1		
		13	16	4	9
		6	22	14	45
		3	8	4	26
		5	11	6	21
	2	45	118	37	142
		1	1		1
			1	3	5
				1	1
		1	1		
			1		
				1	1
					1
					2
					3
			1	1	1
			1		
					2
				1	1
		1	6	10	21
					1
					1
				1	1
		1	1	2	5
			1		
					1
					3
			1	1	2
					1
					1
				1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
False positive investigation result	1	1
Fibrin D dimer increased	9	13
Forced expiratory volume increased		2
Foveal reflex abnormal	1	1
Full blood count abnormal		1
Full blood count increased		1
Gamma-glutamyltransferase increased	1	2
Glucose urine present		1
Grip strength		1
Grip strength decreased	8	22
Haematocrit increased		1
Haemoglobin decreased	2	10
Haemoglobin increased		2
Haptoglobin decreased		1
Heart rate	6	12
Heart rate abnormal	9	30
Heart rate decreased	10	36
Heart rate increased	92	374
Heart rate irregular	12	39
Heart sounds abnormal	1	1
Hepatic enzyme increased	2	4
Histamine level increased		1
Hormone level abnormal		2
Immunology test	1	1
Inflammatory marker increased		7
International normalised ratio abnormal	2	3
International normalised ratio decreased	6	14
International normalised ratio fluctuation		1
International normalised ratio increased	4	34
Intraocular pressure increased		1
Iodine uptake increased		1
Liver function test abnormal	4	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	3	7	10
					2
				1	1
					1
				1	2
					1
					1
		4	7	4	15
					1
			4	2	6
					2
					1
		2	3	4	9
	1	2	8	7	22
		1	5	9	31
		37	117	55	257
		1	3	11	36
				1	1
		1	3	1	1
			1		
					2
		1	1		
			1		6
		1	1	1	2
		1	2	5	12
					1
			8	4	26
					1
					1
		1	3	3	8

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver function test increased	4	10
Lymph node palpable	1	5
Lymph nodes scan abnormal		1
Lymphocyte count decreased	2	2
Lymphocyte count increased		1
Magnetic resonance imaging abnormal	1	1
Magnetic resonance imaging brain abnormal	2	2
Mean cell volume decreased		1
Mini mental status examination abnormal		1
Myocardial necrosis marker increased	1	1
Natural killer T cell count increased		1
Neutrophil count abnormal	1	1
Neutrophil count decreased	2	4
Neutrophil count increased		1
Ophthalmological examination abnormal	1	1
Oxygen consumption decreased	1	1
Oxygen saturation	1	1
Oxygen saturation decreased	5	60
Peak expiratory flow rate	1	1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased	2	3
pH urine		1
pH urine increased		1
Plasma viscosity abnormal	1	1
Platelet count abnormal	1	1
Platelet count decreased	32	40
Platelet count increased	2	3
Polymerase chain reaction positive	1	4
Pregnancy test positive	1	1
Product residue present	1	1
Prostatic specific antigen increased		1
Prothrombin time prolonged	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	4	8
		1	4		1
					1
				2	2
					1
				1	1
				2	2
					1
					1
				1	1
			1		
				1	1
		1	2	1	2
			1		
		1	1		
		1	1		
				1	1
		1	7	4	53
				1	1
					1
				1	1
		1	1		
		7	8	25	32
				2	3
		1	3		1
		1	1		
				1	1
			1		
				1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary function test	1	1
Pulse abnormal	3	8
Quality of life decreased	1	2
Radial pulse abnormal		1
Radioisotope uptake increased		1
Red blood cell sedimentation rate abnormal	1	1
Red blood cell sedimentation rate increased	2	6
Respiratory rate decreased	1	4
Respiratory rate increased	7	30
Reticulocyte count decreased	1	1
Rheumatoid factor increased		1
SARS-CoV-2 antibody test		1
SARS-CoV-2 antibody test negative	2	15
SARS-CoV-2 antibody test positive		2
SARS-CoV-2 test		1
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative	1	3
SARS-CoV-2 test positive	13	48
Serum ferritin decreased	1	1
Serum ferritin increased		1
Sigmoidoscopy abnormal	1	1
Skin temperature	4	7
Sputum abnormal		2
Swollen joint count increased		1
Temperature difference of extremities	1	4
Temperature perception test increased		1
Thyroid function test abnormal		1
Thyroxine free increased	2	2
Transferrin decreased	1	1
Tri-iodothyronine		1
Tri-iodothyronine decreased		2
Troponin increased	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2	2	6
				1	2
					1
				1	1
				2	6
				1	4
		2	6	5	24
				1	1
					1
			1		
			10	2	5
			1		1
					1
			1		
			2	1	1
		5	11	8	37
				1	1
					1
		2	2	2	5
					2
					1
				1	4
					1
			1		
				2	2
		1	1		
			1		
					2
				2	8

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\* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Urine analysis abnormal		3				1			2
Urine ketone body present	1	1					1		1
Urine output	1	3			1	1			2
Urine output decreased	2	6			1	2	1		4
Urine output increased		2				1			1
Viral test		1							1
Vital capacity		1							1
Vitamin B12 decreased	1	1					1		1
Vitamin D	1	1					1		1
Weight decreased	17	45			2	9	15		36
Weight increased	1	5			1	1			4
White blood cell count abnormal	1	1					1		1
White blood cell count decreased	5	8			1	1	4		7
White blood cell count increased	6	15			1	4	5		11
	620	2,033		3	200	618	420		1415

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\* AE=Adverse Event

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal loss of weight		2						2
Abnormal weight gain		3						3
Acidosis	1	3				1	1	2
Alcohol intolerance	2	2					2	2
Appetite disorder	2	8				1	2	7
Body fat disorder	1	1			1	1		
Cachexia		1						1
Dairy intolerance	1	1					1	1
Decreased appetite	169	705		4	62	211	107	494
Decreased insulin requirement	1	1					1	1
Dehydration	21	77			8	24	13	53
Diabetes mellitus	9	21					9	21
Diabetes mellitus inadequate control	2	8					2	8
Diabetic complication	1	2					1	2
Diabetic ketoacidosis	1	8					1	8
Eating disorder symptom		2						2
Feeding disorder	6	52			1	24	5	28
Fluid imbalance	2	2			1	1	1	1
Fluid intake reduced		2						2
Fluid retention	4	11			1	2	3	9
Food aversion	2	5					2	5
Food craving		3				1		2
Food intolerance	3	3			1	1	2	2
Food refusal	1	4			1	1		3
Glucose tolerance impaired		1				1		
Glycopenia	1	1			1	1		
Gout	8	28					8	28
Histamine intolerance		1						1
Hyperglycaemia	11	41			2	5	9	36
Hyperkalaemia		2						2
Hyperphagia		1						1
Hypervolaemia		1						1

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hypocalcaemia	1	3					1	3
Hypoglycaemia	5	37			1	6	4	31
Hypokalaemia		1						1
Hypokalaemic syndrome		2						2
Hyponatraemia	1	6					1	6
Hyponatraemic syndrome	1	1					1	1
Hypophagia	8	15					8	15
Hypovitaminosis	2	3			1	1	1	2
Hypovolaemia		1						1
Increased appetite	1	2			1	1		1
Increased insulin requirement		1						1
Insulin resistance		3				1		2
Iron deficiency	2	3					2	3
Ketoacidosis		3						3
Lactose intolerance		1				1		
Latent autoimmune diabetes in adults		1						1
Malnutrition		1						1
Metabolic acidosis		2						2
Overweight		1						1
Polydipsia	1	3				1	1	2
Poor feeding infant	2	2			1	1	1	1
Postprandial hypoglycaemia		1						1
Salt craving		1						1
Tetany		2				1		1
Type 1 diabetes mellitus	2	8					2	8
Type 2 diabetes mellitus	2	4					2	4
Underweight	2	2					2	2
Vitamin D deficiency	1	3					1	3
Weight loss poor	1	1					1	1
	281	1,117		4	83	288	198	829

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ankylosing spondylitis	1	6					1	6
Antisynthetase syndrome		1				1		
Arthralgia	1,052	3,530	3	23	392	1058	660	2472
Arthritis	29	87			5	10	24	77
Arthritis reactive	3	14					3	14
Arthropathy	4	17			1	5	3	12
Axillary mass	38	86			9	29	29	57
Back pain	248	910		2	91	277	157	633
Bone disorder	1	1					1	1
Bone pain	55	193	2	3	19	58	36	135
Bone swelling	3	9			1	5	2	4
Bursitis	7	14			1	1	6	13
Chondritis		1						1
Coccydynia	1	2			1	2		
Costochondritis	6	18				1	6	17
Crystal arthropathy		1						1
Drooping shoulder syndrome		1				1		
Dupuytren's contracture	1	1					1	1
Enthesopathy		1						1
Epiphyses premature fusion		1						1
Facial asymmetry		1				1		
Fibromyalgia	10	33			2	5	8	28
Finger deformity	1	1			1	1		
Flank pain	7	21			4	10	3	11
Gouty tophus	1	1					1	1
Groin pain	15	50			4	16	11	34
Haemarthrosis	4	4					4	4
Hand deformity	2	2					2	2
Inguinal mass		1						1
Intervertebral disc compression	1	1					1	1
Intervertebral disc protrusion	1	2			1	1		1
Jaw clicking		2				1		1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Jaw disorder	1	1
Joint destruction		1
Joint effusion	1	14
Joint laxity	1	2
Joint lock	1	5
Joint microhaemorrhage		1
Joint noise	3	7
Joint range of motion decreased	41	116
Joint stiffness	29	110
Joint swelling	70	196
Joint vibration		1
Joint warmth	2	6
Ligament disorder	1	1
Ligamentitis	1	1
Limb discomfort	167	570
Limb mass	3	23
Lupus-like syndrome		1
Mandibular mass		1
Mastication disorder	1	4
Medial tibial stress syndrome		1
Mobility decreased	43	185
Muscle atrophy	6	7
Muscle discomfort	1	2
Muscle disorder	1	4
Muscle fatigue	37	126
Muscle mass	1	1
Muscle rigidity		9
Muscle spasms	88	290
Muscle swelling	4	11
Muscle tightness	10	43
Muscle twitching	16	84
Muscular weakness	121	425

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	4		10
				1	2
				1	5
					1
			1	3	6
	1	9	29	32	87
		6	20	23	90
		18	46	52	150
					1
			3	2	3
				1	1
				1	1
1	4	83	246	84	324
			9	3	14
					1
			1		
				1	4
					1
		10	51	33	134
		2	2	4	5
		1	1		1
		1	2		2
		15	28	22	98
				1	1
	1		1		8
1	1	22	77	66	213
		2	4	2	7
		2	14	8	29
		7	32	9	52
		37	111	84	314

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal chest pain	24	90
Musculoskeletal deformity		1
Musculoskeletal discomfort	16	56
Musculoskeletal disorder	4	19
Musculoskeletal pain	6	31
Musculoskeletal stiffness	151	497
Myalgia	1,197	4,307
Myalgia intercostal	1	1
Myofascial pain syndrome		5
Myositis	5	10
Neck mass	2	14
Neck pain	236	797
Nuchal rigidity		3
Osteitis	1	1
Osteoarthritis	6	17
Osteochondritis	1	1
Osteonecrosis of jaw	2	2
Osteoporosis		1
Pain in extremity	1,327	4,397
Pain in jaw	36	128
Palindromic rheumatism	1	1
Patellofemoral pain syndrome	1	1
Periarthritis	9	27
Plantar fasciitis	2	6
Polyarthritis	3	7
Polychondritis	1	2
Polymyalgia rheumatica	12	27
Polymyositis		1
Posture abnormal	1	2
Psoriatic arthropathy	5	12
Purple glove syndrome	1	1
Rhabdomyolysis		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	18	18	72
					1
		5	21	11	35
			3	4	16
		2	8	4	23
	2	60	155	91	342
8	28	572	1547	625	2760
				1	1
			2		3
		1	3	4	7
			5	2	9
	2	88	258	148	539
					3
				1	1
		1	3	5	14
		1	1		
				2	2
					1
5	40	596	1666	731	2731
		10	34	26	94
				1	1
				1	1
	1	1	4	8	23
		1	1	1	5
				3	7
				1	2
				12	27
					1
		1	1		1
				5	12
				1	1
					5

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rheumatic disorder	1	1					1	1
Rheumatoid arthritis	27	61		1			27	61
Rotator cuff syndrome	5	7					5	7
Sacroiliitis	2	4				1	2	3
Sjogren's syndrome	1	4					1	4
Soft tissue swelling	4	4			2	2	2	2
Spinal disorder	1	3				1	1	2
Spinal osteoarthritis		1						1
Spinal pain	9	32			2	8	7	24
Spinal stenosis	1	1					1	1
Spondylitis	1	1					1	1
Symphysiolysis		1						1
Synovial cyst	2	7				1	2	6
Synovitis		4						4
Systemic lupus erythematosus	5	11		1			5	11
Temporomandibular joint syndrome	1	4				3	1	1
Tendonitis	8	16			1	2	7	14
Tendon pain	1	4			1	2		2
Tenosynovitis		1						1
Tenosynovitis stenosans	1	2					1	2
Torticollis		1						1
Trigger finger	1	4				1	1	3
Trismus	5	10			1	1	4	9
Vertebral lesion	1	1					1	1
Weight bearing difficulty	2	8			1	3	1	5
	5,271	17,925	20	110	2101	5920	3170	12005

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acoustic neuroma	1	2			1	2
Acrochordon		1				1
Acute leukaemia		1				1
Basal cell carcinoma	1	2			1	2
B-cell lymphoma		1				1
Bladder neoplasm	1	1			1	1
Bone neoplasm	1	2	1	1		1
Brain neoplasm	1	2			1	2
Breast cancer	6	10			6	10
Breast cancer stage III	1	1			1	1
Chronic lymphocytic leukaemia	1	1			1	1
Colon cancer	1	1			1	1
Essential thrombocythaemia		1				1
Gastric cancer		1				1
Gastrointestinal carcinoma	1	1			1	1
Haemangioma		1		1		
Leukaemia		1				1
Lipoma	1	1	1	1		
Lung neoplasm malignant	2	3			2	3
Lymphangioma		1				1
Lymphoma	2	11			2	11
Melanocytic naevus		1				1
Metastases to lymph nodes		7				7
Metastasis		1				1
Metastatic neoplasm	1	1			1	1
Myelodysplastic syndrome		1				1
Neoplasm	3	4		1	3	3
Neoplasm malignant	2	4			2	4
Neoplasm skin		1				1
Non-Hodgkin's lymphoma	1	1			1	1
Oligodendroglioma	1	1			1	1
Pancreatic carcinoma	2	3			2	3

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\* AE=Adverse Event

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Plasma cell myeloma		1				1
Primary gastrointestinal follicular lymphoma		1				1
Renal cancer	1	2			1	2
Sarcoma		1				1
Second primary malignancy		1				1
Skin cancer		1				1
TEMPI syndrome		1				1
Triple negative breast cancer	1	1			1	1
	32	80	2	4	30	76

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\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute disseminated encephalomyelitis	2	2					2	2
Acute motor axonal neuropathy		1						1
Ageusia	48	155		1	22	57	26	98
Akathisia		1						1
Alexia		1				1		
Allodynia	2	5					2	5
Altered state of consciousness	4	9					4	9
Amnesia	19	47			2	8	17	39
Anosmia	20	79			6	28	14	51
Anticholinergic syndrome		1						1
Aphasia	13	32			3	7	10	25
Apraxia		1				1		
Areflexia		2						2
Ataxia	3	5					3	5
Atonic seizures	1	4					1	4
Aura	4	11			1	5	3	6
Autonomic nervous system imbalance	1	3					1	3
Axonal neuropathy		2						2
Balance disorder	64	197		1	12	36	52	161
Bradykinesia	2	6			1	1	1	5
Brain hypoxia		1						1
Brain injury		2						2
Brain oedema		2						2
Brain stem stroke	1	2					1	2
Brain stem syndrome		2						2
Bulbar palsy	1	1					1	1
Burning feet syndrome		1						1
Burning sensation	69	187			24	54	45	133
Carotid artery disease	1	1					1	1
Carotid artery dissection		1						1
Carotid artery occlusion	1	1					1	1
Carpal tunnel syndrome	5	7			2	2	3	5

\* I=Interval, C=Cumulative

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cataplexy	1	2
Central nervous system lesion	1	1
Central nervous system vasculitis	1	1
Cerebellar haemorrhage	1	1
Cerebellar infarction		2
Cerebellar stroke		3
Cerebral artery embolism	1	1
Cerebral artery occlusion	1	1
Cerebral artery thrombosis	3	3
Cerebral disorder		3
Cerebral haemorrhage	10	24
Cerebral infarction	13	24
Cerebral thrombosis	10	15
Cerebral venous sinus thrombosis	13	16
Cerebral venous thrombosis	2	2
Cerebrospinal fluid leakage		1
Cerebrovascular accident	87	195
Cervical radiculopathy	1	1
Cervicobrachial syndrome		2
Cervicogenic headache	1	2
Chorea		2
Clonic convulsion		2
Clumsiness	2	5
Cluster headache	22	68
Cognitive disorder	7	37
Cold-stimulus headache	3	5
Coma	2	4
Consciousness fluctuating		4
Coordination abnormal	12	36
Cranial nerve disorder		2
Cranial nerve palsies multiple	1	1
Dementia	2	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	1		
				1	1
				1	1
					2
					3
				1	1
				1	1
				3	3
			2		1
				10	24
				13	24
				10	15
				13	16
				2	2
					1
				87	195
				1	1
					2
		1	1		1
					2
					2
				2	5
		8	17	14	51
			2	7	35
		1	1	2	4
				2	4
					4
		3	6	9	30
					2
				1	1
				2	10

\* I=Interval, C=Cumulative

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dementia Alzheimer's type	1	1
Dementia with Lewy bodies		1
Demyelination	3	4
Depressed level of consciousness	7	23
Diabetic coma	1	1
Diplegia	3	6
Disturbance in attention	62	182
Dizziness	858	3,120
Dizziness exertional	8	23
Dizziness postural	78	269
Dreamy state		2
Drooling	4	9
Dysaesthesia	1	2
Dysarthria	21	78
Dysdiadochokinesis	1	1
Dysgeusia	102	380
Dysgraphia		2
Dyskinesia	19	37
Dysstasia	23	67
Dystonia	2	8
Embolic cerebral infarction	1	1
Embolic stroke	2	4
Encephalopathy		2
Epilepsy	21	67
Epileptic aura		1
Epileptic encephalopathy		1
Essential tremor		1
Exertional headache	1	4
Extensor plantar response		1
Facial nerve disorder	1	2
Facial neuralgia	1	8
Facial paralysis	107	367

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				3	4
				7	23
				1	1
				3	6
	1	17	48	45	134
	14	369	998	489	2122
		1	2	7	21
	1	31	76	47	193
			1		1
		1	2	3	7
		1	1		1
		2	13	19	65
				1	1
	1	63	199	39	181
					2
		4	9	15	28
		5	21	18	46
				2	8
				1	1
				2	4
					2
				21	67
					1
					1
					1
		1	2		2
					1
		1	2		
		1	3		5
	2			107	367

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Facial paresis	8	40
Facial spasm	2	12
Febrile convulsion	6	8
Fine motor skill dysfunction	3	6
Focal dyscognitive seizures	1	1
Formication	5	17
Freezing phenomenon	1	3
Generalised tonic-clonic seizure	8	33
Gliososis		1
Guillain-Barre syndrome	11	26
Haemorrhage intracranial	1	5
Haemorrhagic stroke	4	6
Hand-arm vibration syndrome		2
Hand-eye coordination impaired		1
Headache	2,618	9,377
Head discomfort	51	129
Head titubation	1	1
Hemianopia		1
Hemianopia homonymous	2	2
Hemiparaesthesia		1
Hemiparesis	6	21
Hemiplegia	6	14
Hemiplegic migraine	2	5
Horner's syndrome		1
Hyperaesthesia	21	56
Hypergeusia		1
Hyperintensity in brain deep nuclei	1	1
Hyperreflexia		1
Hypersomnia	42	143
Hypertonia		2
Hypoaesthesia	240	758
Hypogeusia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	15	4	25
		1	6	1	6
		5	6	1	2
		1	1	2	5
				1	1
		2	4	3	13
				1	3
				8	33
					1
				11	26
				1	5
				4	6
					2
					1
5	41	1186	3289	1432	6088
		14	41	37	88
				1	1
					1
				2	2
					1
				6	21
				6	14
				2	5
					1
		7	25	14	31
					1
				1	1
					1
		18	52	24	91
					2
	4	101	264	139	494
					1

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoglycaemic coma		1
Hypokinesia	34	54
Hyporeflexia		5
Hyporesponsive to stimuli		1
Hyposmia		5
Hypotonia	1	5
Idiopathic intracranial hypertension	1	2
Illrd nerve disorder	1	2
Illrd nerve paralysis	1	4
Inability to crawl	1	1
Incoherent	3	8
Infant irritability	1	2
Intracranial aneurysm	1	1
Intracranial pressure increased	1	1
Irregular sleep wake rhythm disorder	1	1
Ischaemic stroke	9	26
IVth nerve paralysis		1
Lacunar infarction		2
Lacunar stroke		1
Language disorder	2	2
Lateral medullary syndrome	1	1
Lennox-Gastaut syndrome		1
Lethargy	256	895
Lhermitte's sign	1	1
Locked-in syndrome		1
Long thoracic nerve palsy		1
Loss of consciousness	57	242
Loss of proprioception		1
Medication overuse headache		1
Memory impairment	19	58
Mental impairment	6	20
Migraine	263	839

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		8	14	26	40
			2		3
					1
			2		3
			1	1	4
				1	2
				1	2
				1	4
				1	1
		1	3	2	5
		1	1		1
				1	1
				1	1
		1	1		
				9	26
					1
					2
					1
				2	2
				1	1
					1
1	6	115	318	141	577
				1	1
					1
			1		
				57	242
					1
					1
		6	16	13	42
	1			6	20
3	5	55	182	208	657

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine with aura	24	69
Migraine without aura	3	4
Mononeuropathy		1
Monoparesis	7	21
Monoplegia	5	29
Morton's neuralgia		1
Motor dysfunction	2	6
Movement disorder	23	77
Multiple sclerosis	3	17
Multiple sclerosis relapse	5	22
Muscle contractions involuntary	1	9
Muscle spasticity		3
Muscle tone disorder		1
Myasthenia gravis	3	5
Myasthenia gravis crisis	1	2
Myelitis transverse	3	18
Myoclonus	3	8
Narcolepsy		2
Nerve compression	5	12
Nerve degeneration		1
Nervous system disorder	5	9
Neuralgia	53	140
Neuritis	1	2
Neurological symptom	5	15
Neurologic neglect syndrome		2
Neuromuscular pain	1	1
Neuromyelitis optica spectrum disorder	1	1
Neuromyopathy		1
Neuropathy peripheral	13	43
New daily persistent headache		1
Noninfective encephalitis		1
Numb chin syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	5	17	19	52
				3	4
					1
			2	7	19
				5	29
					1
			1	2	5
		5	14	18	63
				3	17
				5	22
			3	1	6
					3
					1
				3	5
				1	2
				3	18
			2	3	6
					2
		2	4	3	8
					1
		2	3	3	6
		10	35	43	105
		1	1		1
			1	5	14
					2
				1	1
				1	1
					1
				13	43
			1		
					1
					1

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nystagmus	4	7
Occipital neuralgia	2	4
Ophthalmoplegic migraine	1	1
Optic neuritis	4	10
Paraesthesia	315	1,071
Paralysis	18	43
Paraparesis		1
Paresis	1	2
Parkinsonism	1	4
Parkinson's disease	2	7
Parosmia	21	62
Partial seizures	2	10
Patient elopement	1	1
Peripheral sensory neuropathy	1	5
Peroneal nerve palsy	2	7
Persistent postural-perceptual dizziness		3
Petit mal epilepsy	3	15
Phantom limb syndrome		2
Pineal gland cyst	1	1
Poor quality sleep	26	95
Posterior reversible encephalopathy syndrome		1
Post herpetic neuralgia	1	5
Postictal paralysis	1	1
Postictal state		1
Post stroke seizure		1
Presyncope	33	202
Primary cough headache		3
Primary headache associated with sexual activity		1
Psychogenic seizure	1	5
Psychomotor hyperactivity	5	9
Quadrantanopia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	7
				2	4
		1	1		
				4	10
	3	148	410	167	661
	1			18	43
					1
				1	2
			1	1	3
				2	7
		7	22	14	40
				2	10
				1	1
		1	2		3
		1	2	1	5
			1		2
				3	15
					2
				1	1
	1	12	35	14	60
					1
			2	1	3
				1	1
					1
					1
	1	18	82	15	120
			1		2
					1
			1	1	4
		2	3	3	6
				1	2

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Radiculitis brachial		2
Radiculopathy	1	2
Reduced facial expression	2	4
Repetitive speech		1
Restless legs syndrome	9	29
Retinal migraine	2	9
Reversed hot-cold sensation		1
Reversible cerebral vasoconstriction syndrome		1
Sciatica	4	21
Sciatic nerve neuropathy		1
Sedation	1	4
Seizure	51	188
Seizure cluster		4
Seizure like phenomena		1
Senile dementia		1
Sensory disturbance	11	39
Sensory loss	18	34
Serotonin syndrome		1
Sinus headache	41	113
Sleep deficit	1	6
Sleep paralysis		3
Slow response to stimuli		2
Slow speech	2	3
Somnolence	115	431
Speech disorder	18	51
Spinal cord disorder		1
Status epilepticus	11	22
Stiff leg syndrome		1
Stupor	1	1
Subacute inflammatory demyelinating polyneuropathy	1	1
Subarachnoid haemorrhage	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	2
		1	3	1	1
					1
		2	8	7	21
			2	2	7
					1
					1
		2	5	2	16
					1
			1	1	3
				51	188
					4
					1
					1
		5	18	6	21
		7	13	11	21
					1
	1	19	41	22	72
			2	1	4
			2		1
					2
				2	3
	1	50	145	65	286
	1	6	12	12	39
					1
				11	22
					1
				1	1
				1	1
				2	7

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Superior sagittal sinus thrombosis		1						1
Syncope	125	543		1			125	543
Tardive dyskinesia	1	1					1	1
Taste disorder	37	103			19	49	18	54
Temporal lobe epilepsy		1						1
Tension headache	53	158		2	20	49	33	109
Thrombotic stroke	1	1					1	1
Thunderclap headache		2						2
Tongue biting		1						1
Tongue paralysis		1						1
Tonic clonic movements	1	3					1	3
Tonic convulsion	1	9					1	9
Transient global amnesia	2	4					2	4
Transient ischaemic attack	44	78					44	78
Tremor	159	703		3	69	187	90	516
Trigeminal nerve disorder		1				1		
Trigeminal neuralgia	6	15			2	3	4	12
Tumefactive multiple sclerosis	1	1					1	1
Tunnel vision	2	6					2	6
Typical aura without headache	1	2					1	2
Ulnar neuritis	1	1					1	1
Unresponsive to stimuli	4	36					4	36
Vascular dementia	1	4					1	4
Vascular headache	1	7			1	3		4
Vertebral artery stenosis	1	1					1	1
Vestibular migraine	3	8				1	3	7
Visual field defect	3	9				2	3	7
Visual perseveration	1	1					1	1
Vlth nerve paralysis	1	4					1	4
Writer's cramp		1						1
	6,841	23,583	9	94	2528	7046	4313	16537

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion missed		1				1
Abortion spontaneous	25	52			25	52
Foetal death	2	2			2	2
Gestational diabetes	1	1			1	1
Haemorrhage in pregnancy	1	1			1	1
Morning sickness		8				8
Oligohydramnios		1				1
Pregnancy	1	3		2	1	1
Pregnancy with contraceptive device	1	1			1	1
Premature baby		3				3
Premature delivery		1				1
Preterm premature rupture of membranes		2				2
Stillbirth	1	1			1	1
Uterine contractions abnormal		1				1
	32	78		2	32	76

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 \* AE=Adverse Event  
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System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device infusion issue		1				1
Device pacing issue	1	1			1	1
Device stimulation issue		1		1		
Liquid product physical issue		2		2		
Needle issue		2		1		1
Oversensing	3	7	1	1	2	6
Product complaint	1	3		1	1	2
Product contamination		1		1		
Product contamination physical	1	1	1	1		
Product packaging quantity issue		4		4		
Product quality issue		2		2		
Product supply issue		1		1		
Product taste abnormal		1		1		
Product temperature excursion issue	3	71	3	71		
Syringe issue		1		1		
Thrombosis in device	1	2			1	2
	10	101	5	88	5	13

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour	4	7				2	4	5
Abnormal dreams	19	59			14	34	5	25
Adjustment disorder with depressed mood	1	1					1	1
Affective disorder	1	1					1	1
Affect lability	2	4			1	1	1	3
Aggression	3	9				2	3	7
Agitated depression		1						1
Agitation	11	46			3	13	8	33
Alcoholic hangover		1						1
Alexithymia		1				1		
Anger	1	5				3	1	2
Anorgasmia		1						1
Anxiety	62	231			21	72	41	159
Apathy	3	16			2	5	1	11
Attention deficit hyperactivity disorder	2	2					2	2
Autoscopy	5	6			1	1	4	5
Behaviour disorder		3						3
Binge eating		1						1
Bipolar disorder		1						1
Bipolar I disorder	1	1					1	1
Bradyphrenia	5	13			1	3	4	10
Bruxism	2	4					2	4
Bulimia nervosa		1						1
Catatonia		1						1
Communication disorder	2	7				2	2	5
Confusional arousal		1						1
Confusional state	99	350		1	18	64	81	286
Constricted affect		1						1
Conversion disorder	1	1					1	1
Cyclothymic disorder		1						1
Decreased interest	3	8			1	3	2	5
Deja vu	1	1					1	1

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Delirium	15	61
Delusion	3	5
Delusional perception		1
Depersonalisation/derealisation disorder	1	3
Depressed mood	25	92
Depression	22	73
Depression suicidal	1	2
Derealisation	1	5
Disorganised speech		4
Disorientation	32	112
Dissociation	5	18
Dissociative amnesia	1	1
Dissociative disorder		1
Dysphemia	3	4
Dysphoria	1	1
Dyssomnia	1	1
Eating disorder	7	24
Emotional disorder	8	21
Emotional distress	5	18
Enuresis	2	6
Euphoric mood	6	13
Exploding head syndrome		1
Factitious disorder	1	1
Fear	5	16
Fear of falling	1	2
Fear of injection		2
Feeling of despair	3	5
Flashback	1	2
Flat affect	1	3
Frustration tolerance decreased		1
Grief reaction	1	1
Habit cough	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				15	61
		1	2	2	3
					1
			1	1	2
		6	17	19	75
		3	4	19	69
				1	2
			1	1	4
			1		3
		8	20	24	92
		2	9	3	9
		1	1		
			1		
		1	1	2	3
				1	1
		1	1		
			4	7	20
		5	7	3	14
		1	5	4	13
			2	2	4
		3	5	3	8
					1
				1	1
			5	5	11
				1	2
			2		
				3	5
				1	2
		1	2		1
			1		
				1	1
		1	1	2	2

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hallucination	23	87
Hallucination, auditory	1	5
Hallucination, olfactory	1	4
Hallucinations, mixed		2
Hallucination, tactile		1
Hallucination, visual	3	10
Head banging	2	3
Hypervigilance		1
Hypnagogic hallucination		2
Hypomania		1
Hyposomnia		1
Illusion		1
Immunisation anxiety related reaction		1
Inappropriate affect	1	2
Indifference	1	4
Initial insomnia	2	8
Insomnia	166	615
Intentional self-injury	1	3
Intrusive thoughts	2	2
Irritability	16	47
Lack of spontaneous speech	1	4
Laziness		1
Learning disability		1
Libido decreased		1
Libido increased		1
Listless	3	8
Logorrhoea		2
Loss of libido	1	3
Major depression	3	3
Mania	1	4
Mental disorder	6	10
Mental fatigue	15	63

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				23	87
				1	5
				1	4
					2
					1
				3	10
		1	2	1	1
					1
					2
					1
					1
			1		
					1
				1	2
			1	1	3
		1	4	1	4
		50	204	116	411
				1	3
		1	1	1	1
		8	14	8	33
			1	1	3
					1
					1
			1		
				3	8
					2
				1	3
				3	3
				1	4
		3	5	3	5
		4	12	11	51

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mental status changes		1
Middle insomnia	10	43
Mood altered	2	11
Mood disorder due to a general medical condition		1
Mood swings		10
Morose		3
Mutism	2	5
Near death experience	1	1
Negative thoughts		2
Nervousness	31	111
Neuropsychiatric symptoms		1
Nightmare	15	55
Obsessive-compulsive symptom		1
Osmophobia		1
Panic attack	13	31
Panic disorder	1	4
Panic reaction	3	14
Paramnesia	1	2
Paranoia	1	8
Personality change		4
Phobia	1	1
Phonophobia		1
Post-traumatic stress disorder	1	2
Pressure of speech		1
Psychiatric symptom	1	3
Psychotic behaviour		1
Psychotic disorder	1	8
Psychotic symptom		2
Purging	1	1
Reading disorder		1
Restlessness	29	74

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	17	7	26
			3	2	8
					1
			3		7
			2		1
		1	3	1	2
				1	1
					2
		16	32	15	79
			1		
		5	20	10	35
					1
					1
		4	7	9	24
		1	1		3
		1	4	2	10
				1	2
		1	2		6
			1		3
				1	1
			1		
				1	2
					1
		1	1		2
					1
			1	1	7
					2
				1	1
					1
		6	18	23	56

\* I=Interval, C=Cumulative

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Schizophrenia	1	1					1	1	
Self-injurious ideation	1	2					1	2	
Sense of a foreshortened future		4				2		2	
Sleep attacks		2						2	
Sleep disorder	66	201			31	89	35	112	
Sleep disorder due to a general medical condition	3	15			3	9		6	
Sleep disorder due to general medical condition, insomnia type	8	26			1	9	7	17	
Sleep talking	1	1			1	1			
Sleep terror	3	6				1	3	5	
Social avoidant behaviour		1						1	
Social fear		1						1	
Somatic symptom disorder		2						2	
Staring	2	3					2	3	
Stereotypy		1						1	
Stress	12	26			4	8	8	18	
Suicidal behaviour	1	1					1	1	
Suicidal ideation	7	14					7	14	
Suicide attempt	2	4					2	4	
Tachyphrenia		2						2	
Tearfulness	8	22			2	6	6	16	
Tension	3	8			1	4	2	4	
Terminal insomnia	2	4			1	1	1	3	
Thinking abnormal	6	16			2	4	4	12	
Tic	1	1					1	1	
Vomiting psychogenic		1						1	
	873	2,959			1	249	796	624	2163

\* I=Interval, C=Cumulative  
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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	10	34			10	34
Albuminuria	1	1			1	1
Anuria	1	3			1	3
Bladder discomfort		1		1		
Bladder disorder	1	6			1	6
Bladder dysfunction		1				1
Bladder irritation		1				1
Bladder pain	1	7			1	7
Chromaturia	7	23	4	12	3	11
Chronic kidney disease	2	6			2	6
Costovertebral angle tenderness		1		1		
Cystitis interstitial	1	2			1	2
Cystitis-like symptom		1				1
Dysuria	13	32	4	10	9	22
Genitourinary symptom		1				1
Glomerulonephritis		1				1
Glomerulonephritis minimal lesion	2	4			2	4
Glomerulonephritis rapidly progressive		1				1
Haematuria	8	18	1	3	7	15
Haemorrhage urinary tract	3	9		1	3	8
Hypertonic bladder		3		3		
IgA nephropathy	1	1			1	1
Incontinence	5	19	1	3	4	16
Kidney small		1				1
Loss of bladder sensation		2				2
Micturition disorder		3		1		2
Micturition urgency	7	11	1	1	6	10
Nephritis		1				1
Nephrolithiasis		1				1
Nephrotic syndrome	2	9			2	9
Neurogenic bladder		1				1
Nocturia		1		1		

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\* AE=Adverse Event

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oliguria	1	2			1	2
Pollakiuria	7	26	2	6	5	20
Polyuria		2		1		1
Proteinuria	1	3		1	1	2
Renal colic	1	1	1	1		
Renal cyst	2	2			2	2
Renal disorder	2	4			2	4
Renal failure	3	10			3	10
Renal haemorrhage	1	2			1	2
Renal impairment	7	12			7	12
Renal pain	25	88	8	25	17	63
Renal vasculitis		1				1
Tubulointerstitial nephritis		1				1
Ureteric stenosis		1				1
Urethral stenosis		1				1
Urinary bladder haemorrhage	1	1			1	1
Urinary incontinence	9	39	3	8	6	31
Urinary retention	4	28			4	28
Urinary tract disorder		1				1
Urinary tract pain		1				1
Urine abnormality	3	4	2	3	1	1
Urine flow decreased	2	3	1	1	1	2
Urine odour abnormal		6		3		3
	134	445	28	86	106	359

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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adnexa uteri pain		5						5
Amenorrhoea	6	13				2	6	11
Anisomastia		1				1		
Breast cyst	1	2			1	1		1
Breast discomfort	3	6			2	3	1	3
Breast disorder	1	1					1	1
Breast engorgement	1	1					1	1
Breast enlargement	1	3					1	3
Breast inflammation	2	2					2	2
Breast mass	11	21			2	4	9	17
Breast milk discolouration		1				1		
Breast oedema	1	1					1	1
Breast pain	57	128			8	26	49	102
Breast swelling	20	44			6	16	14	28
Breast tenderness	9	17			3	4	6	13
Cervical dysplasia	1	1					1	1
Dysfunctional uterine bleeding		1						1
Dysmenorrhoea	11	29			3	11	8	18
Endometriosis	2	4			1	1	1	3
Erectile dysfunction	5	15					5	15
Erection increased	1	2					1	2
Galactorrhoea	2	3					2	3
Genital haemorrhage		1						1
Genital pain		2						2
Genital tract inflammation		1				1		
Genital ulceration		1						1
Haematospermia	1	1					1	1
Hypomenorrhoea	3	9			2	6	1	3
Infertility		1						1
Lactation disorder	1	2					1	2
Menopausal symptoms	2	4				2	2	2
Menorrhagia	34	71	1	1	12	21	22	50

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\* AE=Adverse Event

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System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Menstrual discomfort	1	1
Menstrual disorder	9	19
Menstruation delayed	14	42
Menstruation irregular	18	29
Metrorrhagia	6	10
Nipple exudate bloody	1	1
Nipple pain	4	10
Nipple swelling	2	4
Oligomenorrhoea	3	4
Ovarian cyst	1	1
Ovulation pain		1
Pelvic discomfort		1
Pelvic haemorrhage		3
Pelvic pain	7	23
Penile swelling		2
Perineal pain	1	1
Polymenorrhoea	3	9
Postmenopausal haemorrhage	5	7
Premature menopause		1
Premenstrual syndrome	1	1
Prostatic disorder	1	1
Prostatic pain	1	1
Prostatitis	1	2
Prostatomegaly	1	3
Pruritus genital		1
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain	1	4
Scrotal swelling		3
Semen discolouration	1	1
Suppressed lactation		2
Testicular pain	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
1	1	4	9	5	10
		4	13	10	29
1	1	4	9	14	20
		2	4	4	6
				1	1
		1	3	3	7
			2	2	2
				3	4
		1	1		
					1
					1
					3
		2	6	5	17
					2
		1	1		
		1	4	2	5
				5	7
					1
				1	1
		1	1		
				1	1
				1	2
			2	1	1
			1		
					1
					1
		1	2		2
					3
				1	1
					2
		2	3	2	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Testicular swelling	2	5			2	3		2
Testicular torsion		1						1
Testis discomfort	1	2			1	1		1
Uterine haemorrhage	3	3					3	3
Uterine pain		2						2
Uterine spasm		1				1		
Vaginal cyst	1	2					1	2
Vaginal discharge		2				1		1
Vaginal disorder	1	2				1	1	1
Vaginal haemorrhage	20	51			6	12	14	39
Vaginal ulceration	1	1					1	1
Vulval haemorrhage	2	4					2	4
Vulval oedema		1				1		
Vulval ulceration	1	1			1	1		
Vulvovaginal burning sensation	1	1					1	1
Vulvovaginal pain	1	5				2	1	3
Vulvovaginal pruritus		1				1		
Vulvovaginal rash		1				1		
Vulvovaginal swelling		1						1
Vulvovaginal ulceration	2	3					2	3
	298	682	3	3	74	186	224	496

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		1						1
Acute respiratory failure		2						2
Allergic cough	2	5					2	5
Allergic sinusitis		1						1
Alveolitis	1	1					1	1
Aphonia	6	26	1	1	4	6	2	20
Apnoea	1	2					1	2
Aspiration		5						5
Asthma	27	137			4	23	23	114
Asthma late onset		1						1
Atelectasis		1						1
Bronchial disorder		1						1
Bronchial secretion retention	1	1			1	1		
Bronchiectasis	2	5					2	5
Bronchospasm	3	8			1	2	2	6
Catarrh	1	6			1	4		2
Choking	3	10					3	10
Choking sensation	1	5				1	1	4
Chronic obstructive pulmonary disease	5	14					5	14
Cough	203	785	1	3	85	255	118	530
Cough decreased		1				1		
Cyanosis central		1						1
Diaphragmalgia	2	4			1	1	1	3
Diaphragmatic disorder	1	1					1	1
Dry throat	22	66	1	2	16	29	6	37
Dysphonia	17	63			7	19	10	44
Dyspnoea	363	1,357		1	90	273	273	1084
Dyspnoea at rest	1	5					1	5
Dyspnoea exertional	7	57				17	7	40
Emphysema		2						2
Epiglottic oedema		1						1

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\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis	91	205
Haemoptysis	9	21
Hiccups		2
Hyperactive pharyngeal reflex		1
Hypercapnia		1
Hyperoxia	1	1
Hypersensitivity pneumonitis		1
Hyperventilation	3	13
Hypopnoea	11	33
Hypoventilation	2	2
Hypoxia	4	19
Increased bronchial secretion		1
Increased upper airway secretion	1	6
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion	2	5
Interstitial lung disease	2	2
Intranasal hyposaesthesia		1
Intranasal paraesthesia	1	3
Irregular breathing	1	10
Laryngeal disorder		1
Laryngeal obstruction		1
Laryngeal pain		3
Laryngospasm		1
Lower respiratory tract congestion	1	1
Lung consolidation	1	2
Lung disorder	4	9
Lung infiltration	2	2
Lung opacity	1	1
Mouth breathing		3
Nasal congestion	29	96
Nasal discharge discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		32	64	59	141
		3	3	6	18
					2
					1
					1
				1	1
					1
		2	7	1	6
			2	11	31
				2	2
				4	19
					1
			2	1	4
					1
			1	2	4
				2	2
					1
		1	3		
		1	2		8
					1
					1
			1		2
					1
		1	1		
				1	2
		1	2	3	7
		1	1	1	1
				1	1
					3
	1	10	33	19	63
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nasal discomfort	8	26
Nasal disorder	1	3
Nasal dryness	4	7
Nasal obstruction		3
Nasal odour	1	3
Nasal oedema	1	5
Nasal pruritus	1	5
Neonatal pneumothorax		1
Neonatal respiratory distress		1
Nocturnal dyspnoea		2
Obstructive airways disorder		2
Oropharyngeal blistering		10
Oropharyngeal discomfort	11	39
Oropharyngeal oedema		1
Oropharyngeal pain	217	820
Oropharyngeal spasm		1
Orthopnoea		4
Painful respiration	10	32
Paranasal sinus discomfort	3	11
Paranasal sinus hypersecretion	1	1
Paranasal sinus inflammation		1
Pharyngeal disorder		1
Pharyngeal enanthema		1
Pharyngeal erythema	3	5
Pharyngeal haemorrhage		1
Pharyngeal hypoaesthesia	3	10
Pharyngeal inflammation		8
Pharyngeal leukoplakia		1
Pharyngeal oedema	2	9
Pharyngeal paraesthesia	10	30
Pharyngeal swelling	21	119
Pharyngeal ulceration	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	9	7	17
			2	1	1
		2	3	2	4
			2		1
			1	1	2
		1	2		3
			1	1	4
					1
					1
					2
					2
					10
		5	15	6	24
					1
1	4	107	281	110	539
					1
			1		3
			5	10	27
		2	5	1	6
				1	1
					1
					1
		2	2	1	3
					1
		2	5	1	5
			1		7
			1		
			1	2	8
		8	12	2	18
		10	28	11	91
			1	1	6

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pleural effusion	5	10
Pleurisy	1	13
Pleuritic pain	3	11
Pneumonia aspiration		7
Pneumonitis	3	13
Pneumothorax	1	1
Pneumothorax spontaneous		1
Productive cough	19	68
Pulmonary artery dilatation		1
Pulmonary artery thrombosis		1
Pulmonary congestion	1	4
Pulmonary embolism	79	152
Pulmonary fibrosis	2	2
Pulmonary haemorrhage	1	1
Pulmonary hypertension		2
Pulmonary infarction	1	4
Pulmonary oedema	6	16
Pulmonary pain	10	42
Pulmonary sarcoidosis		2
Pulmonary thrombosis	6	14
Rales		3
Respiration abnormal	4	24
Respiratory acidosis		1
Respiratory arrest	3	13
Respiratory depression		1
Respiratory disorder	3	24
Respiratory distress	2	9
Respiratory failure		7
Respiratory muscle weakness		1
Respiratory symptom	1	3
Respiratory tract congestion		1
Respiratory tract irritation	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	10
				1	13
			1	3	10
					7
			1	3	12
				1	1
					1
		4	18	15	50
					1
					1
				1	4
				79	152
				2	2
				1	1
					2
				1	4
				6	16
		3	10	7	32
			1		1
	1			6	14
					3
		2	7	2	17
					1
	1			3	13
					1
			6	3	18
				2	9
					7
					1
	1			1	3
					1
			2	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract oedema		3
Reversible airways obstruction		1
Rhinalgia	4	8
Rhinitis allergic		3
Rhinorrhoea	57	217
Sinonasal obstruction	1	5
Sinus congestion	5	18
Sinus disorder	2	6
Sinus pain	17	55
Sleep apnoea syndrome	2	5
Sneezing	23	105
Snoring		2
Sputum discoloured	1	4
Sputum increased		1
Stridor	2	12
Suffocation feeling		1
Tachypnoea	2	22
Throat clearing		4
Throat irritation	23	103
Throat tightness	24	153
Tonsillar cyst	1	1
Tonsillar disorder		2
Tonsillar erythema	1	2
Tonsillar haemorrhage		1
Tonsillar hypertrophy	7	21
Tonsillar inflammation	1	4
Tonsillar ulcer		1
Tracheal inflammation		1
Tracheal pain		1
Upper-airway cough syndrome	1	5
Upper airway obstruction		2
Upper respiratory tract congestion	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
		3	4	1	4
			1		2
2	5	23	70	34	147
		1	2		3
		1	5	4	13
				2	6
		4	15	13	40
				2	5
	1	12	43	11	62
			1		1
			1	1	3
					1
		1	1	1	11
			1		
		1	6	1	16
					4
		11	34	12	69
		12	42	12	111
		1	1		
			1		1
		1	1		1
					1
		6	9	1	12
		1	3		1
					1
			1		
			1		
			2	1	3
					2
			1	2	4

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vocal cord disorder		1							1
Wheezing	35	173			14	43	21		130
Yawning	3	9			1	2	2		7
	1,499	5,608	6	21	504	1470	995		4138

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne	9	13			3	4	6	9
Acute febrile neutrophilic dermatosis		1						1
Alopecia	13	28				4	13	24
Alopecia areata	2	2					2	2
Alopecia totalis	1	1					1	1
Androgenetic alopecia	1	1					1	1
Angioedema	21	107					21	107
Blister	38	108			13	33	25	75
Blister rupture		1				1		
Blood blister	6	13			1	1	5	12
Butterfly rash	1	3				1	1	2
Chronic spontaneous urticaria		1						1
Circumoral swelling		1				1		
Cold sweat	67	272			23	86	44	186
Cold urticaria	1	1			1	1		
Cutaneous sarcoidosis	1	2					1	2
Cutaneous symptom		1						1
Cutaneous vasculitis	1	2					1	2
Decubitus ulcer	2	2					2	2
Dermal cyst		1						1
Dermatitis	14	38			4	14	10	24
Dermatitis acneiform		1						1
Dermatitis allergic	14	58			6	18	8	40
Dermatitis atopic	2	8				1	2	7
Dermatitis bullous	1	7					1	7
Dermatitis contact	2	2					2	2
Dermatitis diaper	1	1			1	1		
Dermatitis exfoliative		2						2
Dermatitis exfoliative generalised	1	1					1	1
Dermatomyositis		3						3
Dermatosis		1				1		
Drug eruption	2	7			1	2	1	5

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\* AE=Adverse Event

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dry skin	29	59
Dyshidrotic eczema		4
Eczema	15	47
Eczema asteatotic	1	1
Eczema nummular		1
Eczema weeping		1
Ephelides	1	1
Erythema	237	747
Erythema annulare	1	2
Erythema multiforme	5	18
Erythema nodosum	4	6
Excessive granulation tissue		1
Exfoliative rash	1	6
Fixed eruption		1
Fracture blisters		1
Granuloma skin	1	1
Guttate psoriasis	2	2
Haemorrhage subcutaneous	3	5
Hair colour changes		1
Hair disorder	1	1
Hair texture abnormal	3	3
Hidradenitis		1
Hyperhidrosis	221	827
Itching scar	1	6
Lichenoid keratosis	1	2
Livedo reticularis	3	16
Macule	1	4
Madarosis		1
Mechanical urticaria		1
Miliaria	14	33
Nail discolouration	1	5
Nail pigmentation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	25	17	34
					4
	1	2	11	13	36
			1	1	1
			1		
		1	1		
	1	145	368	92	379
				1	2
				5	18
		1	1	3	5
					1
				1	6
			1		
			1		
		1	1		
				2	2
				3	5
			1		
		1	1		
		1	1	2	2
					1
	1	76	252	145	575
		1	4		2
				1	2
		2	4	1	12
		1	2		2
					1
			1		
		8	14	6	19
		1	2		3
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nail ridging	1	1
Night sweats	61	217
Onychoclasia	2	2
Pain of skin	39	126
Palmar erythema	1	3
Papule	4	17
Peau d'orange		1
Pemphigoid	1	8
Pemphigus		2
Perioral dermatitis	1	1
Petechiae	14	35
Photosensitivity reaction	6	28
Pigmentation disorder	3	4
Piloerection	2	8
Pityriasis	1	5
Pityriasis lichenoides et varioliformis acuta	1	1
Pityriasis rosea	6	12
Plantar erythema	1	1
Pruritus	369	1,214
Pseudofolliculitis		1
Psoriasis	14	31
Purpura	7	18
Pustular psoriasis		1
Rash	407	1,187
Rash erythematous	111	380
Rash macular	48	175
Rash maculo-papular	6	24
Rash morbilliform	3	8
Rash papular	34	95
Rash pruritic	99	331
Rash vesicular	6	28
Red man syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
	3	30	87	31	130
		1	1	1	1
		15	36	24	90
			1	1	2
		1	6	3	11
			1		
				1	8
					2
		1	1		
		9	14	5	21
		1	6	5	22
		1	2	2	2
				2	8
		1	3		2
		1	1		
		3	6	3	6
				1	1
		186	525	183	689
					1
		2	9	12	22
		5	8	2	10
					1
		206	518	201	669
1	2	53	160	58	220
		29	92	19	83
		4	9	2	15
		1	3	2	5
		17	40	17	55
		45	119	54	212
		1	9	5	19
					1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rosacea	1	3
Scab	4	6
Scar pain	1	3
Scleroderma associated digital ulcer		1
Seborrhoea	1	1
Sensitive skin	27	69
Skin burning sensation	18	68
Skin depigmentation		2
Skin discharge	1	2
Skin discolouration	18	56
Skin disorder	7	15
Skin erosion	2	8
Skin exfoliation	14	36
Skin fissures	2	3
Skin haemorrhage	5	5
Skin hypertrophy		1
Skin induration	1	3
Skin irritation	17	42
Skin laxity		1
Skin lesion	5	22
Skin mass		8
Skin odour abnormal	1	3
Skin plaque	1	1
Skin reaction	12	28
Skin sensitisation	7	11
Skin swelling	11	31
Skin tightness	5	25
Skin ulcer	2	6
Skin warm	18	90
Skin weeping	2	5
Skin wrinkling	2	2
Solar lentigo	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
		2	4	2	2
			2	1	1
					1
				1	1
		15	30	12	39
	2	4	19	14	49
					2
				1	2
		8	17	10	39
		2	3	5	12
		1	2	1	6
		7	11	7	25
			1	2	2
		2	2	3	3
			1		
			2	1	1
		6	12	11	30
					1
		3	10	2	12
			3		5
		1	3		
				1	1
		6	14	6	14
		2	3	5	8
		7	17	4	14
		2	11	3	14
				2	6
	1	8	34	10	56
				2	5
		1	1	1	1
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Splinter haemorrhages		1						1
Stevens-Johnson syndrome		3						3
Systemic lupus erythematosus rash	2	5			1		2	4
Telangiectasia	1	1					1	1
Toxic epidermal necrolysis		2						2
Toxic skin eruption		1						1
Trichodynia		1						1
Urticaria	139	465			84	191	55	274
Urticaria chronic	3	4					3	4
Urticaria papular	1	2			1	1		1
Urticaria thermal	1	2			1	2		
Vasculitic rash	2	7			1	2	1	5
Vitiligo	1	1					1	1
Yellow skin		7				5		2
	2,332	7,522	1	11	1083	2924	1249	4598

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	7	21	1	3	6	18
Breast prosthesis user	1	1	1	1		
Immobile	2	7			2	7
Impaired driving ability	6	17	3	7	3	10
Impaired quality of life	3	3	1	1	2	2
Impaired work ability	9	18	2	5	7	13
Joint prosthesis user		1				1
Loss of personal independence in daily activities	49	131	13	41	36	90
Menopause	1	1			1	1
Non-tobacco user	1	1	1	1		
Physical disability		1				1
Sight disability		1				1
Sitting disability	1	2	1	1		1
Walking aid user	1	1	1	1		
Water pollution	1	1			1	1
	82	207	24	61	58	146

System Organ Class

**SOC Not Yet Coded**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
	4	22	4	22
	4	22	4	22

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess drainage		1				1
Airway secretion clearance therapy		1				1
Anaphylaxis prophylaxis	1	1			1	1
Asthma prophylaxis		1				1
Axillary lymphadenectomy	1	1			1	1
Bed rest	1	1			1	1
COVID-19 immunisation	3	4		1	3	3
Dermal filler injection	1	1	1	1		
Diabetic diet		1				1
Gastrointestinal surgery	1	1			1	1
Immunisation	1	2			1	2
Limb immobilisation	1	5		4	1	1
Limb operation	1	1			1	1
Mass excision		1		1		
Migraine prophylaxis	1	1			1	1
Multiple sclerosis relapse prophylaxis	1	1			1	1
Prophylaxis of nausea and vomiting		1				1
Splenic artery embolisation	1	1			1	1
Therapeutic procedure	1	1	1	1		
Tooth extraction	1	1			1	1
Weight loss diet		1				1
Wheat-free diet	1	1			1	1
	17	30	2	8	15	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Achenbach syndrome		1				1		
Aneurysm	1	1					1	1
Aortic aneurysm		1						1
Aortic aneurysm rupture		1						1
Aortic arteriosclerosis		1						1
Aortic dissection		1						1
Aortic embolus	3	3					3	3
Aortic stenosis		2						2
Arterial disorder	1	1					1	1
Arterial occlusive disease	1	2					1	2
Arterial rupture		1						1
Arterial stenosis		1						1
Arterial thrombosis	2	3					2	3
Arteritis		1						1
Behcet's syndrome	2	5					2	5
Blood pressure fluctuation	3	10				2	3	8
Bloody discharge	1	1					1	1
Blue toe syndrome	3	6			1	2	2	4
Circulatory collapse	8	51					8	51
CT hypotension complex		2						2
Cyanosis	11	25			6	9	5	16
Deep vein thrombosis	59	98		1			59	98
Diastolic hypertension		1						1
Embolism	37	41					37	41
Essential hypertension		3						3
Extremity necrosis	1	1					1	1
Flushing	46	214		1	28	89	18	125
Giant cell arteritis	1	5					1	5
Haematoma	3	13			1	4	2	9
Haemodynamic instability		1						1
Haemorrhage	38	72	1	2		1	38	71
Hot flush	109	329			56	127	53	202

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertension	78	301
Hypertensive crisis	4	5
Hypertensive urgency	1	1
Hypoperfusion		1
Hypotension	43	175
Hypovolaemic shock	1	1
Infarction	4	6
Internal haemorrhage		1
Ischaemia	2	2
Jugular vein thrombosis	2	3
Labile blood pressure		2
Lymphangiopathy	1	1
Lymphoedema	19	48
MAGIC syndrome		1
Malignant hypertension	2	2
Microembolism	1	1
Neurogenic shock		15
Orthostatic hypertension		1
Orthostatic hypotension	2	10
Pallor	22	119
Pelvic venous thrombosis		2
Peripheral circulatory failure		3
Peripheral coldness	42	160
Peripheral embolism		1
Peripheral ischaemia	3	5
Peripheral vascular disorder		1
Peripheral vein stenosis	1	1
Peripheral vein thrombus extension	1	1
Phlebitis	7	13
Poor peripheral circulation		2
Prehypertension	1	1
Raynaud's phenomenon	7	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	23	77	55	224
				4	5
				1	1
					1
		14	43	29	132
				1	1
				4	6
					1
				2	2
		1	1	1	2
					2
				1	1
	1	2	12	17	36
					1
				2	2
				1	1
					15
					1
		2	3		7
		12	45	10	74
					2
					3
	1	15	51	27	109
					1
		2	2	1	3
			1		
				1	1
				1	1
		5	5	2	8
			2		
		1	1		
		2	7	5	15

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Shock	2	13					2	13
Shock symptom	1	1					1	1
Subclavian vein thrombosis		2						2
Superficial vein prominence		1				1		
Systolic hypertension		2						2
Thrombophlebitis	5	9			3	3	2	6
Thrombophlebitis superficial	3	6			3	3		3
Thrombosis	63	112		1			63	112
Varicose vein	2	6				2	2	4
Vascular pain	2	4			1	2	1	2
Vasculitis	13	26			5	6	8	20
Vasoconstriction		2						2
Vasodilatation	3	9			1	2	2	7
Vasospasm		1				1		
Vein discolouration	1	1			1	1		
Vein disorder	3	7			1	2	2	5
Vein rupture		2						2
Vena cava embolism		1						1
Vena cava thrombosis		1						1
Venous haemorrhage		1						1
Venous thrombosis	4	5					4	5
Venous thrombosis limb	1	1					1	1
	677	2,019	1	8	186	508	491	1511

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED STATES**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal clotting factor	1	2					1	2
Anaemia	2	9			1	4	1	5
Anaemia vitamin B12 deficiency	1	1			1	1		
Autoimmune haemolytic anaemia	1	2					1	2
Blood disorder	3	7			3	5		2
Coagulopathy	6	10			2	3	4	7
Coombs negative haemolytic anaemia		1						1
Disseminated intravascular coagulation	1	2					1	2
Eosinophilia		1				1		
Febrile neutropenia		1						1
Haemolysis	1	1					1	1
Haemolytic anaemia	3	6					3	6
Heparin-induced thrombocytopenia		1						1
Immune thrombocytopenia	5	21					5	21
Increased tendency to bruise		2				2		
Leukocytosis		6				2		4
Lymphadenitis	2	19			2	16		3
Lymphadenopathy	190	981	1	1	178	919	12	62
Lymph node pain	34	197			31	185	3	12
Lymphocytosis		1				1		
Lymphopenia		1						1
Microangiopathic haemolytic anaemia	1	1					1	1
Neutropenia	1	4					1	4
Neutropenia neonatal		1						1
Normocytic anaemia		1				1		
Pancytopenia		4						4
Platelet disorder	2	4			1	2	1	2
Polycythaemia		1				1		
Red blood cell abnormality	1	1					1	1
Sickle cell anaemia with crisis	2	2					2	2
Spleen disorder	1	1					1	1
Splenic infarction	1	1					1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Splenic vein thrombosis		1							1
Splenomegaly		3			1				2
Thrombocytopenia	14	29					14		29
Thrombotic microangiopathy	1	1					1		1
	274	1,327	1	1	219	1144	55		183

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute coronary syndrome	1	2					1	2
Acute myocardial infarction	3	7					3	7
Angina pectoris	19	35					19	35
Angina unstable		1						1
Aortic valve disease		1						1
Arrhythmia	21	58					21	58
Arrhythmia supraventricular		1						1
Arteriosclerosis coronary artery	1	1			1	1		
Arteriospasm coronary	1	3					1	3
Atrial fibrillation	40	119				1	40	118
Atrial flutter	5	6			2	2	3	4
Atrioventricular block	1	1					1	1
Atrioventricular block complete	1	1					1	1
Bradycardia	5	7					5	7
Bundle branch block left	1	1					1	1
Cardiac arrest	17	39					17	39
Cardiac discomfort	1	4			1	4		
Cardiac disorder	24	55			15	33	9	22
Cardiac failure	1	5					1	5
Cardiac failure chronic		1						1
Cardiac failure congestive	2	10					2	10
Cardiac fibrillation	1	2					1	2
Cardiac flutter	18	37					18	37
Cardiac valve disease		2				1		1
Cardiac valve sclerosis		1						1
Cardiogenic shock		3						3
Cardiomyopathy	1	5					1	5
Cardio-respiratory arrest	1	4					1	4
Cardiovascular disorder	2	5			2	4		1
Congestive cardiomyopathy		1						1
Coronary artery disease		1						1
Coronary artery occlusion		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cor pulmonale acute	1	1
Dilatation ventricular		1
Extrasystoles	4	12
Heart valve incompetence	2	2
Hypertensive heart disease		1
Intracardiac thrombus	1	2
Mitral valve disease	1	1
Mitral valve incompetence		1
Mitral valve prolapse		1
Myocardial infarction	39	99
Myocarditis	9	19
Nodal rhythm		1
Palpitations	85	443
Pericardial disease		1
Pericardial effusion	2	11
Pericarditis	5	22
Postural orthostatic tachycardia syndrome	2	8
Prinzmetal angina	1	2
Pulseless electrical activity	1	1
Right ventricular dysfunction		1
Sinus bradycardia		3
Sinus tachycardia		9
Supraventricular extrasystoles	1	5
Supraventricular tachycardia		8
Tachycardia	28	283
Tachycardia foetal		1
Torsade de pointes		1
Tricuspid valve incompetence	1	1
Ventricular arrhythmia		2
Ventricular extrasystoles	4	21
Ventricular fibrillation		4
Ventricular hypertrophy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		4	11		1
		1	1	1	1
					1
				1	2
				1	1
					1
					1
		1	1	38	98
				9	19
			1		
		62	341	23	102
					1
				2	11
				5	22
1	1	1	2	1	6
				1	2
				1	1
					1
			1		2
			4		5
		1	3		2
			2		6
		11	177	17	106
					1
					1
				1	1
					2
		3	12	1	9
					4
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ventricular tachycardia	354	1,393	1	1	105	602	249	791

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anomalous pulmonary venous connection		1				1
Cerebral palsy	3	3			3	3
Dermoid cyst		1				1
Ductus arteriosus premature closure		1				1
Factor V Leiden mutation	1	1			1	1
Foetal cystic hygroma		1				1
Hereditary haemorrhagic telangiectasia		1		1		
Huntington's disease	1	1	1	1		
Macroglossia	1	2			1	2
Methylenetetrahydrofolate reductase gene mutation	1	1	1	1		
Porphyria acute		1				1
Retinitis pigmentosa		1				1
Tourette's disorder	1	1			1	1
Type V hyperlipidaemia	1	2			1	2
Von Willebrand's disease		1				1
	9	19	2	3	7	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling	1	2		1	1	1
Cerumen impaction	1	1	1	1		
Conductive deafness		1				1
Deafness	36	84	1	2	35	82
Deafness bilateral	1	2			1	2
Deafness neurosensory	3	12			3	12
Deafness transitory	2	4			2	4
Deafness unilateral	15	38			15	38
Ear congestion	3	8	2	5	1	3
Ear discomfort	25	82	21	74	4	8
Ear disorder	5	19	5	16		3
Ear haemorrhage		1		1		
Ear pain	44	155	36	138	8	17
Ear pruritus	8	18	7	17	1	1
Ear swelling	3	18	2	15	1	3
Eustachian tube disorder		1		1		
Eustachian tube dysfunction	1	2	1	1		1
Excessive cerumen production	3	5	3	5		
External ear disorder		1		1		
External ear pain	1	2	1	2		
Hyperacusis	7	20	6	17	1	3
Hypoacusis	20	70	15	59	5	11
Inner ear disorder	1	3	1	2		1
Mastoid disorder	1	2	1	1		1
Meniere's disease	4	6			4	6
Middle ear effusion		1		1		
Motion sickness	1	9		8	1	1
Otorrhoea		1		1		
Paraesthesia ear		1		1		
Red ear syndrome		1		1		
Sudden hearing loss	6	9			6	9
Tinnitus	138	300	97	220	41	80

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	77	263	51	214	26	49
Vertigo positional	4	8	3	5	1	3
Vestibular disorder	2	3	1	2	1	1
	413	1,153	255	812	158	341

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal disorder	1	3	1	2		1
Adrenal insufficiency		2				2
Adrenocortical insufficiency acute		2				2
Autoimmune thyroid disorder	1	1			1	1
Autoimmune thyroiditis	2	6			2	6
Basedow's disease	2	3			2	3
Goitre	1	4	1	3		1
Hyperparathyroidism		1		1		
Hyperthyroidism	1	1			1	1
Hypothyroidism	1	5		1	1	4
Thyroid disorder	4	8	3	7	1	1
Thyroiditis	1	3	1	3		
Thyroiditis acute		1				1
Thyroiditis subacute	1	3		2	1	1
Thyroid mass	2	3	1	2	1	1
Thyroid pain	2	4	2	4		
Thyrotoxic crisis	3	3			3	3
	22	53	9	25	13	28

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	2	8	2	8		
Altered visual depth perception	1	1	1	1		
Amaurosis fugax		1				1
Angle closure glaucoma	1	1			1	1
Anterior chamber cell		1				1
Asthenopia	8	25	7	23	1	2
Binocular eye movement disorder	1	1			1	1
Blepharitis		1		1		
Blepharochalasis		1		1		
Blepharospasm	3	10	3	10		
Blindness	12	35			12	35
Blindness transient	3	11			3	11
Blindness unilateral	5	11			5	11
Cataract	4	7		1	4	6
Cataract nuclear		1				1
Chalazion		1		1		
Chromatopsia		3		3		
Ciliary muscle spasm		1		1		
Conjunctival haemorrhage	6	10			6	10
Conjunctival hyperaemia		1				1
Conjunctival irritation		1		1		
Conjunctival oedema		1		1		
Conjunctivitis allergic		3		3		
Corneal disorder		1				1
Corneal infiltrates		1				1
Corneal oedema		1		1		
Diplopia	18	35	15	27	3	8
Dry eye	5	24	5	23		1
Dyschromatopsia		1		1		
Endocrine ophthalmopathy	1	2			1	2
Episcleritis		2		2		
Erythema of eyelid	2	11	1	8	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Excessive ocular convergence	1	1			1	1
Exophthalmos	2	3			2	3
Extraocular muscle disorder	1	1	1	1		
Extraocular muscle paresis	2	3			2	3
Eye allergy		2		2		
Eye colour change	1	2		1	1	1
Eye discharge	4	14	4	14		
Eye disorder	22	55	19	45	3	10
Eye haemorrhage	19	36			19	36
Eye inflammation	1	9	1	6		3
Eye irritation	8	52	8	48		4
Eyelid disorder	3	6	2	5	1	1
Eyelid function disorder	2	4		2	2	2
Eyelid haematoma		1		1		
Eyelid irritation	1	3		2	1	1
Eyelid oedema	2	4	2	4		
Eyelid pain	5	12	5	11		1
Eyelid ptosis	5	14	3	8	2	6
Eyelid sensory disorder	1	2	1	2		
Eyelids pruritus	3	7	2	5	1	2
Eyelid vascular disorder	1	1	1	1		
Eye movement disorder	4	12	3	7	1	5
Eye oedema	1	8	1	8		
Eye pain	31	136	28	123	3	13
Eye paraesthesia		2		1		1
Eye pruritus	11	68	10	58	1	10
Eye swelling	33	142	23	108	10	34
Eye ulcer		1		1		
Foreign body sensation in eyes	2	4	2	4		
Glare		2		2		
Glaucoma	1	6			1	6
Heterophoria	1	1			1	1

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypermetropia		1
Hypoaesthesia eye	2	8
Iridocyclitis	2	3
Iritis	1	2
Keratic precipitates		2
Keratitis		2
Lacrimonal disorder		1
Lacrimation decreased		1
Lacrimation increased	12	63
Macular degeneration		5
Macular hole		1
Macular oedema		1
Maculopathy	1	1
Metamorphopsia		1
Miosis	1	2
Mydriasis	4	6
Myopia		1
Necrotising retinitis	1	1
Ocular discomfort	15	39
Ocular hyperaemia	15	74
Ocular vascular disorder	3	3
Ophthalmic vein thrombosis	1	1
Optic ischaemic neuropathy	3	3
Optic nerve disorder	1	1
Orbital oedema	1	2
Periorbital discomfort		1
Periorbital disorder		2
Periorbital oedema		3
Periorbital pain		2
Periorbital swelling	4	35
Photophobia	10	48
Photopsia	3	13

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	8		
		2	3
1	2		
			2
	1		1
	1		
			1
10	57	2	6
			5
			1
			1
		1	1
			1
1	2		
4	6		
	1		
		1	1
15	35		4
13	65	2	9
2	2	1	1
		1	1
		3	3
		1	1
		1	2
	1		
	2		
	2		1
	1		1
3	29	1	6
8	45	2	3
2	8	1	5

\* I=Interval, C=Cumulative  
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pupil fixed	1	1			1	1
Pupillary disorder	1	2	1	2		
Pupils unequal	1	1			1	1
Retinal artery occlusion	1	3			1	3
Retinal detachment	2	3			2	3
Retinal disorder		1		1		
Retinal haemorrhage	1	1			1	1
Retinal tear	2	3			2	3
Retinal vascular thrombosis	2	2	1	1	1	1
Retinal vein occlusion	4	6			4	6
Retinopathy hypertensive		1				1
Scleral discolouration		1		1		
Scleral haemorrhage	1	1			1	1
Scleritis	1	3			1	3
Strabismus	1	5		1	1	4
Sudden visual loss	2	2			2	2
Swelling of eyelid	11	43	8	38	3	5
Uveitis		4				4
Vision blurred	61	205	42	153	19	52
Visual acuity reduced	4	8	4	7		1
Visual impairment	35	114	23	84	12	30
Vitreous degeneration		2				2
Vitreous detachment	2	3			2	3
Vitreous floaters	3	9	1	5	2	4
Xanthopsia		1		1		
	456	1,582	291	1150	165	432

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	63	232			60	220	3	12
Abdominal distension	16	57			15	53	1	4
Abdominal pain	49	227			35	185	14	42
Abdominal pain lower	5	24			4	18	1	6
Abdominal pain upper	98	320			84	286	14	34
Abdominal rigidity	3	7			3	6		1
Abdominal symptom		1				1		
Abdominal tenderness	1	1			1	1		
Abdominal wall haematoma		1						1
Abdominal wall haemorrhage		1						1
Abnormal faeces	1	8				6	1	2
Achlorhydria	1	1			1	1		
Anal haemorrhage	2	3			1	2	1	1
Anal incontinence	6	10			5	9	1	1
Anal pruritus	1	1			1	1		
Anal skin tags		1				1		
Angular cheilitis		1				1		
Anorectal discomfort	1	3			1	3		
Aphthous ulcer	3	10			3	10		
Appendix disorder	1	1					1	1
Aptyalism		2				2		
Barrett's oesophagus	1	1					1	1
Bowel movement irregularity	5	16			5	16		
Breath odour		3				2		1
Burning mouth syndrome		1				1		
Cardiospasm	4	4			3	3	1	1
Chapped lips	2	5			2	5		
Cheilitis	1	4			1	3		1
Colitis	7	10			5	7	2	3
Colitis ischaemic	3	3					3	3
Colitis microscopic		1						1
Colitis ulcerative	4	7					4	7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Constipation	21	59
Crohn's disease	2	6
Defaecation disorder	1	1
Defaecation urgency	2	5
Dental caries	1	1
Dental discomfort	1	9
Dental paraesthesia	1	3
Diarrhoea	257	1,077
Diarrhoea haemorrhagic	5	16
Diverticulum intestinal		1
Dry mouth	30	121
Dumping syndrome	1	1
Duodenogastric reflux	1	2
Dyspepsia	23	78
Dysphagia	46	172
Enlarged uvula	3	10
Enteritis		1
Eosinophilic oesophagitis	1	1
Epigastric discomfort	1	1
Erosive oesophagitis		1
Eructation	4	13
Faecaloma	1	1
Faeces discoloured	11	18
Faeces pale	1	1
Faeces soft	3	7
Flatulence	13	43
Food poisoning	2	4
Frequent bowel movements	2	10
Functional gastrointestinal disorder	3	4
Gastric dilatation	1	1
Gastric disorder	10	23
Gastric haemorrhage	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		18	54	3	5
			1	2	5
		1	1		
		2	5		
		1	1		
		1	9		
		1	3		
		224	984	33	93
				5	16
					1
		23	104	7	17
		1	1		
		1	2		
		20	74	3	4
1	1	32	114	14	58
		2	6	1	4
					1
		1	1		
		1	1		
					1
		3	12	1	1
				1	1
		10	16	1	2
		1	1		
		2	4	1	3
		13	41		2
		2	4		
		1	9	1	1
		3	4		
		1	1		
		9	22	1	1
				1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric ulcer		2
Gastritis	2	6
Gastrointestinal disorder	14	52
Gastrointestinal haemorrhage	4	10
Gastrointestinal hypomotility	1	2
Gastrointestinal inflammation		1
Gastrointestinal motility disorder		2
Gastrointestinal oedema		1
Gastrointestinal pain	11	26
Gastrointestinal sounds abnormal	1	7
Gastrointestinal tract irritation	2	2
Gastrooesophageal reflux disease	10	39
Gingival bleeding	2	9
Gingival blister		2
Gingival discolouration		1
Gingival discomfort	1	2
Gingival disorder		1
Gingival erythema		4
Gingival pain		11
Gingival recession		1
Gingival swelling	2	14
Gingival ulceration		1
Glossitis		7
Glossodynia	8	34
Haematemesis	5	11
Haematochezia	18	48
Haemorrhoidal haemorrhage		1
Haemorrhoids	4	9
Hiatus hernia		1
Hyperaesthesia teeth		4
Hyperchlorhydria		1
Hypoaesthesia oral	41	216

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		2	5		1
		13	46	1	6
				4	10
		1	1		1
			1		
			2		
					1
		9	23	2	3
		1	7		
		2	2		
		10	37		2
		1	7	1	2
			1		1
					1
		1	1		1
			1		
			4		
			9		2
			1		
		2	14		
			1		
			7		
		8	32		2
				5	11
		1	1	17	47
			1		
		3	7	1	2
			1		
			4		
					1
		33	171	8	45

\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoesthesia teeth		2
Ileus		1
Impaired gastric emptying	2	2
Infantile vomiting		2
Inflammatory bowel disease		1
Infrequent bowel movements		1
Intestinal haemorrhage	2	2
Intestinal ischaemia		1
Intestinal obstruction		2
Intestinal perforation		1
Intra-abdominal haematoma		1
Irritable bowel syndrome	5	10
Large intestinal haemorrhage		1
Large intestinal obstruction		1
Large intestine perforation	1	1
Large intestine polyp		1
Lip blister	3	11
Lip discolouration		1
Lip disorder	3	11
Lip dry		2
Lip erythema	1	6
Lip exfoliation		1
Lip haemorrhage	1	1
Lip oedema		8
Lip pain	1	6
Lip pruritus		15
Lip swelling	42	186
Lip ulceration		1
Lower gastrointestinal haemorrhage		1
Melaena	1	2
Mesenteric artery aneurysm	1	1
Mesenteric panniculitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					1
				2	2
			2		
					1
			1		
				2	2
					1
					2
					1
					1
		4	8	1	2
					1
					1
			1	1	1
		2	8	1	3
					1
		3	11		
			2		
		1	5		1
			1		
				1	1
			5		3
		1	6		
			9		6
		31	134	11	52
			1		
					1
				1	2
				1	1
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mesenteric vein thrombosis	1	1
Mouth haemorrhage	1	6
Mouth swelling	6	36
Mouth ulceration	4	14
Mucous stools	1	4
Nausea	556	2,733
Noninfective gingivitis		4
Odynophagia	5	20
Oedema mouth		1
Oesophageal achalasia	1	1
Oesophageal disorder		2
Oesophageal pain		3
Oesophageal stenosis	1	1
Oesophagitis	1	1
Oral blood blister	1	2
Oral discomfort	8	34
Oral disorder	2	17
Oral dysaesthesia		1
Oral lichen planus	1	1
Oral mucosal blistering	3	10
Oral mucosal eruption		6
Oral mucosal erythema		4
Oral mucosal exfoliation		1
Oral mucosal roughening	1	1
Oral pain	11	32
Oral pruritus	5	23
Palatal disorder		2
Palatal swelling	2	9
Pancreatic disorder	2	3
Pancreatitis	2	11
Pancreatitis acute	3	7
Paraesthesia oral	35	263

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			4	1	2
		5	25	1	11
		4	13		1
		1	4		
1	1	478	2479	78	254
			4		
		5	16		4
					1
		1	1		
			1		1
			3		
				1	1
		1	1		
				1	2
		7	31	1	3
		2	15		2
					1
		1	1		
		2	9	1	1
			5		1
			3		1
			1		
		1	1		
		10	29	1	3
		4	16	1	7
			1		1
		2	7		2
		1	1	1	2
				2	11
				3	7
		27	212	8	51

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Parotid duct obstruction		1
Plicated tongue		1
Proctalgia		2
Rectal discharge		1
Rectal haemorrhage	4	12
Rectal tenesmus		1
Regurgitation		1
Retching	7	51
Saliva discolouration		1
Salivary gland disorder	2	3
Salivary gland enlargement		2
Salivary gland pain		1
Salivary hypersecretion	7	13
Small intestinal haemorrhage	1	2
Small intestinal obstruction	1	3
Stiff tongue		1
Stomatitis	6	29
Strawberry tongue		1
Swollen tongue	47	168
Teeth brittle	1	1
Tongue blistering	3	7
Tongue coated		3
Tongue discolouration	2	7
Tongue discomfort	7	30
Tongue disorder	6	29
Tongue dry		6
Tongue eruption	2	4
Tongue erythema	2	8
Tongue haematoma		1
Tongue haemorrhage		1
Tongue movement disturbance	2	3
Tongue oedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			2		
			1		
				4	12
			1		
			1		
1	1	5	43	2	8
					1
		1	2	1	1
			2		
			1		
		4	10	3	3
				1	2
				1	3
					1
		5	25	1	4
			1		
1	1	22	93	25	75
		1	1		
		2	6	1	1
			3		
		1	5	1	2
		5	26	2	4
		5	24	1	5
			6		
		2	2		2
		2	8		
			1		
			1		
		2	2		1
			1		1

\* I=Interval, C=Cumulative

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue pruritus	3	16			2	12	1	4
Tongue ulceration	1	6			1	5		1
Toothache	19	58			17	51	2	7
Tooth discolouration	1	1			1	1		
Tooth disorder	3	10			3	9		1
Tooth loss		1						1
Upper gastrointestinal haemorrhage	1	1					1	1
Uvulitis		1				1		
Volvulus		1						1
Vomiting	235	916	1	1	173	762	62	154
Vomiting projectile	5	13			5	13		
	1,937	8,146	5	5	1544	6907	393	1239

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 \* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adhesion		1						1
Administration site erythema		1				1		
Administration site irritation	1	1			1	1		
Administration site reaction		1				1		
Adverse drug reaction		1				1		
Adverse event	5	11			5	11		
Application site erythema	1	1			1	1		
Application site haemorrhage		1						1
Application site swelling	1	1			1	1		
Asthenia	298	1,135			245	974	53	161
Axillary pain	28	143			25	138	3	5
Brain death		2						2
Chest discomfort	112	417			87	301	25	116
Chest pain	118	437			72	301	46	136
Chills	732	3,916			676	3688	56	228
Chronic fatigue syndrome	1	1			1	1		
Complication associated with device		2						2
Condition aggravated	97	328			66	246	31	82
Crying	6	33			4	28	2	5
Cyst		3				3		
Cyst rupture		1				1		
Death	41	117	1	1			41	117
Decreased activity		1				1		
Discharge		1				1		
Discomfort	36	156			35	145	1	11
Disease progression		3				2		1
Disease recurrence	27	115			10	63	17	52
Drowning	1	1					1	1
Drug effective for unapproved indication	1	1			1	1		
Drug ineffective	534	1,675	2	4		1	534	1674
Drug interaction	7	26			4	18	3	8
Enanthema		1				1		

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Energy increased	5	13
Exercise tolerance decreased		3
Extensive swelling of vaccinated limb		1
Face oedema	2	7
Facial discomfort	3	12
Facial pain	14	71
Fatigue	968	4,303
Feeling abnormal	298	1,024
Feeling cold	50	271
Feeling drunk	5	24
Feeling hot	102	485
Feeling jittery	4	30
Feeling of body temperature change	19	69
Feeling of relaxation	1	1
Fever neonatal	2	2
Foaming at mouth	2	2
Gait disturbance	86	292
Gait inability	21	85
General physical health deterioration	3	7
Glassy eyes	1	7
Hangover	3	17
Hernia		1
Hunger	1	10
Hyperpyrexia	6	10
Hyperthermia		2
Hypothermia	1	7
Idiosyncratic drug reaction		1
Ill-defined disorder	1	3
Illness	180	469
Impaired healing	1	4
Impaired self-care	1	1
Induration		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	13		
			3		
			1		
		1	4	1	3
		3	12		
		11	62	3	9
2	3	898	4077	70	226
		265	933	33	91
		42	245	8	26
		4	20	1	4
		85	420	17	65
		4	25		5
		17	64	2	5
		1	1		
				2	2
		2	2		
		57	215	29	77
		10	48	11	37
		2	2	1	5
			6	1	1
		3	15		2
					1
		1	10		
				6	10
			2		
				1	7
			1		
		1	3		
1	1	156	424	24	45
		1	3		1
				1	1
			6		1

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Inflammation	26	80
Inflammatory pain		2
Influenza like illness	104	412
Inhibitory drug interaction		1
Injected limb mobility decreased	2	8
Injection site bruising	2	7
Injection site discolouration		2
Injection site discomfort	1	8
Injection site erythema	12	47
Injection site extravasation	1	5
Injection site haematoma		1
Injection site haemorrhage	1	6
Injection site indentation		1
Injection site induration		2
Injection site inflammation		1
Injection site mass		6
Injection site nodule	1	2
Injection site oedema		1
Injection site pain	23	176
Injection site papule		1
Injection site pruritus	2	14
Injection site rash		12
Injection site reaction	1	5
Injection site swelling	9	40
Injection site urticaria		2
Injection site warmth	2	11
Instillation site pain		1
Irritability postvaccinal		1
Localised oedema	1	4
Local reaction		1
Loss of control of legs	1	4
Malaise	333	1,477

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		23	71	3	9
			2		
		95	385	9	27
			1		
		2	8		
		2	7		
			2		
		1	8		
		12	47		
		1	5		
					1
		1	6		
			1		
			2		
			1		
			6		
		1	2		
			1		
		23	174		2
			1		
		2	14		
			12		
		1	5		
		9	40		
			2		
		2	11		
			1		
			1		
		1	3		1
			1		
				1	4
		307	1378	26	99

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mass	11	39
Moaning	2	3
Mucosal disorder		6
Mucosal dryness		1
Mucosal inflammation		1
Mucosa vesicle		1
Multi-organ disorder	2	2
Multiple organ dysfunction syndrome		3
Necrosis	1	1
No adverse event	31	80
Nodule	7	15
Non-pitting oedema	1	1
Oedema	1	13
Oedema peripheral	5	18
Organ failure	1	1
Pain	700	3,383
Pelvic mass	2	2
Peripheral swelling	131	507
Physical deconditioning		1
Polyserositis		1
Potentiating drug interaction	2	11
Pre-existing condition improved	2	5
Pyrexia	773	3,905
Screaming	2	6
Secretion discharge	9	16
Sensation of blood flow		2
Sensation of foreign body	3	45
Sensitivity to weather change	1	4
Shoulder injury related to vaccine administration	1	2
Sluggishness	12	29
Stenosis		1
Sudden cardiac death		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	35	1	4
		2	3		
			5		1
			1		
			1		
					1
		1	1	1	1
					3
				1	1
		31	80		
		5	13	2	2
				1	1
		1	11		2
		4	14	1	4
				1	1
1	1	634	3172	66	211
				2	2
1	1	111	454	20	53
			1		
					1
		2	11		
		2	5		
		696	3619	77	286
		1	4	1	2
		8	14	1	2
					2
		3	34		11
		1	4		
		1	2		
		10	27	2	2
					1
					2

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sudden death	2	3
Swelling	90	357
Swelling face	88	320
Systemic inflammatory response syndrome		3
Temperature intolerance	1	10
Temperature regulation disorder		4
Tenderness	19	62
Therapeutic product effect delayed	1	1
Therapeutic product effect incomplete		1
Therapeutic product effect prolonged		1
Therapeutic response unexpected	28	67
Thirst	14	51
Thirst decreased		1
Ulcer		6
Ulcer haemorrhage		1
Vaccination site bruising	11	67
Vaccination site coldness	1	8
Vaccination site discharge	1	4
Vaccination site discolouration	6	25
Vaccination site discomfort	10	51
Vaccination site dryness	1	1
Vaccination site erythema	72	473
Vaccination site exfoliation	1	1
Vaccination site extravasation	5	13
Vaccination site haematoma		2
Vaccination site haemorrhage	16	57
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity		4
Vaccination site hypoaesthesia	7	27
Vaccination site induration	5	51
Vaccination site inflammation	4	20
Vaccination site injury		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
		79	307	11	50
		68	242	20	78
					3
		1	8		2
			4		
		18	58	1	4
		1	1		
					1
			1		
		28	67		
		13	47	1	4
			1		
			5		1
					1
		11	63		4
		1	8		
		1	4		
		6	24		1
		10	49		2
		1	1		
		71	453	1	20
		1	1		
		5	13		
			1		1
		16	54		3
			1		
			4		
		6	25	1	2
		5	49		2
		4	18		2
			4		

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site irritation	4	9
Vaccination site joint erythema		2
Vaccination site joint movement impairment	2	14
Vaccination site joint pain	2	11
Vaccination site joint swelling	1	2
Vaccination site lymphadenopathy	5	18
Vaccination site macule		5
Vaccination site mass	25	114
Vaccination site movement impairment	6	52
Vaccination site nodule	1	12
Vaccination site oedema	2	7
Vaccination site pain	379	2,489
Vaccination site pallor		1
Vaccination site papule		3
Vaccination site paraesthesia	4	31
Vaccination site pruritus	50	243
Vaccination site rash	28	114
Vaccination site reaction	6	35
Vaccination site scab		4
Vaccination site scar	1	2
Vaccination site streaking	1	1
Vaccination site swelling	77	457
Vaccination site thrombosis	1	1
Vaccination site ulcer		1
Vaccination site urticaria	6	46
Vaccination site vesicles	1	13
Vaccination site warmth	24	207
Vessel puncture site haemorrhage		1
Vessel puncture site injury		1
	7,058	31,816

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	9		
			1		1
		2	11		3
		2	9		2
		1	1		1
		5	17		1
			5		
		24	108	1	6
		6	51		1
		1	11		1
		2	5		2
2	2	368	2428	11	61
			1		
			3		
		4	28		3
		49	230	1	13
		26	107	2	7
		5	33	1	2
			4		
		1	2		
		1	1		
		74	438	3	19
				1	1
			1		
		5	42	1	4
		1	13		
		24	198		9
			1		
			1		
		10	13	1298	4287

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System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure		2				2
Biliary tract disorder	2	2	1	1	1	1
Cholecystitis	1	2			1	2
Cholelithiasis	1	1			1	1
Cholestasis	1	4			1	4
Gallbladder disorder	2	9		4	2	5
Gallbladder oedema	1	1			1	1
Gallbladder polyp		1		1		
Hepatic cirrhosis		1				1
Hepatic cyst		1		1		
Hepatic function abnormal	1	1			1	1
Hepatic haemorrhage	1	1			1	1
Hepatic lesion		1				1
Hepatic necrosis		1				1
Hepatic pain	1	3		1	1	2
Hepatitis	2	5			2	5
Hepatitis acute		2				2
Hepatomegaly	1	3	1	2		1
Hyperbilirubinaemia	1	1			1	1
Jaundice	5	12	1	4	4	8
Liver disorder	2	6	1	4	1	2
Liver injury	2	4			2	4
Liver tenderness		1		1		
Ocular icterus		1		1		
Portal vein thrombosis	6	6			6	6
	30	72	4	20	26	52

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient		2		2		
Allergy to arthropod sting	1	2	1	2		
Allergy to chemicals	1	1	1	1		
Allergy to vaccine	10	73	4	50	6	23
Amyloidosis		1				1
Anaphylactic reaction	113	320	1	2	112	318
Anaphylactic shock	11	23			11	23
Anaphylactoid reaction		5				5
Autoimmune disorder	9	22			9	22
Contrast media allergy		1		1		
Corneal graft rejection		1				1
Cytokine storm		1				1
Drug hypersensitivity	10	47	9	42	1	5
Food allergy	3	4	2	3	1	1
Haemophagocytic lymphohistiocytosis		1				1
Hypersensitivity	109	340	81	237	28	103
Immune system disorder	10	27	7	19	3	8
Immunisation reaction	1	1			1	1
Immunodeficiency	2	7			2	7
Immunosuppression		1				1
Multiple allergies	1	1	1	1		
Reaction to excipient	2	10	2	7		3
Reaction to preservatives	2	2	2	2		
Rubber sensitivity		1		1		
Sarcoidosis	2	2			2	2
Seasonal allergy	6	14	6	14		
Sensitisation		2		2		
Serum sickness	1	2	1	1		1
Systemic immune activation		1				1
Type III immune complex mediated reaction		1				1
Type IV hypersensitivity reaction		2		2		
	294	918	118	389	176	529

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal infection	2	2					2	2
Abscess	1	1					1	1
Acarodermatitis		2				1		1
Amniotic cavity infection	1	1					1	1
Anal infection		1				1		
Appendicitis	22	45					22	45
Appendicitis perforated	6	7					6	7
Arthropod infestation		1						1
Asymptomatic COVID-19	15	52			3	14	12	38
Atypical pneumonia		1						1
Bacteraemia		2						2
Bacterial infection	3	5			2	3	1	2
Bacterial pyelonephritis	1	1					1	1
Bacterial vaginosis	2	2			2	2		
Bacteriuria		1						1
Body tinea		1				1		
Bronchitis	12	29			7	21	5	8
Candida infection	1	4			1	4		
Cardiac valve vegetation		1						1
Cellulitis	17	39					17	39
Cellulitis gangrenous		1						1
Cholecystitis infective	1	1					1	1
Clostridium difficile colitis	1	1					1	1
Clostridium difficile infection	1	2					1	2
Coccidioidomycosis		2						2
Complicated appendicitis	1	1					1	1
Conjunctivitis	2	11			2	11		
Conjunctivitis viral		1				1		
Corneal infection		1						1
Coronavirus infection		1				1		
COVID-19	882	2,157	3	5	279	569	603	1588

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
COVID-19 pneumonia	11	42
Cystitis	6	18
Cystitis bacterial	1	1
Cystitis escherichia	1	1
Dermatophytosis of nail	1	1
Dermo-hypodermatitis	1	1
Diabetic foot infection		1
Disseminated varicella zoster virus infection	1	1
Diverticulitis	12	23
Dysentery	1	4
Ear infection	9	21
Ear infection viral	1	1
Ebola disease		1
Encephalitis	1	6
Endocarditis		2
Epstein-Barr virus infection reactivation		1
Escherichia bacteraemia	1	1
Escherichia infection		1
Escherichia urinary tract infection	1	1
Eye infection		6
Eyelid infection		1
Folliculitis	1	3
Fungal infection	2	8
Fungal peritonitis	1	1
Fungal skin infection	1	1
Furuncle		2
Gangrene	1	1
Gastric infection		1
Gastritis bacterial		1
Gastroenteritis	1	2
Gastroenteritis viral	6	12
Gastrointestinal infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				11	42
		5	12	1	6
		1	1		
				1	1
		1	1		
		1	1		
			1		
				1	1
				12	23
				1	4
		8	17	1	4
		1	1		
					1
				1	6
					2
					1
				1	1
					1
				1	1
			6		
			1		
		1	3		
		2	7		1
				1	1
		1	1		
			2		
				1	1
					1
		1	1		1
		4	8	2	4
			1		

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gastrointestinal viral infection		1
Genital herpes	2	5
Genital herpes simplex		2
Gingivitis	1	2
Haemorrhagic varicella syndrome		1
Helicobacter infection		1
Hepatitis D	1	1
Herpes simplex	2	13
Herpes simplex reactivation		2
Herpes virus infection	3	11
Herpes zoster	75	231
Herpes zoster oticus	2	3
Hordeolum	1	7
Impetigo		1
Infection	12	32
Infection parasitic		1
Infectious mononucleosis	3	4
Influenza	32	104
Kidney infection	7	16
Labyrinthitis		3
Large intestine infection	1	1
Laryngitis	3	9
Lip infection		1
Localised infection	3	11
Lower respiratory tract infection	3	8
Lyme disease	1	3
Lymphangitis		1
Lymph gland infection		2
Mastitis	3	6
Measles	2	2
Meningitis	2	4
Meningitis aseptic		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	4	1	1
			2		
		1	2		
					1
					1
				1	1
		2	12		1
			2		
		2	10	1	1
		63	197	12	34
				2	3
		1	6		1
			1		
		7	20	5	12
			1		
		2	3	1	1
		29	97	3	7
				7	16
					3
				1	1
		2	7	1	2
			1		
		2	10	1	1
				3	8
				1	3
					1
			2		
				3	6
				2	2
				2	4
					2

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Meningitis viral		7
Nasopharyngitis	84	268
Nipple infection	1	1
Omphalitis	1	1
Ophthalmic herpes simplex		1
Oral candidiasis	2	6
Oral fungal infection	1	3
Oral herpes	12	55
Oral viral infection		2
Orchitis		2
Osteomyelitis		3
Otitis media	2	2
Pelvic inflammatory disease		1
Periodontitis		1
Periorbital cellulitis		1
Pertussis		1
Pharyngitis	5	9
Pharyngitis streptococcal	1	7
Pneumocystis jirovecii pneumonia		1
Pneumonia	33	107
Pneumonia bacterial		1
Pneumonia staphylococcal	1	1
Pneumonia viral	1	3
Postoperative wound infection		1
Post procedural infection		1
Post viral fatigue syndrome	1	1
Prostate infection		1
Pseudomonas infection	1	1
Pustule	1	9
Rash pustular		2
Respiratory tract infection	2	8
Retinitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					7
		80	261	4	7
		1	1		
				1	1
					1
		2	6		
		1	3		
		10	52	2	3
			2		
			1		1
					3
		2	2		
					1
			1		
					1
		4	7	1	2
			6	1	1
					1
				33	107
					1
				1	1
				1	3
					1
					1
		1	1		
					1
				1	1
			5	1	4
			2		
				2	8
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rhinitis		5
Rhinovirus infection		2
Root canal infection	1	1
Scrotal infection		1
Sepsis	8	21
Sialoadenitis	1	4
Sinusitis	30	73
Sinusitis bacterial		2
Skin bacterial infection	1	1
Skin infection	2	2
Staphylococcal infection	3	6
Staphylococcal skin infection		1
Streptobacillus infection		1
Streptococcal infection		3
Subcutaneous abscess	1	3
Suspected COVID-19	34	103
Sweating fever	1	1
Syphilis		1
Tetanus	1	1
Tinea pedis	1	1
Tongue fungal infection	1	1
Tonsillitis		2
Tooth abscess	3	4
Tooth infection	4	10
Tracheitis		1
Tuberculosis		2
Upper respiratory tract infection	2	9
Urinary tract infection	30	84
Urinary tract infection bacterial		3
Urosepsis		1
Vaccination site cellulitis	2	16
Vaccination site infection		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		1
			2		
		1	1		
					1
				8	21
				1	4
		25	67	5	6
					2
				1	1
		1	1	1	1
				3	6
					1
					1
			2		1
			1	1	2
		13	35	21	68
				1	1
					1
				1	1
		1	1		
		1	1		
			2		
		3	3		1
		3	9	1	1
			1		
					2
		2	9		
		21	58	9	26
					3
					1
			4	2	12
			8		

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pustule	1	2			1	2		
Vaginal infection		2				2		
Varicella	1	3			1	3		
Varicella zoster virus infection		1				1		
Vestibular neuronitis	1	3				1	1	2
Viral infection	2	6			1	3	1	3
Viral myocarditis		1						1
Viral rash		1				1		
Viral upper respiratory tract infection		2				1		1
Vulvovaginal mycotic infection	1	3			1	3		
Wound infection	1	1					1	1
	1,473	3,945	3	5	610	1647	863	2298

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accident	4	6			1	2	3	4
Accidental exposure to product	5	41			5	41		
Accidental overdose	2	46			2	43		3
Accidental underdose		4				4		
Adverse event following immunisation	1	1			1	1		
Animal bite	1	2			1	2		
Ankle fracture	3	3					3	3
Arthropod bite	3	9			3	9		
Arthropod sting	3	4			3	4		
Avulsion fracture	1	1			1	1		
Back injury	2	6			2	5		1
Booster dose missed		3				3		
Burn oesophageal	1	1			1	1		
Burn oral cavity		1						1
Cartilage injury		1				1		
Chest injury	1	3					1	3
Chillblains	3	8			3	7		1
Circumstance or information capable of leading to device use error		4				4		
Circumstance or information capable of leading to medication error	61	383			61	383		
Concussion	5	13			1	5	4	8
Contraindicated product administered		4				4		
Contusion	38	125			32	112	6	13
Decreased embryo viability	1	1			1	1		
Dental restoration failure		2				2		
Ear injury	1	1			1	1		
Epicondylitis		2				2		
Expired product administered	17	39			17	39		
Exposure during pregnancy	17	51			13	42	4	9
Exposure to SARS-CoV-2	42	99			40	85	2	14
Exposure via breast milk	11	94			9	91	2	3

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Exposure via eye contact	1	3
Exposure via skin contact	4	34
Extra dose administered		3
Eye contusion	2	10
Eye injury	1	1
Face injury	3	9
Facial bones fracture	3	4
Fall	78	208
Femur fracture	1	2
Foetal exposure during pregnancy		1
Foot fracture	3	3
Foreign body aspiration		1
Foreign body in eye		1
Foreign body in throat	2	4
Fracture		1
Frostbite		1
Gastrointestinal injury	1	1
Gastrointestinal stoma complication		1
Hair injury		1
Hand fracture		4
Head injury	16	38
Heart injury	4	6
Heat illness	1	1
Hip fracture	4	10
Iliotibial band syndrome		1
Inappropriate schedule of product administration	154	777
Incision site haemorrhage		1
Incomplete course of vaccination	5	15
Incorrect dosage administered	1	3
Incorrect dose administered	9	48
Incorrect dose administered by device	1	1
Incorrect route of product administration	23	131

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
		4	34		
			3		
		2	10		
				1	1
		1	5	2	4
				3	4
		44	120	34	88
				1	2
					1
		1	1	2	2
					1
			1		
				2	4
					1
			1		
		1	1		
			1		
					4
		10	18	6	20
				4	6
		1	1		
				4	10
			1		
		152	775	2	2
					1
		5	15		
		1	3		
		9	46		2
		1	1		
		21	125	2	6

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Injury	8	13
Intentional dose omission		2
Intentional overdose		1
Intentional product misuse	1	3
Intercepted medication error		2
Joint dislocation		7
Joint injury	7	14
Ligament injury		2
Ligament rupture	1	2
Ligament sprain	4	9
Limb injury	6	33
Lip injury	4	6
Lower limb fracture	3	3
Maternal exposure before pregnancy		1
Maternal exposure during breast feeding		1
Maternal exposure during pregnancy	21	124
Maternal exposure timing unspecified	1	5
Medication error	1	5
Mouth injury	1	3
Multiple fractures		1
Muscle injury	1	1
Muscle rupture		1
Muscle strain	3	15
Nasal injury	1	4
Neck injury	1	3
Nerve injury	8	17
Occupational exposure to product	5	8
Occupational exposure to SARS-CoV-2		6
Off label use	106	634
Overdose	108	225
Pelvic fracture		1
Peripheral nerve injury		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	7	3	6
			2		
			1		
		1	3		
			2		
			1		6
		6	12	1	2
			2		
			1	1	1
		4	9		
		6	32		1
		4	5		1
				3	3
			1		
			1		
		17	115	4	9
		1	5		
		1	5		
		1	3		
					1
		1	1		
					1
		2	13	1	2
		1	4		
		1	3		
		6	12	2	5
		5	8		
			5		1
		103	625	3	9
		108	223		2
					1
					2

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Phrenic nerve injury		1
Poisoning	2	3
Poor quality product administered	74	329
Post procedural complication		1
Post procedural haemorrhage		1
Post procedural oedema		1
Post-traumatic neck syndrome		3
Prescribed overdose		1
Procedural haemorrhage		1
Procedural pain		2
Procedural site reaction		1
Product administered at inappropriate site	27	89
Product administered to patient of inappropriate age	9	19
Product administration error	2	28
Product communication issue		1
Product confusion		2
Product dispensing issue	1	1
Product dose omission in error	1	3
Product dose omission issue	37	66
Product preparation error	18	125
Product preparation issue	102	196
Product prescribing error		3
Product storage error	19	31
Product use in unapproved indication	1	1
Product use issue	21	396
Rib fracture	2	5
Road traffic accident	4	6
Scar	4	8
Scratch	5	16
Skeletal injury		1
Skin abrasion		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	3
		74	329		
	1				1
			1		
					3
			1		
			1		1
					1
		25	85	2	4
		9	19		
		2	26		2
			1		
			2		
		1	1		
		1	3		
		37	66		
		18	123		2
		102	193		3
			3		
		19	31		
		1	1		
		20	389	1	7
			1	2	4
		1	2	3	4
		3	4	1	4
		5	13		3
			1		
			2		

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin injury		3
Skin laceration	3	14
Soft tissue injury		1
Spinal compression fracture	1	1
Splinter	1	1
Stoma site haemorrhage		1
Stoma site pruritus		1
Subdural haematoma	1	1
Subdural haemorrhage		1
Sunburn	1	7
Superficial injury of eye		1
Suture related complication		1
Thermal burn		2
Thoracic vertebral fracture		1
Tongue injury		1
Tooth fracture	3	3
Tooth injury	2	3
Toxicity to various agents		1
Tracheal obstruction	1	1
Transplant failure		1
Underdose	31	210
Upper limb fracture	4	6
Vaccination complication	2	5
Vaccination error	2	3
Vaccination failure	85	128
Wound	4	10
Wound complication	1	1
Wound haemorrhage	3	7
Wound secretion		1
Wrist fracture		1
Wrong dose		1
Wrong product administered	8	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		2	8	1	6
			1		
				1	1
		1	1		
					1
			1		
				1	1
					1
		1	6		1
			1		
					1
			1		1
					1
		3	3		
		2	2		1
					1
				1	1
					1
		31	209		1
		1	1	3	5
1	1	1	4	1	1
		2	3		
1	1			85	128
		2	7	2	3
		1	1		
		3	5		2
					1
					1
			1		
		8	40		

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Wrong schedule		2				2			
Wrong technique in device usage process		2				2			
Wrong technique in product usage process	11	94			11	92			2
	1,324	5,337	2	3	1112	4855	212		482

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged		2		1		1
Alanine aminotransferase abnormal		1		1		
Alanine aminotransferase decreased		1				1
Alanine aminotransferase increased	1	6	1	5		1
Albumin globulin ratio decreased		1		1		
Allergy test positive		1		1		
Ammonia increased		1				1
Anion gap abnormal		1		1		
Anion gap decreased		1		1		
Anion gap increased		1		1		
Antibody test abnormal	1	6	1	6		
Antibody test negative		5		5		
Anti Kell antibody test positive	1	1	1	1		
Antinuclear antibody positive		1		1		
Aspartate aminotransferase decreased		1		1		
Aspartate aminotransferase increased	1	5	1	5		
Bacterial test positive		1		1		
Band neutrophil count increased		1				1
Basophil count abnormal		1		1		
Basophil count increased		1		1		
Bilirubin urine present		1		1		
Biopsy	1	1	1	1		
Blast cell count increased		1				1
Blood albumin decreased		2		2		
Blood bilirubin abnormal	1	1			1	1
Blood bilirubin decreased		1		1		
Blood bilirubin increased	1	6	1	4		2
Blood calcium decreased		1		1		
Blood calcium increased		3		2		1
Blood chloride decreased		3		2		1
Blood chloride increased		3		3		
Blood cholesterol	1	1	1	1		

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System Organ Class

Investigations

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood cholesterol abnormal	2	2
Blood cholesterol increased	2	8
Blood chromium increased	1	1
Blood copper increased	1	2
Blood count abnormal	1	6
Blood creatine increased		3
Blood creatine phosphokinase abnormal	1	1
Blood creatine phosphokinase increased	2	6
Blood creatinine abnormal	1	1
Blood creatinine decreased		1
Blood creatinine increased	2	9
Blood electrolytes decreased	1	1
Blood fibrinogen decreased		1
Blood folate decreased		1
Blood folate increased	1	1
Blood follicle stimulating hormone increased	1	1
Blood glucose abnormal	1	7
Blood glucose decreased	9	32
Blood glucose fluctuation		3
Blood glucose increased	16	82
Blood immunoglobulin E increased		1
Blood immunoglobulin G decreased		3
Blood immunoglobulin G increased		1
Blood insulin increased	1	1
Blood iron decreased	1	6
Blood iron increased		1
Blood ketone body increased		1
Blood lactic acid increased	2	4
Blood magnesium decreased		2
Blood phosphorus decreased	1	1
Blood potassium decreased	6	18
Blood potassium increased	1	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
2	8		
		1	1
1	2		
1	5		1
	2		1
1	1		
	2	2	4
		1	1
	1		
2	7		2
		1	1
			1
	1		
1	1		
		1	1
	5	1	2
5	19	4	13
	3		
10	62	6	20
			1
	3		
	1		
1	1		
	3	1	3
	1		
			1
	1	2	3
			2
		1	1
3	10	3	8
	1	1	3

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal	5	25	4	18	1	7
Blood pressure decreased	23	65	11	38	12	27
Blood pressure diastolic decreased		3		3		
Blood pressure diastolic increased		3		2		1
Blood pressure increased	69	318	39	191	30	127
Blood pressure measurement	1	1	1	1		
Blood pressure orthostatic increased	1	1	1	1		
Blood pressure systolic increased	2	13	1	5	1	8
Blood sodium decreased	3	7	2	4	1	3
Blood test abnormal	7	9	5	7	2	2
Blood testosterone decreased		1		1		
Blood thyroid stimulating hormone decreased		1				1
Blood thyroid stimulating hormone increased	1	5	1	4		1
Blood triglycerides abnormal	1	1	1	1		
Blood triglycerides increased	1	4	1	2		2
Blood urea increased		2		2		
Blood uric acid increased		1				1
Blood urine present	10	28	8	22	2	6
Body height decreased	5	29	5	28		1
Body temperature	1	3	1	3		
Body temperature abnormal	2	24	2	21		3
Body temperature decreased	10	27	8	24	2	3
Body temperature fluctuation	3	7	3	7		
Body temperature increased	27	135	26	130	1	5
Bone density abnormal	1	1	1	1		
Breath sounds abnormal	4	4	4	4		
Capillary nail refill test abnormal	1	2	1	2		
Carbohydrate antigen 125 increased		1		1		
Carbon dioxide increased		1		1		
Cardiac murmur		1				1
Cell marker decreased	1	1			1	1
Chest X-ray abnormal		1				1

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System Organ Class

Investigations

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
	1		1
		1	2
	11	1	6
	1		
			1
	1		
			1
1	1		
	1		
		1	4
3	9		2
		1	1
			3
		1	1
1	1		
	1		
			1
1	2		3
	1		
		1	1
		1	1
			1
	2		1
	1		
	1		
1	4	2	2

Coagulation time prolonged		1
Computerised tomogram normal		1
Corneal reflex decreased		2
Coronavirus test positive	1	2
C-reactive protein increased	1	17
Crystal urine		1
CSF protein increased		1
Culture urine positive		1
Differential white blood cell count abnormal		1
Drug screen positive	1	1
Ejection fraction abnormal		1
Ejection fraction decreased	1	4
Electrocardiogram abnormal	3	11
Electrocardiogram PR shortened	1	1
Electrocardiogram QT prolonged		3
Electrocardiogram ST segment depression	1	1
Electrocardiogram ST segment elevation	1	1
Electrocardiogram T wave abnormal	1	1
Electrocardiogram T wave peaked		1
Eosinophil count decreased		1
Eosinophil count increased	1	5
Epinephrine increased		1
Exercise electrocardiogram abnormal	1	1
False negative investigation result	1	1
False positive investigation result		1
Fibrin D dimer increased	5	14
Foetal heart rate abnormal		1
Foetal heart rate decreased	1	1
Full blood count abnormal		3
Gastric pH decreased		1
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	3	6

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System Organ Class

Investigations

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	3
1	1		
6	11	1	1
	3		1
	1		
	1		
			1
	8	2	10
	1		
1	1		
8	25	3	6
4	17	3	12
91	492	35	145
13	41	6	13
		2	3
7	10	4	5
1	1		
	2		1
2	3		
		1	1
	1		
	1		
	1		
	3	1	2
	3		4
2	4		1
	1		
2	3	1	1
	1		
	1		

Glycosylated haemoglobin increased 2 4  
 Granulocytes abnormal 1 1  
 Grip strength decreased 7 12  
 Haematocrit decreased 4 4  
 Haematocrit increased 1 1  
 Haematology test abnormal 1 1  
 Haemoglobin abnormal 1 1  
 Haemoglobin decreased 2 18  
 Haemoglobin increased 1 1  
 Haptoglobin increased 1 1  
 Heart rate abnormal 11 31  
 Heart rate decreased 7 29  
 Heart rate increased 126 637  
 Heart rate irregular 19 54  
 Hepatic enzyme abnormal 2 3  
 Hepatic enzyme increased 11 15  
 Hepatitis A virus test positive 1 1  
 Histamine level increased 3 3  
 HIV test false positive 2 3  
 HIV test negative 1 1  
 Hormone level abnormal 2 2  
 Immunoglobulins decreased 1 1  
 Inflammatory marker increased 1 1  
 Influenza B virus test positive 1 1  
 Inspiratory capacity decreased 1 1  
 International normalised ratio decreased 1 5  
 International normalised ratio increased 7 7  
 Intraocular pressure increased 2 5  
 Intraocular pressure test abnormal 1 1  
 Laboratory test abnormal 3 4  
 Laboratory test normal 1 1  
 Lipase decreased 1 1

\* I=Interval, C=Cumulative  
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lipase increased	1	2
Lipids increased		2
Liver function test abnormal		3
Liver function test increased	1	2
Low density lipoprotein increased	1	2
Lumbar puncture abnormal		1
Lymph node palpable	1	3
Lymphocyte count abnormal		2
Lymphocyte count decreased		4
Mammogram abnormal	1	1
Mast cell degranulation present		1
Mean cell volume increased		1
Mean platelet volume decreased		1
Metabolic function test abnormal		2
Metamyelocyte count increased		1
Monocyte count abnormal		1
Monocyte count increased		4
Myelocyte count increased		1
Myocardial necrosis marker increased	1	5
Myocardial strain	1	1
Neurological examination normal		1
Neutrophil count abnormal		2
Neutrophil count decreased	1	4
Neutrophil count increased		3
Nitrite urine present		1
Orthostatic heart rate response increased		1
Oxygen consumption		1
Oxygen consumption decreased		1
Oxygen saturation abnormal	1	7
Oxygen saturation decreased	16	68
Physical examination abnormal		1
Platelet count decreased	18	52

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	1	1
	2		
	1		2
1	2		
1	2		
			1
1	3		
	1		1
	4		
1	1		
	1		
	1		
	2		
			1
	1		
	3		1
			1
		1	5
		1	1
	1		
			2
1	2		2
	2		1
	1		
	1		
1	7		
6	28	10	40
			1
7	20	11	32

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count increased	1	7	1	5		2
PO2 decreased		2		1		1
Prostatic specific antigen increased		1		1		
Protein total decreased	1	2	1	2		
Protein total increased		1		1		
Protein urine present	1	1	1	1		
Prothrombin level increased		1				1
Prothrombin time prolonged	1	3	1	2		1
Pulmonary arterial pressure abnormal		1				1
Pulse abnormal	2	15	1	8	1	7
Pulse absent	3	4			3	4
Pulse pressure decreased	1	1			1	1
Pulse pressure increased		1		1		
Pulse volume decreased	1	1	1	1		
Quality of life decreased	1	3		2	1	1
Red blood cell count abnormal	1	2	1	2		
Red blood cell count decreased	3	8	1	4	2	4
Red blood cell sedimentation rate abnormal		1		1		
Red blood cell sedimentation rate increased		7		3		4
Red blood cells urine positive		1		1		
Red cell distribution width decreased		1		1		
Red cell distribution width increased		1				1
Respiratory rate decreased	4	7	3	5	1	2
Respiratory rate increased	4	21		8	4	13
SARS-CoV-1 test positive	1	1	1	1		
SARS-CoV-2 antibody test negative	12	63	11	59	1	4
SARS-CoV-2 antibody test positive	2	20	1	17	1	3
SARS-CoV-2 test		1				1
SARS-CoV-2 test false positive	2	4	1	3	1	1
SARS-CoV-2 test negative	1	2	1	2		
SARS-CoV-2 test positive	51	316	16	61	35	255
Sensory level abnormal	1	2	1	2		

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System Organ Class

Investigations

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
	1		
		1	1
	1		2
1	3		
1	1		
	1		
	1		
1	1		
		1	1
	1		1
		1	1
1	1		
10	21	8	17
	1		
	1		
	1		
			1
3	7		
1	2		
4	4		
	3		
	1		
1	1		
		1	2
1	1		
4	7	1	1
33	98	13	23
11	21	1	1
2	2		
5	15	1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count increased	7	35	4	21	3	14
White blood cells urine		1		1		
White blood cells urine positive	1	2	1	2		
	691	2,871	431	1866	260	1005

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acetonaemia		1		1			
Acidosis	1	1			1	1	
Appetite disorder		6		6			
Decreased appetite	93	391	78	349	15	42	
Dehydration	29	114	12	67	17	47	
Diabetes mellitus	2	16			2	16	
Diabetes mellitus inadequate control	1	5			1	5	
Diabetic ketoacidosis		1				1	
Diet refusal		1				1	
Dyslipidaemia		1		1			
Electrolyte imbalance		1				1	
Feeding disorder	17	51	13	42	4	9	
Fluid imbalance		1				1	
Fluid intake reduced	1	5	1	4		1	
Fluid overload		1				1	
Fluid retention	6	12	5	8	1	4	
Food aversion	1	3	1	3			
Food intolerance	1	1	1	1			
Gout	4	17	3	15	1	2	
Hypercholesterolaemia		1		1			
Hyperglycaemia	2	6		2	2	4	
Hyperlipidaemia		1				1	
Hyperphagia		1		1			
Hypocalcaemia		1				1	
Hypoglycaemia	1	13		7	1	6	
Hypokalaemia	1	5			1	5	
Hypokalaemic syndrome	1	1	1	1			
Hypomagnesaemia		1				1	
Hyponatraemic syndrome	1	1	1	1			
Hypophagia	1	7	1	4		3	
Increased appetite	1	4	1	4			
Insulin resistance	1	1	1	1			

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insulin resistant diabetes	1	1			1	1
Iron deficiency	1	1	1	1		
Lactic acidosis		1				1
Latent autoimmune diabetes in adults		1				1
Malnutrition		1		1		
Metabolic acidosis		1		1		
Obesity		1		1		
Oligodipsia		1				1
Overweight		4		3		1
Polydipsia		2		2		
Poor feeding infant		1		1		
Tetany		2				2
Type 1 diabetes mellitus	1	2			1	2
Type 2 diabetes mellitus		1				1
Vitamin D deficiency	2	5	1	4	1	1
Weight fluctuation	3	6	3	6		
	173	703	124	539	49	164

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ankylosing spondylitis		1						1
Arthralgia	382	1,794	1	1	347	1679	35	115
Arthritis	15	63			14	58	1	5
Arthritis allergic		1				1		
Arthritis reactive	1	1					1	1
Arthropathy	10	30			10	29		1
Axillary mass	5	22			5	19		3
Back disorder	3	12			3	12		
Back pain	168	595			135	514	33	81
Bone development abnormal	1	1			1	1		
Bone disorder	2	6			1	5	1	1
Bone pain	36	114			33	103	3	11
Bone swelling		8				6		2
Bursitis	4	8			2	5	2	3
Chondritis		1				1		
Coccydynia	2	2			2	2		
Costochondritis	1	4				2	1	2
Degenerative bone disease		1				1		
Dupuytren's contracture		1						1
Extremity contracture		1				1		
Facet joint syndrome		1				1		
Facial asymmetry		1				1		
Fasciitis		2						2
Fibromyalgia	4	11			4	9		2
Finger deformity		2				2		
Fistula		1				1		
Flank pain	1	16			1	14		2
Foot deformity	1	3			1	3		
Groin pain	4	13			3	9	1	4
Growing pains		1				1		
Hand deformity		1						1
Head deformity	1	1					1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Immune-mediated arthritis		1
Intervertebral disc protrusion	2	6
Jaw clicking	1	3
Jaw cyst		1
Jaw disorder	3	8
Joint effusion	1	4
Joint instability		4
Joint lock	5	7
Joint noise	1	2
Joint range of motion decreased	17	66
Joint stiffness	9	38
Joint swelling	38	123
Joint warmth	1	2
Ligament disorder		1
Limb deformity		1
Limb discomfort	53	208
Limb mass	6	14
Loose body in joint	1	1
Lupus myositis	1	1
Mastication disorder	3	11
Mixed connective tissue disease		1
Mobility decreased	27	93
Muscle atrophy		2
Muscle contracture	1	2
Muscle discomfort	3	18
Muscle disorder	7	18
Muscle fatigue	8	20
Muscle mass		1
Muscle rigidity	1	5
Muscle spasms	74	276
Muscle swelling	4	10
Muscle tightness	18	90

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	4	1	2
		1	3		
			1		
1	1	3	7		1
			3	1	1
			1		3
		5	7		
		1	2		
		13	58	4	8
		9	35		3
		31	106	7	17
		1	2		
			1		
			1		
		45	184	8	24
		6	13		1
				1	1
				1	1
		3	9		2
					1
		21	73	6	20
			2		
		1	2		
		3	18		
		7	15		3
		7	19	1	1
			1		
		1	2		3
		55	229	19	47
		3	8	1	2
		14	77	4	13

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle twitching	17	64
Muscular weakness	69	270
Musculoskeletal chest pain	8	51
Musculoskeletal discomfort	21	71
Musculoskeletal disorder	6	18
Musculoskeletal pain	8	24
Musculoskeletal stiffness	69	279
Myalgia	319	1,839
Myositis		4
Neck mass	3	16
Neck pain	100	466
Nuchal rigidity		3
Osteoarthritis		6
Osteochondritis		1
Osteopenia		1
Osteoporosis		1
Pain in extremity	806	3,161
Pain in jaw	24	93
Periarthritis		3
Plantar fasciitis	1	2
Polyarthritis		1
Polychondritis		1
Polymyalgia rheumatica	2	7
Polymyositis		1
Posture abnormal		2
Psoriatic arthropathy	2	5
Rhabdomyolysis	2	3
Rheumatic disorder	1	2
Rheumatoid arthritis	22	41
Rotator cuff syndrome		3
Sacroiliitis	1	1
Scleroderma	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	52	4	12
		45	197	24	73
		6	45	2	6
		19	65	2	6
		5	11	1	7
		6	18	2	6
		65	257	4	22
1	1	290	1733	29	106
			1		3
		3	16		
		81	414	19	52
			2		1
			6		
			1		
			1		
			1		
2	3	747	3004	59	157
1	1	22	80	2	13
			2		1
		1	2		
					1
					1
			2		
				2	5
				2	3
		1	2		
2	2		1	22	40
			2		1
		1	1		
				2	2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Seronegative arthritis		2						2
Sinus tarsi syndrome		1			1			
Sjogren's syndrome	1	4					1	4
Soft tissue disorder		1			1			
Soft tissue swelling	2	2			2	2		
Spinal disorder	1	4				2	1	2
Spinal osteoarthritis		2				2		
Spinal pain	3	31			3	28		3
Spinal stenosis		2				2		
Spondylitis	1	2					1	2
Still's disease	1	1					1	1
Synovial cyst		1				1		
Synovitis		1				1		
Systemic lupus erythematosus	6	11			1	1	5	10
Systemic scleroderma		1						1
Temporomandibular joint syndrome	1	3				1	1	2
Tendon discomfort		1				1		
Tendonitis	1	7			1	6		1
Tendon pain	1	4				3	1	1
Tenosynovitis		2				2		
Torticollis		1				1		
Trigger finger	6	6			6	6		
Trismus	4	9			2	6	2	3
Undifferentiated connective tissue disease		1						1
Weight bearing difficulty	1	2			1	1		1
Winged scapula		1				1		
	2,438	10,302	8	9	2114	9348	324	954

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myeloid leukaemia		4				4
Adenoma benign		1		1		
Basal cell carcinoma		1				1
Blast cell crisis		1				1
Bone neoplasm	1	2		1	1	1
Brain cancer metastatic	1	1			1	1
Breast cancer		2				2
Breast cancer metastatic		1				1
Cardiac neoplasm unspecified		1				1
Chronic lymphocytic leukaemia	2	2			2	2
Chronic myeloid leukaemia recurrent		1				1
Colon cancer		1				1
Ear neoplasm		1		1		
Good syndrome		1				1
Haemangioma		1				1
Leukaemia	1	6		1	1	5
Leukaemia recurrent	1	1			1	1
Lipoma	1	1			1	1
Lung carcinoma cell type unspecified stage I		1				1
Lung neoplasm malignant	1	3			1	3
Lymphoma	1	4			1	4
Melanoma recurrent	2	2			2	2
Metastases to meninges		1				1
Monoclonal gammopathy	1	1	1	1		
Neoplasm	6	7	5	6	1	1
Neoplasm malignant	5	11			5	11
Neoplasm progression	1	3		1	1	2
Neoplasm skin	1	3	1	3		
Non-Hodgkin's lymphoma		2				2
Ovarian cancer		1				1
Pituitary tumour benign		1				1
Plasma cell myeloma		1				1

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Prostate cancer	3	5			3	5
Thyroid cancer	1	1			1	1
	29	76	7	15	22	61

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acoustic neuritis		2				1		1
Acute disseminated encephalomyelitis		2						2
Adrenergic syndrome		1				1		
Ageusia	43	189			39	171	4	18
Allodynia		1				1		
Altered state of consciousness	2	6					2	6
Amnesia	17	40			12	28	5	12
Anaesthesia	1	3			1	3		
Anosmia	36	165			31	144	5	21
Aphasia	16	37			6	17	10	20
Arachnoid cyst		1						1
Areflexia	1	2			1	1		1
Ataxia	1	5				2	1	3
Aura	1	2				1	1	1
Autonomic nervous system imbalance	1	4			1	3		1
Balance disorder	48	145			31	113	17	32
Basal ganglia haemorrhage		3						3
Basal ganglia infarction	1	1					1	1
Basal ganglia stroke		2						2
Brachial plexopathy		3				1		2
Bradykinesia	2	5			2	5		
Brain injury	2	6					2	6
Brain oedema	1	4					1	4
Brain stem haemorrhage		1						1
Brain stem infarction	1	1					1	1
Brain stem stroke	1	1					1	1
Brain stem syndrome		2						2
Burning sensation	67	240			56	201	11	39
Burning sensation mucosal		1				1		
Carotid artery occlusion	1	1					1	1
Carpal tunnel syndrome	2	4			1	3	1	1
Central nervous system lesion		2				1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebellar ataxia		1
Cerebellar stroke	2	3
Cerebral artery embolism	1	1
Cerebral artery occlusion	2	2
Cerebral disorder	2	7
Cerebral haemorrhage	7	17
Cerebral infarction		3
Cerebral thrombosis	6	8
Cerebral venous sinus thrombosis	4	4
Cerebrospinal fluid leakage	1	1
Cerebrovascular accident	76	173
Cervical radiculopathy	1	2
Chorea		1
Chronic inflammatory demyelinating polyradiculoneuropathy	1	2
Circadian rhythm sleep disorder	2	3
Clonus	1	1
Clumsiness	2	4
Cluster headache	1	4
Cognitive disorder	5	31
Coma		4
Complex regional pain syndrome		1
Consciousness fluctuating	1	1
Coordination abnormal	2	8
Cranial nerve disorder		1
Cranial nerve paralysis		1
Dementia	4	18
Dementia Alzheimer's type	1	2
Demyelinating polyneuropathy		3
Depressed level of consciousness	3	13
Diabetic coma	1	1
Diabetic neuropathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				2	3
				1	1
				2	2
		2	7		
				7	17
					3
				6	8
				4	4
				1	1
				76	173
			1	1	1
					1
				1	2
		2	3		
		1	1		
		1	3	1	1
		1	4		
		5	19		12
					4
			1		
				1	1
			3	2	5
					1
					1
				4	18
				1	2
					3
				3	13
				1	1
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diplegia	1	2
Disturbance in attention	14	70
Dizziness	516	2,254
Dizziness exertional		2
Dizziness postural	7	36
Dreamy state	1	1
Droling	2	7
Dropped head syndrome		1
Dysaesthesia	1	7
Dysarthria	15	43
Dysgeusia	49	256
Dysgraphia	2	3
Dyskinesia	13	36
Dyslexia		1
Dysstasia	30	87
Dystonia	6	8
Embolic stroke		2
Encephalopathy	1	3
Epilepsy	2	2
Exaggerated startle response	1	1
Facial nerve disorder	1	5
Facial neuralgia	1	3
Facial paralysis	120	351
Facial paresis	5	16
Facial spasm	1	3
Febrile convulsion		2
Fine motor skill dysfunction		5
Formication	6	12
Freezing phenomenon	1	2
Generalised tonic-clonic seizure	4	9
Guillain-Barre syndrome	7	27
Haemorrhage intracranial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		9	57	5	13
1	1	416	1927	100	327
			2		
		6	32	1	4
		1	1		
		2	6		1
					1
		1	6		1
		10	25	5	18
		46	242	3	14
		1	2	1	1
		9	28	4	8
			1		
		18	53	12	34
		1	1	5	7
					2
				1	3
				2	2
		1	1		
			2	1	3
		1	2		1
		1	3	119	348
		5	10		6
			1	1	2
					2
			4		1
		6	11		1
		1	2		
				4	9
			1	7	26
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemorrhagic stroke		5
Hand-eye coordination impaired		1
Headache	1,086	5,312
Head discomfort	38	141
Head titubation	1	3
Hemiparesis	8	15
Hemiplegia		6
Hyperaesthesia	4	29
Hyperreflexia		1
Hypersomnia	23	103
Hypertonia		2
Hypoaesthesia	187	768
Hypogeusia	1	12
Hypokinesia	10	29
Hyporeflexia		1
Hyporesponsive to stimuli		2
Hyposmia		6
Hypotonia	1	3
Idiopathic intracranial hypertension	1	1
IIIrd nerve paralysis	1	3
Incoherent	4	11
Infant irritability	1	4
Intracranial aneurysm	1	3
Intracranial mass	1	1
Intracranial pressure increased	3	4
Irregular sleep wake rhythm disorder		2
Ischaemic cerebral infarction	1	1
Ischaemic stroke	3	11
IVth nerve paralysis		2
Lacunar infarction		1
Lethargy	59	232
Loss of consciousness	144	331

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
					1
		988	4960	98	352
		30	120	8	21
		1	3		
		1	1	7	14
					6
		4	28		1
			1		
		19	94	4	9
			1		1
		134	601	53	167
			11	1	1
		6	23	4	6
					1
			1		1
			6		
		1	3		
				1	1
				1	3
		1	4	3	7
			3	1	1
				1	3
				1	1
			2		
				1	1
				3	11
					2
					1
		51	212	8	20
		2	3	142	328

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Loss of proprioception		1
Lumbar radiculopathy		1
Memory impairment	26	67
Meningeal disorder		1
Meningism		1
Meningitis noninfective		1
Mental impairment	11	49
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Migraine	74	301
Migraine with aura	5	14
Migraine without aura	1	1
Mononeuropathy		1
Monoparesis		1
Monoplegia	1	8
Motor dysfunction	5	12
Movement disorder	23	101
Multiple sclerosis	3	10
Multiple sclerosis relapse	5	7
Muscle contractions involuntary	3	9
Muscle spasticity	1	3
Myasthenia gravis	1	4
Myelitis transverse	6	12
Myelopathy		1
Myoclonus		5
Narcolepsy	1	2
Nerve compression	6	21
Nervous system disorder	6	21
Neuralgia	27	86
Neuralgic amyotrophy		3
Neuritis		4
Neurological symptom	5	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		25	54	1	13
					1
			1		
					1
				11	49
					1
					1
		58	261	16	40
		4	12	1	2
		1	1		
					1
					1
				1	8
		2	5	3	7
		16	86	7	15
				3	10
				5	7
		3	7		2
		1	2		1
				1	4
				6	12
					1
			1		4
				1	2
		4	19	2	2
		4	14	2	7
		18	71	9	15
			1		2
			4		
		2	7	3	5

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neuromyelitis optica spectrum disorder	1	1
Neuropathy peripheral	31	79
Noninfective encephalitis		5
Nystagmus	1	5
Occipital neuralgia	1	4
Oculofacial paralysis	1	1
On and off phenomenon		1
Optic neuritis	3	8
Oromandibular dystonia		1
Orthostatic intolerance	1	1
Paraesthesia	168	833
Paraesthesia mucosal		1
Paralysis	12	38
Paraplegia	2	2
Parkinsonism	2	2
Parkinson's disease	1	4
Parosmia	12	50
Patient elopement		1
Peripheral paralysis	1	1
Peripheral sensory neuropathy		3
Peroneal nerve palsy	1	6
Phantom limb syndrome		1
Polyneuropathy	1	3
Poor quality sleep	7	46
Post herpetic neuralgia		1
Postictal state		2
Post-traumatic neuralgia		1
Presyncope	45	157
Psychomotor hyperactivity	3	7
Radial nerve palsy	1	1
Radiculitis brachial		2
Reduced facial expression	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	3	30	76
					5
		1	3		2
		1	3		1
				1	1
			1		
				3	8
			1		
		1	1		
		137	696	31	137
			1		
				12	38
				2	2
		1	1	1	1
				1	4
		8	45	4	5
			1		
				1	1
			1		2
		1	3		3
			1		
				1	3
		7	46		
			1		
			1		1
			1		
		32	119	13	38
		2	5	1	2
		1	1		
					2
			1	1	2

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Restless legs syndrome	5	11
Ruptured cerebral aneurysm		2
Sciatica	6	19
Sedation		8
Seizure	68	137
Seizure like phenomena	2	4
Sensorimotor disorder		1
Sensory disturbance	5	24
Sensory loss	8	20
Serotonin syndrome		1
Sinus headache	11	31
Sleep deficit	3	4
Sleep paralysis		2
Slow response to stimuli		1
Slow speech	1	3
Small fibre neuropathy		1
Somnolence	68	303
Speech disorder	26	114
Spinal cord disorder		3
Subarachnoid haemorrhage		5
Superior sagittal sinus thrombosis	1	1
Syncope	119	292
Tardive dyskinesia	1	1
Taste disorder	23	83
Tension headache	5	17
Thalamic infarction		1
Thoracic outlet syndrome		1
Thrombotic stroke	2	2
Thunderclap headache		1
Tongue biting	1	2
Tongue paralysis	3	4
Tonic clonic movements		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	10	1	1
					2
		6	13		6
			7		1
		1	1	67	136
				2	4
					1
		4	22	1	2
		5	13	3	7
					1
		11	31		
		3	4		
			2		
			1		
		1	3		
					1
		62	280	6	23
		15	75	11	39
					3
					5
				1	1
		1	5	118	287
				1	1
		19	74	4	9
		4	15	1	2
					1
			1		
				2	2
					1
		1	1		1
				3	4
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Transient global amnesia	1	2			1	2		
Transient ischaemic attack	15	35					15	35
Transverse sinus stenosis	1	1					1	1
Tremor	124	440		1	101	352	23	88
Trigeminal nerve disorder	1	5			1	3		2
Trigeminal neuralgia	1	11			1	6		5
Trigeminal neuritis		1				1		
Tunnel vision	6	18					6	18
Unresponsive to stimuli	6	29					6	29
Vagus nerve disorder	1	1					1	1
Vascular dementia		1						1
Vertebral artery dissection	1	1					1	1
Vestibular migraine	1	1			1	1		
VIIIth nerve lesion		1						1
Visual field defect	4	11			3	9	1	2
VIth nerve paralysis	1	5					1	5
Vocal cord paralysis		1						1
White matter lesion		1						1
	3,783	15,206	1	2	2542	11654	1241	3552

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion	1	1			1	1
Abortion missed		1				1
Abortion spontaneous	8	30			8	30
Foetal death	2	4			2	4
Foetal hypokinesia	2	2			2	2
Morning sickness	1	1			1	1
Premature baby	5	7			5	7
Premature delivery		1				1
Premature labour	1	2			1	2
Premature rupture of membranes		1				1
Uterine contractions during pregnancy		2		1		1
	20	52		1	20	51

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 \* AE=Adverse Event  
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System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device breakage		1				1
Device leakage	1	1	1	1		
Liquid product physical issue	1	12	1	12		
Needle issue	1	11	1	10		1
Product colour issue	2	4	2	4		
Product complaint	2	4	2	4		
Product container issue		2		2		
Product formulation issue		1				1
Product leakage		13		13		
Product lot number issue		1		1		
Product odour abnormal		1		1		
Product packaging quantity issue		4		4		
Product quality issue	5	14	5	14		
Product supply issue	11	19	11	19		
Product temperature excursion issue	53	188	53	188		
Suspected counterfeit product		1		1		
Syringe issue	1	4	1	4		
	77	281	77	278		3

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour	5	11			3	7	2	4
Abnormal dreams	9	34			7	30	2	4
Affective disorder	1	2			1	2		
Affect lability	2	2					2	2
Aggression	2	7			1	5	1	2
Agitation	8	24			8	23		1
Anger	1	9			1	6		3
Anhedonia	1	1			1	1		
Anxiety	67	249			58	219	9	30
Anxiety disorder	1	2			1	1		1
Apathy	3	6			2	5	1	1
Autism spectrum disorder	1	1					1	1
Autoscopy	1	4			1	3		1
Behaviour disorder		1						1
Belligerence		1						1
Bipolar disorder	1	1					1	1
Bradyphrenia	2	8			2	5		3
Breathing-related sleep disorder	1	1			1	1		
Bruxism		1				1		
Catatonia		1				1		
Change in sustained attention	1	1			1	1		
Claustrophobia		1				1		
Communication disorder		5				2		3
Completed suicide	1	1					1	1
Confusional state	43	139			28	95	15	44
Conversion disorder	1	1			1	1		
Daydreaming	1	3			1	3		
Decreased interest		1				1		
Delirium	12	32					12	32
Delirium febrile	1	1					1	1
Delusion	2	4				1	2	3
Delusional perception	1	3			1	2		1

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\* AE=Adverse Event

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Depersonalisation/derealisation disorder	1	3
Depressed mood	9	28
Depression	9	27
Derealisation		1
Discouragement	1	1
Disorganised speech	2	2
Disorientation	28	79
Dissociation		4
Disturbance in social behaviour		2
Dysphemia	1	9
Eating disorder	16	48
Emotional disorder	3	16
Emotional distress	4	6
Euphoric mood	6	10
Fear	7	34
Fear of death	2	2
Fear of falling		1
Fear of injection	1	1
Frustration tolerance decreased	3	11
Generalised anxiety disorder	1	2
Hallucination	16	45
Hallucination, auditory	2	9
Hallucination, visual	3	13
Head banging		1
Hydrophobia		1
Hypervigilance	1	2
Illness anxiety disorder		1
Impulsive behaviour		1
Inappropriate affect	1	1
Initial insomnia	2	8
Insomnia	115	414
Intrusive thoughts		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
	1	9	26		2
		7	21	2	6
			1		
		1	1		
				2	2
		14	49	14	30
			3		1
			2		
		1	6		3
		13	39	3	9
		3	15		1
		3	4	1	2
		6	9		1
		6	31	1	3
		1	1	1	1
			1		
		1	1		
		3	10		1
		1	2		
				16	45
				2	9
				3	13
			1		
			1		
		1	2		
			1		
			1		
		1	1		
		2	8		
		100	375	15	39
			1		

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Irritability	10	30
Lack of spontaneous speech	2	3
Laziness		4
Listless	1	2
Major depression	1	3
Mania	1	3
Mental disorder	5	18
Mental fatigue	1	3
Mental status changes	3	6
Middle insomnia	5	41
Mood altered	1	2
Mood swings	1	4
Mutism		2
Near death experience	12	27
Nervousness	33	119
Nightmare	7	39
Obsessive thoughts		1
Panic attack	12	30
Panic disorder	3	6
Panic reaction	5	16
Paranoia	2	8
Personality change	2	4
Post-traumatic stress disorder		2
Posturing		1
Pressure of speech		2
Psychiatric symptom		2
Psychotic disorder	3	4
Reading disorder		1
Restlessness	13	45
Schizophrenia	1	1
Self-injurious ideation	1	1
Sitophobia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	28		2
				2	3
			4		
		1	2		
				1	3
		1	2		1
		4	14	1	4
		1	3		
		3	5		1
		5	39		2
		1	2		
		1	2		2
			1		1
		1	1	11	26
		30	111	3	8
		7	36		3
					1
		8	23	4	7
		3	6		
		5	15		1
		1	7	1	1
		1	2	1	2
			2		
					1
			1		1
			2		
		1	1	2	3
					1
		11	39	2	6
				1	1
		1	1		
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sleep attacks	1	1			1	1		
Sleep disorder	28	96			27	92	1	4
Sleep disorder due to a general medical condition		7				7		
Sleep disorder due to general medical condition, insomnia type		3				3		
Sleep talking	1	2			1	2		
Sleep terror		1				1		
Somatic symptom disorder	1	2			1	2		
Somnambulism	1	1			1	1		
Speech sound disorder	1	1			1	1		
Staring	1	4				1	1	3
Stress	8	37			7	35	1	2
Substance abuse		1						1
Suicidal ideation	4	12					4	12
Suicide attempt		1						1
Tachyphrenia		6				6		
Tearfulness	1	2			1	2		
Tension		5				5		
Terminal insomnia		4				4		
Thanatophobia		1				1		
Thinking abnormal	9	35			8	33	1	2
Tic		3				2		1
	584	1,998		1	437	1582	147	416

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\* AE=Adverse Event

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	9			1	9
Bladder discomfort	1	4		3	1	1
Bladder disorder	2	5	2	5		
Bladder dysfunction		1		1		
Bladder pain		2		2		
Bladder spasm		1		1		
Chromaturia	4	16	4	16		
Chronic kidney disease	2	5			2	5
Costovertebral angle tenderness		1		1		
Dysuria	6	22	3	18	3	4
Glomerulonephritis minimal lesion	1	1			1	1
Haematuria		9		4		5
Haemorrhage urinary tract	1	6			1	6
Hydronephrosis		1				1
Incontinence	1	5	1	3		2
Micturition disorder		3		1		2
Micturition urgency	3	8	2	6	1	2
Nephrolithiasis	10	22			10	22
Nephropathy	3	4		1	3	3
Nephrotic syndrome	1	1			1	1
Nocturia	1	3	1	2		1
Oliguria		1		1		
Pollakiuria	9	37	9	37		
Polyuria	4	10	3	8	1	2
Proteinuria	1	2	1	1		1
Renal atrophy	1	2			1	2
Renal cyst		2		1		1
Renal disorder	3	14	1	7	2	7
Renal failure	5	13			5	13
Renal impairment	3	9			3	9
Renal infarct	1	1			1	1
Renal injury	1	1			1	1

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\* AE=Adverse Event

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System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal pain	4	25	3	22	1	3
Renal tubular disorder	1	1			1	1
Renal tubular injury		1				1
Stress urinary incontinence	1	1	1	1		
Ureteric stenosis		1				1
Urethral disorder		1		1		
Urethral haemorrhage		1				1
Urge incontinence		1		1		
Urinary incontinence	8	25	5	18	3	7
Urinary retention	3	7			3	7
Urinary tract disorder		1		1		
Urine abnormality	1	3	1	3		
Urine odour abnormal		2		1		1
	83	291	37	167	46	124

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal withdrawal bleeding		1		1		
Adnexa uteri pain		1		1		
Amenorrhoea	1	1	1	1		
Breast discharge		4		4		
Breast discomfort		4		3		1
Breast disorder	2	4	2	4		
Breast engorgement		1		1		
Breast induration		2		2		
Breast mass	4	8	3	7	1	1
Breast milk discolouration		1		1		
Breast pain	21	58	19	55	2	3
Breast swelling	6	12	6	12		
Breast tenderness	2	8	2	7		1
Dysmenorrhoea	6	12	5	11	1	1
Dyspareunia		1		1		
Endometriosis	1	1			1	1
Erectile dysfunction	4	11			4	11
Genital haemorrhage		1				1
Genital lesion		1		1		
Genital swelling	1	1	1	1		
Genital ulceration		1		1		
Infertility female	1	1			1	1
Menopausal symptoms		1		1		
Menorrhagia	22	33	20	29	2	4
Menstrual discomfort	1	1	1	1		
Menstrual disorder	9	24	7	22	2	2
Menstruation delayed	2	4	2	3		1
Menstruation irregular	10	24	10	24		
Metrorrhagia	4	13	3	11	1	2
Nipple exudate bloody		1		1		
Nipple pain	2	9	2	9		
Nipple swelling	1	4	1	4		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oligomenorrhoea		1		1			
Orchitis noninfective		1		1			
Ovarian cyst	1	1			1	1	
Ovarian disorder	1	1			1	1	
Ovarian enlargement	1	1	1	1			
Pelvic pain	4	10	3	9	1	1	
Penile haemorrhage		1				1	
Polymenorrhoea	1	2	1	2			
Postmenopausal haemorrhage	6	8			6	8	
Premenstrual syndrome	1	5	1	5			
Pruritus genital		1				1	
Scrotal disorder		1		1			
Scrotal erythema		1		1			
Scrotal inflammation		1		1			
Scrotal pain	1	2	1	2			
Suppressed lactation		1		1			
Testicular pain	1	4		3	1	1	
Testicular swelling	1	3	1	2		1	
Uterine disorder		1		1			
Uterine haemorrhage	1	2			1	2	
Uterine inflammation		1				1	
Uterine pain	1	1			1	1	
Vaginal discharge		2		2			
Vaginal disorder		1		1			
Vaginal haemorrhage	11	25	7	17	4	8	
Vaginal lesion		1		1			
Varicocele	1	1	1	1			
Vulval disorder		1		1			
Vulvovaginal burning sensation	1	2	1	2			
Vulvovaginal pain	2	2	1	1	1	1	
Vulvovaginal pruritus		1				1	
Vulvovaginal rash		1				1	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vulvovaginal swelling		2		1			1
Withdrawal bleed		1		1			
	135	339	103	278	32		61

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Acute pulmonary oedema		1							1
Acute respiratory distress syndrome		2							2
Acute respiratory failure	1	2					1		2
Allergic cough	1	1			1	1			
Allergic respiratory disease		1				1			
Allergic sinusitis		1				1			
Aphonia	9	22			7	14	2		8
Apnoea	1	2					1		2
Aspiration	1	2					1		2
Asthma	28	80			18	58	10		22
Asthma exercise induced		1				1			
Atelectasis	2	5			1	1	1		4
Bronchial disorder	1	1			1	1			
Bronchial oedema	1	1					1		1
Bronchospasm	4	25			2	15	2		10
Choking	9	20	1	1			9		20
Choking sensation	5	11			4	7	1		4
Chronic obstructive pulmonary disease	4	12	1	1	1	4	3		8
Cough	177	699	1	1	152	599	25		100
Diaphragmalgia		1				1			
Diaphragmatic disorder	1	2			1	2			
Diaphragmatic paralysis		1							1
Dry throat	9	41			9	36			5
Dysphonia	31	122			22	83	9		39
Dyspnoea	334	1,090	2	2	197	682	137		408
Dyspnoea at rest	2	3					2		3
Dyspnoea exertional	3	24			2	18	1		6
Emphysema	2	2			1	1	1		1
Epistaxis	35	106			25	82	10		24
Grunting	2	7			2	6			1
Haemoptysis	8	24			4	15	4		9
Hiccups		8				8			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperactive pharyngeal reflex		1
Hyperventilation	7	28
Hypopnoea	5	13
Hypoxia	7	13
Increased bronchial secretion		1
Increased upper airway secretion	1	8
Increased viscosity of bronchial secretion		2
Increased viscosity of upper respiratory secretion	2	3
Intranasal hypoaesthesia		1
Intranasal paraesthesia		3
Irregular breathing	1	2
Laryngeal discomfort		1
Laryngeal oedema		5
Laryngeal pain	1	2
Laryngospasm		4
Lower respiratory tract congestion		2
Lung disorder	8	16
Lung hyperinflation	1	2
Lung infiltration	1	4
Lung opacity	1	2
Nasal congestion	76	313
Nasal crusting		1
Nasal discharge discolouration		1
Nasal discomfort	5	22
Nasal disorder	3	6
Nasal dryness	1	5
Nasal mucosal disorder		1
Nasal oedema	5	19
Nasal pruritus	2	5
Nocturnal dyspnoea	1	1
Obstructive airways disorder	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		7	21		7
		3	8	2	5
			1	7	13
			5	1	3
			1		1
		2	2		1
			1		
			3		
		1	2		
			1		
					5
		1	2		
			1		3
			2		
	1	6	12	2	4
		1	2		
			1	1	3
		1	1		1
		71	291	5	22
			1		
			1		
		5	19		3
		2	5	1	1
		1	4		1
			1		
		4	13	1	6
		1	4	1	1
		1	1		
			1	2	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Organising pneumonia		1
Oropharyngeal blistering	1	3
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	18	61
Oropharyngeal pain	121	513
Oropharyngeal spasm		3
Oropharyngeal swelling		1
Orthopnoea		1
Painful respiration	3	13
Paranasal sinus discomfort	5	32
Paranasal sinus hypersecretion		7
Paranasal sinus hyposecretion		1
Pharyngeal disorder	2	7
Pharyngeal enanthema		2
Pharyngeal erythema	5	14
Pharyngeal haemorrhage	2	2
Pharyngeal hypoaesthesia	4	16
Pharyngeal inflammation	1	5
Pharyngeal mass	1	6
Pharyngeal oedema	4	8
Pharyngeal paraesthesia	4	28
Pharyngeal swelling	42	171
Pharyngeal ulceration		1
Pleural effusion	4	10
Pleurisy	1	5
Pleuritic pain		6
Pneumonia aspiration	2	4
Pneumonitis	2	5
Pneumothorax	3	4
Productive cough	15	47
Pulmonary artery occlusion	1	1
Pulmonary artery thrombosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	3
			1		
		15	50	3	11
		111	476	10	37
					3
					1
					1
		1	7	2	6
		5	32		
			7		
			1		
		1	6	1	1
			2		
		5	13		1
				2	2
		3	11	1	5
		1	5		
		1	5		1
		3	3	1	5
		3	20	1	8
		20	91	22	80
			1		
		1	2	3	8
		1	2		3
			5		1
				2	4
			1	2	4
				3	4
		14	43	1	4
				1	1
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulmonary congestion	10	21
Pulmonary embolism	49	78
Pulmonary fibrosis	2	6
Pulmonary hypertension		1
Pulmonary infarction	1	2
Pulmonary mass	1	4
Pulmonary oedema	8	18
Pulmonary pain	6	23
Pulmonary thrombosis	25	35
Pulmonary venous thrombosis	1	1
Respiration abnormal	3	8
Respiratory arrest	4	14
Respiratory disorder	8	33
Respiratory disorder neonatal	1	1
Respiratory distress	9	47
Respiratory failure		9
Respiratory symptom	2	5
Respiratory tract congestion	11	35
Respiratory tract inflammation	1	1
Respiratory tract irritation	2	3
Respiratory tract oedema	1	5
Restrictive pulmonary disease		1
Rhinalgia	2	11
Rhinitis allergic	2	6
Rhinorrhoea	85	330
Sinus congestion	7	33
Sinus disorder	16	53
Sinus pain	4	16
Sleep apnoea syndrome	1	1
Sneezing	28	112
Snoring		3
Sputum discoloured	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				10	21
				49	78
				2	6
					1
				1	2
		1	2		2
				8	18
		3	17	3	6
				25	35
				1	1
		3	7		1
				4	14
		4	21	4	12
				1	1
				9	47
					9
		1	3	1	2
		7	31	4	4
		1	1		
		1	2	1	1
				1	5
					1
		1	10	1	1
		2	5		1
		81	311	4	19
		6	31	1	2
		15	49	1	4
		4	16		
				1	1
		25	108	3	4
			2		1
		3	5	2	3

\* I=Interval, C=Cumulative  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sputum increased	1	1			1	1		
Status asthmaticus		1						1
Stridor	1	8			1	3		5
Suffocation feeling		2				2		
Tachypnoea	2	27			1	17	1	10
Throat clearing	2	9			1	5	1	4
Throat irritation	44	212			34	166	10	46
Throat tightness	56	232			38	124	18	108
Tonsillar disorder		2				1		1
Tonsillar erythema		1				1		
Tonsillar hypertrophy		7				7		
Tonsillar inflammation	1	1			1	1		
Tonsillar ulcer		1				1		
Tonsillolith		1				1		
Tracheomalacia		1						1
Upper-airway cough syndrome	6	23			6	21		2
Upper airway obstruction	1	3					1	3
Upper respiratory tract congestion	6	37			4	34	2	3
Use of accessory respiratory muscles		5				4		1
Vocal cord disorder	1	3					1	3
Wheezing	41	112			27	76	14	36
	1,499	5,407	5	6	1014	3915	485	1492

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	8	21	8	20		1
Acute febrile neutrophilic dermatosis	1	2			1	2
Alopecia	15	32	14	27	1	5
Alopecia areata		2		2		
Alopecia universalis		1		1		
Angioedema	17	62	2	2	15	60
Angiokeratoma	1	1	1	1		
Blister	21	73	15	58	6	15
Blood blister	2	4	1	1	1	3
Butterfly rash		2		1		1
Circumoral swelling	2	3	2	3		
Cold sweat	26	112	21	99	5	13
Cold urticaria		1		1		
Cutaneous lupus erythematosus		1				1
Cutaneous vasculitis	1	1	1	1		
Dermatitis	6	21	3	18	3	3
Dermatitis acneiform		3		3		
Dermatitis allergic	1	6	1	4		2
Dermatitis atopic	1	1	1	1		
Dermatitis contact	1	5	1	5		
Dermatitis diaper		1				1
Dermatitis exfoliative		1				1
Dermatomyositis	1	3			1	3
Diabetic wound		1				1
Diffuse alopecia	1	1			1	1
Drug eruption	1	3		2	1	1
Dry skin	6	27	6	24		3
Ecchymosis	4	5	4	5		
Eczema	5	11	5	10		1
Erythema	125	537	105	457	20	80
Erythema marginatum		1		1		
Erythema multiforme	2	7			2	7

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Erythema nodosum	1	2
Granuloma skin		1
Haemorrhage subcutaneous		2
Haemorrhagic urticaria	1	1
Hair growth abnormal	1	1
Henoch-Schonlein purpura	1	2
Hidradenitis		2
Hyperhidrosis	138	561
Hypersensitivity vasculitis	3	6
Hypertrichosis		1
Lichenoid keratosis		1
Lichen planus		1
Livedo reticularis		6
Macule		4
Madarosis		1
Mechanical urticaria		1
Miliaria		3
Nail discolouration	2	3
Night sweats	18	119
Onychalgia		1
Onychoclasia	1	1
Pain of skin	12	42
Palmar erythema		7
Palpable purpura		1
Papule		2
Pemphigoid		2
Pemphigus		2
Perivascular dermatitis		1
Petechiae	5	30
Photosensitivity reaction	5	18
Pigmentation disorder		2
Piloerection	2	8

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
			1
			2
		1	1
1	1		
		1	2
	2		
114	492	24	69
		3	6
	1		
			1
	1		
	3		3
	4		
	1		
	3		
2	2		1
15	109	3	10
	1		
1	1		
10	38	2	4
	6		1
	1		
	2		
			2
			2
	1		
2	18	3	12
2	14	3	4
	1		1
2	7		1

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pityriasis		1
Pityriasis rosea	1	2
Plantar erythema		2
Pruritus	223	986
Pseudofolliculitis		1
Psoriasis	4	10
Purpura	1	4
Rash	273	1,037
Rash erythematous	29	155
Rash macular	28	120
Rash maculo-papular	1	16
Rash morbilliform	5	12
Rash neonatal	1	1
Rash papular	12	57
Rash pruritic	30	156
Rash vesicular	4	20
Rosacea		3
Scab	2	8
Seborrhoea		1
Sensitive skin	4	22
Skin burning sensation	9	46
Skin depigmentation	1	3
Skin discolouration	24	73
Skin discomfort		2
Skin disorder	10	46
Skin erosion	1	1
Skin exfoliation	9	24
Skin fissures	3	4
Skin haemorrhage	6	8
Skin hyperpigmentation		1
Skin indentation	1	2
Skin irritation	4	18

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	2		
	2		
191	858	32	128
	1		
2	8	2	2
1	3		1
233	878	40	159
25	128	4	27
21	102	7	18
1	16		
4	7	1	5
1	1		
9	52	3	5
25	138	5	18
3	17	1	3
	3		
2	7		1
	1		
4	22		
9	44		2
1	3		
18	57	6	16
	2		
9	40	1	6
1	1		
7	21	2	3
3	3		1
5	7	1	1
	1		
1	2		
4	18		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin laxity		2		2		
Skin lesion	6	20	6	19		1
Skin mass	6	9	6	8		1
Skin odour abnormal		2		2		
Skin oedema		1		1		
Skin reaction	1	12		9	1	3
Skin sensitisation	1	2	1	2		
Skin swelling	3	13	2	11	1	2
Skin tightness	3	6	2	4	1	2
Skin ulcer		4		4		
Skin warm	3	8	3	8		
Skin wrinkling	1	1	1	1		
Solar lentigo		1				1
Splinter haemorrhages		1		1		
Stevens-Johnson syndrome	1	3			1	3
Sticky skin	1	1	1	1		
Urticaria	123	616	90	487	33	129
Urticaria chronic	1	1	1	1		
Urticaria thermal		1		1		
Vasculitic rash		1		1		
Yellow skin	1	3		1	1	2
	1,275	5,337	1035	4469	240	868

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	9	27	7	22	2	5
Caffeine consumption	1	1	1	1		
Contraindication to medical treatment		1		1		
Contraindication to vaccination		3		3		
Disability		1				1
Exercise lack of		1		1		
Hearing disability		1		1		
Immobile	3	5			3	5
Impaired driving ability	3	17	2	13	1	4
Impaired quality of life		1				1
Impaired work ability	3	17	1	14	2	3
Job dissatisfaction	1	1	1	1		
Loss of personal independence in daily activities	36	115	25	92	11	23
Menopause	1	1	1	1		
Sitting disability		4		3		1
Urinary assistance device user		1		1		
Walking aid user	4	5	3	4	1	1
Walking disability	1	2	1	1		1
Water pollution		1		1		
	62	205	42	160	20	45

System Organ Class

**SOC Not Yet Coded**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	2	5	2	5
	2	5	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abortion induced		1				1	
Bed rest	2	2	2	2			
Cardiac pacemaker insertion		1		1			
Contraceptive diaphragm	1	1	1	1			
COVID-19 immunisation		1		1			
Drainage	1	2	1	2			
Hernia repair	1	1	1	1			
Hysterectomy	1	1			1	1	
Immunisation	1	3	1	3			
Local anaesthesia		1		1			
Skin lesion removal		1		1			
Spinal fusion surgery		1					1
Thyroidectomy	1	1	1	1			
Tooth extraction	2	2	2	2			
Wound closure		1		1			
	10	20	9	17	1	3	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aneurysm		1						1
Aneurysm ruptured		1						1
Angiopathy	1	5				4	1	1
Aortic arteriosclerosis	1	1			1	1		
Aortic disorder	1	1					1	1
Aortitis		1						1
Arterial occlusive disease	1	1					1	1
Arterial thrombosis		1						1
Arteriosclerosis		2						2
Blood pressure fluctuation	7	31			6	23	1	8
Blue toe syndrome	2	2					2	2
Capillary disorder	1	1			1	1		
Capillary fragility	1	1			1	1		
Circulatory collapse	1	6					1	6
Cyanosis	7	21			4	14	3	7
Deep vein thrombosis	46	69			1	1	45	68
Diastolic hypotension		1						1
Embolism		2						2
Essential hypertension	1	1			1	1		
Flushing	38	306			31	242	7	64
Haematoma	7	13			7	12		1
Haemorrhage	25	65				2	25	63
Hot flush	30	153			26	137	4	16
Hyperaemia		1				1		
Hypertension	66	285	1	1	28	156	38	129
Hypertensive crisis	1	5					1	5
Hypertensive emergency		4						4
Hypotension	23	83			9	39	14	44
Hypovolaemic shock	1	2					1	2
Internal haemorrhage	4	5					4	5
Labile hypertension		1				1		
Lymphoedema		15				15		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malignant hypertension		1
May-Thurner syndrome		1
Microembolism		2
Orthostatic hypotension	1	6
Pallor	13	62
Peripheral artery thrombosis	2	2
Peripheral coldness	21	84
Peripheral ischaemia		1
Peripheral vascular disorder		2
Peripheral venous disease	4	5
Phlebitis	1	3
Phlebitis superficial	2	2
Poor peripheral circulation	2	7
Poor venous access	1	1
Raynaud's phenomenon	3	8
Shock	3	14
Shock symptom		4
Superficial vein prominence	1	2
Systolic hypertension		1
Thrombophlebitis	2	2
Thrombophlebitis superficial	7	12
Thrombosis	116	173
Varicose vein	2	4
Vascular occlusion	1	1
Vascular pain	2	3
Vascular rupture	1	1
Vasculitis	1	2
Vasodilatation		1
Vein discolouration		3
Vein disorder	2	5
Vein rupture	1	1
Venous thrombosis limb	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					2
			3	1	3
		8	44	5	18
		1	1	1	1
		17	75	4	9
					1
			2		
		3	4	1	1
		1	3		
		2	2		
		2	5		2
		1	1		
		3	7		1
		1	1	2	13
					4
			1	1	1
					1
		2	2		
		4	6	3	6
1	1	2	3	114	170
		1	3	1	1
				1	1
		1	2	1	1
		1	1		
		1	2		
			1		
			3		
		1	4	1	1
				1	1
				1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	455	1,505	2	2	168	827	287	678

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED STATES MINOR OUTLYING ISLA**

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain		1		1
		1		1

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**URUGUAY**

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inflammation	1	1	1	1
Pain	1	1	1	1
	2	2	2	2

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Synovial cyst	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

**APPENDIX 2.5.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Age Group by Preferred Term per Country**

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

Total Number of Adverse Events (PT): 112,695 (Interval) / 414,597 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Erythema		1		1		
Facial paralysis		1				1
Feeling of body temperature change		1		1		
Muscle tightness		1		1		
Paraesthesia		1		1		
Pruritus		1		1		
Rash		1		1		
Swelling face		1		1		
		9		8		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ALBANIA**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Off label use	1	1	1	1
Product use issue	1	1	1	1
	2	2	2	2

Age Range

**Unknown**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**AMERICAN SAMOA**

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ANDORRA**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ANGOLA**

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration		1		1		
Nasopharyngitis		1				1
Pyrexia		1				1
Swollen tongue		1				1
Vomiting		1				1
		5		1		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**ARGENTINA**

Age Range

**65 - 79 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetes mellitus	1	1			1	1
Hypersensitivity	1	1	1	1		
Intentional product misuse	1	1	1	1		
SARS-CoV-2 antibody test negative		1		1		
	3	4	2	3	1	1

Age Range

**Unknown**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error		1		1
Pain in extremity		1		1
		2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRALIA**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure via breast milk	1	1	1	1		
Respiratory distress	1	1			1	1
Wheezing	1	1	1	1		
	3	3	2	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Adrenocortical insufficiency acute	1	1			1	1
Anaphylactic reaction	4	4			4	4
Anxiety		1				1
Apnoea	1	1			1	1
Arthralgia	2	2	2	2		
Chills	3	3	3	3		
Cough	3	3	3	3		
Cyanosis	1	1	1	1		
Diarrhoea	2	2	2	2		
Dizziness	4	6	4	5		1
Dyspnoea	1	1	1	1		
Erythema	1	2	1	2		
Eye discharge		1		1		
Eye pain		1		1		
Fatigue	3	3	3	3		
Feeling abnormal	1	1	1	1		
Feeling of body temperature change	1	1	1	1		
Flushing	1	1	1	1		
Hallucination	1	1			1	1
Headache	9	9	9	9		
Hypotension	1	1	1	1		
Insomnia	1	1	1	1		
Joint stiffness	1	1	1	1		
Lethargy	5	5	5	5		
Loss of consciousness	1	1			1	1
Malaise	1	1	1	1		
Myalgia	3	3	3	3		
Nausea	3	5	3	4		1
Neutrophil count decreased	1	1	1	1		
Ocular hyperaemia		1		1		
Oropharyngeal pain	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Presyncope	2	2			2	2
Pruritus		1		1		
Pyrexia	5	5	5	5		
Rash	1	1	1	1		
Rectal haemorrhage	1	1			1	1
Rhinorrhoea	1	1	1	1		
Seizure	1	1			1	1
Somatic symptom disorder		1				1
Somnolence		1		1		
Syncope	4	4			4	4
Throat tightness		1		1		
Urticaria	1	1	1	1		
Vaccination site bruising		1		1		
Vaccination site pain	1	2	1	2		
Vaccination site reaction	3	3	3	3		
Vaccination site swelling	1	3	1	3		
Vomiting	2	2	2	2		
White blood cell count decreased	1	1	1	1		
	84	101	68	81	16	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Anaphylactic reaction	4	6			4	6
Angioedema	1	1			1	1
Anxiety		2				2
Appendicitis	1	1			1	1
Arthralgia	3	3	3	3		
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Balance disorder		1				1
Blood pressure increased	1	2	1	1		1
Body temperature increased		1		1		
Cardiac arrest	1	1			1	1
Chest discomfort	3	3	3	3		
Chills	1	1	1	1		
Contusion	1	1	1	1		
Cough	4	4	4	4		
COVID-19		1		1		
Decreased appetite		1		1		
Deep vein thrombosis	2	2			2	2
Demyelination	1	1			1	1
Dizziness	3	5	3	3		2
Dry throat	1	1	1	1		
Dysarthria		1				1
Dysphagia	1	1	1	1		
Dyspnoea	3	3	2	2	1	1
Erythema	1	1	1	1		
Extensive swelling of vaccinated limb	1	1	1	1		
Eye pruritus	1	1	1	1		
Face oedema	1	1	1	1		
Facial pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	4	5	4	5		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		1				1
Feeling hot	1	1	1	1		
Feeling of body temperature change	1	1	1	1		
Flushing	2	4	2	4		
Haematemesis	1	1			1	1
Hallucination, tactile		1				1
Headache	13	13	13	13		
Hyperhidrosis	1	1	1	1		
Hypertension	3	3	3	3		
Hypoaesthesia	1	2	1	2		
Lethargy	1	1	1	1		
Malaise	2	3	2	2		1
Migraine	1	2	1	2		
Monoplegia	1	1			1	1
Multiple sclerosis	1	1			1	1
Multiple sclerosis relapse	1	1			1	1
Muscle tightness	2	2	2	2		
Musculoskeletal stiffness		1		1		
Myalgia	8	8	8	8		
Nausea	3	3	3	3		
Neck pain	1	1	1	1		
Nerve injury	1	1	1	1		
Odynophagia	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity		1		1		
Palpitations		1		1		
Paraesthesia	3	3	3	3		
Paraesthesia oral	1	1	1	1		
Presyncope	1	1	1	1		
Pruritus	3	3	3	3		
Pulmonary embolism	1	1			1	1
Pupil fixed		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	7	7	7	7		
Rash	6	6	6	6		
Rash macular		1				1
Respiratory rate increased		1				1
Sensation of foreign body	1	1	1	1		
Sensory disturbance		1		1		
Sepsis	1	1			1	1
Skin sensitisation	1	1	1	1		
Syncope	5	6			5	6
Tachycardia	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	1	1	1	1		
Thrombophlebitis	1	1	1	1		
Transient ischaemic attack	1	1			1	1
Tremor	1	1	1	1		
Trigeminal neuralgia	1	1	1	1		
Urticaria	2	2	2	2		
Vaccination site pain	3	4	3	4		
Vaccination site reaction	3	3	3	3		
Vision blurred	1	1	1	1		
Visual impairment	1	1	1	1		
Vomiting	3	3	2	2	1	1
Wheezing	2	2	2	2		
	143	172	117	130	26	42

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	2	2	2		
Anaphylactic reaction	6	7			6	7
Anxiety		1				1
Arrhythmia	1	1			1	1
Arthralgia		1		1		
Blood pressure increased		1				1
Chest discomfort	2	2	1	1	1	1
Chills	2	2	2	2		
Circumstance or information capable of leading to medication error	1	1	1	1		
Cold sweat	2	2	2	2		
Cough	1	2	1	2		
Crying		1		1		
Deafness	1	1			1	1
Depressed mood		1		1		
Diarrhoea	1	1	1	1		
Dizziness	1	3	1	1		2
Dry throat	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	2	2	1	1	1	1
Ear pain	1	1	1	1		
Eye pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	1	2	1	2		
Feeling abnormal		1		1		
Feeling hot	1	2	1	1		1
Feeling jittery		1		1		
Flushing	1	1	1	1		
Gait disturbance	1	1	1	1		
Headache	4	6	3	4	1	2
Hyperhidrosis	1	2	1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	3	3	2	2	1	1
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral		1				1
Illness	1	1	1	1		
Inadequate aseptic technique in use of product	1	1	1	1		
Incontinence	1	1	1	1		
Inflammation	1	1	1	1		
Influenza like illness	1	1	1	1		
Lethargy	3	3	2	2	1	1
Lymphadenopathy	2	2	2	2		
Myalgia		2		2		
Nausea	1	1	1	1		
Nervousness		1		1		
Ocular discomfort	1	1	1	1		
Oral herpes	1	1	1	1		
Oropharyngeal pain		1		1		
Orthostatic tremor	1	1	1	1		
Oxygen saturation decreased	1	1	1	1		
Pain	1	1	1	1		
Paraesthesia	3	3	3	3		
Paraesthesia oral	2	2	1	1	1	1
Poor quality product administered	1	1	1	1		
Pruritus	2	2	2	2		
Pyrexia	1	3	1	3		
Rash	3	3	3	3		
Rhinorrhoea	2	3	2	3		
Rhinovirus infection	1	1	1	1		
Scar	1	1	1	1		
Swollen tongue	1	1			1	1
Syncope	2	2			2	2
Tachycardia	2	3	1	1	1	2
Tachypnoea	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	1	1			1	1
Thrombophlebitis	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site reaction	3	3	3	3		
Venous thrombosis	1	1	1	1		
Vertigo positional		1				1
Visual impairment	1	1	1	1		
Wheezing		1		1		
	88	116	68	86	20	30

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Altered state of consciousness		1				1	
Asthenia	1	1	1	1			
Blood pressure increased		1		1			
Cardiac arrest		1				1	
Cold sweat	1	1	1	1			
Concomitant disease aggravated	1	1			1	1	
Condition aggravated		2				2	
Consciousness fluctuating		1				1	
Contusion		1				1	
Cough		1		1			
Depressed level of consciousness	2	2			2	2	
Dyskinesia		1		1			
Dysphagia		1				1	
Facial paralysis		1				1	
Fall		1				1	
Fatigue		1		1			
General physical health deterioration	1	2			1	2	
Hypotension	1	1	1	1			
Loss of consciousness		2				2	
Myalgia		1				1	
Oxygen saturation decreased		1		1			
Pupil fixed	1	1			1	1	
Pyrexia	3	4	1	1	2	3	
Rash	2	2	1	1	1	1	
Respiratory rate increased		1		1			
Sepsis		1				1	
Somnolence		1				1	
Tachycardia		1				1	
Tachypnoea		1				1	
Tremor		2		2			
Unresponsive to stimuli	1	1			1	1	
Vaccination site erythema		1				1	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain		1				1
Vaccination site swelling		1				1
Vomiting	1	1	1	1		
Weight decreased		1				1
Wheezing		1		1		
	15	46	6	15	9	31

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		2		2		
Acute coronary syndrome		1				1
Acute kidney injury		1				1
Acute pulmonary oedema		1				1
Adverse event following immunisation	2	2			2	2
Anaphylactic reaction		1				1
Anxiety	1	1			1	1
Aphasia		1				1
Areflexia	1	1			1	1
Aspiration		1				1
Cardiac arrest	2	3			2	3
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	2			1	2
Circulatory collapse		1				1
Cognitive disorder		1				1
Cold sweat		2				2
Coma scale abnormal		1				1
Condition aggravated		1				1
Confusional state		2		1		1
Cough	3	4	2	2	1	2
Cyanosis	1	1			1	1
Death	3	5			3	5
Decreased appetite	1	2			1	2
Depressed level of consciousness	1	2			1	2
Diabetic ketoacidosis		1				1
Disease progression	1	1			1	1
Drooling	1	1			1	1
Dysarthria	1	2			1	2
Dysphagia		1				1
Dyspnoea	5	7			5	7
Facial paralysis		1				1
Fall	1	3		1	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	1	2		1	1	1
Flushing	1	1	1	1		
Foaming at mouth		1				1
General physical health deterioration	1	2			1	2
Heart rate increased		1				1
Hyperglycaemia		1				1
Hyperglycaemic hyperosmolar nonketotic syndrome		1				1
Hyperhidrosis	1	1			1	1
Hypertension	1	1	1	1		
Hypophagia		1				1
Hyporesponsive to stimuli		1				1
Hypotension		2				2
Hypoxia		1				1
Ischaemic stroke	1	2			1	2
Lethargy	1	1			1	1
Lip swelling	1	1	1	1		
Loss of consciousness	1	3			1	3
Malaise	4	5			4	5
Monoplegia		1				1
Multiple organ dysfunction syndrome		1				1
Mydriasis		2				2
Myocardial infarction	1	1			1	1
Oedema peripheral		1				1
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased	1	4			1	4
Pelvic fracture		1				1
Pneumonia	5	9			5	9
Pneumonia aspiration	2	2			2	2
Product preparation error		2		2		
Pulmonary congestion	1	1			1	1
Pulmonary embolism	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pulmonary sepsis		1				1	
Pupil fixed		1				1	
Pupils unequal		1				1	
Pyrexia	2	3	1	1	1	2	
Rales		1				1	
Respiratory distress	1	1			1	1	
Respiratory failure	2	3			2	3	
Respiratory rate increased	1	1			1	1	
Rhinorrhoea	1	2	1	2			
Seizure		1				1	
Septic shock		1				1	
Somnolence	1	2		1	1	1	
Swelling face	1	1	1	1			
Tremor		1		1			
Unresponsive to stimuli	4	6			4	6	
Urinary incontinence		1				1	
Urosepsis		2				2	
Vaccination site pain	1	1	1	1			
Vomiting	5	9		1	5	8	
Wheezing		1				1	
	69	152	10	21	59	131	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	4	4	4	4		
Abdominal tenderness	1	1	1	1		
Acute kidney injury	1	1			1	1
Anal haemorrhage	1	1	1	1		
Anaphylactic reaction	19	36			19	36
Angioedema	2	2			2	2
Anxiety	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	10	11	10	11		
Asthenia	1	1	1	1		
Balance disorder	1	1	1	1		
Blood creatine phosphokinase increased	1	1			1	1
Blood disorder	1	1	1	1		
Blood pressure decreased	2	2	2	2		
Blood pressure increased	2	2	2	2		
Bradycardia	2	4			2	4
Burning sensation	1	1	1	1		
Cellulitis	2	2			2	2
Cerebrovascular accident	3	5			3	5
Chest discomfort	8	8	8	8		
Chest pain	2	2	2	2		
Chills	11	12	11	11		1
Cold sweat	2	4	2	3		1
Confusional state	2	2	2	2		
Conjunctival haemorrhage	2	2			2	2
Contusion	4	4	4	4		
Cough	12	16	12	16		
COVID-19	1	1			1	1
Deafness	2	2			2	2
Deafness unilateral	2	2			2	2
Death		1				1
Decreased appetite	1	2	1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deep vein thrombosis		1
Delirium	1	2
Depressed level of consciousness		1
Diabetes mellitus	1	1
Diarrhoea	7	7
Disorientation	2	2
Dizziness	13	16
Drug ineffective	1	1
Dysgeusia	2	2
Dysphagia	1	1
Dyspnoea	9	11
Erythema	2	4
Extensive swelling of vaccinated limb	1	1
Eye pain	1	1
Eye pruritus	1	1
Facial paralysis	5	5
Facial paresis	3	5
Fall	1	1
Fatigue	17	18
Feeling abnormal		1
Feeling hot	3	4
Flushing	4	4
Food refusal		1
Gait disturbance	1	2
Gastrointestinal haemorrhage		1
Hallucination	1	1
Headache	28	32
Head discomfort	1	1
Heart rate increased	3	3
Heart rate irregular		1
Hemiparesis	1	1
Herpes zoster	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	2
			1
		1	1
7	7		
2	2		
13	15		1
		1	1
2	2		
1	1		
7	8	2	3
2	4		
		1	1
1	1		
1	1		
		5	5
	1	3	4
1	1		
17	18		
	1		
3	4		
4	4		
	1		
1	2		
			1
		1	1
28	32		
1	1		
3	3		
			1
		1	1
2	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	1	3	1	3		
Hyperhidrosis	4	5	4	5		
Hypersensitivity	1	1	1	1		
Hypertension	6	6	6	6		
Hyperthyroidism	2	2			2	2
Hypoaesthesia	4	4	4	4		
Hypopnoea	1	2	1	2		
Hypotension	6	8	6	7		1
Hypoxia	1	2			1	2
Influenza like illness	2	2	2	2		
Injected limb mobility decreased	1	1	1	1		
Insomnia	1	1	1	1		
Iridocyclitis	1	1			1	1
Lethargy	15	18	15	18		
Limb discomfort	1	1	1	1		
Lip swelling	2	2	2	2		
Liver function test increased	1	1	1	1		
Liver injury	1	1			1	1
Localised oedema	1	1	1	1		
Loss of consciousness	3	3			3	3
Lymphadenopathy	6	6	5	5	1	1
Malaise	4	5	4	5		
Migraine	1	1	1	1		
Migraine with aura	1	1	1	1		
Mobility decreased	1	1	1	1		
Multiple sclerosis	1	1			1	1
Muscle spasms	1	2	1	2		
Muscle twitching	1	1	1	1		
Muscular weakness	1	1	1	1		
Myalgia	15	16	15	16		
Nasal congestion	3	3	3	3		
Nasopharyngitis	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	19	26	19	25		1
Neck pain	2	2	2	2		
Nervousness		1				1
Neuropathy peripheral	1	1			1	1
Occipital neuralgia	1	1	1	1		
Ocular hyperaemia	2	2	2	2		
Off label use	2	2	2	2		
Oropharyngeal pain	7	8	7	8		
Pain		1		1		
Pain in extremity	4	4	4	4		
Pallor	1	2	1	1		1
Palpitations	4	5	4	5		
Pancreatitis	1	1			1	1
Panic reaction	1	1	1	1		
Paraesthesia	7	8	7	8		
Paraesthesia ear	1	1	1	1		
Paraesthesia oral	5	5	5	5		
Peripheral circulatory failure	1	1			1	1
Peripheral coldness	1	1	1	1		
Peripheral swelling		1		1		
Pharyngeal swelling	1	2			1	2
Photophobia	2	2	2	2		
Pleuritic pain	1	1	1	1		
Pneumonia	1	2			1	2
Pneumonia aspiration		1				1
Pneumonia viral		1				1
Presyncope	6	7	6	7		
Product use issue	2	3	2	3		
Pruritus	5	7	5	7		
Pulmonary embolism	3	3			3	3
Pulmonary oedema	1	1			1	1
Pyrexia	18	19	18	19		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	10	12	9	11	1	1
Rash pruritic	2	3	2	3		
Rectal haemorrhage	2	2			2	2
Respiratory tract infection	1	1			1	1
Retching	1	1	1	1		
Retinal artery occlusion	1	1			1	1
Rhinorrhoea	3	5	3	5		
Seizure	7	8			7	8
Sensitive skin	1	1	1	1		
Sensory loss	1	1	1	1		
Sepsis		1				1
Sinus pain	1	1	1	1		
Soft tissue inflammation	1	1	1	1		
Somnolence		2		2		
Speech disorder	1	1	1	1		
Spinal pain	1	1	1	1		
Swelling face	1	1	1	1		
Swollen tongue	2	3	2	3		
Syncope	21	27			21	27
Tachycardia	6	6	6	6		
Tachypnoea	1	1	1	1		
Throat irritation	5	5	5	5		
Throat tightness	3	3	2	2	1	1
Tinnitus	2	2	2	2		
Transient ischaemic attack	1	1			1	1
Tremor	3	4	3	4		
Unresponsive to stimuli	2	2			2	2
Urticaria	6	8	6	8		
Vaccination site bruising	1	1	1	1		
Vaccination site cellulitis	1	1	1	1		
Vaccination site erythema	2	3	2	3		
Vaccination site pain	5	7	5	7		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	9	9	9	9		
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Vasoconstriction	1	1	1	1		
Vertigo	1	1	1	1		
Visual impairment	1	1	1	1		
Vomiting	7	8	7	7		1
Wheezing	1	1	1	1		
	526	639	416	479	110	160

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRIA**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness		1				1
Dyspnoea exertional		1				1
Facial paresis	1	1			1	1
Hypotension		1				1
Malaise		1		1		
Nausea		1				1
Off label use	1	2	1	2		
Product use issue	1	2	1	2		
Pyrexia		1		1		
Rash		1				1
Sinus tachycardia		1				1
Tachycardia		1				1
	3	14	2	6	1	8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower	1	1			1	1
Amenorrhoea		1				1
Angina pectoris		1				1
Anxiety		1		1		
Arthralgia	1	4	1	3		1
Asthenia	2	6	1	4	1	2
Asymptomatic COVID-19	3	3			3	3
Back pain	1	1			1	1
Blood creatine phosphokinase increased	1	2			1	2
Blood pressure increased		1				1
Bradycardia		2				2
Cardiac arrest		1				1
Cardiovascular disorder		1		1		
Chest discomfort	2	2			2	2
Chest pain	1	1	1	1		
Chills	4	13	4	9		4
Circulatory collapse	1	4			1	4
Clonus		1				1
Confusional state		1				1
Cough	1	2	1	2		
COVID-19	1	3		2	1	1
Dermatitis allergic		1				1
Diarrhoea	2	3	2	3		
Diarrhoea haemorrhagic		1				1
Diplopia		1		1		
Disturbance in attention		2				2
Dizziness	3	10	2	6	1	4
Drug eruption		1				1
Dry mouth		2		1		1
Dysaesthesia	1	2			1	2
Dysarthria	1	1			1	1
Dyspnoea	4	8	1	2	3	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional	1	1			1	1
Ear discomfort		1		1		
Electrocardiogram change		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram ST-T change	1	1			1	1
Erythema		2		2		
Eye pruritus		1		1		
Fatigue		13		9		4
Febrile convulsion		1		1		
Feeling cold		1				1
Feeling hot		1				1
Feeling jittery		1		1		
Flushing		3				3
Foreign body aspiration		1				1
Gait disturbance		1		1		
Headache	4	26	4	21		5
Head discomfort		1				1
Heart rate increased		1				1
Hemianaesthesia		1				1
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	1			1	1
Hot flush	1	2			1	2
Hyperhidrosis	1	1	1	1		
Hyperreflexia		1				1
Hypersensitivity		1				1
Hypertension	2	4			2	4
Hypertensive crisis		1				1
Hypertonia		1				1
Hypoaesthesia		4		2		2
Hypoaesthesia oral		2		1		1
Hypotension		2		1		1
Impaired work ability		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect route of product administration	1	1	1	1		
Influenza like illness	2	3	2	3		
Injection site bruising		1		1		
Injection site pain		1		1		
Injection site paraesthesia		1		1		
Leukopenia		1				1
Loss of consciousness		1				1
Lymphadenopathy	2	6	1	3	1	3
Lymph node pain		2		1		1
Memory impairment		1				1
Metrorrhagia		1				1
Migraine	1	1			1	1
Muscle contractions involuntary	1	2			1	2
Muscle spasms		1		1		
Muscle spasticity		1				1
Muscular weakness	1	2			1	2
Myalgia		3		2		1
Myocarditis		1				1
Nausea	4	7	3	6	1	1
Neck pain		2		2		
Neurological symptom		1				1
Oropharyngeal pain	1	4	1	4		
Pain	1	4	1	3		1
Painful respiration	1	1	1	1		
Pain in extremity	4	10	3	9	1	1
Pallor		1				1
Palpitations		3		2		1
Pancytopenia	1	1			1	1
Paraesthesia	5	7			5	7
Parosmia		1		1		
Peripheral swelling		2		2		
Petechiae		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling	1	3			1	3
Pneumothorax spontaneous	1	1			1	1
Poor peripheral circulation		1		1		
Pruritus		2				2
Pruritus allergic		1				1
Pulmonary function test decreased	1	1	1	1		
Pyrexia	6	20	6	16		4
Rash		6				6
Rash macular		1				1
Rash pruritic	2	2	1	1	1	1
Restlessness		1		1		
Rhinitis	1	2	1	2		
SARS-CoV-2 test positive	1	1			1	1
Sensation of foreign body		2				2
Sense of oppression	1	1			1	1
Sensory level abnormal	2	2			2	2
Somnolence		3		3		
Speech disorder		1				1
Spontaneous haematoma	1	1			1	1
Swelling		3		3		
Swelling face		1				1
Swollen tongue		1				1
Syncope	1	4			1	4
Tachycardia	2	4			2	4
Taste disorder		1		1		
Throat irritation		1				1
Thrombocytopenia	1	1			1	1
Troponin T increased	1	2			1	2
Urticaria	1	3	1	1		2
Vaccination failure	4	4			4	4
Vaccination site anaesthesia		1				1
Vaccination site erythema	1	4	1	3		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia		2		1		1
Vaccination site induration		1				1
Vaccination site lymphadenopathy	1	3	1	3		
Vaccination site pain	3	14	3	13		1
Vaccination site paraesthesia		1				1
Vaccination site reaction		1		1		
Vaccination site swelling		4		3		1
Vaccination site warmth		2		1		1
Ventricular fibrillation		1				1
Vertigo		4		3		1
Vomiting	3	5	3	5		
	103	361	49	186	54	175

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3		1	1	2
Abdominal pain upper		1		1		
Activated partial thromboplastin time prolonged	1	1			1	1
Acute disseminated encephalomyelitis	1	3			1	3
Acute macular outer retinopathy	1	1			1	1
Administration site hypoaesthesia	1	1	1	1		
Administration site joint pain		1		1		
Ageusia	1	2	1	2		
Agitation		1		1		
Alanine aminotransferase increased		1		1		
Alopecia		2		2		
Altered visual depth perception	1	1	1	1		
Amnesia	1	1	1	1		
Anaphylactic reaction	2	8			2	8
Anaphylactic shock		3				3
Anaphylactoid reaction		1				1
Angina pectoris	2	2			2	2
Anosmia		1		1		
Anxiety		1				1
Apathy		1		1		
Application site pain		1		1		
Arrhythmia	2	4			2	4
Arthralgia	3	31	2	19	1	12
Arthritis		1		1		
Aspartate aminotransferase increased		1		1		
Asthenia	2	8	2	8		
Asthma		1				1
Asymptomatic COVID-19	4	4			4	4
Autoimmune thyroiditis		1				1
Axillary pain	1	2		1	1	1
Back pain	1	4		2	1	2
Balance disorder	1	2	1	2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Beta globulin increased		1		1		
Blister		1				1
Blood albumin decreased		1		1		
Blood pressure abnormal	1	1			1	1
Blood pressure increased	1	6	1	3		3
Blood pressure systolic increased		1				1
Blood urea increased		1		1		
Body temperature abnormal		1		1		
Body temperature increased	3	11	3	11		
Bone pain		1		1		
Burning sensation	1	3	1	2		1
Bursitis		1		1		
Cardiovascular disorder	1	5	1	4		1
Chapped lips		1				1
Chest discomfort		5		1		4
Chest pain	1	6	1	3		3
Chills	4	42	4	24		18
Circulatory collapse	7	13			7	13
Concomitant disease aggravated		1				1
Condition aggravated	1	2	1	1		1
Confusional state	1	3	1	1		2
Contusion	1	1			1	1
Cough	1	4	1	4		
COVID-19	4	7	1	1	3	6
C-reactive protein increased		2		1		1
Decreased appetite		1		1		
Defaecation urgency		1		1		
Dermatitis allergic		1				1
Diarrhoea	1	11	1	8		3
Disorganised speech		1		1		
Disturbance in attention	2	3	2	3		
Dizziness	11	36	8	25	3	11

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Drug ineffective		4				4	
Dry mouth	1	5	1	4		1	
Dry throat		1		1			
Dysaesthesia	3	5	1	2	2	3	
Dysgeusia	2	4	1	1	1	3	
Dysgraphia		1		1			
Dysphagia		5		1		4	
Dyspnoea	4	17	2	4	2	13	
Dyspnoea exertional		5		1		4	
Dysuria		1		1			
Ear infection		1				1	
Ear pain		2		2			
Electrocardiogram abnormal		1		1			
Endocrine ophthalmopathy	1	1			1	1	
Epilepsy	1	1			1	1	
Epistaxis	1	3	1	2		1	
Erythema	2	7	1	3	1	4	
Exercise tolerance decreased		1		1			
External ear pain	1	1			1	1	
Extrasystoles		2		1		1	
Eye haemorrhage		1				1	
Eyelid oedema		1				1	
Eye pain	1	3		2	1	1	
Eye swelling		1		1			
Face oedema		1				1	
Facial paralysis	1	3			1	3	
Facial paresis	2	5			2	5	
Facial spasm		1				1	
Fall	1	2		1	1	1	
Fatigue	9	57	8	45	1	12	
Feeling abnormal	2	5	2	5			
Feeling cold		4		1		3	

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Feeling drunk		2		2			
Feeling hot	1	4		1	1	3	
Feeling of body temperature change		1		1			
Fibrin D dimer increased		1		1			
Flushing		3				3	
Formication		1		1			
Gait disturbance	2	3	1	1	1	2	
Gastrointestinal disorder		2		2			
Gastrointestinal motility disorder		1		1			
Generalised oedema		1		1			
General physical health deterioration	1	1			1	1	
Glossodynia		1				1	
Glossopharyngeal nerve disorder	1	1			1	1	
Grunting		1		1			
Haematuria	1	2			1	2	
Haemorrhage		1				1	
Hand dermatitis	1	1	1	1			
Hangover		1		1			
Headache	12	84	5	55	7	29	
Head discomfort		1		1			
Heart rate increased	1	2	1	2			
Hemianaesthesia		1				1	
Hemidysaesthesia		2				2	
Hemiparaesthesia		1				1	
Hepatic pain		1		1			
Hereditary angioedema with normal C1 esterase inhibitor		1				1	
Herpes zoster	1	4		3	1	1	
Hot flush		3		2		1	
Hyperhidrosis	2	3	2	2		1	
Hypersensitivity	2	11			2	11	
Hypersomnia		1		1			

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		5		1		4
Hypertensive crisis		2				2
Hyperventilation	1	2	1	1		1
Hypoacusis	1	1			1	1
Hypoaesthesia	4	18	2	6	2	12
Hypoaesthesia oral	1	6	1	2		4
Hypoglossal nerve paresis	1	1			1	1
Hypokalaemia	1	1			1	1
Hypokinesia		1		1		
Hypotension		2				2
Hypotonia		1		1		
Idiopathic angioedema		1				1
Immune thrombocytopenia		1				1
Impaired work ability	2	5	1	3	1	2
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		3		3		
Injected limb mobility decreased	1	1			1	1
Injection site pain		1		1		
Injury	1	1			1	1
Insomnia		4		3		1
Intervertebral disc protrusion	1	1			1	1
Joint range of motion decreased		1				1
Joint swelling	2	4	1	2	1	2
Lacrimation increased		1		1		
Laryngeal oedema		1				1
Laryngeal pain		1				1
Leukopenia	1	2			1	2
Lip dry		2		1		1
Lip erythema		1				1
Lip pruritus		1				1
Lip swelling		5				5
Lividity		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Localised oedema		1				1
Loss of consciousness	2	4			2	4
Lung disorder		1		1		
Lymphadenopathy	1	18		7	1	11
Lymph node pain		2		2		
Lymphopenia		1		1		
Malaise		7		5		2
Mania		1				1
Memory impairment	1	3	1	2		1
Meningism		1				1
Menorrhagia	1	1			1	1
Menstruation irregular	1	1			1	1
Migraine	1	4	1	4		
Monoparesis		2				2
Monoplegia	1	2			1	2
Mouth swelling		1				1
Movement disorder		1		1		
Multiple sclerosis		2				2
Muscle contractions involuntary		1		1		
Muscle disorder	1	1			1	1
Muscle spasms	2	5	1	3	1	2
Muscle twitching		1		1		
Muscular weakness	2	7		1	2	6
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal disorder	1	1			1	1
Myalgia	2	25	2	17		8
Myocardial infarction		1				1
Myocarditis		1				1
Narcolepsy		1				1
Nausea	9	36	7	20	2	16
Neck pain		2		2		
Neoplasm malignant		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nerve conduction studies abnormal		1				1
Neuralgia		2				2
Neuralgic amyotrophy		1				1
Neuritis		1				1
Night sweats		1				1
Nuchal rigidity		1		1		
Obstructive airways disorder		1		1		
Occipital neuralgia		1		1		
Ocular hyperaemia		1		1		
Oedema		1				1
Oedema peripheral	1	2			1	2
Off label use		4		4		
Onychoclasia		1		1		
Oral discomfort		2				2
Oral pruritus		2				2
Oral pustule		1		1		
Oropharyngeal pain	2	3	2	2		1
Oxygen saturation decreased	1	3		1	1	2
Pain	1	9		6	1	3
Pain in extremity	7	39	4	28	3	11
Pain of skin		2		1		1
Palatal swelling		1				1
Pallor		2		1		1
Palmar erythema		1				1
Palpitations	4	14	3	5	1	9
Panic attack		1				1
Paraesthesia	4	23	1	10	3	13
Paraesthesia oral		2				2
Paresis		1				1
Performance status decreased	1	1	1	1		
Pericardial effusion	2	2			2	2
Periorbital swelling		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		1		1		
Peripheral swelling		5		1		4
Peripheral vascular disorder	1	1	1	1		
Peroneal nerve palsy	1	1			1	1
Petechiae		2		1		1
Pharyngeal swelling		2		1		1
Photophobia		2		2		
Platelet count increased		1		1		
Pleural effusion	1	1			1	1
Pneumonia	1	1			1	1
Pollakiuria	1	1	1	1		
Poor quality product administered		1		1		
Presyncope	2	11		2	2	9
Product preparation error		1		1		
Product use issue		3		3		
Prurigo	1	1			1	1
Pruritus	3	20		5	3	15
Psychotic disorder		1				1
Pulmonary embolism	2	2			2	2
Pupils unequal		1				1
Pustule		1		1		
Pyrexia	11	58	6	34	5	24
Rash	6	16	3	6	3	10
Rash macular		2		1		1
Rash morbilliform		1				1
Rash pruritic		4				4
Rash pustular		1				1
Red blood cell sedimentation rate increased		1		1		
Reduced facial expression		1		1		
Renal pain		2				2
Respiratory disorder		1		1		
Respiratory distress		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restlessness		3		2		1
Rhabdomyolysis	1	1			1	1
Rhinitis allergic		1				1
SARS-CoV-2 antibody test negative		1				1
SARS-CoV-2 test positive	1	1			1	1
Seizure	1	1			1	1
Sensation of foreign body		3				3
Sensory disturbance		1				1
Serum ferritin decreased		1		1		
Shock		1				1
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin discolouration		1				1
Skin exfoliation	1	2	1	1		1
Skin indentation		1		1		
Skin reaction		1		1		
Skin tightness		1				1
Sleep attacks		1		1		
Sleep disorder due to general medical condition, hypersomnia type		1		1		
Somatic symptom disorder		1				1
Somnolence	2	16	2	12		4
Speech disorder		1				1
Spinal pain		3		2		1
Splenic vein thrombosis	1	1			1	1
Strabismus		1		1		
Swelling		3		1		2
Swelling face		4		1		3
Swollen tongue		8		2		6
Syncope		9				9
Syringe issue		1		1		
Tachycardia	1	7		2	1	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tachycardia paroxysmal		1					1
Taste disorder		1					1
Tension		1		1			
Thirst	1	1	1	1			
Throat irritation	1	4	1	2			2
Throat tightness		4					4
Thrombocytopenia		1					1
Tinnitus	1	1	1	1			
Tongue discomfort		2					2
Tonsillitis bacterial		1					1
Toothache	1	1			1		1
Transferrin increased		1		1			
Tremor		2		2			
Trichoglossia		1		1			
Trigeminal neuralgia	1	2			1		2
Troponin increased		1					1
Underdose		1		1			
Urinary tract infection	1	1			1		1
Urticaria		8					8
Urticaria pressure		1					1
Use of accessory respiratory muscles		1		1			
Vaccination failure	8	8			8		8
Vaccination site discolouration		2					2
Vaccination site dysaesthesia		1					1
Vaccination site erythema	2	6		1	2		5
Vaccination site hypoaesthesia		4		2			2
Vaccination site induration		3		2			1
Vaccination site inflammation	1	1			1		1
Vaccination site lymphadenopathy		5		2			3
Vaccination site movement impairment	1	4	1	4			
Vaccination site pain	8	55	5	44	3		11
Vaccination site paraesthesia	1	1	1	1			

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site pruritus		4		1		3	
Vaccination site pustule		1		1			
Vaccination site rash		1		1			
Vaccination site reaction	1	3	1	3			
Vaccination site swelling		8		4		4	
Vaccination site urticaria	1	1			1	1	
Vaccination site warmth	1	3		2	1	1	
Vasculitis		1				1	
Ventricular extrasystoles		1				1	
Vertigo	2	10	1	6	1	4	
Vestibular neuronitis	1	1			1	1	
Viral infection		1		1			
Viral rash		1				1	
Vision blurred	1	5	1	4		1	
Visual field defect	1	2			1	2	
Visual impairment	2	4		1	2	3	
Vomiting	4	8	4	5		3	
Weight bearing difficulty	1	1	1	1			
White blood cell count increased		1		1			
White blood cells urine		1				1	
	270	1,322	123	667	147	655	

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain		1				1
Abdominal pain lower		1				1
Abdominal pain upper	1	1	1	1		
Ageusia		1		1		
Analgesic drug level above therapeutic		1				1
Anaphylactic shock		1				1
Anaphylactoid reaction		1				1
Angina pectoris		1				1
Antibody test abnormal		1		1		
Anxiety		1		1		
Aphasia	1	2		1	1	1
Aphonia		1				1
Arrhythmia		1				1
Arthralgia	4	17	2	10	2	7
Asthenia	1	6	1	6		
Asthma		1				1
Asymptomatic COVID-19	1	1			1	1
Atelectasis		1				1
Back pain	1	3	1	1		2
Balance disorder		1				1
Basilar migraine	1	1			1	1
Bedridden	1	1	1	1		
Biliary colic	1	1			1	1
Blepharospasm		1				1
Blood glucose fluctuation		1				1
Blood lactate dehydrogenase increased		1		1		
Blood pressure abnormal	1	1			1	1
Blood pressure increased		3		1		2
Bone marrow oedema		1				1
Bronchial obstruction	1	1			1	1
Bundle branch block right		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bursitis		1				1
Cardiomyopathy		1				1
Cardiovascular disorder		3		3		
Cerebellar stroke	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Chest pain		1				1
Chills	7	26	7	19		7
Chronic obstructive pulmonary disease		1				1
Circulatory collapse	1	2			1	2
Coagulopathy	1	1			1	1
Concomitant disease aggravated		1				1
Concomitant disease progression		1				1
Condition aggravated	1	1			1	1
Conjunctival haemorrhage	2	2			2	2
Conjunctivitis		1				1
Cough		4		3		1
COVID-19	1	3		1	1	2
Death	1	1			1	1
Decreased appetite	1	2	1	2		
Deep vein thrombosis	1	1			1	1
Delirium	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea	2	8	2	6		2
Diarrhoea haemorrhagic	1	1			1	1
Diplopia		1				1
Discomfort		1		1		
Disease progression		1				1
Disorientation		2		1		1
Disturbance in attention	1	2			1	2
Dizziness	2	15	2	10		5
Drug ineffective		1				1
Dry mouth		1		1		

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Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		1
	2		
1		1	6
	1		
	1		1
1		1	1
			1
1	4		2
			1
			1
	1		
	1		1
			1
		2	4
1		1	1
3	25		7
			2
	2		
	1		
1		1	1
1	1		
	1		3
			1
	1		
1	1		
		1	1
8	28	1	11
			1
1		1	1
	1		1
			1
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperaesthesia		1				1
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	4		1	1	3
Hypertension		1				1
Hypertensive crisis	1	4			1	4
Hypoaesthesia		2		2		
Hypoaesthesia oral		1		1		
Hypogeusia		2		1		1
Hypoglycaemia		1				1
Hyposmia		1				1
Hypotension	1	3			1	3
Hypotonia		1		1		
Illness		1				1
Impaired driving ability		1				1
Impaired quality of life	1	1			1	1
Impaired work ability		4		1		3
Incorrect route of product administration		1		1		
Inflammation		1				1
Influenza like illness	1	2	1	1		1
Insomnia		2		1		1
Intentional overdose		1				1
Intraocular pressure increased		1				1
Laryngospasm		1				1
Leukopenia		1				1
Limb discomfort		1				1
Lip swelling	1	1			1	1
Locked-in syndrome	1	1			1	1
Loss of consciousness		2				2
Loss of personal independence in daily activities		1				1
Lymphadenopathy		5		2		3
Lymph node pain		1		1		
Lymph node palpable		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	3	1	2		1
Memory impairment	1	1			1	1
Migraine		1		1		
Mouth swelling		1				1
Movement disorder		1		1		
Muscle spasms		1		1		
Muscular weakness		1		1		
Myalgia	1	20	1	13		7
Nausea	3	22	3	15		7
Neck pain		2		1		1
Neuralgia		1		1		
Neuropathy peripheral		1				1
Night sweats		1		1		
Nuchal rigidity		1				1
Ocular hyperaemia		1		1		
Oedema mucosal		1		1		
Off label use		1		1		
Opiates positive		1				1
Oral mucosal erythema		1				1
Oropharyngeal pain		2				2
Oxygen saturation decreased		1				1
Pain		2		1		1
Pain in extremity	4	11	3	8	1	3
Pallor		1		1		
Palpitations		1				1
Panic reaction		1		1		
Paraesthesia		9		5		4
Paraesthesia oral		2		1		1
Parosmia		1		1		
Peripheral coldness	1	2	1	1		1
Peripheral swelling	1	1	1	1		
Personality change		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling		2		1		1
Photophobia	1	2	1	2		
Pneumonia aspiration		1				1
Presyncope	1	6		2	1	4
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Pruritus	1	7		1	1	6
Pulmonary embolism	1	2			1	2
Pyrexia	5	35	5	21		14
Radial nerve palsy	1	1			1	1
Radiculopathy		1				1
Rash		6		1		5
Rash macular		1				1
Rash pruritic		1		1		
Rash pustular		2		1		1
Renal pain	1	1			1	1
Respiratory failure		1				1
Retinal tear	1	1			1	1
Rheumatoid arthritis		1				1
Road traffic accident	1	1			1	1
Ruptured cerebral aneurysm		1				1
SARS-CoV-2 antibody test negative		1				1
Sensation of foreign body		1				1
Serum ferritin increased		1		1		
Shift to the left		1				1
Sinus congestion		1		1		
Skin lesion		1				1
Sleep disorder		1				1
Somnolence		2		1		1
Speech disorder		1		1		
Spinal pain	1	1			1	1
Status epilepticus		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stomatitis	1	1
Subarachnoid haemorrhage		1
Sudden hearing loss	2	2
Suspected COVID-19		1
Swelling		2
Swelling face		3
Swelling of eyelid		1
Swollen tongue		1
Syncope		3
Tachycardia	1	2
Tachypnoea		1
Taste disorder		1
Tendon disorder		1
Tension headache		2
Thinking abnormal		1
Throat irritation		1
Tinnitus	1	3
Tongue discomfort		2
Toxicity to various agents		1
Transaminases increased	1	2
Tremor	1	1
Troponin I increased		1
Tunnel vision		2
Urticaria	1	2
Vaccination failure	1	2
Vaccination site erythema	1	2
Vaccination site haemorrhage		1
Vaccination site hypoaesthesia		1
Vaccination site joint pain	1	2
Vaccination site movement impairment		1
Vaccination site pain	2	18
Vaccination site rash		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
			1
		2	2
			1
	1		1
	1		2
			1
			1
			3
		1	2
	1		
	1		
	1		
	1		1
	1		1
1	2		1
	1		1
			1
	1	1	1
		1	1
			1
		1	2
		1	2
1	2		
	1		
	1		
	1	1	1
			1
2	14		4
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	2	5	1	4	1	1
Vaccination site urticaria		1		1		
Vaccination site warmth		1		1		
Vaginal haemorrhage	1	1			1	1
Venous thrombosis limb		1				1
Vertigo		5		2		3
Vision blurred		1				1
Visual impairment	3	5			3	5
Vitreous haemorrhage	1	1			1	1
Vomiting	1	7	1	3		4
Wrong technique in product usage process		1		1		
	117	605	57	302	60	303

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis	1	1	1	1		
Acute coronary syndrome	1	2			1	2
Agitation		1		1		
Angioedema	1	1			1	1
Anti-platelet antibody	1	1			1	1
Anxiety	1	1			1	1
Arrhythmia	1	1			1	1
Arterial occlusive disease	1	1			1	1
Arthralgia	1	2			1	2
Asthenia	2	5		2	2	3
Atrial fibrillation	1	3			1	3
Autoimmune disorder		1				1
Autoimmune haemolytic anaemia		1				1
Bacterial sepsis		1				1
Balance disorder		1				1
Basal ganglia stroke	1	1			1	1
Blood creatine phosphokinase increased		1		1		
Blood pressure increased		1		1		
Body temperature increased		1		1		
Bradycardia		1				1
Bradykinesia		2		1		1
Brain natriuretic peptide increased		1				1
Breast pain		1		1		
Bronchitis	1	1			1	1
Cachexia		1				1
Cardiopulmonary failure		1				1
Cardiovascular disorder	1	1			1	1
Central nervous system infection		1				1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebral ischaemia		1				1
Cerebrovascular accident		2				2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	1	1			1	1
Chest pain		1				1
Chills	2	3	2	2		1
Chronic obstructive pulmonary disease	1	1	1	1		
Circulatory collapse		2				2
Confusional state	1	1			1	1
COVID-19		3				3
COVID-19 pneumonia		2				2
C-reactive protein increased		1		1		
Daydreaming		1				1
Death	1	7			1	7
Decreased appetite	1	2		1	1	1
Deep vein thrombosis	1	1			1	1
Dermatitis bullous	1	1			1	1
Disease recurrence		1				1
Disorientation		1		1		
Dizziness	1	5	1	2		3
Drug eruption		1				1
Drug ineffective		2				2
Dysphagia	1	1			1	1
Dyspnoea		4				4
Dyspnoea exertional		1		1		
Dysstasia		1				1
Extrasystoles	1	1			1	1
Facial asymmetry	1	1			1	1
Facial bones fracture	1	1			1	1
Facial paresis		1				1
Fall	1	3			1	3
Fatigue	3	7	3	5		2
Feeling cold		1				1
Fibrin D dimer increased		1				1
Gait disturbance		1		1		

\* I=Interval, C=Cumulative  
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Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			4
	1		
			1
1		1	4
			1
			1
			1
1		1	1
1		1	1
			1
			1
			1
			1
		1	1
		1	1
			1
			1
		1	1
			2
			2
			1
1	1		
1		1	1
1		1	2
1		1	1
			1
			1
			1
			1
1		1	1
1			1
			1
1		1	1
1			1
			1
1		1	1
1			1
			1
1		1	1
1			1
			1
1		1	1
1			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	1	1			1	1
Pain in extremity		3		1		2
Palpitations	1	1			1	1
Peripheral swelling	1	1			1	1
Petit mal epilepsy		1				1
Pharyngeal lesion	1	1	1	1		
Pleurisy		1				1
Pneumonia		1				1
Pneumonia aspiration		2				2
Post herpetic neuralgia	1	1			1	1
Presyncope	1	1			1	1
Pulmonary embolism	2	7			2	7
Pulmonary infarction		1				1
Pupillary reflex impaired		1				1
Pyrexia	4	14	1	5	3	9
Rash		1				1
Respiratory failure		1				1
Restlessness		1		1		
Retching	1	1	1	1		
Retinal artery occlusion	1	1			1	1
SARS-CoV-2 antibody test negative	1	1			1	1
SARS-CoV-2 test positive		2				2
Seizure		1				1
Sepsis	1	1			1	1
Sinus tachycardia	1	1			1	1
Somnolence	2	2	1	1	1	1
Speech disorder	1	1			1	1
Supraventricular tachycardia	1	1			1	1
Syncope		2				2
Systemic inflammatory response syndrome		1				1
Thrombocytopenia	1	2			1	2
Troponin T increased		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria		2				2
Vaccination site pain	1	4	1	3		1
Vaccination site rash		1				1
Vaccination site swelling	1	1			1	1
Vaginal haemorrhage		1				1
Venous thrombosis limb		1		1		
Vertigo	4	4			4	4
Vitreous haemorrhage	1	1			1	1
Vomiting		1		1		
	75	223	17	54	58	169

\* I=Interval, C=Cumulative  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Acute kidney injury	1	1			1	1
Acute left ventricular failure	1	1			1	1
Acute myocardial infarction		1				1
Agranulocytosis		1				1
Allodynia	1	1	1	1		
Anaemia	1	1			1	1
Anaphylactic shock		2				2
Angina pectoris	1	1			1	1
Angioedema	1	1			1	1
Aphasia	2	2			2	2
Apnoea	1	1			1	1
Arrhythmia		1				1
Arthralgia	2	3			2	3
Asthenia	3	6	2	3	1	3
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation	1	3			1	3
Back pain	1	1			1	1
Blood glucose increased	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure decreased		2		1		1
Blood pressure immeasurable		1				1
Body temperature increased		2		1		1
Bradycardia		1				1
Breath sounds		1		1		
Breath sounds abnormal	1	1			1	1
Bundle branch block left	1	1			1	1
Cachexia	1	1			1	1
Cardiac arrest	3	3			3	3
Cardiac death		1				1
Cardiac failure	2	8			2	8
Cardiopulmonary failure	1	1			1	1

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 \* AE=Adverse Event  
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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cardio-respiratory arrest		2					2
Cerebral artery occlusion	1	1			1		1
Cerebral haemorrhage	1	1			1		1
Cerebral infarction	2	2			2		2
Cerebrovascular accident	3	5			3		5
Chest discomfort		1		1			
Chest pain	3	5		1	3		4
Chills		3					3
Choking		1					1
Cholestasis		1					1
Circulatory collapse		3					3
Cold sweat		1					1
Colitis		1					1
Concussion	1	1			1		1
Confusional state	2	2			2		2
Cough		2		1			1
COVID-19	1	15			1		15
COVID-19 pneumonia		2					2
Cranio-cerebral injury	1	1			1		1
C-reactive protein increased		1					1
Death	2	10			2		10
Decreased appetite		1		1			
Deep vein thrombosis	2	6			2		6
Dehydration	1	1			1		1
Diarrhoea		2		1			1
Diarrhoea haemorrhagic		1					1
Disease recurrence	1	1			1		1
Disseminated varicella zoster virus infection	1	1			1		1
Dizziness	1	3	1	2			1
Dizziness postural		1		1			
Drug ineffective		7					7
Dysarthria		1					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesia	1	1			1	1
Dysphagia	2	2			2	2
Dyspnoea	6	9			6	9
Dysstasia		1		1		
Eczema		1				1
Emphysema		1				1
Epilepsy		2				2
Escherichia sepsis		1				1
Eye contusion	1	1			1	1
Eyelid contusion	1	1			1	1
Eye movement disorder		1				1
Face oedema		1				1
Facial paralysis	3	3	1	1	2	2
Fall	3	3			3	3
Fatigue	5	13	3	8	2	5
Feeling hot		2		1		1
Flushing		1				1
Gait disturbance		2		2		
Gastroenteritis		1		1		
Generalised tonic-clonic seizure		2				2
General physical health deterioration	3	8		2	3	6
Haematemesis		1				1
Haematoma	1	1			1	1
Hallucination		1				1
Headache	1	3	1	3		
Heart rate decreased		2				2
Hemiparesis	1	1			1	1
Hemiplegia	1	1			1	1
Herpes zoster		1				1
Hyperglycaemia		1				1
Hypernatraemia		1				1
Hypertension		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypertensive crisis		2					2
Hypertensive emergency		1					1
Hyperventilation	1	1			1		1
Hypophagia		1					1
Hypopnoea	1	1			1		1
Hypotonia		2		1			1
Inappropriate schedule of product administration		2		2			
Incontinence	1	1			1		1
Incorrect route of product administration		3		3			
Infection	1	1			1		1
Interleukin level increased		1					1
Ischaemic stroke	1	1			1		1
Lack of spontaneous speech	1	1			1		1
Language disorder	1	1	1	1			
Left ventricular failure		2					2
Leukocytosis		2					2
Leukoencephalopathy	1	1			1		1
Loss of consciousness		1					1
Lung infiltration		1					1
Lymph node pain	1	1			1		1
Lymphocyte count increased		1					1
Lymphocytosis		1					1
Malaise	1	2			1		2
Marasmus		1					1
Meningitis bacterial		1					1
Multiple organ dysfunction syndrome	1	2			1		2
Muscle spasms		1					1
Myalgia	2	3	2	2			1
Myocardial infarction	2	3			2		3
Myocarditis		1					1
Myoclonus	1	1			1		1
Nausea	2	9	2	5			4

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutropenia		1				1
Off label use		2		2		
Oxygen saturation		1				1
Oxygen saturation decreased	1	2		1	1	1
Oxygen saturation immeasurable		1				1
Pain	2	3	1	1	1	2
Pain in extremity	1	3			1	3
Pallor	1	3			1	3
Palpitations	1	1			1	1
Paraesthesia	2	2			2	2
Paraesthesia oral		1				1
Pemphigus		1				1
Pericarditis		1				1
Peripheral swelling		1				1
Pleural effusion		2				2
Pneumonia	2	7			2	7
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Presyncope		1				1
Productive cough		1		1		
Pruritus		2				2
Psoriasis	1	1			1	1
Pulmonary embolism	7	11			7	11
Pulmonary hypertensive crisis	1	1			1	1
Pulmonary infarction		1				1
Pulmonary oedema		2				2
Pyrexia	3	9	1	4	2	5
Rales		2		1		1
Rash		2				2
Rash macular		1				1
Renal failure	1	2			1	2
Respiratory depression		1				1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Respiratory rate decreased		1					1
Retching		1		1			
Rib fracture	1	1			1		1
SARS-CoV-2 test positive		1					1
Seizure	1	3			1		3
Sensory disturbance	1	1			1		1
Sepsis		1					1
Septic shock		1					1
Skin wrinkling	1	1	1	1			
Somnolence	1	4	1	1			3
Sopor	1	1			1		1
Speech disorder	1	1			1		1
Subcutaneous haematoma	1	1			1		1
Subdural haemorrhage	1	1			1		1
Syncope		4					4
Tachycardia		2					2
Thalamic infarction	1	1			1		1
Thrombophlebitis	2	2	1	1	1		1
Thrombosed varicose vein	1	1			1		1
Thrombosis	4	4			4		4
Thrombosis mesenteric vessel		1					1
Transient ischaemic attack	1	1			1		1
Tremor		1					1
Type I hypersensitivity	1	1			1		1
Unresponsive to stimuli		4					4
Urinary retention		1					1
Urine ketone body present	1	1	1	1			
Urticaria	1	1			1		1
Vaccination complication		1					1
Vaccination failure	2	3			2		3
Vaccination site erythema		2		2			
Vaccination site pain		1		1			

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Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		2		2		
Vaginal discharge		1		1		
Vascular encephalopathy	1	1			1	1
Venous thrombosis limb	3	3			3	3
Vertigo		1				1
Vomiting	3	7	1	4	2	3
Wound haemorrhage	1	1			1	1
Wrong technique in product usage process		1		1		
	151	405	21	76	130	329

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Aneurysm ruptured		1				1
Antibody test abnormal		1		1		
Antiphospholipid syndrome		1				1
Apathy		1		1		
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Asthenia		2		2		
Atrial fibrillation		1				1
Back pain		2		1		1
Blood creatine phosphokinase MB increased		1				1
Blood pressure decreased		1				1
Body temperature increased		1				1
Bronchiolitis		1				1
Cardiac hypertrophy		1				1
Cardiomegaly		1		1		
Cardiovascular disorder		1		1		
Cerebral haemorrhage		1				1
Chest discomfort		1				1
Chills		2		2		
Complication associated with device		1		1		
Congestive hepatopathy		1				1
Coronavirus infection		1				1
Cough		1				1
COVID-19	2	16		1	2	15
Diarrhoea		2		1		1
Drug ineffective	3	17			3	17
Dyspnoea		2		1		1
Dyspnoea exertional		1				1
Emphysema		1		1		
Facial paralysis		1				1
Fatigue		7		6		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal pain		1				1
Headache		8		7		1
Helicobacter infection		1				1
Hepatic steatosis		1		1		
Hirsutism		1		1		
Impaired work ability		1				1
Incorrect dose administered	1	1	1	1		
Influenza like illness		5		4		1
Lymphadenopathy		2		2		
Maternal exposure during pregnancy	1	1	1	1		
Muscle spasms		1				1
Myalgia		1				1
Nasopharyngitis		1		1		
Nausea	1	3	1	3		
Neutralising antibodies negative		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		5		4		1
Palpitations		1				1
Paraesthesia		1		1		
Performance status decreased		2		1		1
Pneumonia		1				1
Pneumonia bacterial		1				1
Presyncope		1				1
Pruritus		1		1		
Pulmonary congestion		1				1
Pulmonary embolism		1				1
Pulmonary oedema		1				1
Pyrexia	1	6	1	6		
Renal disorder		1		1		
SARS-CoV-2 antibody test negative		1		1		
Skin striae		1		1		
Subarachnoid haemorrhage		1				1

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Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19	1	1			1	1
Syncope	1	1			1	1
Therapeutic response unexpected		1		1		
Urticaria		1		1		
Vaccination site erythema		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain		3		3		
Vaccination site pruritus		1		1		
Vomiting	1	1	1	1		
Wrong technique in product usage process		1		1		
	12	142	5	69	7	73

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**BAHRAIN**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
Myalgia		1		1
Vaccination site pain		1		1
		3		3

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	1	1			1	1
Chills	1	3		2	1	1
Dyspnoea	1	1			1	1
Heart rate increased	1	1			1	1
Hot flush		1		1		
Hyperhidrosis	1	1			1	1
Lymphadenopathy		1		1		
Muscle spasms	1	1			1	1
Myalgia		1		1		
Nausea		1		1		
Neck pain		1		1		
Pain	1	2		1	1	1
Paraesthesia	1	1			1	1
Pruritus		1		1		
Pyrexia	1	3		2	1	1
Swelling	1	1			1	1
	10	21		11	10	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**BELGIUM**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Exposure via breast milk	1	1	1	1		
Syncope		1				1
	1	3	1	1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension		1		1		
Abdominal pain		2				2
Acute macular outer retinopathy		1				1
Alanine aminotransferase increased	1	1	1	1		
Anaphylactic reaction	1	4			1	4
Angina pectoris		1				1
Apathy	1	1			1	1
Appendicitis		2				2
Arthralgia	8	34	1	1	7	33
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	1	8	1	2		6
Autoimmune disorder	1	1			1	1
Axillary mass		1				1
Axillary pain	2	5		1	2	4
Back pain	1	3			1	3
Blood pressure decreased	2	2			2	2
Blood pressure increased		1				1
Blood test abnormal	1	1			1	1
Body temperature fluctuation		1				1
Body temperature increased	1	2			1	2
Bone pain		1				1
Bradycardia	1	1			1	1
Burning sensation	1	1	1	1		
Cardiac arrest		2				2
Cardiovascular disorder	2	5	1	1	1	4
Chest discomfort	1	3	1	1		2
Chest pain	1	1			1	1
Chills	35	105	3	7	32	98
Coagulopathy	2	2			2	2
Condition aggravated		1				1
Contusion	1	2			1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1			1	1
COVID-19	1	2	1	1		1
Crying		1				1
Cyanosis		1				1
Deafness unilateral		1				1
Decreased appetite		2		1		1
Diarrhoea	3	5	1	1	2	4
Diarrhoea haemorrhagic	1	1			1	1
Disorientation		1				1
Disturbance in attention	1	1	1	1		
Dizziness	5	9		1	5	8
Drug ineffective		1				1
Dry mouth		1				1
Dysgeusia	1	1	1	1		
Dysphagia	1	1	1	1		
Dyspnoea	5	7			5	7
Dyspnoea exertional	1	1			1	1
Endolymphatic hydrops		1				1
Epilepsy		1				1
Epistaxis	1	1			1	1
Erythema		1				1
Eye pain	2	6	2	3		3
Eye swelling		1				1
Facial paralysis	1	4			1	4
Fatigue	43	127	6	15	37	112
Feeling abnormal		1				1
Feeling cold	1	3		2	1	1
Feeling hot		2		2		
Feeling of body temperature change	2	3			2	3
Fibrin D dimer increased	1	1			1	1
Gamma-glutamyltransferase increased	1	1	1	1		
Gastric disorder		1				1

\* I=Interval, C=Cumulative  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised tonic-clonic seizure	1	1			1	1
Haematoma		1				1
Hallucination		1				1
Headache	43	138	6	16	37	122
Heart rate increased		4		1		3
Hepatic enzyme increased	1	1	1	1		
Hepatitis		1				1
Herpes ophthalmic		1				1
Herpes zoster		1		1		
Hyperaesthesia	1	1			1	1
Hyperhidrosis	1	3			1	3
Hypersensitivity	1	4			1	4
Hypersomnia		1				1
Hyperventilation	1	2			1	2
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypothermia		1				1
Illness		2		2		
Influenza like illness	9	24	3	3	6	21
Injection site reaction	2	4	1	1	1	3
Insomnia	1	5		2	1	3
Joint range of motion decreased	1	1			1	1
Joint stiffness		1				1
Ketoacidosis		3				3
Lacrimation increased	1	1			1	1
Laryngeal oedema		1				1
Limb discomfort	1	2		1	1	1
Localised infection		1				1
Loss of consciousness		2				2
Lung disorder	1	1			1	1
Lymphadenitis		1				1
Lymphadenopathy	4	10	2	3	2	7

\* I=Interval, C=Cumulative  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymph node pain	2	3			2	3
Malaise	21	63	2	4	19	59
Migraine	1	4			1	4
Muscle contracture		1				1
Muscle fatigue	1	1			1	1
Muscle strain	3	3			3	3
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness	6	20	5	11	1	9
Myalgia	32	106	3	7	29	99
Nausea	19	80	2	4	17	76
Neck pain	1	3			1	3
Nervous system disorder	1	4			1	4
Ocular discomfort	2	2	2	2		
Odynophagia		1		1		
Off label use		1		1		
Oropharyngeal pain		3		2		1
Pain	2	5			2	5
Painful respiration	1	2			1	2
Pain in extremity	8	14	6	9	2	5
Pain of skin	1	1			1	1
Palpitations	3	4	2	2	1	2
Paraesthesia	1	2	1	1		1
Paraesthesia oral	1	1	1	1		
Parosmia	1	1	1	1		
Peripheral swelling	2	8	1	1	1	7
Photopsia		1				1
Poor quality sleep		2		1		1
Presyncope	1	3	1	1		2
Product use issue		1		1		
Pruritus	1	1	1	1		
Pulmonary arterial hypertension	1	1			1	1
Pulmonary embolism	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyelonephritis	1	2			1	2
Pyrexia	36	112	5	14	31	98
Rash	1	1	1	1		
Rash erythematous	1	2	1	1		1
Renal disorder	1	2			1	2
Renal pain		1				1
Respiratory arrest		1				1
Respiratory disorder	4	7			4	7
Rhinitis		1				1
Rhinorrhoea	1	2		1	1	1
Scleral discolouration		1				1
Seizure		4				4
Sensitive skin	1	1			1	1
Skin burning sensation		1				1
Skin disorder	2	6			2	6
Skin sensitisation		1				1
Sleep disorder	1	1	1	1		
Somnolence	1	3		1	1	2
Swelling of eyelid		1				1
Swollen tongue		1				1
Syncope	1	3			1	3
Tachycardia	4	5			4	5
Tinnitus		1				1
Tonsillitis		1		1		
Tremor	1	4		1	1	3
Unresponsive to stimuli		1				1
Urosepsis		1				1
Vaccination site erythema	3	5	3	4		1
Vaccination site lymphadenopathy	1	2			1	2
Vaccination site pain	8	25	4	9	4	16
Vaccination site pruritus		1				1
Vaccination site reaction	18	51	6	7	12	44

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	1	3	1	1		2
Vaccination site warmth	1	3	1	2		1
Vaginal haemorrhage		1				1
Vertigo	1	3			1	3
Vision blurred	1	1			1	1
Visual field defect		1				1
Visual impairment		2				2
Vomiting	4	13			4	13
	415	1,233	90	175	325	1058

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2	2	2		
Abdominal distension		1				1
Abdominal pain		4				4
Abdominal pain upper	2	5		1	2	4
Abdominal symptom		1		1		
Abnormal dreams		1				1
Agitation		1				1
Allergic reaction to excipient	1	1			1	1
Altered state of consciousness		2				2
Anaphylactic reaction	1	12			1	12
Anaphylactic shock	1	3			1	3
Angioedema		4				4
Anxiety		3				3
Aphonia		1		1		
Aphthous ulcer	1	3			1	3
Arrhythmia		1				1
Arthralgia	34	77	4	4	30	73
Arthritis		1				1
Asthenia	7	14	3	4	4	10
Asthenopia	1	2	1	2		
Asthma		2				2
Asymptomatic COVID-19		1				1
Autoimmune disorder	1	1			1	1
Axillary pain	1	1			1	1
Back pain		2				2
Balance disorder		2				2
Biliary colic		1				1
Blood pressure abnormal		1				1
Blood pressure decreased	1	3			1	3
Blood pressure increased	1	3	1	1		2
Body temperature increased	1	4	1	2		2
Bone pain		2				2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bradycardia		4					4
Bradypnoea		1					1
Brain injury	1	1			1		1
Breast pain	3	3	1	1	2		2
Breath odour		1					1
Bronchospasm		1					1
Burning sensation	2	2			2		2
Cardiac arrest	1	1	1	1			
Cardiovascular disorder	3	17	1	3	2		14
Cerebrovascular accident	1	2			1		2
Chest discomfort		4					4
Chest pain	4	12	2	4	2		8
Chills	58	148	12	14	46		134
Coagulopathy		4		2			2
Cold sweat		1					1
Contusion	1	1	1	1			
Cough	3	8	1	2	2		6
COVID-19	4	9	2	2	2		7
Crying		1					1
Cyanosis	1	2			1		2
Deafness	1	1			1		1
Decreased appetite	1	6			1		6
Deep vein thrombosis		1					1
Dehydration		1					1
Depressed level of consciousness		2					2
Diaphragmalgia	1	1			1		1
Diarrhoea	7	13	1	2	6		11
Diplopia		1					1
Discomfort	1	1			1		1
Disease recurrence		1					1
Dizziness	7	22	1	3	6		19
Dizziness postural		1					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	1	4			1	4
Dry mouth	1	1			1	1
Dysacusis	1	1			1	1
Dysgeusia		3		1		2
Dysphonia		1		1		
Dyspnoea	5	14	1	1	4	13
Dyspnoea exertional	1	2			1	2
Ear pain	3	5	1	1	2	4
Endolymphatic hydrops		1				1
Erythema		6				6
Exercise tolerance decreased		2				2
Expired product administered		2		1		1
Extensive swelling of vaccinated limb	5	6			5	6
Eye swelling		1				1
Face oedema	1	2	1	1		1
Facial asymmetry	1	1			1	1
Facial paralysis	1	6			1	6
Facial paresis		2				2
Facial spasm	2	2	2	2		
Faeces discoloured		1				1
Fatigue	56	188	8	22	48	166
Feeling abnormal	3	4	1	1	2	3
Feeling cold		6		1		5
Feeling hot		3		1		2
Feeling of body temperature change		3				3
Flatulence	2	2	2	2		
Flushing		1				1
Gastric dilatation	1	1	1	1		
Gastrointestinal disorder		1				1
Gastrointestinal pain		2				2
Gastrooesophageal reflux disease	1	1			1	1
General physical health deterioration		2		1		1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination		2				2
Headache	72	213	15	34	57	179
Heart rate decreased		1				1
Heart rate increased		2		1		1
Heart rate irregular		1		1		
Hemianaesthesia		1				1
Hemiparaesthesia		1				1
Hemiparesis		1				1
Herpes simplex		1				1
Herpes zoster		1		1		
Hot flush	1	7			1	7
Hyperhidrosis	3	7	1	4	2	3
Hypersensitivity	2	5			2	5
Hypersomnia		1				1
Hypertension	3	13		1	3	12
Hypertensive crisis		1				1
Hyperventilation		1		1		
Hypoaesthesia	2	4	1	1	1	3
Hypoglycaemia		1				1
Hypotension		7		1		6
Hypothermia		1				1
Impaired work ability	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration		1		1		
Infection	1	2	1	2		
Influenza	2	3	1	2	1	1
Influenza like illness	8	24	1	5	7	19
Injection site discomfort	1	1	1	1		
Injection site hypersensitivity		1				1
Injection site pain	1	1	1	1		
Injection site reaction		1				1
Insomnia	4	9	1	2	3	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaw disorder	1	1	1	1		
Joint swelling		1				1
Leukocyturia		1		1		
Limb discomfort		3				3
Lip swelling		1				1
Liver disorder	1	1	1	1		
Loss of consciousness		4				4
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	5	16	2	2	3	14
Lymph node pain	2	4			2	4
Lymphoedema		1				1
Malaise	31	101	4	7	27	94
Migraine	1	5			1	5
Migraine with aura		1				1
Mobility decreased	1	2		1	1	1
Muscle contractions involuntary	1	1			1	1
Muscle fatigue	1	1	1	1		
Muscle spasms		1		1		
Muscle strain	4	5	1	1	3	4
Muscular weakness		1				1
Musculoskeletal chest pain		2		1		1
Musculoskeletal stiffness	10	20	8	14	2	6
Myalgia	50	156	8	17	42	139
Mydriasis	1	1	1	1		
Myosclerosis		1				1
Nasal congestion		1		1		
Nausea	37	125	9	13	28	112
Neck pain	2	6			2	6
Nervous system disorder	3	10	1	1	2	9
Neuralgia		1		1		
Neuritis		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neurogenic shock		1				1
Nightmare	1	1			1	1
Night sweats		2				2
Oedema peripheral	1	1			1	1
Off label use	2	3	2	3		
Oral herpes		2				2
Oral pruritus		1				1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	2	7	2	3		4
Orthostatic hypotension		1		1		
Orthostatic intolerance		1				1
Oxygen saturation decreased	1	3	1	1		2
Pain	4	7	2	3	2	4
Painful respiration		1				1
Pain in extremity	12	29	11	18	1	11
Pain in jaw		1				1
Pallor		1				1
Palpitations		8		2		6
Paraesthesia	3	8	2	4	1	4
Paraesthesia oral		2				2
Parapharyngeal space infection		1				1
Peripheral motor neuropathy	1	1			1	1
Peripheral swelling	5	18	2	4	3	14
Pharyngeal swelling		1				1
Photophobia	1	1			1	1
Pneumonia		1				1
Pneumonitis	1	1			1	1
Poor quality sleep		1		1		
Presyncope		4				4
Product administered at inappropriate site	1	1			1	1
Product use issue	2	3	2	3		
Pruritus	2	8		1	2	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus allergic		1				1
Pyrexia	52	144	11	18	41	126
Rash	1	5	1	2		3
Rash erythematous	1	1	1	1		
Rash macular		1				1
Rash pruritic		1				1
Respiratory disorder	9	19		1	9	18
Respiratory distress		1				1
Restless legs syndrome		1		1		
Retching	1	1			1	1
Rhinorrhoea		3		1		2
Scarlet fever		1				1
Seizure	1	1			1	1
Sense of oppression	1	2	1	1		1
Sensitive skin	2	2	1	1	1	1
Sensory disturbance		2		2		
Serum ferritin increased	1	1	1	1		
Sinus headache		1				1
Sinusitis		1				1
Skin disorder	4	11	1	1	3	10
Sleep deficit		1				1
Sleep disorder		3				3
Sneezing	1	1	1	1		
Somnolence		2				2
Speech disorder		1		1		
Spinal pain		2		2		
Sudden hearing loss		1				1
Suffocation feeling		1				1
Suppressed lactation	1	1			1	1
Swelling		1				1
Swelling face		1				1
Swollen tongue		4		1		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		7				7
Tachyarrhythmia		1				1
Tachycardia	3	15		1	3	14
Tachypnoea		1				1
Taste disorder		1		1		
Tetany		1				1
Therapeutic response unexpected	1	1	1	1		
Thinking abnormal		1				1
Thirst		2		1		1
Thoracic outlet syndrome		1				1
Throat tightness		1				1
Thrombocytopenia		1				1
Thrombophlebitis		1				1
Thrombosis		1				1
Tinnitus	2	4	1	1	1	3
Tongue discomfort		1				1
Tonsillar inflammation		1				1
Tonsillitis		1				1
Tremor	1	3			1	3
Urticaria	1	3			1	3
Vaccination failure		1				1
Vaccination site erythema	2	7	2	5		2
Vaccination site haematoma		1				1
Vaccination site induration	2	2	2	2		
Vaccination site movement impairment		3		1		2
Vaccination site pain	12	30	4	9	8	21
Vaccination site pruritus		1				1
Vaccination site reaction	40	93	6	9	34	84
Vaccination site swelling	2	5	1	4	1	1
Vaccination site warmth		2		1		1
Vasculitis		1		1		
Ventricular tachycardia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	5	15	2	2	3	13
Vertigo positional		1		1		
Vestibular neuronitis		1				1
Vision blurred	1	4	1	1		3
Visual field defect		1				1
Visual impairment	2	3	2	2		1
Vomiting	3	14	2	2	1	12
Weight decreased		1				1
Wheezing	1	2			1	2
White blood cell count decreased		1		1		
Wrong product administered		1		1		
	687	2,087	182	345	505	1742

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		1		1
Abdominal pain upper	1	2	1	1		1
Ageusia	1	1	1	1		
Allergy to vaccine		1				1
Altered state of consciousness		2				2
Anaphylactic reaction	2	7			2	7
Anaphylactic shock		1				1
Anaphylactoid reaction		1				1
Anosmia		1				1
Anxiety		2				2
Aphasia	1	2			1	2
Arthralgia	11	38	1	5	10	33
Arthritis	1	2			1	2
Asthenia		6		1		5
Asthma exercise induced		1				1
Autoimmune disorder	2	3			2	3
Axillary pain		1				1
Back pain		2		1		1
Balance disorder	2	4			2	4
Blindness	1	3			1	3
Blood glucose decreased		1		1		
Blood glucose increased		1		1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	1	3			1	3
Blood pressure systolic increased		1		1		
Body temperature decreased		1				1
Body temperature increased	2	3	1	1	1	2
Bone pain		1				1
Bronchospasm		1				1
Bundle branch block left		1				1
Burning sensation		2		1		1
Cardiac arrest		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure		1				1
Cardiovascular disorder	6	12	1	3	5	9
Cerebral thrombosis		1				1
Cerebrovascular accident	1	2			1	2
Chest discomfort		4		1		3
Chest pain	3	5	1	2	2	3
Chillblains		1				1
Chills	20	72	2	3	18	69
Coagulopathy	3	5			3	5
Cough		1				1
COVID-19	1	4	1	1		3
Death	1	1			1	1
Decreased appetite	2	2			2	2
Deep vein thrombosis	2	2			2	2
Delirium		1				1
Depressed level of consciousness		2				2
Dermo-hypodermatitis		1				1
Diabetic complication		1				1
Diarrhoea		3				3
Discomfort	1	2		1	1	1
Disturbance in attention	1	1			1	1
Dizziness	5	16	1	5	4	11
Drug administered in wrong device		1		1		
Drug ineffective		1				1
Dry mouth		1				1
Dry throat		1				1
Dysgeusia		3				3
Dysphagia		1				1
Dysphonia		2				2
Dyspnoea	1	10		1	1	9
Dyspnoea exertional	1	2			1	2
Dyspraxia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
			1
		1	1
			5
			1
2	2	1	5
			1
1	1	1	1
			1
	1		
			1
		1	1
		1	3
		1	2
	1		1
8	11	25	77
	2		1
	1		
	1	1	1
			1
			1
		1	1
		1	1
			1
5	8	21	78
			1
	1	1	2
		1	1
		1	1
	2		1
1	3		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			4
1	3		3
		2	8
			1
	1		2
			1
1		1	1
	2		
			1
			1
3	1	3	13
1		1	1
	1		
	1		
1		1	1
	1		2
			1
			1
1		1	1
	1		
2			2
			1
2	1	1	1
			1
1	1	1	1
		1	1
3		3	4
18	6	15	55
1	1	1	1
			2
			1
			1
			2
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscular weakness		2					2
Musculoskeletal chest pain		1		1			
Musculoskeletal stiffness	3	7	1	1	2		6
Myalgia	17	63	5	8	12		55
Nausea	15	49	2	4	13		45
Neck pain	1	2			1		2
Nervous system disorder	1	8		2	1		6
Neuropathy peripheral		1					1
Oral herpes	1	1			1		1
Oropharyngeal pain		2					2
Oxygen saturation decreased	1	5			1		5
Pain	4	5	1	1	3		4
Pain in extremity	4	7	2	2	2		5
Pain of skin	1	2			1		2
Pallor		2					2
Palmoplantar pustulosis		1		1			
Papule	1	1	1	1			
Paraesthesia	3	8	1	3	2		5
Paraesthesia oral		2					2
Parosmia		1					1
Pericarditis	1	1			1		1
Peripheral swelling	2	7			2		7
Pharyngeal swelling	1	4			1		4
Phlebitis		1					1
Photophobia		1					1
Poor quality sleep		1					1
Procedural pain	1	1			1		1
Pruritus	5	10	3	4	2		6
Pulmonary embolism	1	1			1		1
Pyrexia	25	64	6	9	19		55
Rash	1	4	1	1			3
Rash maculo-papular		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorder	1	1			1	1
Renal failure		1				1
Renal pain		1				1
Respiratory disorder	3	8		1	3	7
Respiratory rate increased		1				1
Restlessness		1				1
Retching		1				1
Rhinorrhoea		1				1
SAPHO syndrome		1				1
SARS-CoV-2 antibody test positive		1		1		
Seizure	1	4			1	4
Sense of oppression	1	4		2	1	2
Septic shock	1	1			1	1
Sinus pain		1				1
Skin disorder	3	12	2	3	1	9
Skin mass	1	1			1	1
Sleep disorder due to a general medical condition		1		1		
Somnolence	1	2			1	2
Sudden death	1	1			1	1
Supraventricular tachycardia	1	1			1	1
Swelling face		1				1
Swollen tongue	1	3			1	3
Syncope	1	7			1	7
Tachycardia	1	5		1	1	4
Throat tightness	1	1			1	1
Tinnitus		1				1
Tremor		5				5
Troponin increased		1				1
Urticaria		2				2
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	7	1	1	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypersensitivity		1				1
Vaccination site hypertrophy		1				1
Vaccination site induration		5		1		4
Vaccination site inflammation		1		1		
Vaccination site pain	3	16	3	3		13
Vaccination site rash		1		1		
Vaccination site reaction	18	45	4	5	14	40
Vaccination site swelling	1	7	1	1		6
Vaccination site warmth	1	4			1	4
Vasculitis		1				1
Vertigo	2	6	2	4		2
Vision blurred	2	4	1	3	1	1
Visual impairment	1	1			1	1
Vomiting	1	6			1	6
Wheezing		1				1
Yellow skin		1				1
	325	1,073	71	156	254	917

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	1	1			1	1
Acute kidney injury	1	1			1	1
Acute pulmonary oedema		1				1
Acute respiratory failure		2				2
Allodynia		1				1
Anal incontinence	1	1	1	1		
Anaphylactic reaction	1	6			1	6
Apathy		1		1		
Arrhythmia	2	2			2	2
Arthralgia	1	8		1	1	7
Asthenia	1	3			1	3
Atrial fibrillation		2				2
Blood pressure abnormal	1	1	1	1		
Blood pressure decreased		2		1		1
Blood pressure increased		1				1
Body temperature increased	2	3	1	2	1	1
Breath odour		1				1
Cardiac arrest	1	2			1	2
Cardiac disorder		1				1
Cardiac failure	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiomegaly	1	1			1	1
Cardio-respiratory arrest		2				2
Cardiovascular disorder	1	5			1	5
Cerebral haemorrhage	1	1			1	1
Chest pain		2				2
Chills	9	20	3	4	6	16
Coagulopathy	1	1			1	1
Constipation	1	1			1	1
Coronary artery thrombosis		1				1
Cough	1	3	1	2		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	6	10			6	10
COVID-19 pneumonia		1				1
C-reactive protein increased	1	2	1	1		1
Death		1				1
Decreased appetite	1	2	1	2		
Decreased vibratory sense		1				1
Deep vein thrombosis	1	1			1	1
Diarrhoea		1				1
Dizziness		2				2
Drug ineffective	3	5			3	5
Drug resistance		1				1
Dysaesthesia		1				1
Dysgeusia		2				2
Dysphagia		2		1		1
Dyspnoea	1	4			1	4
Epilepsy	1	1			1	1
Erysipelas		1				1
Erythema	1	2	1	1		1
Extensive swelling of vaccinated limb	1	1			1	1
Facial pain	1	1	1	1		
Faecal vomiting	1	1			1	1
Fall	1	2			1	2
Fatigue	9	24	4	6	5	18
Feeling abnormal	1	2			1	2
Gait disturbance		1				1
Gastric dilatation	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	3			1	3
Haematoma	1	1	1	1		
Haemorrhagic stroke		1				1
Headache	8	22	4	7	4	15
Hypersensitivity	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	2	4	1	1	1	3
Hypoaesthesia		1				1
Hypoglycaemia		1				1
Hyporeflexia		1				1
Hyporesponsive to stimuli		1				1
Hypotension	1	3			1	3
Illness		1		1		
Inflammation	1	1	1	1		
Influenza		1				1
Influenza like illness	3	5			3	5
Insomnia		3				3
Intestinal obstruction	1	1			1	1
Irritability		1				1
Joint range of motion decreased	1	1			1	1
Lactic acidosis	1	1			1	1
Lip swelling		1		1		
Malaise	6	17	1	2	5	15
Migraine		1				1
Mobility decreased	1	1			1	1
Multiple organ dysfunction syndrome		1				1
Muscle spasms	1	2			1	2
Muscular weakness	1	2		1	1	1
Musculoskeletal stiffness	3	5	3	3		2
Myalgia	7	18	3	5	4	13
Nausea	5	18		3	5	15
Nervous system disorder	1	2			1	2
Neuralgia		1				1
Neutrophilia		1				1
Oropharyngeal pain	1	1	1	1		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	1	5			1	5
Pain	1	1	1	1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	2	1	1		1
Parkinson's disease		2				2
Pericardial effusion		1				1
Peripheral swelling		2				2
Pleural effusion		1				1
Pneumonia		1				1
Pneumonitis		1				1
Polyneuropathy		1				1
Presyncope	1	1	1	1		
Prohormone brain natriuretic peptide increased	1	1			1	1
Pulmonary embolism		1				1
Pulmonary oedema	1	1			1	1
Pyrexia	8	21	4	4	4	17
Rales	1	1			1	1
Renal failure		1				1
Respiratory acidosis	1	1			1	1
Respiratory disorder	2	4			2	4
Respiratory distress		1				1
Respiratory tract infection	1	1			1	1
Retching		1				1
Salivary hypersecretion		2		1		1
SARS-CoV-2 test positive		1				1
Seizure	1	1			1	1
Sensation of foreign body		2		1		1
Sensitive skin		1				1
Sinus tachycardia		1				1
Skin disorder	2	2	1	1	1	1
Sleep disorder		1				1
Speech disorder		1		1		
Stress cardiomyopathy		1		1		
Sudden death	2	4			2	4
Swelling face	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		2				2
Throat tightness		1				1
Thrombosis	1	1			1	1
Troponin T increased	1	1			1	1
Vaccination failure	1	1			1	1
Vaccination site erythema	3	3	3	3		
Vaccination site induration	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vaccination site reaction	3	9		1	3	8
Vaccination site swelling	1	1	1	1		
Vertigo	1	1			1	1
Vitamin D deficiency		1				1
Vomiting	1	4			1	4
	145	377	45	72	100	305

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper	1	1			1	1
Acute kidney injury		2				2
Acute psychosis	1	1			1	1
Acute respiratory failure		2				2
Agitation	1	5	1	1		4
Altered state of consciousness		1				1
Amnesia		1				1
Angina pectoris		1				1
Angle closure glaucoma		1				1
Anxiety	1	2	1	1		1
Arrhythmia		1				1
Arthralgia	1	2	1	1		1
Asthenia	2	2	1	1	1	1
Atrial fibrillation		1				1
Atrioventricular block complete		2				2
Blood lactic acid increased		2				2
Blood pressure abnormal		1				1
Blood pressure decreased	1	1			1	1
Blood urine present		1				1
Body temperature increased	1	1	1	1		
Bradycardia		4				4
Bronchial disorder		1				1
Cardiac arrest		3				3
Cardiac disorder		1				1
Cardiac failure		2				2
Cardiogenic shock		1				1
Cardio-respiratory arrest		1				1
Cardiovascular disorder	4	16	1	1	3	15
Cerebral ischaemia	1	1			1	1
Cerebrovascular accident	2	6			2	6
Chest pain	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cheyne-Stokes respiration		1					1
Chills	4	8	3	3	1		5
Coagulopathy	2	4		1	2		3
Cold sweat		1					1
Coma		1					1
Concussion		1					1
Confusional state	2	5	2	2			3
Cough		2					2
COVID-19	9	17	2	2	7		15
COVID-19 pneumonia	1	2			1		2
C-reactive protein increased		2		1			1
Death	1	2			1		2
Decreased appetite	1	1	1	1			
Depressed level of consciousness		5					5
Diarrhoea	1	3	1	1			2
Disorientation		1					1
Dizziness	1	2	1	1			1
Drug ineffective	6	10			6		10
Dry skin		1					1
Dyspnoea		9					9
Dysstasia	1	2			1		2
Epilepsy		3					3
Erythema		1					1
Eschar		1					1
Eye movement disorder		1					1
Eye pain		1		1			
Facial paresis		1					1
Fall	2	7		1	2		6
Fatigue	8	16	6	8	2		8
Fibrin D dimer increased		1					1
Generalised tonic-clonic seizure		1					1
General physical health deterioration		11					11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glaucoma		1				1
Haemorrhage intracranial		1				1
Hallucination	1	1			1	1
Hallucination, visual		1				1
Headache	4	8	2	3	2	5
Heart rate increased		1				1
Hemiparesis		1				1
Hemiplegia		2				2
Hepatic failure		1				1
Herpes ophthalmic		2				2
Hypertension	1	4			1	4
Hyperthermia	1	1	1	1		
Hypoglycaemia		1				1
Hypokalaemia		1				1
Hyponatraemia		1				1
Hypotension		5				5
Hypovolaemic shock		1				1
Hypoxia		1				1
Illusion		1				1
Inappropriate schedule of product administration	1	1	1	1		
Influenza like illness	3	3	2	2	1	1
Injection site reaction	1	1	1	1		
Intestinal dilatation		1				1
Intestinal ischaemia		2				2
Lacrimation increased		1		1		
Lactic acidosis		1				1
Leukocytosis		1				1
Lip swelling		1				1
Livedo reticularis		1				1
Liver function test abnormal		3				3
Loss of consciousness		1				1
Lower respiratory tract congestion		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lung infiltration		1					1
Malaise	6	20	4	5	2		15
Metabolic acidosis		1					1
Multiple organ dysfunction syndrome		1					1
Myalgia	3	5	3	3			2
Myocardial infarction		1					1
Nausea	5	11	3	3	2		8
Neck pain		1					1
Nervous system disorder	2	9	1	2	1		7
Neurogenic shock		1					1
Neutropenia		1					1
N-terminal prohormone brain natriuretic peptide increased		1					1
Ocular hyperaemia		1		1			
Oral herpes		2		1			1
Oxygen saturation decreased		11					11
Pain		1					1
Pain in extremity	1	1			1		1
Paresis		1					1
Patient elopement		1					1
Peripheral coldness		1					1
Peripheral swelling		1					1
Pleural effusion		1					1
Pneumonia		1					1
Pneumonia aspiration		1					1
Pneumonia bacterial		1					1
Pneumonitis		1					1
Presyncope		2					2
Productive cough		1					1
Pulmonary embolism	2	6			2		6
Pulmonary infarction		1					1
Pulmonary oedema		2					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	12	25	11	11	1	14
Rales		1				1
Rash macular	1	1			1	1
Red blood cell sedimentation rate increased		1		1		
Renal disorder		2				2
Renal failure		1				1
Respiration abnormal		2				2
Respiratory disorder	1	11			1	11
Respiratory distress		2				2
Respiratory failure		1				1
Respiratory tract infection		2				2
Restlessness	1	2		1	1	1
Retching		1				1
Rhythm idioventricular		1				1
Sedation		2				2
Seizure		1				1
Sepsis		1				1
Septic shock		1				1
Skin disorder	1	2			1	2
Sneezing		1		1		
Somnolence		2				2
Staring		1				1
Sudden death		11				11
Swelling face		1				1
Syncope	2	6			2	6
Tachycardia		1				1
Tachypnoea		1				1
Thrombocytopenia		1				1
Tremor	1	1	1	1		
Troponin increased		2				2
Unresponsive to stimuli		2				2
Urinary retention		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infection		1		1		
Vaccination site erythema	9	11	9	10		1
Vaccination site haematoma	1	2	1	2		
Vaccination site induration	2	2	2	2		
Vaccination site pain	2	2	2	2		
Vaccination site pruritus		1		1		
Vaccination site reaction	6	9	5	5	1	4
Vaccination site swelling	3	3	3	3		
Vision blurred	1	1	1	1		
Vomiting	1	3	1	1		2
Wrong product administered	1	1	1	1		
	132	463	77	96	55	367

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		4				4
Anaphylactic shock		1				1
Angina pectoris		1				1
Anxiety		1				1
Apathy		1				1
Arthralgia	4	17	2	3	2	14
Arthritis		1		1		
Asthenia	2	3	1	1	1	2
Asymptomatic COVID-19	3	24			3	24
Autoimmune disorder	1	1			1	1
Axillary pain		1		1		
Back pain		1		1		
Balance disorder	1	2			1	2
Bone pain		1				1
Bradycardia		1				1
Bronchospasm		1				1
Burning sensation	1	1			1	1
Cardiovascular disorder	1	2			1	2
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort		2				2
Chest pain	1	3			1	3
Chills	10	32	3	5	7	27
Coagulopathy	1	1			1	1
Condition aggravated	1	1	1	1		
Cough	1	2			1	2
COVID-19	2	49		11	2	38
Deafness		1				1
Decreased appetite		1				1
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea		5		3		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort	1	1			1	1
Disease recurrence		1				1
Dizziness		4		1		3
Drug ineffective	5	47			5	47
Dry throat		1		1		
Dysgeusia	1	1	1	1		
Dyspepsia	1	1			1	1
Dysphagia		1				1
Dyspnoea	5	10	1	2	4	8
Ear discomfort		1		1		
Eczema	1	1	1	1		
Erythema	2	4	2	3		1
Exposure during pregnancy		1		1		
Exposure via breast milk		1		1		
Exposure via skin contact		1		1		
Eye irritation	1	1			1	1
Facial paresis		1				1
Fatigue	18	44	6	11	12	33
Feeling abnormal	1	1	1	1		
Feeling cold	1	1			1	1
Food allergy	1	1			1	1
Formication		1				1
Gait disturbance		1				1
Gastrointestinal pain		1				1
Gingival pain		1				1
Headache	16	47	5	10	11	37
Head discomfort		1				1
Heart rate increased		1				1
Hemiplegia	1	1			1	1
Hyperacusis		1				1
Hyperaesthesia teeth		1				1
Hypersensitivity	2	5			2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity vasculitis	1	1			1	1
Hypertension	3	7	1	1	2	6
Hyperthermia	1	1	1	1		
Hypoacusis		1				1
Hypoaesthesia	1	1			1	1
Hypoglycaemia		2				2
Hypotension	1	2	1	1		1
Hypothermia	1	1			1	1
Illness	1	2		1	1	1
Immobile		1				1
Incorrect route of product administration	34	125	34	125		
Inflammation		1				1
Influenza		1		1		
Influenza like illness	1	5	1	3		2
Injection site pain	1	1	1	1		
Injection site reaction	1	1			1	1
Insomnia	1	1	1	1		
Lip swelling		1				1
Liver disorder		1				1
Loss of consciousness		1				1
Lymphadenopathy	3	5	1	1	2	4
Lymph node pain		1				1
Malaise	9	27	2	5	7	22
Maternal exposure during pregnancy		1		1		
Migraine	1	3			1	3
Muscle strain		1		1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	15	41	6	11	9	30
Nasopharyngitis	1	2			1	2
Nausea	8	28	3	7	5	21
Neck pain	1	2	1	2		
Nervous system disorder	4	5	1	1	3	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia	1	1			1	1
Noninfective gingivitis		1				1
Occupational exposure to product		1		1		
Oxygen saturation decreased		1				1
Pain		1		1		
Pain in extremity		6		2		4
Pain of skin		1		1		
Palpitations	1	2	1	1		1
Papule	1	1			1	1
Paraesthesia	1	3		2	1	1
Paraesthesia oral		1				1
Paralysis		1				1
Peripheral swelling	3	6	2	2	1	4
Pharyngeal erythema		1				1
Pharyngeal swelling		1				1
Photophobia		1				1
Posture abnormal	1	1	1	1		
Presyncope	1	2			1	2
Product preparation issue		1		1		
Pruritus	1	5	1	2		3
Pyrexia	19	39	10	15	9	24
Rash	1	1	1	1		
Rash erythematous	1	1	1	1		
Renal pain		1				1
Respiratory disorder	5	7	1	1	4	6
Rhinorrhoea		1		1		
Seizure		1				1
Sensory loss		1				1
Sepsis		1				1
Skin disorder	1	4			1	4
Sleep disorder	1	1	1	1		
Sneezing	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence		2		1		1
Speech disorder	1	1	1	1		
Stomatitis		1				1
Suspected COVID-19	1	1			1	1
Swelling		1				1
Swelling face		1				1
Syncope		4				4
Syringe issue		1		1		
Tachycardia	1	3			1	3
Tinnitus		1				1
Transient ischaemic attack	1	1			1	1
Underdose		1		1		
Upper airway obstruction		1				1
Urticaria		1				1
Vaccination failure	1	15			1	15
Vaccination site erythema	1	2	1	2		
Vaccination site haematoma		2		1		1
Vaccination site induration		1		1		
Vaccination site movement impairment		1				1
Vaccination site pain	6	11	6	8		3
Vaccination site reaction	3	13	1	2	2	11
Vaccination site swelling	1	3		1	1	2
Vertigo		3				3
Vomiting	1	4		1	1	3
Wrong technique in product usage process	34	112	34	112		
	269	911	141	394	128	517

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**BERMUDA**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Diarrhoea		1		1
Feeling cold		1		1
Night sweats		1		1
Paraesthesia		1		1
Pyrexia		1		1
		6		6

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear congestion	1	1	1	1		
Ear discomfort	1	1	1	1		
Erythema	1	1			1	1
Pain	1	1			1	1
Peripheral swelling	1	1			1	1
Sudden visual loss		1				1
	5	6	2	2	3	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Dizziness		1		1		
Dyspnoea	1	1			1	1
Rash	1	1	1	1		
	2	4	1	3	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**BOSNIA AND HERZEGOVINA**

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred  
**BRAZIL**

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Pain	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BULGARIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Asthenia	2	2	2	2		
Blood pressure fluctuation		1		1		
Body temperature abnormal		1		1		
Body temperature increased		1		1		
Chills		1		1		
COVID-19		1				1
Deafness unilateral		1				1
Dizziness		2		2		
Drug eruption		1		1		
Drug ineffective		1				1
Dry mouth		1		1		
Dyspnoea	1	1	1	1		
Erythema		1		1		
Fatigue	2	2	2	2		
Headache	1	3	1	3		
Heart rate increased		1		1		
HIV test positive	1	1	1	1		
Hot flush		1		1		
Lymphocyte count decreased		1		1		
Malaise		3		3		
Myalgia	2	3	2	3		
Nausea	1	3	1	3		
Neuralgia		1		1		
Pain	1	1	1	1		
Pain in extremity	2	3	2	3		
Palpitations		1		1		
Paraesthesia	1	3	1	3		
Pyrexia	2	3	2	3		
Renal pain		1		1		
Seizure		1				1
Spinal pain		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling		1		1		
Tremor		1		1		
Vaccination site erythema		1		1		
Vaccination site pain		2		2		
Vaccination site swelling		1		1		
Vertigo		1				1
	18	57	18	52		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		2		2		
Allergy to vaccine	1	1	1	1		
Anaphylactoid reaction		1				1
Anti-thyroid antibody positive		1				1
Arthralgia	2	10	2	10		
Asthenia		11		9		2
Axillary pain	1	1	1	1		
Back pain		1		1		
Blood pressure ambulatory increased	1	1			1	1
Blood pressure inadequately controlled		1		1		
Blood pressure increased	1	3	1	2		1
Body temperature increased	1	17	1	16		1
Bone pain	1	1	1	1		
Breast pain	1	1	1	1		
Chest pain		1		1		
Chills	3	17	3	15		2
Circulatory collapse	1	1			1	1
Cough	1	3	1	3		
COVID-19	2	4	1	3	1	1
COVID-19 pneumonia		2				2
Diarrhoea		1		1		
Disturbance in attention		1		1		
Dizziness	3	5	3	5		
Drug ineffective	1	1			1	1
Dyspnoea	2	4	2	3		1
Epigastric discomfort		1		1		
Erythema	2	2	2	2		
Eye pain		1		1		
Facial bones fracture	1	1			1	1
Fatigue	5	15	5	15		
Feeling hot	1	1	1	1		
Gait disturbance		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	8	29	8	27		2
Head discomfort		1		1		
Heart alternation	1	1	1	1		
Hyperhidrosis		4		3		1
Hypertension	1	1			1	1
Hypothermia		1				1
Injection site erythema		1		1		
Injection site pain		5		5		
Injection site swelling		2		2		
Joint injury	1	1			1	1
Jugular vein distension		1				1
Lacrimation increased		1		1		
Leukopenia	1	1			1	1
Limb discomfort		1		1		
Lip swelling		1				1
Lymphadenopathy	1	8	1	8		
Lymph node pain	1	2	1	2		
Malaise	3	5	3	5		
Mastication disorder		1		1		
Meningism		1		1		
Movement disorder	1	1	1	1		
Muscle spasms		1		1		
Musculoskeletal stiffness		2		1		1
Myalgia	3	18	3	18		
Nasopharyngitis	2	2	2	2		
Nausea	1	4	1	4		
Neck pain		1		1		
Oropharyngeal pain		1		1		
Overdose	2	2	2	2		
Pain		1		1		
Painful respiration		1		1		
Pain in extremity	4	6	4	6		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	2	2	1	1	1	1
Paraesthesia	2	3	2	2		1
Paranasal sinus discomfort	1	1	1	1		
Photophobia		1		1		
Pneumonia	1	1			1	1
Pruritus	2	2	1	1	1	1
Pyrexia	4	11	4	10		1
Rash		1		1		
Rash macular	1	1			1	1
Sweating fever		1				1
Swelling	1	2	1	2		
Swollen tongue		1				1
Syncope	2	2			2	2
Tachycardia	2	3	1	1	1	2
Thirst		1		1		
Tinnitus	1	2	1	2		
Tremor	1	3		2	1	1
Trismus		1		1		
Urticaria		2		1		1
Vaccination site erythema	1	7		5	1	2
Vaccination site induration	1	1			1	1
Vaccination site oedema		1		1		
Vaccination site pain	9	32	9	31		1
Vaccination site paraesthesia		1		1		
Vaccination site reaction		1				1
Vaccination site swelling		9		8		1
Vasospasm		1				1
Ventricular extrasystoles		1				1
Vertigo	2	6	1	4	1	2
Vomiting		2		2		
	94	325	75	275	19	50

\* I=Interval, C=Cumulative  
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Angina pectoris		1				1	
Anosmia		1		1			
Antibody test abnormal	1	1	1	1			
Arthralgia	2	7	2	7			
Arthritis		1		1			
Back pain	1	1	1	1			
Blood glucose increased	2	2	1	1	1	1	
Blood pressure decreased	1	1			1	1	
Blood pressure increased	2	4	1	3	1	1	
Body temperature increased		6		6			
Bronchitis	1	1	1	1			
Chills	3	5	3	5			
Condition aggravated	1	1	1	1			
Conjunctivitis allergic		1		1			
COVID-19	2	5		1	2	4	
Dental discomfort		1		1			
Dizziness		1		1			
Drug ineffective	2	4			2	4	
Dry mouth		1		1			
Dysphonia	1	1	1	1			
Erythema		2		2			
Extrasystoles		2		2			
Eye pain		1		1			
Facial paralysis	1	1			1	1	
Fatigue	3	7	3	7			
Gait disturbance		1		1			
Headache	2	11	2	11			
Herpes simplex		1		1			
Hypertension		1		1			
Influenza like illness	1	2	1	2			
Injection site pain		1		1			
Injection site swelling		1		1			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Interstitial lung disease		1				1	
Lacrimation increased	1	1	1	1			
Limb discomfort	1	1	1	1			
Lymphadenopathy		6		5			1
Malaise	1	2	1	2			
Mobility decreased		1		1			
Movement disorder		1					1
Myalgia	1	8	1	8			
Myelitis transverse		1					1
Nasopharyngitis	1	1	1	1			
Nausea	2	4	2	4			
Neuromyelitis optica spectrum disorder		1					1
Oedema peripheral	1	2	1	2			
Oropharyngeal pain	2	3	2	3			
Pain		1		1			
Pain in extremity		1		1			
Palpitations		1		1			
Paraesthesia		1		1			
Peripheral sensory neuropathy		1		1			
Peripheral swelling		2		2			
Presyncope	1	1	1	1			
Productive cough	1	1	1	1			
Pyrexia	1	6	1	6			
Rash	1	2	1	2			
Rash erythematous		1		1			
Rash pruritic		1		1			
Rheumatoid arthritis		1					1
Rheumatoid factor increased		1					1
Rheumatoid factor positive		1		1			
Sinusitis	1	1	1	1			
Tracheitis	1	1	1	1			
Vaccination site erythema		8		8			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site extravasation		1		1		
Vaccination site induration		1		1		
Vaccination site pain	2	14	2	14		
Vaccination site reaction		1		1		
Vaccination site swelling		8		8		
Vertigo	1	2	1	2		
	45	169	37	149	8	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Arthralgia		6		6		
Asthenia		3		3		
Back pain		2		2		
Blood pressure diastolic decreased		1		1		
Body temperature increased		5		4		1
Chills	2	4	2	3		1
Cold sweat		1		1		
Cough	1	2	1	2		
COVID-19	1	2			1	2
Decreased appetite		2		1		1
Diarrhoea		1		1		
Discomfort		1		1		
Dizziness		6		5		1
Dizziness postural		1		1		
Drug ineffective	1	2			1	2
Dyspnoea		1				1
Erectile dysfunction		1				1
Facial paralysis		2				2
Fatigue	1	2	1	2		
Feeling cold		1		1		
Gait disturbance	1	1			1	1
Haematoma	1	1			1	1
Headache		2		1		1
Head discomfort		1				1
Heart rate irregular	1	1	1	1		
Hyperhidrosis		2		1		1
Insomnia		1		1		
Lethargy	1	1	1	1		
Malaise		1		1		
Myalgia		5		5		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nausea		3		2		1	
Oropharyngeal pain		1		1			
Pain	1	1	1	1			
Pallor		1		1			
Paraesthesia	1	2	1	2			
Paraesthesia oral		1		1			
Peripheral coldness		1		1			
Pruritus	1	1	1	1			
Pyrexia	1	5	1	4			1
Rash	1	1	1	1			
Rhinorrhoea	1	2	1	2			
SARS-CoV-2 test positive		1					1
Throat irritation	1	1	1	1			
Tremor		1		1			
Urticaria		1		1			
Vaccination site erythema		1					1
Vaccination site pain	1	9	1	9			
Vaccination site swelling		1					1
Vasodilatation	1	1	1	1			
Vertigo		3		2			1
Vomiting		2		2			
	19	104	15	81	4		23

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		1				1
Epistaxis	1	1	1	1		
Headache		1				1
Vomiting		1				1
	1	5	1	1		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		1		1		
Arrhythmia	1	1			1	1
Arthralgia	1	3	1	3		
Asthenia		2		2		
Back pain		1		1		
Body temperature increased		2		2		
Chills		1		1		
Communication disorder		1		1		
COVID-19		3				3
C-reactive protein increased	1	1			1	1
Decreased appetite		1		1		
Discomfort		1		1		
Dizziness		1		1		
Drug ineffective		3				3
Fatigue		2		2		
Gastrointestinal disorder		1		1		
Groin abscess		1				1
Headache		1		1		
Hypersensitivity		1		1		
Hypertension	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Injection site erythema		1		1		
Injection site oedema		1		1		
Insomnia		1		1		
Lymphadenopathy	1	2	1	2		
Lymph node pain	1	2	1	2		
Malaise		1		1		
Musculoskeletal pain	1	1	1	1		
Myalgia		3		3		
Nausea		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use		1		1		
Pain		1		1		
Pain in extremity	2	2	2	2		
Pyrexia	2	7	2	7		
Swelling face		1		1		
Vaccination site pain		1		1		
	12	58	10	49	2	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**CANADA**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea		1		1		
Dysphonia		1		1		
Ear infection		1				1
Exposure via breast milk		20		20		
Nasopharyngitis		1		1		
Pyrexia		1				1
Rhinorrhoea		1		1		
Roseola		1		1		
Sleep disorder		1		1		
		28		26		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain		1		1		
Ageusia		1		1		
Anaphylactic reaction		2				2
Anxiety		1		1		
Arthralgia		4		4		
Asthenia		3		3		
Back pain		2		1		1
Beta haemolytic streptococcal infection		1				1
Blood glucose increased		1		1		
Blood pressure decreased		1		1		
Breast tenderness		1		1		
Cardiac flutter		1				1
Chest discomfort		1				1
Chest pain		2		1		1
Chills		6		6		
Condition aggravated	1	1			1	1
Cough		1		1		
COVID-19		1				1
Decreased appetite		2		2		
Dermatitis	1	1			1	1
Diarrhoea		3		3		
Disease recurrence	1	1			1	1
Distractibility		1		1		
Disturbance in attention		1		1		
Dizziness	1	4	1	4		
Drug ineffective		1				1
Dysgeusia		1		1		
Dysmenorrhoea	1	1	1	1		
Dysphagia		2		2		
Dyspnoea		3		3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear discomfort		1
Erythema	1	2
Exposure during pregnancy		5
Eyelid function disorder		1
Eye pain		1
Facial pain		1
Facial paralysis		2
Fatigue		14
Feeling abnormal		2
Feeling hot		2
Flushing		2
Gastroenteritis viral		1
Headache		12
Heart rate increased		1
Herpes zoster	1	2
Hot flush		1
Hyperaesthesia	1	1
Hypoacusis		2
Hypoesthesia		3
Hypoesthesia eye		1
Hypotension		1
Impaired work ability		1
Inappropriate schedule of product administration		2
Influenza like illness		2
Injection site erythema		1
Injection site hypersensitivity		1
Injection site pain		3
Injection site swelling		1
Insomnia		1
Intentional product use issue		1
Lip swelling		1
Liver function test increased		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1	1	1
	5		
			1
	1		
	1		
			2
	14		
	2		
	2		
	2		
	1		
	12		
	1		
1	2		
	1		
		1	1
	2		
	2		1
	1		
	1		
	1		
	2		
	2		
	1		
	1		
	3		
	1		
	1		
	1		
	1		
	1		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness		1				1
Lung disorder		1				1
Lymphadenopathy		3		3		
Malaise		3		3		
Maternal exposure before pregnancy		2		2		
Maternal exposure during pregnancy		3		3		
Menorrhagia	1	1			1	1
Menstrual disorder		1		1		
Menstruation irregular		1		1		
Migraine		3		3		
Mobility decreased		1		1		
Motion sickness		1		1		
Multiple sclerosis	1	1			1	1
Muscle spasms		1		1		
Muscle tightness		1		1		
Muscle twitching		1		1		
Muscular weakness		2		1		1
Musculoskeletal stiffness		1		1		
Myalgia		9		9		
Nausea		10		10		
Neck pain		2		2		
Neurological symptom	1	1			1	1
Odynophagia		1		1		
Off label use		8		8		
Oropharyngeal pain		4		4		
Overdose		1		1		
Pain		4		4		
Pain in extremity		8		8		
Pain in jaw		1		1		
Palpitations		2		2		
Paraesthesia		3		2		1
Penis disorder		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		1				1
Polydipsia		1		1		
Polyuria		1		1		
Product use issue		5		5		
Pruritus	1	2		1	1	1
Psychotic disorder due to a general medical condition		1				1
Pulmonary pain		1				1
Pyrexia		10		10		
Rash	1	5	1	5		
Rash pruritic		1		1		
Rash pustular		1		1		
Seizure	1	1			1	1
Sensory disturbance		1				1
Sensory loss		1		1		
Skin burning sensation		1		1		
Speech disorder		1		1		
Swelling		1		1		
Swelling face		1		1		
Swollen tongue		2		2		
Tachycardia		1		1		
Taste disorder		1		1		
Temporomandibular joint syndrome		1		1		
Testicular retraction		1				1
Threatened labour		1		1		
Tremor		1		1		
Type IV hypersensitivity reaction		1		1		
Underdose		1		1		
Urinary incontinence		1				1
Urticaria	1	4		3	1	1
Vaccination site erythema		1		1		
Vaccination site inflammation		1		1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	1		
	1		
	5		
	1	1	1
			1
	10		
1	5		
	1		
	1		
		1	1
			1
	1		
	1		
	1		
	2		
	1		
	1		
	1		
			1
	1		
	1		
	1		
			1
	3	1	1
	1		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain		9		9		
Vaccination site rash		1		1		
Vaccination site swelling		2		2		
Vertigo	1	2		1	1	1
Vision blurred		1		1		
Visual impairment		1				1
Vomiting	1	3	1	3		
Vomiting projectile		1		1		
	17	283	5	245	12	38

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain lower		1		1		
Abdominal pain upper		2		2		
Abortion induced	1	1	1	1		
Abortion spontaneous	1	3			1	3
Affect lability		1		1		
Ageusia	1	1	1	1		
Anaphylactic reaction	3	8			3	8
Anaphylactic shock	1	2			1	2
Angioedema		1				1
Angiopathy		1		1		
Anosmia	1	1	1	1		
Anxiety	3	7	3	6		1
Aphthous ulcer		1		1		
Arthralgia	2	16	1	13	1	3
Asthenia	1	7	1	5		2
Autoimmune disorder	1	1			1	1
Axillary mass		1		1		
Axillary pain		3		3		
Back pain		1				1
Balance disorder		1		1		
Blindness	1	1			1	1
Blood glucose decreased		1				1
Blood pressure increased	1	1			1	1
Body temperature increased		1		1		
Breast pain		1				1
Burning sensation		1		1		
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cerebrovascular accident		1				1
Chest discomfort	1	9	1	7		2
Chest pain		4		4		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	3	22	3	22		
Cold sweat	1	2		1	1	1
Condition aggravated	3	4	1	1	2	3
Conjunctivitis		1		1		
Contusion	1	3	1	2		1
Cough	1	4	1	4		
COVID-19	1	5		2	1	3
COVID-19 pneumonia		1				1
C-reactive protein increased	1	1	1	1		
Deafness unilateral	1	1			1	1
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Depression	1	2	1	2		
Dermatitis infected	1	1	1	1		
Dermatochalasis	1	1	1	1		
Diarrhoea	1	10	1	9		1
Discomfort		1		1		
Disease recurrence		2				2
Disturbance in attention	1	1	1	1		
Dizziness	5	18	4	14	1	4
Drug ineffective	1	1			1	1
Drug interaction	1	1			1	1
Drug level increased	1	1	1	1		
Dry eye	1	1	1	1		
Dry mouth	1	1	1	1		
Dysgeusia	2	2	2	2		
Dysmenorrhoea		1		1		
Dysphagia		2		2		
Dyspnoea	5	12	4	11	1	1
Ear discomfort	1	2	1	2		
Ectopic pregnancy		1				1
Eczema		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	4	1	2		2
Erythema multiforme		1				1
Exposure during pregnancy	1	5	1	5		
Eyelid ptosis	1	1			1	1
Eye swelling		2		2		
Face oedema		1				1
Facial pain		2		2		
Facial paralysis		3				3
Fatigue	7	43	6	38	1	5
Fear		1		1		
Feeling abnormal		4		4		
Feeling cold		2		1		1
Feeling drunk		1		1		
Feeling hot		5		4		1
Feeling of body temperature change		1		1		
Fibromyalgia		1		1		
Fluid retention	1	3	1	3		
Flushing		1				1
Fungal skin infection		1		1		
Gait disturbance	1	1			1	1
Gastric disorder		1		1		
Gastrointestinal disorder	1	1	1	1		
Gastroesophageal reflux disease		1		1		
Gestational diabetes		1				1
Grip strength decreased		1		1		
Haematemesis		1				1
Headache	9	48	5	42	4	6
Heart rate decreased		1				1
Heart rate increased	1	3		1	1	2
Hepatic enzyme increased		1				1
Herpes zoster	2	3	2	2		1
Hot flush	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperaesthesia		2
Hyperhidrosis		3
Hypersensitivity	1	4
Hypersomnia		1
Hypertension	2	7
Hypertensive crisis		1
Hypoaesthesia	4	12
Hypoaesthesia oral	1	4
Hypotension	1	3
Illness		1
Inappropriate schedule of product administration		5
Incomplete course of vaccination		1
Incorrect route of product administration		1
Inflammation	1	1
Influenza like illness		3
Injection site pain	2	8
Injection site scar		1
Joint noise		1
Joint range of motion decreased		1
Joint swelling	1	2
Laryngospasm		1
Lethargy		1
Leukoplakia		1
Limb discomfort		1
Lipoma		1
Loss of consciousness		1
Lymphadenopathy		16
Lymph node pain		1
Malaise	2	7
Maternal exposure before pregnancy	1	1
Maternal exposure during pregnancy	2	9
Meningitis aseptic		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
	2		1
	2	1	2
	1		
1	2	1	5
			1
3	6	1	6
	1	1	3
1	1		2
	1		
	5		
	1		
	1		
1	1		
	3		
2	8		
	1		
	1		
	1		
	1	1	1
			1
	1		
	1		
			1
	13		3
	1		
2	7		
1	1		
2	9		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Menstruation delayed		1		1			
Menstruation irregular	1	2	1	2			
Migraine	1	6		4	1	2	
Mobility decreased		1		1			
Muscle injury		1		1			
Muscle spasms		1				1	
Muscular weakness		3		3			
Musculoskeletal stiffness	1	4	1	4			
Myalgia	1	20	1	18		2	
Myocarditis	2	2			2	2	
Nasal congestion		1		1			
Nasopharyngitis		2		2			
Nausea	5	22	3	18	2	4	
Neck pain		3		3			
Necrosis		1				1	
Neuralgia		2				2	
Night sweats	1	1	1	1			
No adverse event	1	1	1	1			
Ocular hyperaemia	1	1	1	1			
Oedema peripheral		1		1			
Off label use	1	28	1	27		1	
Oral herpes		1		1			
Oropharyngeal pain		4		4			
Overdose		3		3			
Oversensing		1		1			
Oxygen saturation decreased		1				1	
Pain	3	13	2	12	1	1	
Pain in extremity	1	21	1	17		4	
Pain in jaw		1		1			
Pain of skin	1	1	1	1			
Pallor		2		1		1	
Palpitations		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	2	14	1	8	1	6
Paraesthesia oral		6		4		2
Pericarditis		1				1
Periorbital swelling	1	1	1	1		
Peripheral swelling		2		1		1
Petechiae		1		1		
Pharyngeal hypoaesthesia		2		1		1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	1	3	1	2		1
Pneumonia		1				1
Polymenorrhoea	1	1	1	1		
Presyncope		4		3		1
Product administered at inappropriate site	1	3	1	3		
Product preparation issue		2		2		
Product supply issue		1		1		
Product use issue	1	25	1	24		1
Pruritus	2	9	2	7		2
Pulmonary embolism		2				2
Pulmonary infarction		1				1
Pulse volume decreased		2		1		1
Pyrexia	2	21	2	21		
Rash	3	9	3	8		1
Rash erythematous		1				1
Rash macular		2		2		
Rash papular		1				1
Rash pruritic		1				1
Raynaud's phenomenon	1	1			1	1
Rectal haemorrhage	1	1			1	1
Reflexes abnormal		1				1
Rheumatoid arthritis		1				1
Rhinorrhoea		1				1
Seizure	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis	1	1			1	1
Sinus pain		1		1		
Skin burning sensation		1		1		
Skin discolouration	1	1	1	1		
Skin lesion		1		1		
Skin reaction	1	2	1	2		
Sleep disorder	1	1	1	1		
Sneezing		1		1		
Stress		1		1		
Superior sagittal sinus thrombosis	1	1			1	1
Swelling		3		2		1
Swelling face		4		2		2
Swelling of eyelid		2		2		
Swollen tongue		3		1		2
Syncope	3	8			3	8
Systemic lupus erythematosus		1				1
Tachycardia	2	8	2	4		4
Tachypnoea		1		1		
Tendonitis	1	2	1	2		
Testicular pain		1		1		
Therapeutic response unexpected	1	1	1	1		
Thirst		1		1		
Throat irritation		2		2		
Throat tightness		2		1		1
Thrombosis	1	3			1	3
Tinnitus	1	2		1	1	1
Tongue disorder	1	4	1	3		1
Transient ischaemic attack		1				1
Tremor		1		1		
Troponin increased	1	1	1	1		
Type I hypersensitivity		1				1
Urticaria	1	13	1	11		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination failure		1				1	
Vaccination site discomfort	2	2	1	1	1	1	
Vaccination site erythema		3		3			
Vaccination site induration		1		1			
Vaccination site joint movement impairment	1	1	1	1			
Vaccination site mass		1		1			
Vaccination site movement impairment		1		1			
Vaccination site pain	1	22	1	21		1	
Vaccination site rash	1	1	1	1			
Vaccination site swelling		3		3			
Vaccination site urticaria		1				1	
Vaccination site warmth		2		2			
Vaginal discharge		1		1			
Vaginal haemorrhage		2		2			
Vertebral artery dissection		1				1	
Vertigo		1		1			
Viral rash		1		1			
Vision blurred	1	3	1	2		1	
Vomiting	1	2		1	1	1	
Vulval disorder		1				1	
Vulvitis		1		1			
Weight increased		1		1			
Wheezing		2		2			
	158	847	107	643	51	204	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper	1	1	1	1		
Acne		1		1		
Ageusia		1		1		
Alanine aminotransferase increased	1	1	1	1		
Anaphylactic reaction	1	6			1	6
Arrhythmia	1	2			1	2
Arthralgia	2	10	2	10		
Asthenia	1	3	1	3		
Asymptomatic COVID-19		1				1
Ataxia	1	1	1	1		
Axillary mass		1		1		
Axillary pain		2		2		
Balance disorder	2	2	2	2		
Blood glucose decreased	1	1			1	1
Blood pressure increased	1	2	1	2		
Bronchospasm		1				1
Cardiac flutter	1	1			1	1
Cerumen impaction		1		1		
Chest discomfort	2	2	1	1	1	1
Chills	3	10	2	9	1	1
Cold sweat		1		1		
Colitis ulcerative	1	1			1	1
Condition aggravated	2	2	1	1	1	1
Contusion		1				1
Cough	1	2			1	2
Deep vein thrombosis	1	1			1	1
Defaecation urgency		1		1		
Dehydration		1		1		
Delirium	1	1			1	1
Diabetes mellitus	1	1			1	1
Diarrhoea	2	4	1	3	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
	1	1	1
1	2		
	5	1	1
		1	1
		1	1
1	1	1	1
	4		
	1		
2	3	1	1
1	1		1
1	1	2	6
1	2		
1	1		
	1		
1	1		
		2	2
		1	1
4	14	2	4
1	1		
			1
	2		
	1		
1	1		
		1	1
1	1		
	1		
8	26	1	1
	1		
			1
1	1	1	1
		1	1

Diplopia 1 2

Disease recurrence 1 2

Disturbance in attention 1 2

Dizziness 1 6

Drug interaction 1 1

Drug level increased 1 1

Dry mouth 2 2

Dysgeusia 4

Dyskinesia 1

Dysphagia 3 4

Dysphonia 1 2

Dyspnoea 3 7

Ear discomfort 1 2

Ear swelling 1 1

Excessive cerumen production 1

Eye swelling 1 1

Facial paralysis 2 2

Fall 1 1

Fatigue 6 18

Feeling abnormal 1 1

Feeling cold 1

Feeling hot 2

Flushing 1

Gait disturbance 1 1

Gastric ulcer 1 1

Gastrointestinal pain 1 1

Gout 1

Headache 9 27

Head discomfort 1

Heart rate decreased 1

Heart rate increased 2 2

Hepatic enzyme increased 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster		1		1		
Hiatus hernia	1	1	1	1		
Hyperaesthesia		1		1		
Hyperaesthesia teeth		1		1		
Hyperhidrosis		2		1		1
Hypersomnia	1	1	1	1		
Hypertension	1	4	1	2		2
Hypoaesthesia	2	2	1	1	1	1
Hypoaesthesia oral	1	2	1	1		1
Hypotension		1				1
Inappropriate schedule of product administration	2	4	2	4		
Incontinence	1	1			1	1
Incorrect dose administered		1		1		
Infection		1		1		
Influenza like illness	1	1			1	1
Infusion site warmth	1	1	1	1		
Injection site bruising		1		1		
Injection site erythema	1	1	1	1		
Injection site pain	1	2	1	2		
Insomnia	1	1	1	1		
IVth nerve paralysis		1				1
Joint swelling	1	2	1	1		1
Lacrimation increased	1	1	1	1		
Lip disorder	1	1	1	1		
Lip pain	1	1	1	1		
Lip swelling		1				1
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities	2	3	2	2		1
Lymphadenopathy	1	5		4	1	1
Lymph node pain		1		1		
Malaise	1	5		4	1	1
Mass		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menorrhagia	1	1	1	1		
Mental impairment	1	1			1	1
Mouth swelling		1				1
Muscle spasms		1		1		
Muscle twitching	1	1	1	1		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	3	12	3	12		
Nasal congestion	1	1			1	1
Nausea	3	16	2	13	1	3
Neck pain	1	3	1	2		1
Nervousness		1				1
Oesophageal disorder		1				1
Oesophagitis	1	1			1	1
Off label use	2	5	2	5		
Oral candidiasis		1		1		
Oral discomfort	1	2	1	2		
Oral mucosal blistering		1		1		
Oropharyngeal pain	1	1	1	1		
Overdose		1		1		
Pain	1	6		4	1	2
Pain in extremity	2	10	2	9		1
Pain of skin		1		1		
Palpitations	1	1	1	1		
Paraesthesia	1	5		1	1	4
Paraesthesia oral	1	3	1	3		
Parvovirus infection	1	1	1	1		
Pericardial effusion	1	1			1	1
Periorbital swelling	1	1	1	1		
Peripheral swelling	2	4	2	4		
Petechiae		1		1		
Pharyngeal swelling		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion	1	1			1	1
Presyncope		3		1		2
Product administered at inappropriate site		2		2		
Productive cough		1				1
Product use issue		1		1		
Pruritus	2	6	2	5		1
Purpura		1		1		
Pyrexia	5	12	4	10	1	2
Rash	2	7	2	7		
Rash erythematous	1	3	1	3		
Rash maculo-papular	1	1	1	1		
Rash pruritic		2		1		1
Rheumatoid arthritis		1				1
Sleep disorder	1	1	1	1		
Somnolence		3		1		2
Speech disorder	1	1	1	1		
Splenitis	1	1			1	1
Stress	1	1	1	1		
Swelling face	1	2	1	1		1
Swollen tongue	1	1	1	1		
Tachycardia		2		1		1
Taste disorder		1		1		
Tendon disorder		1		1		
Tension headache	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	2	5	1	1	1	4
Thrombocytopenia		2				2
Thrombosis	2	2			2	2
Thyroid disorder	1	1	1	1		
Tinnitus	3	8	1	5	2	3
Tongue disorder		1		1		
Tongue pruritus		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxicity to various agents	1	1			1	1
Tremor		3		2		1
Type I hypersensitivity		1				1
Urticaria	4	7	4	6		1
Uveitis		1				1
Vaccination failure		1				1
Vaccination site induration		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site pain	1	12	1	11		1
Vaccination site reaction		2		2		
Vaccination site swelling		1		1		
Vaccination site urticaria		1		1		
Vaccination site warmth		1		1		
Vision blurred		1		1		
Visual impairment		1		1		
Vitreous detachment		1				1
Vitreous floaters		1		1		
Vomiting	2	7	1	4	1	3
Wheezing		1				1
Wrong product administered	1	1	1	1		
	157	433	104	312	53	121

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal pain		1		1		
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Alanine aminotransferase increased	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Aphthous ulcer		1		1		
Aspartate aminotransferase increased	1	1			1	1
Asthenia	1	2	1	2		
Atrial fibrillation		1				1
Back pain	2	3	2	3		
Balance disorder	1	1			1	1
Bladder spasm		1		1		
Blood creatine phosphokinase increased	1	1			1	1
Blood pressure decreased	2	2			2	2
Blood urine present	1	2	1	2		
Bradycardia		1				1
Bronchitis	1	1	1	1		
Burning sensation	1	1	1	1		
Cardiac flutter	1	1			1	1
Cerebrovascular accident	2	2			2	2
Chapped lips		1		1		
Chest discomfort		2		1		1
Chills	3	6	3	6		
Chronic obstructive pulmonary disease	1	1			1	1
Cold sweat	1	1	1	1		
Condition aggravated	1	1			1	1
Cough	1	3	1	3		
COVID-19	1	2			1	2
C-reactive protein increased	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Death	1	1			1	1
Decreased appetite	2	2	2	2		
Depressed level of consciousness	1	1			1	1
Diarrhoea	2	3	1	2	1	1
Discomfort	1	2	1	2		
Disturbance in attention	2	2	1	1	1	1
Dizziness	11	12	7	8	4	4
Drug ineffective	1	1			1	1
Dry mouth	1	1	1	1		
Dysarthria	1	1			1	1
Dysgeusia	3	3	3	3		
Dysphagia	2	2	1	1	1	1
Dysphonia		1		1		
Dyspnoea	4	4	3	3	1	1
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		
Erythema	4	5	3	4	1	1
Eye irritation		1				1
Eyelid sensory disorder		1		1		
Eye pruritus		1		1		
Facial asymmetry	1	1	1	1		
Facial paralysis	2	3			2	3
Fall	1	1			1	1
Fatigue	8	15	6	13	2	2
Feeling abnormal	3	3	3	3		
Feeling cold	1	1	1	1		
Feeling of body temperature change	1	1	1	1		
Flatulence	1	1	1	1		
Gait disturbance	1	1			1	1
Gastroenteritis		1		1		
Generalised tonic-clonic seizure		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased	1	1	1	1		
Haemorrhage urinary tract	3	3			3	3
Headache	11	17	10	16	1	1
Heart rate decreased	1	1			1	1
Heart rate increased		1				1
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	1			1	1
Herpes simplex	1	1			1	1
Herpes zoster	1	1			1	1
Herpes zoster oticus	1	1			1	1
Hot flush	1	1	1	1		
Hypersensitivity	5	5	3	3	2	2
Hypersomnia	1	2	1	2		
Hypertension	1	1	1	1		
Hyperuricaemia	1	1	1	1		
Hypoesthesia	6	8	3	5	3	3
Hypoesthesia oral	1	2	1	1		1
Hypotension	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1		1		
Insomnia	1	1	1	1		
Ischaemic stroke	1	1			1	1
Lacrimation increased	1	2	1	2		
Lethargy		1		1		
Lip blister		1		1		
Lip haemorrhage		1		1		
Lip pain		1		1		
Lip swelling	3	3	3	3		
Loss of consciousness	4	4			4	4
Loss of personal independence in daily activities	1	1	1	1		
Lung disorder	1	1			1	1
Malaise	2	3	2	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Micturition urgency		1		1		
Migraine	1	1	1	1		
Monoparesis	1	1			1	1
Mucosal discolouration	1	1	1	1		
Mucosal disorder		1		1		
Multiple sclerosis relapse	1	1			1	1
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	3	3	3	3		
Myalgia	2	4	2	4		
Nausea	8	10	6	8	2	2
Neck pain	2	2	2	2		
Nervous system disorder	1	1			1	1
No adverse event		1		1		
Off label use		1		1		
Oral discomfort		1		1		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort	1	1	1	1		
Overdose		1		1		
Pain	4	7	3	6	1	1
Pain in extremity	5	7	5	7		
Pain in jaw	1	1			1	1
Palpitations	1	2	1	1		1
Paraesthesia	3	5	1	3	2	2
Paraesthesia oral		1				1
Paralysis	1	1			1	1
Peripheral arterial occlusive disease	1	1	1	1		
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pharyngeal hypoaesthesia		1		1		
Pneumonia	1	1			1	1
Poor peripheral circulation	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Productive cough	1	2	1	2		
Product preparation issue		1		1		
Pruritus	3	7	1	5	2	2
Pulmonary embolism	1	1			1	1
Pyrexia	5	8	4	7	1	1
Rash	2	2	1	1	1	1
Rash erythematous	2	2	2	2		
Rash pruritic	1	2	1	2		
Respiratory disorder	1	1	1	1		
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	3	4	3	4		
Screaming	1	1	1	1		
Secretion discharge		2		2		
Seizure	1	1			1	1
Sepsis	1	1			1	1
Shoulder injury related to vaccine administration	1	1	1	1		
Skin exfoliation		1		1		
Skin warm		1		1		
Sneezing	1	2	1	2		
Somnolence	1	1			1	1
Stevens-Johnson syndrome		1				1
Stomatitis		1		1		
Suicidal ideation	1	1			1	1
Suspected COVID-19	1	1	1	1		
Swelling		2		2		
Swelling face	2	2	1	1	1	1
Syncope	5	5			5	5
Tachycardia	1	1			1	1
Tenderness		1		1		
Therapeutic response unexpected	1	1	1	1		
Thirst	2	2	2	2		
Thrombosis	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1	1	1		
Transient ischaemic attack	1	1	1	1		
Tremor	1	1	1	1		
Upper-airway cough syndrome		1		1		
Urinary tract infection		1		1		
Urticaria	2	3	1	2	1	1
Vaccination failure		1				1
Vaccination site erythema	2	2	2	2		
Vaccination site pain	6	6	6	6		
Vaccination site swelling	1	2	1	2		
Vaccination site urticaria	1	1			1	1
Vaccination site warmth	2	2	2	2		
Ventricular tachycardia		1				1
Vertigo	1	1	1	1		
Vision blurred	1	1			1	1
Vitamin B12 increased	1	1			1	1
Vomiting	6	7	4	5	2	2
Wheezing		1		1		
	245	354	153	247	92	107

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	3		2	1	1
Acute kidney injury		1				1
Agitation		1		1		
Aphasia	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	2	2	1	1	1	1
Asthenia	5	9	3	5	2	4
Atrial fibrillation	2	2			2	2
Balance disorder	1	1			1	1
Blood pressure decreased	1	2			1	2
Blood urine		1		1		
Bursitis	1	1	1	1		
Cardiac disorder	1	1			1	1
Cellulitis		1				1
Cerebrovascular accident	1	2			1	2
Change of bowel habit		1		1		
Chills	2	4	1	3	1	1
Chromaturia		1		1		
Circumstance or information capable of leading to medication error		1		1		
Confusional state	1	1	1	1		
Contusion	1	1	1	1		
COVID-19		2				2
Deafness		1				1
Death		1				1
Decreased appetite		2		1		1
Diarrhoea	1	3	1	3		
Disseminated varicella zoster virus infection		1				1
Dizziness	1	3		2	1	1
Drug ineffective		2				2
Dyspnoea	2	4	1	2	1	2
Dysuria	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid disorder	1	1	1	1		
Facial paralysis	1	1			1	1
Faeces soft	1	1	1	1		
Fall	2	4		1	2	3
Fatigue	1	1			1	1
Feeling abnormal	1	1	1	1		
Gastric ulcer	1	1			1	1
Gout		1		1		
Haemorrhage urinary tract		1				1
Headache	1	3	1	3		
Heart rate increased	1	1			1	1
Herpes zoster	2	2	2	2		
Hip fracture	1	1			1	1
Hypertension	1	1			1	1
Hypoacusis	1	1	1	1		
Hypokinesia		1		1		
Hypotension		2		2		
Impaired quality of life	1	1	1	1		
Inappropriate schedule of product administration		2		2		
Influenza like illness	1	1	1	1		
Insomnia	1	2	1	2		
Lethargy		1		1		
Ligament sprain	1	1	1	1		
Limb discomfort		2		2		
Lip swelling	1	1	1	1		
Lymphadenopathy		1		1		
Lymphoedema		1		1		
Malaise	1	2	1	2		
Memory impairment	1	1			1	1
Myalgia	1	2		1	1	1
Myocardial infarction	2	2			2	2
Nausea	2	2	2	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Night sweats	1	1			1	1
Oedema		1		1		
Pain	3	5	2	4	1	1
Pallor	1	1	1	1		
Pruritus	1	1	1	1		
Pulmonary oedema	1	1			1	1
Pyrexia	2	4	1	3	1	1
Rash	2	3	1	2	1	1
Rash macular		1		1		
Rash maculo-papular		1				1
Rash papular	1	1	1	1		
Rib fracture	1	1			1	1
Seizure	1	1			1	1
Skin injury		1		1		
Skin laceration	1	1	1	1		
Somnolence	1	3		2	1	1
Swollen tongue	2	2	2	2		
Syncope	1	2			1	2
Therapeutic response unexpected		1		1		
Transient ischaemic attack	1	1			1	1
Urticaria	2	3	1	2	1	1
Vaccination site bruising		1		1		
Varicella		1		1		
Vital functions abnormal		1				1
Vomiting	1	2	1	2		
	76	145	38	87	38	58

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Ageusia	1	1	1	1		
Allergy to vaccine		1		1		
Anaphylactic reaction	1	22			1	22
Anaphylactic shock		1				1
Aphasia		1		1		
Arthralgia	1	1	1	1		
Breast pain		1		1		
Chills		3		3		
Circumstance or information capable of leading to medication error		1		1		
Coeliac disease		1				1
Cognitive disorder		1		1		
Confusional state		1		1		
Contusion	1	1	1	1		
COVID-19	5	37	1	1	4	36
Decreased appetite		1		1		
Diarrhoea	1	3	1	3		
Disease recurrence		1		1		
Disturbance in attention		1		1		
Dizziness	1	8	1	7		1
Drug ineffective	5	37			5	37
Ear pruritus		1		1		
Eosinophil count increased		1		1		
Erythema		1		1		
Exposure during pregnancy		4		2		2
Exposure via breast milk		5		5		
Eyelid oedema		1				1
Eyelids pruritus		1				1
Facial paralysis		3				3
Fatigue		7		7		
Feeling abnormal	1	3	1	3		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling hot		1
Foetal growth restriction	1	3
Headache		5
Heart rate increased		1
Hypersensitivity		8
Hypertension		3
Hypotension		1
Impaired work ability		1
Inappropriate schedule of product administration		31
Incomplete course of vaccination		1
Incorrect dose administered		2
Influenza like illness		1
Lethargy		1
Lip pruritus		1
Lip swelling		1
Lymphadenopathy		1
Malaise	1	6
Maternal exposure before pregnancy	1	1
Maternal exposure during pregnancy	1	7
Maternal exposure timing unspecified		2
Menorrhagia		1
Migraine		1
Monocyte count increased		1
Muscular weakness		1
Musculoskeletal stiffness		1
Myalgia		1
Nausea	1	3
Neck pain	1	1
Neutrophil count decreased		1
No adverse event	1	1
Oedema		1
Off label use		38

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	3
	4		1
	1		
			8
	3		
	1		
	1		
	31		
	1		
	2		
	1		
	1		
	1		1
	1		
1	6		
		1	1
1	7		
	2		
	1		
	1		
	1		
	1		
1	3		
1	1		
	1		
1	1		
			1
	38		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Overdose		5		5		
Pain		3		3		
Pain in extremity		4		4		
Paraesthesia		1		1		
Periorbital swelling		1		1		
Polymenorrhoea		2		2		
Postpartum haemorrhage		1		1		
Product complaint	4	4	4	4		
Product container issue		1		1		
Product physical issue		1		1		
Product preparation error		2		2		
Product preparation issue		10		10		
Product quality issue		1		1		
Product supply issue		1		1		
Product use issue		10		10		
Pruritus		2		1		1
Pyrexia		5		5		
Rash		3		3		
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive		1				1
Somnolence		1		1		
Suspected COVID-19	2	2	1	1	1	1
Swelling face		1		1		
Syncope		1				1
Taste disorder	1	1	1	1		
Therapeutic response unexpected		1		1		
Thrombosis	1	1			1	1
Tongue pruritus		1		1		
Underdose	4	12	4	12		
Urticaria		1		1		
Vaccination site oedema		3		3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain		2		2		
Vaccination site rash	1	1	1	1		
Vaccination site urticaria		2		2		
Vaginal haemorrhage		1		1		
Vomiting		2		2		
Weight decreased		2		2		
White blood cell count decreased		1		1		
Wrong product administered		1		1		
Wrong technique in product usage process		1		1		
	39	379	24	253	15	126

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CAYMAN ISLANDS**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dyspepsia		1		1
Fatigue		1		1
Headache		1		1
Irritability		1		1
Muscle spasms		1		1
Muscle twitching		1		1
Palpitations		1		1
		8		8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CHILE**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Blood glucose increased	1	1			1	1
Cough		1		1		
Exposure via breast milk	1	1	1	1		
Fall		1				1
Fatigue		1		1		
Headache		1		1		
Head injury		1				1
Malaise	1	1	1	1		
Myalgia		1		1		
Nasal congestion	1	1	1	1		
Seizure		1				1
Vaccination site pain		1		1		
Wound haemorrhage		1				1
	5	14	3	8	2	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic reaction		1				1	
Aphasia	1	1			1	1	
Arthralgia	1	2	1	2			
Back pain		1		1			
Breast pain		1		1			
Chills	2	2	2	2			
Complement factor C3 decreased		1		1			
C-reactive protein decreased		1		1			
Diarrhoea	1	1	1	1			
Dysgeusia		1					1
Dyspnoea		1					1
Erythema nodosum	1	1			1	1	
Eye discharge	1	1	1	1			
Eye movement disorder	1	1			1	1	
Face oedema		1					1
Fatigue		2		2			
Feeling abnormal		1		1			
Gait disturbance	1	2		1	1	1	
Gait inability	1	1			1	1	
Headache	3	3	3	3			
Hemiparesis		1					1
Loss of consciousness	1	1			1	1	
Loss of personal independence in daily activities		1		1			
Lymphadenopathy		1		1			
Lymph node pain		1		1			
Malaise		1		1			
Maternal exposure during pregnancy		1		1			
Monocyte count decreased		1		1			
Muscular weakness		1		1			
Myalgia	1	3	1	3			
Nausea	1	1	1	1			
Pain		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		1		1		
Peripheral swelling	1	1	1	1		
Pyrexia	2	3	2	3		
Rhabdomyolysis		1				1
SARS-CoV-2 antibody test negative		1		1		
Seizure	1	1			1	1
Tongue movement disturbance	1	1			1	1
Toothache	1	1	1	1		
Vaccination site pain	1	2	1	1		1
Vasculitis	1	1			1	1
Venous thrombosis		1				1
Vomiting		1		1		
Wrong product administered	1	1	1	1		
	25	56	16	39	9	17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper		1		1		
Anaphylactic reaction		2				2
Angioedema		1				1
Arrhythmia		1				1
Arthralgia	1	4	1	3		1
Arthritis		1				1
Asthenia		1		1		
Back pain		1		1		
Blood pressure fluctuation	1	1	1	1		
Breast engorgement	1	1	1	1		
Chest pain	1	2	1	1		1
Chills	1	4	1	3		1
Choking		1				1
COVID-19	1	1			1	1
Cyst	1	1	1	1		
Diarrhoea	1	4	1	4		
Discomfort	1	1	1	1		
Disease recurrence		1		1		
Dizziness	1	2	1	2		
Drug ineffective	1	1			1	1
Dry skin		1		1		
Dysbiosis		1				1
Dyspnoea		2				2
Eye pruritus		1				1
Eye swelling		1				1
Facial paralysis	1	1			1	1
Fatigue	5	7	5	7		
Feeling cold	1	2	1	2		
Galactostasis	1	1	1	1		
Glossitis		1		1		
Headache	2	8	2	7		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort	1	1	1	1		
Hemiparaesthesia	1	1			1	1
Hyperaesthesia	2	2	2	2		
Hyperhidrosis		1		1		
Hypersensitivity	2	5	2	5		
Hyperventilation		1				1
Hypoaesthesia	3	4	3	3		1
Hypotension		1				1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1		1		
Internal haemorrhage	1	1			1	1
Joint swelling		2		1		1
Loss of consciousness		1				1
Lymphadenopathy	1	3	1	2		1
Lymph node pain		2		2		
Malaise	2	4	2	4		
Muscle discomfort	1	1	1	1		
Muscle spasms	1	3	1	3		
Musculoskeletal pain	1	1	1	1		
Myalgia	5	6	5	5		1
Nasal congestion		1		1		
Nausea	2	3	2	3		
Neck pain	1	1	1	1		
Neuralgia	1	1			1	1
Ocular hyperaemia		1				1
Off label use	1	2	1	2		
Pain		2		1		1
Pain in extremity		2		2		
Pallor		1				1
Paraesthesia	3	5	3	4		1
Peripheral swelling	1	1			1	1
Photophobia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	1	1	1	1		
Pruritus		1		1		
Pyrexia	3	7	3	6		1
Rash		2		1		1
Rash pruritic		1				1
Respiratory distress		1				1
Rhinorrhoea	1	1	1	1		
Sensory loss		1		1		
Skin burning sensation	1	1	1	1		
Splenic rupture	1	1			1	1
Splenomegaly	1	1			1	1
Stenosis	1	1	1	1		
Swelling face		1				1
Swollen tongue		1		1		
Syncope	1	1			1	1
Synovial cyst		1		1		
Tachycardia		1				1
Urticaria		1				1
Vaccination site pain	3	4	2	2	1	2
Vaccination site paraesthesia		1		1		
Vestibular disorder		1		1		
Vomiting	1	1	1	1		
	66	154	55	108	11	46

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	2	1	1		1
Abnormal faeces		1		1		
Chills	2	2	2	2		
Decreased appetite		2		2		
Diarrhoea		1		1		
Drug-induced liver injury	1	1			1	1
Erythema	1	1	1	1		
Fatigue		1		1		
Headache	3	4	3	4		
Hepatic enzyme increased		1				1
Hepatic steatosis		1		1		
Hypersensitivity	1	1	1	1		
Hypertension	1	1	1	1		
Insomnia	1	1	1	1		
Malaise	2	2	2	2		
Myalgia	3	4	3	4		
Nausea	1	3	1	2		1
Neck pain	1	1	1	1		
Overdose		1		1		
Oxygen saturation decreased	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	1	1	1	1		
Pancreatitis		1				1
Product preparation error		1		1		
Pruritus	1	1	1	1		
Pyrexia	2	3	2	3		
Skin burning sensation	1	1	1	1		
Transaminases increased	1	1	1	1		
Urine analysis abnormal		1				1
Vaccination site discomfort	1	1	1	1		
Vaccination site pain		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
28	42	1	6

29

48

28

42

1

6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain upper	3	3	3	3		
Angioedema		1				1
Anxiety	1	1	1	1		
Arthralgia	1	2	1	2		
Asthenia	1	1	1	1		
Aversion	1	1	1	1		
Axillary mass	1	1	1	1		
Axillary pain		1		1		
Back pain	1	1	1	1		
Blood glucose decreased	1	1	1	1		
Blood pressure increased	1	1	1	1		
Blood test abnormal		1		1		
Bone pain	1	2	1	2		
Burning sensation		2		2		
Chest discomfort	2	2	2	2		
Chest pain	2	2	2	2		
Chills	2	4	2	4		
Cold sweat	1	1	1	1		
Colitis	1	1	1	1		
Contusion	2	2	2	2		
Cough	1	1	1	1		
Crying		1				1
Depressed mood	1	1	1	1		
Dermatitis allergic	1	5		4	1	1
Diarrhoea	1	3	1	3		
Discomfort		1		1		
Discouragement		1		1		
Dizziness	2	3	2	3		
Dry mouth		1				1
Dyspnoea	1	2	1	2		
Ear discomfort		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Emotional distress	1	1	1	1		
Erythema		2		2		
Eye swelling	1	1	1	1		
Face oedema		1				1
Fatigue	5	7	5	7		
Fear	1	1	1	1		
Feeling cold	2	2	2	2		
Gait disturbance	2	2	2	2		
Guillain-Barre syndrome		2				2
Headache	18	26	18	26		
Hemiplegia		1				1
Hot flush	1	1	1	1		
Hypersensitivity		2		2		
Hypertonia	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incomplete course of vaccination		9		9		
Inflammation		1		1		
Insomnia	2	2	2	2		
Limb discomfort	1	1	1	1		
Localised oedema		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenopathy	1	3	1	3		
Malaise	5	9	5	9		
Mass	1	1	1	1		
Maternal exposure timing unspecified		1		1		
Mental disorder		1		1		
Musculoskeletal chest pain	1	1	1	1		
Myalgia	11	15	11	15		
Nausea	6	8	6	8		
Oedema peripheral		1		1		
Off label use		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	1	2	1	2		
Pain	6	8	6	8		
Pain in extremity	6	7	6	7		
Panic attack	1	1	1	1		
Panic reaction	1	1	1	1		
Paraesthesia		1				1
Peripheral swelling	1	2	1	2		
Polydipsia		1		1		
Product supply issue	1	1	1	1		
Product use issue		1		1		
Pyrexia	14	17	14	17		
Respiratory disorder		1				1
Rhinorrhoea	2	2	2	2		
Somnolence	2	3	2	3		
Stress	1	1	1	1		
Suspected COVID-19		1				1
Tachycardia	3	3	3	3		
Therapeutic response unexpected	1	1	1	1		
Throat irritation	2	2	2	2		
Tinnitus	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema	2	3	2	3		
Vaccination site inflammation	3	4	3	4		
Vaccination site mass		1		1		
Vaccination site pain	6	12	6	12		
Vaccination site pruritus		1		1		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
Wrong product administered	1	1	1	1		
	150	242	149	230	1	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**COLOMBIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic shock		1				1	
Arthralgia		1		1			
Asphyxia		1				1	
Asthenia	1	2	1	1		1	
Bone pain		1		1			
Chills	1	2	1	1		1	
Cough	1	1	1	1			
Decreased appetite	1	1	1	1			
Discomfort		1					1
Dyspnoea		1		1			
Erythema	1	2	1	2			
Eye pain		1		1			
Fatigue		1					1
Gait inability		1		1			
Headache	3	3	3	3			
Lymphadenopathy	1	1	1	1			
Lymph node pain	1	1	1	1			
Malaise	1	1	1	1			
Myalgia		1		1			
Nausea	1	2	1	2			
Ocular hyperaemia		1		1			
Oropharyngeal pain	1	1	1	1			
Oxygen saturation decreased		1		1			
Paraesthesia		1		1			
Pharyngeal erythema	1	1	1	1			
Puncture site pain	1	1	1	1			
Pyrexia		1		1			
Respiratory distress		1					1
Secretion discharge	1	1	1	1			
Sneezing	1	1	1	1			
Urticaria		1		1			
Vaccination site pain	2	2	2	2			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Vertigo

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
19	32		8

19

40

19

32

8

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic reaction		1				1	
Arthralgia	1	2	1	2			
Asthenia		1		1			
Asymptomatic COVID-19	1	1			1		1
Chills	1	2	1	2			
Cough		2		1			1
COVID-19		1		1			
Diarrhoea	1	1	1	1			
Dizziness	1	2	1	2			
Dyspnoea	1	2	1	1			1
Exposure during pregnancy	1	1	1	1			
Feeling hot		1		1			
Headache	1	8	1	6			2
Hypertension		2		1			1
Influenza like illness		1		1			
Lymph node palpable		1		1			
Malaise	2	6	2	5			1
Musculoskeletal pain		1		1			
Myalgia		1		1			
Odynophagia		1		1			
Oropharyngeal pain		1		1			
Pyrexia	1	2	1	1			1
Rash		2		1			1
Tachycardia	1	1	1	1			
Urticaria		1		1			
Vaccination site pain		1		1			
Vomiting	1	2	1	2			
	13	48	12	38	1		10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper		1		1
Back pain	1	1	1	1
Cough	1	2	1	2
Drug hypersensitivity	1	1	1	1
Dyspnoea	1	1	1	1
Erythema	1	1	1	1
Headache		2		2
Hypersensitivity	1	1	1	1
Hypoaesthesia		1		1
Influenza		1		1
Lymphadenopathy	1	1	1	1
Malaise	1	1	1	1
Muscle spasms	1	1	1	1
Oedema	1	1	1	1
Pain	1	2	1	2
Paraesthesia	1	1	1	1
Rhinorrhoea	1	1	1	1
	13	20	13	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister		1		1		
Burning sensation		1		1		
Candida infection		1		1		
Chills		1		1		
COVID-19	1	1	1	1		
Death	1	1			1	1
Erythema		1		1		
Gingivitis		1		1		
Hypersensitivity		2		2		
Leukocytosis		1		1		
Malaise	1	1	1	1		
Off label use		1		1		
Oral candidiasis		1		1		
Product use issue		1		1		
Pruritus		1		1		
Pyrexia		1		1		
Stomatitis		1		1		
		1		1		
	3	19	2	18	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		2				2
Anxiety		1				1
Arthralgia	2	3	2	3		
Asthenia		2		2		
Blood pressure increased		1		1		
Chest pain	1	1	1	1		
Chills	1	2	1	2		
Cough		1		1		
COVID-19	1	2	1	1		1
Cyanosis		1		1		
Diarrhoea		1				1
Discomfort		1		1		
Dizziness		1		1		
Dysphonia		1		1		
Feeling hot		2		2		
Headache	1	2	1	2		
Hyperhidrosis		1		1		
Hypersensitivity	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Influenza	1	1	1	1		
Malaise	1	2	1	2		
Myalgia	1	2	1	2		
Paraesthesia		1		1		
Pyrexia	2	2	2	2		
Rash		3		2		1
Seizure		1				1
Skin discolouration		1		1		
Skin plaque		1		1		
Syncope		1				1
Underdose	1	1	1	1		
Urticaria	2	2	2	2		
Vaccination site erythema	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	4	1	4		
Vomiting		1				1
	18	51	18	42		9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**COSTA RICA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		1				1
Adnexa uteri pain		1		1		
Anaphylactic shock		1				1
Application site inflammation		1		1		
Application site pain		1		1		
Arthralgia	1	1	1	1		
Axillary pain	1	1	1	1		
Burning sensation		2		2		
Chills		2		2		
Condition aggravated		1		1		
COVID-19	1	1	1	1		
Dermatitis allergic		2		1		1
Dyspnoea		1		1		
Encephalopathy		1				1
Erythema		1		1		
Eye pruritus		1		1		
Fatigue	3	4	3	4		
Feeling cold		1		1		
Feeling hot		1		1		
Headache	2	7	2	7		
Hyperthermia		1		1		
Hyposmia	1	1	1	1		
Incorrect route of product administration		2		2		
Infection	1	2	1	2		
Lethargy	1	1	1	1		
Limb discomfort	1	3	1	3		
Lymph node pain		1		1		
Mobility decreased		1		1		
Muscle spasms		1		1		
Myalgia	1	3	1	3		
Nasal congestion	1	1	1	1		
Nausea		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	1	1	1	1		
Nervous system disorder		1		1		
Ocular hyperaemia		1		1		
Odynophagia	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	1	2	1	2		
Pain in extremity	4	7	4	7		
Pruritus	1	2	1	2		
Pyrexia	1	2	1	2		
Rash	1	2	1	2		
Rash papular	1	1	1	1		
Seizure		1				1
Skin lesion		1		1		
Somnolence		1		1		
Tachycardia		1		1		
Throat irritation	1	1	1	1		
Throat tightness		1				1
Urticaria		1		1		
Vaccination site discomfort		1		1		
Vaccination site mass		1		1		
Vaccination site pain	10	16	10	16		
Vaccination site urticaria		1		1		
	37	98	37	91		7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	4		1	1	3
Anaphylactic reaction		1				1
Anaphylactic shock	1	1			1	1
Application site pain		2		2		
Arthralgia		5		5		
Asthenia		2				2
Back pain	1	2	1	2		
Bone pain		1		1		
Chest discomfort		1				1
Chest pain		1				1
Chills		5		3		2
Cold sweat		1		1		
Condition aggravated		1				1
Contusion	1	1			1	1
Cough	2	3	2	3		
COVID-19		2		1		1
Deafness	1	1			1	1
Diarrhoea	2	3	1	1	1	2
Discomfort		1				1
Dizziness		4		2		2
Drug ineffective		1				1
Dry mouth		1				1
Dysgeusia		2		1		1
Dyspepsia	1	2			1	2
Dysphonia	1	2	1	2		
Dyspnoea	1	2	1	1		1
Ear discomfort	1	1	1	1		
Energy increased		1		1		
Epistaxis	1	1			1	1
Euphoric mood		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Extensive swelling of vaccinated limb		1
Eye pruritus		1
Fall		1
Fatigue	5	11
Feeling abnormal		2
Feeling cold		1
Gastritis		1
Gingival bleeding	1	1
Gingival disorder	1	1
Gingival pain	1	1
Gingivitis	1	1
Haemorrhage	1	1
Headache	4	14
Heart rate increased		1
Heart rate irregular		1
Hyperhidrosis		2
Hypertension		1
Hypoaesthesia		2
Immune thrombocytopenia	1	1
Influenza		1
Influenza like illness		1
Insomnia		1
Joint swelling	1	1
Lethargy	1	1
Limb discomfort	1	1
Lymphadenopathy		1
Malaise	1	5
Migraine		2
Miosis		1
Mobility decreased	1	1
Muscle spasms		2
Myalgia		9

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
			1
4	8	1	3
	2		
	1		
			1
1	1		
1	1		
1	1		
		1	1
3	10	1	4
			1
	1		
	1		1
	2		
		1	1
	1		
1	1		
1	1		
1	1		
	1		
1	5		
	1		1
			1
1	1		
	2		
	8		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nasopharyngitis		1		1			
Nausea		3		2		1	
Ocular hyperaemia		1		1			
Oropharyngeal discomfort		1				1	
Oropharyngeal pain	1	1	1	1			
Oxygen saturation abnormal	1	1	1	1			
Pain	2	4	2	4			
Pain in extremity	4	8	4	8			
Paraesthesia	1	3	1	3			
Peripheral swelling	1	1	1	1			
Petechiae	1	1			1	1	
Photopsia		1		1			
Platelet count abnormal	1	1			1	1	
Pruritus	2	3	2	3			
Pyrexia	2	9	2	9			
Rash		1		1			
Red blood cell sedimentation rate increased		1		1			
Respiratory disorder	1	1			1	1	
Respiratory distress		1				1	
Respiratory tract congestion	1	1	1	1			
Sensation of foreign body		1		1			
Sleep disorder		1		1			
Somnolence	2	3	2	3			
Tachycardia		2		2			
Tachypnoea	1	2	1	2			
Thirst		2					2
Throat clearing		1		1			
Throat irritation	1	1	1	1			
Tooth disorder	1	1	1	1			
Vaccination site nodule	1	1	1	1			
Vaccination site pain	3	9	3	9			
Vasculitis		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred		1		1		
Vomiting		3		2		1
	63	203	48	148	15	55

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	2	1	2
Diarrhoea		2		2
Eye pain		1		1
Fatigue	1	1	1	1
Headache	1	2	1	2
Lymphadenopathy	1	1	1	1
Malaise		1		1
Migraine		1		1
Myalgia		2		2
Pain		2		2
Pain in extremity		1		1
Pyrexia	1	1	1	1
Vaccination site pain	3	3	3	3
	8	20	8	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Asthenia	1	1	1	1		
Cerebrovascular accident	2	2			2	2
Cough	1	1	1	1		
COVID-19	1	1			1	1
Death	1	1			1	1
Diarrhoea	2	2	2	2		
Dizziness	2	2	1	1	1	1
Dyspnoea	1	1	1	1		
Fatigue	1	2	1	2		
Feeling abnormal	1	1			1	1
Headache	1	2	1	2		
Hepatic enzyme increased		1				1
Hypothermia		1				1
Influenza	1	1	1	1		
Joint range of motion decreased		1				1
Malaise		1				1
Mobility decreased		1				1
Muscle contracture		1		1		
Myalgia	1	3	1	2		1
Myocardial infarction	1	1			1	1
Nausea	1	2		1	1	1
Oxygen saturation abnormal	1	1			1	1
Pain	1	1	1	1		
Pain in extremity	3	3	3	3		
Pruritus	1	1	1	1		
Pyrexia	2	3	1	1	1	2
Splenomegaly		1				1
Syncope	1	1			1	1
Vaccination failure	1	1			1	1
Vaccination site pain	5	6	5	6		
Vomiting	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	34	49	21	28	13	21

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Death	1	1			1	1
Dizziness		1		1		
Dry eye	1	1	1	1		
Erythema of eyelid	1	1	1	1		
Eyelid irritation	1	1	1	1		
Feeling cold		1		1		
Hypersensitivity		1		1		
Mouth swelling		1		1		
Myocardial infarction		1				1
Nausea		1		1		
Pain	1	1	1	1		
Pain in extremity	1	2	1	2		
Peripheral swelling	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia		1		1		
Swelling face		1		1		
Vaccination site erythema	1	1	1	1		
Vomiting		1		1		
	9	20	8	18	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Aphonia		1		1		
Apthous ulcer		1		1		
Arthralgia		1		1		
Asthenia	1	4	1	4		
Blood pressure increased	1	1	1	1		
Bronchospasm	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Chills	1	4	1	4		
Communication disorder		1		1		
Constipation		2		2		
Contusion		1		1		
COVID-19	4	7			4	7
Depression		1		1		
Diarrhoea	1	2	1	2		
Discomfort		1		1		
Dizziness	1	2	1	2		
Drug ineffective	3	5			3	5
Dysgeusia		1		1		
Dyspnoea		4		3		1
Dysstasia		1		1		
Ecchymosis	1	1	1	1		
Epistaxis	1	1	1	1		
Eye allergy		1		1		
Eye inflammation		1		1		
Eye pain		1		1		
Faeces soft		1		1		
Fatigue	5	16	5	16		
Feeling abnormal		2		2		
Feeling cold		2		2		
Fibrin D dimer increased		1		1		
Flatulence		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric disorder		1		1		
Gastritis		1		1		
Gastrointestinal pain		1		1		
Gastrointestinal sounds abnormal		1		1		
Headache	1	12	1	12		
Hyperhidrosis		1		1		
Hypersomnia		1		1		
Hypertensive crisis		1				1
Impaired work ability		1		1		
Incoherent		1		1		
Ischaemia	1	1	1	1		
Loss of personal independence in daily activities	1	2	1	2		
Lung disorder	1	2	1	1		1
Lymphadenopathy		1		1		
Lymphangitis		1				1
Lymph node pain		1		1		
Malaise	1	1	1	1		
Migraine		1		1		
Myalgia	2	5	2	5		
Nausea	1	3	1	3		
Oropharyngeal pain	1	2	1	2		
Oxygen saturation decreased		2				2
Pain	4	10	4	10		
Pain in extremity	1	8	1	8		
Peripheral swelling		1		1		
Petechiae	1	1	1	1		
Platelet count abnormal	1	1			1	1
Pleural effusion		1				1
Pleuritic pain		1		1		
Pneumonitis		1				1
Pyrexia	2	9	2	9		
Rash		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorder	1	1	1	1		
Rhinorrhoea		1		1		
SARS-CoV-2 antibody test negative		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Suspected COVID-19		1		1		
Tinnitus	2	2	2	2		
Tremor		1		1		
Vaccination failure	1	1			1	1
Vaccination site induration		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	2	9	2	9		
Venous thrombosis		1				1
Vomiting		1		1		
	45	171	35	147	10	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CROATIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		2		2		
Asthenia	1	4	1	3		1
Blister		1				1
Body temperature increased		4		4		
Chest discomfort		2		1		1
Chills	1	9	1	8		1
Choking sensation		1				1
Cold sweat		2		1		1
COVID-19		1		1		
Dermatitis allergic		1				1
Disturbance in attention		1		1		
Dizziness		2		1		1
Dysgeusia		1				1
Dysphagia		1				1
Dyspnoea	1	3		1	1	2
Erythema		2				2
Extensive swelling of vaccinated limb		1				1
Eye pain		1		1		
Facial paresis		1				1
Fatigue		4		3		1
Feeling abnormal	1	1			1	1
Feeling cold		1		1		
Feeling hot		2		1		1
Headache	3	17	2	14	1	3
Hyperhidrosis	1	1	1	1		
Immune system disorder		1		1		
Insomnia		1		1		
Lymphadenopathy		1				1
Lymph node pain		1				1
Malaise		3		3		
Muscle tightness		1		1		
Muscular weakness		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	2	10	1	8	1	2
Myosclerosis		1				1
Nausea		4		4		
Neck pain		1		1		
Pain	1	3	1	3		
Pain in extremity		3		3		
Pallor		1				1
Palpitations		1				1
Panic attack		1				1
Paraesthesia		3		1		2
Pharyngeal paraesthesia		1				1
Presyncope	1	1			1	1
Pruritus		2				2
Pyrexia	2	14	1	11	1	3
Rash		1				1
Rash maculo-papular		2				2
Salivary hypersecretion		1				1
Sleep paralysis		1		1		
Sleep terror		1		1		
Spinal pain		1		1		
Throat tightness	1	1			1	1
Tongue oedema		2				2
Tremor	1	2	1	1		1
Type I hypersensitivity		3				3
Urticaria		2				2
Vaccination site erythema		2		1		1
Vaccination site joint movement impairment		1		1		
Vaccination site oedema		3		2		1
Vaccination site pain	1	20	1	16		4
Vaccination site swelling		3		2		1
Vertigo	1	1			1	1
Vomiting		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

18

Cumulative Total #  
Spontaneous AE

169

Spontaneous			
Nonserious		Serious	
I	C	I	C
10	109	8	60

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		2		2		
Abortion spontaneous	1	1			1	1
Allergy to chemicals		1		1		
Anaphylactic shock		1				1
Angioedema		1				1
Anosmia	1	1			1	1
Aphthous ulcer		1		1		
Application site oedema		1		1		
Arrhythmia	2	2			2	2
Arthralgia		8		8		
Asthenia	1	14	1	11		3
Axillary pain	1	1			1	1
Back pain		3		2		1
Blood pressure increased	2	5	1	3	1	2
Body temperature increased	1	10	1	9		1
Bone pain	1	5	1	5		
Bronchospasm		1				1
Burning sensation		1				1
Catarrh	1	1			1	1
Chest discomfort	1	3			1	3
Chest pain		1		1		
Chills	8	29	6	23	2	6
Condition aggravated		1				1
Confusional state		3		2		1
Conjunctivitis allergic		1				1
Cough		1				1
COVID-19	2	4		1	2	3
Cyanosis		1				1
Deafness bilateral		1				1
Decreased appetite	1	4	1	4		
Dermatitis allergic		1		1		
Diaphragmatic spasm		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	3	1	3		
Discomfort		1		1		
Disturbance in attention		1		1		
Dizziness		4		3		1
Dry mouth		1		1		
Dyskinesia		1				1
Dyspnoea		6		3		3
Dyspnoea exertional		1		1		
Ear canal erythema		1				1
Ear pain		2				2
Ear pruritus		1				1
Encephalitis post immunisation		1				1
Epilepsy		1				1
Erythema	1	11		2	1	9
Exposure during pregnancy	1	1	1	1		
Extensive swelling of vaccinated limb	1	11			1	11
Extrapyramidal disorder		1				1
Eyelid function disorder		1				1
Eyelid oedema		2		1		1
Eyelid pain		1		1		
Eyelid ptosis		2				2
Facial nerve disorder		1		1		
Facial pain		1		1		
Facial paralysis		1				1
Facial paresis	1	4			1	4
Fatigue	6	24	3	20	3	4
Fear		1				1
Feeding disorder		1		1		
Feeling abnormal		1		1		
Feeling hot	1	8	1	5		3
Gastrointestinal pain		1		1		
Gingival bleeding		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematoma	1	1	1	1		
Headache	3	43	2	31	1	12
Head discomfort		1				1
Heart rate increased		1				1
Hot flush		2		1		1
Hyperaesthesia		1		1		
Hyperhidrosis	1	6	1	4		2
Hypersensitivity		1				1
Hypertension	3	6		1	3	5
Hypoacusis		1		1		
Hypoaesthesia	1	4		3	1	1
Hypoaesthesia oral		1				1
Hypogeusia		1		1		
Hypokinesia		1		1		
Hypotension		2		1		1
Insomnia	1	3	1	3		
Irritable bowel syndrome		1		1		
Lacrimation increased		1		1		
Lip disorder		1				1
Lip oedema	1	2			1	2
Lip swelling		1				1
Livedo reticularis		1				1
Localised oedema		1		1		
Loss of consciousness	1	3			1	3
Lymphadenitis		2		1		1
Lymphadenopathy	2	7	1	6	1	1
Lymph node pain	1	2	1	2		
Malaise	3	11	3	10		1
Menstrual disorder		1		1		
Moaning		1				1
Monoparesis		1				1
Muscle contractions involuntary		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	1	2	1	1		1
Muscular weakness	1	2	1	1		1
Musculoskeletal stiffness		1				1
Myalgia	4	29	3	27	1	2
Nasopharyngitis		1		1		
Nausea	2	16	2	12		4
Neck pain		4		3		1
Neuritis		1		1		
Neurological symptom	1	1	1	1		
Nystagmus		1				1
Ocular hyperaemia		1		1		
Oedema mouth		1				1
Oedema peripheral		1				1
Off label use		1		1		
Oral mucosal erythema		1		1		
Oral pain		1		1		
Oropharyngeal pain	2	3	2	3		
Pain		2		2		
Pain in extremity	1	10		9	1	1
Pain of skin		1				1
Pallor		1				1
Palpitations	3	7	2	4	1	3
Panic attack		1				1
Paraesthesia	1	8	1	6		2
Paraesthesia oral	1	3		1	1	2
Paresis		1				1
Peripheral coldness	1	1	1	1		
Peripheral swelling		2		2		
Pleural effusion		1				1
Pneumonia		1				1
Polymenorrhoea		1		1		
Presyncope		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue		1				
Pruritus	1	11		1		
Pulmonary embolism		1		4	1	7
Pulmonary pain		1				1
Pulse absent		1		1		
Pyrexia	7	40				1
Rash		8	4	30	3	10
Rash erythematous		1		2		6
Rash macular	1	3			1	3
Rash maculo-papular		2				2
Rectal haemorrhage		1				1
Renal pain		1		1		
Restlessness		1				1
Retching		1		1		
Rhinorrhoea	1	1			1	1
SARS-CoV-2 antibody test positive		1		1		
Sensation of foreign body		1		1		
Sensory loss		1				1
Serum sickness		1				1
Skin burning sensation	1	3		1	1	2
Skin oedema		1		1		
Skin sensitisation		1		1		
Skin tightness	1	2			1	2
Sneezing		1				1
Snoring	1	1			1	1
Somnolence		3		1		2
Swollen tongue		1				1
Syncope		1				1
Tachycardia	3	8		2	3	6
Tension		1		1		
Tinnitus		3		1		2
Tongue oedema		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor		6		5		1
Type I hypersensitivity	1	10			1	10
Urticaria		2		1		1
Use of accessory respiratory muscles		1				1
Vaccination failure	2	3			2	3
Vaccination site erythema	3	22	1	15	2	7
Vaccination site haematoma		2		2		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		4		3		1
Vaccination site joint erythema		1		1		
Vaccination site lymphadenopathy	1	2	1	2		
Vaccination site mass		1				1
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema	2	6	1	4	1	2
Vaccination site pain	7	56	4	47	3	9
Vaccination site pruritus		3		3		
Vaccination site reaction		1		1		
Vaccination site swelling	1	12	1	9		3
Vertigo	1	3	1	2		1
Vision blurred		1				1
Visual impairment		1				1
Vomiting	2	6	2	4		2
Wheezing		1				1
Wrong technique in product usage process		1		1		
	108	682	56	429	52	253

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Anaemia		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema		1				1
Arrhythmia	2	4			2	4
Arthralgia		4		4		
Asthenia	3	9	3	9		
Asthma		1				1
Atrial fibrillation		1				1
Back pain		2		1		1
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased	1	1	1	1		
Blood pressure increased	3	9	1	1	2	8
Body temperature increased		2		2		
Bone pain	1	2	1	2		
Breast pain	1	1	1	1		
Breath sounds abnormal		1				1
Bronchospasm		2				2
Burning sensation		2				2
Chest discomfort	1	1	1	1		
Chest pain	2	3	1	2	1	1
Chills	3	12	3	12		
Condition aggravated		1				1
Cough	3	6	3	4		2
COVID-19	3	3			3	3
Death		1				1
Decreased appetite		1		1		
Deep vein thrombosis	1	2			1	2
Defaecation urgency	1	1	1	1		
Diarrhoea	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		
		1	1
			1
1	1		
	1		
1	1		
			1
			1
1	1	1	5
1	1		
	1		
	2	1	5
		1	9
			1
			1
	1		
1	2		
2	2	2	2
3	6		1
	1		
			1
1	1		
5	14	1	5
1	1		
		1	1
		1	1
	1	1	1
	1	1	1
1	1		
1	1		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Incorrect dose administered		1					1
Incorrect route of product administration	1	1	1	1			
Lacrimation increased	1	1	1	1			
Loss of consciousness	1	1			1		1
Lymphadenopathy		1		1			
Lymphopenia		1		1			
Malaise	1	5	1	4			1
Memory impairment	1	1	1	1			
Migraine		1		1			
Multi-organ disorder		1					1
Muscle contractions involuntary		1					1
Muscle spasms	1	1	1	1			
Muscular weakness		1		1			
Musculoskeletal stiffness	1	1	1	1			
Myalgia	1	10	1	10			
Nasal congestion		1		1			
Nausea	2	6	2	5			1
Neck pain	1	1	1	1			
Night sweats		1		1			
Ocular discomfort	2	2	2	2			
Oedema peripheral	1	1	1	1			
Oropharyngeal discomfort		1		1			
Oropharyngeal pain	1	1	1	1			
Overdose		1		1			
Pain	1	1	1	1			
Pain in extremity	3	10	2	6	1		4
Pallor		1					1
Palpitations		3		1			2
Paraesthesia		1					1
Paraesthesia oral		3		1			2
Peripheral coldness	2	2			2		2
Pharyngeal swelling		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia		1
Poor peripheral circulation	1	1
Product preparation error		1
Psoriasis		1
Pulmonary embolism	1	1
Pyrexia	9	30
Rales		1
Rash	1	5
Rash erythematous	1	1
Respiratory tract oedema		1
Retching	1	2
Rheumatoid factor positive		1
Rhinorrhoea	1	3
Sensory disturbance		1
Skin discolouration	1	1
Skin hypertrophy	1	1
Skin reaction		1
Somnolence		1
Stridor		2
Suffocation feeling		1
Swelling face		1
Swollen tongue		1
Syncope	3	3
Tachycardia	2	5
Tachypnoea		1
Throat tightness		1
Thrombocytopenia		1
Thrombophlebitis	1	1
Thrombosis	1	1
Tinnitus		1
Tongue disorder		1
Tremor	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
	1		
	1		
		1	1
7	20	2	10
			1
	2	1	3
1	1		
			1
1	2		
	1		
1	3		
			1
		1	1
		1	1
			1
	1		
			2
			1
			1
		3	3
2	4		1
			1
			1
		1	1
		1	1
	1		
			1
1	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Type I hypersensitivity		5				5
Underdose		1				1
Urine odour abnormal		1		1		
Urticaria		1				1
Use of accessory respiratory muscles		1				1
Vaccination error		1		1		
Vaccination failure	3	3			3	3
Vaccination site erythema	1	11	1	9		2
Vaccination site haematoma		1		1		
Vaccination site induration		1				1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site oedema		2		2		
Vaccination site pain	2	22	2	20		2
Vaccination site pruritus		1				1
Vaccination site swelling		3		1		2
Vaccination site warmth		1		1		
Viral infection		1		1		
Vitreous detachment		1				1
Vomiting	2	2	2	2		
Wheezing		2				2
	113	366	71	213	42	153

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2			2	2
Asthenia		1		1		
Balance disorder	1	1			1	1
Blood creatine phosphokinase increased	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased		1		1		
Blood pressure increased	1	1	1	1		
Body temperature increased	1	2		1	1	1
Bronchospasm		1				1
Capillary fragility		1		1		
Cardiac failure acute	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest pain	1	1			1	1
Chills		1		1		
Coma	1	1			1	1
Conjunctival haemorrhage	1	3			1	3
Cough		2		1		1
COVID-19	1	2			1	2
Cyanosis	1	1			1	1
Deafness unilateral	1	1			1	1
Death	1	1			1	1
Diabetes mellitus		1				1
Disorganised speech	1	1			1	1
Dizziness		1		1		
Drug ineffective		1				1
Dysphagia		1				1
Dyspnoea	1	1			1	1
Erythema		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extensor plantar response	1	1	1	1		
Facial paresis		1				1
Fall	1	1			1	1
Headache	2	3	1	2	1	1
Head titubation	1	1			1	1
Hemiparesis	1	1			1	1
Hypersensitivity		2				2
Hypertension		1				1
Intraocular pressure increased		1		1		
Ischaemic stroke	1	1			1	1
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities	1	1			1	1
Muscular weakness		1				1
Myalgia	2	2			2	2
Neutrophil count increased	1	1	1	1		
Pyrexia	1	1			1	1
Respiratory distress	1	1			1	1
Respiratory rate decreased	1	1	1	1		
Speech disorder	1	1			1	1
Stress cardiomyopathy	1	1			1	1
Swollen tongue		1				1
Tinnitus		1		1		
Type I hypersensitivity		1				1
Unresponsive to stimuli		1				1
Urinary tract infection		1				1
Urticaria		1				1
Vaccination failure	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site pain	1	3		2	1	1
Vaccination site swelling		1		1		
Vertigo		1		1		
White blood cell count increased	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE

42

Cumulative Total #  
Spontaneous AE

77

Spontaneous			
Nonserious		Serious	
I	C	I	C
8	23	34	54

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Asthenia	2	4			2	4
Atrial fibrillation		1				1
Balance disorder	1	1			1	1
Blood glucose increased	1	1			1	1
Blood pressure increased	1	1			1	1
Cardiac arrest		1				1
Cardiac disorder	1	1			1	1
Cardiac failure		3				3
Cardiac failure congestive		1				1
Cardiomyopathy		1				1
Cerebral haemorrhage		1				1
Cerebrovascular disorder	1	1			1	1
Chest discomfort		1				1
Chest pain		1				1
Communication disorder		1				1
COVID-19	8	8			8	8
Cyanosis		2				2
Death		1				1
Decreased appetite		1				1
Diarrhoea		1				1
Disorientation		1				1
Dizziness	1	1			1	1
Drug ineffective	1	1			1	1
Dyspnoea		4				4
Ear infection	1	1			1	1
Escherichia urinary tract infection		1				1
Fall	1	2			1	2
Fatigue		1				1
Gait disturbance	1	2			1	2
General physical health deterioration		1				1
Haemorrhage subcutaneous		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased		1		1		
Hypersensitivity		1				1
Hypertension		2				2
Hypopnoea		1				1
Hyporesponsive to stimuli		1				1
Hypotension		2				2
Hypoxia	1	1			1	1
Ischaemic cerebral infarction		1				1
Loss of personal independence in daily activities	1	1			1	1
Malaise		1				1
Melaena	1	1			1	1
Nausea	2	2			2	2
Oedema peripheral		1				1
Oxygen saturation decreased		1				1
Palpitations	1	1			1	1
Peripheral swelling		1				1
Pneumonia klebsiella		1				1
Pneumonia staphylococcal		1				1
Pyrexia	1	2		1	1	1
Snoring		1		1		
Speech disorder		1				1
Swelling face		1				1
Tinnitus	1	1			1	1
Transient ischaemic attack	1	1			1	1
Type I hypersensitivity		1				1
Urinary incontinence		1				1
Vaccination failure	7	7			7	7
Vomiting	2	3			2	3
Wheezing		1				1
	38	91		3	38	88

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Arthralgia		1		1		
Blood glucose increased	1	1	1	1		
Bronchitis		1				1
Facial paresis		1		1		
Fatigue	1	1	1	1		
Hypertension	1	1			1	1
Insomnia	1	1	1	1		
Joint swelling		1		1		
Organic brain syndrome		1				1
Pyrexia		2		2		
Respiratory failure		1				1
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	1	2	1	2		
	8	17	6	12	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CYPRUS**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Axillary pain		1		1		
Chills		1		1		
Headache		2		2		
Head titubation		1		1		
Hyperhidrosis		1		1		
Myalgia		1		1		
Oxygen saturation decreased		1		1		
Pain in extremity		1		1		
Pallor		1		1		
Pyrexia		1		1		
Syncope		2				2
Tremor		1		1		
Vaccination site oedema		1		1		
Vomiting		1		1		
		17		14		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		3		3		
Asthenia		2		2		
Axillary pain		1		1		
Back pain		1		1		
Body temperature increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Cerebrovascular accident	1	1			1	1
Chills		5		5		
Condition aggravated		1		1		
Contusion		1		1		
COVID-19		2		1		1
Dermatitis atopic		1		1		
Dizziness		3		3		
Drug ineffective		1				1
Dyspnoea		1		1		
Ear pain		1		1		
Eczema		1		1		
Epistaxis		1				1
Eyelid ptosis		1		1		
Eye pain		1		1		
Facial paresis		3				3
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Headache		8		8		
Hyperhidrosis		2		2		
Hypersensitivity		1		1		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Hypotension		2				2
Inappropriate schedule of product administration		1		1		
Insomnia		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy		4		4		
Malaise		3		3		
Migraine		1		1		
Myalgia		8		8		
Nausea		5		5		
Neck pain		1		1		
Off label use		1		1		
Product use issue		1		1		
Pyrexia		5		5		
SARS-CoV-2 antibody test negative		1				1
Syncope		1				1
Vaccination site pain		7		7		
Vaccination site swelling		1		1		
Vomiting		2		2		
		1		1		
	1	95		80	1	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic reaction		1				1	
Angina pectoris	1	1			1	1	
Arthralgia	1	2	1	2			
Asthenia		1		1			
Cervix oedema		1		1			
Chest pain	1	1	1	1			
Chills		4		4			
Condition aggravated		1		1			
Cough		1		1			
COVID-19		1				1	
Dizziness		3		3			
Drug ineffective		1				1	
Drug interaction		1		1			
Dysaesthesia		1				1	
Dyspnoea		2		2			
Ear discomfort		1		1			
Erythema		1		1			
Face oedema		1		1			
Facial paralysis		1				1	
Fatigue	1	3	1	3			
Headache		1		1			
Hypertension		1				1	
Hypoacusis		1		1			
Hypoaesthesia eye		1				1	
Hypoaesthesia oral		1				1	
Inflammation		1		1			
Influenza like illness	1	1	1	1			
Injection site pain	1	1	1	1			
Lymphadenopathy		1		1			
Malaise	2	2	2	2			
Mobility decreased		1		1			
Muscle contracture		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	3	6	3	6		
Myocardial infarction		1				1
Nasal congestion		1		1		
Nausea	1	2	1	2		
Oropharyngeal pain		1		1		
Overdose		1		1		
Pain	1	1	1	1		
Peripheral swelling		1		1		
Pyrexia	1	4	1	4		
Rash		1		1		
Respiratory distress		1				1
Sinus congestion		1		1		
Tachyarrhythmia		1				1
Tachycardia		2		1		1
Therapeutic response unexpected	1	1	1	1		
Upper respiratory tract congestion		1		1		
Vaccination site oedema	1	2	1	2		
Vaccination site pain		1		1		
Vasculitis		1		1		
Vertigo		1		1		
	16	73	15	60	1	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Aortic aneurysm	1	1			1	1
Arthralgia		2		2		
Asthenia		1		1		
Bacterial sepsis	1	1			1	1
Balance disorder		1		1		
Blood pressure increased		1				1
Chills		1		1		
Confusional state		1		1		
COVID-19	1	3			1	3
Death	1	1			1	1
Dehydration	1	1			1	1
Diarrhoea	1	1	1	1		
Discomfort		1		1		
Drug ineffective	1	2			1	2
Dysgeusia		1		1		
Dysphagia		1		1		
Dyspnoea	1	1	1	1		
Facial paresis		1				1
Fatigue	3	3	3	3		
Gait disturbance		1		1		
Gastrointestinal infection	1	1			1	1
Hypoaesthesia		1		1		
Hypoaesthesia oral		1		1		
Hypotension	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Insomnia		1		1		
Lymphadenopathy		1				1
Malaise	1	2	1	2		
Multiple organ dysfunction syndrome	1	1			1	1
Myalgia	2	3	2	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	1	1	1		
Off label use	1	1	1	1		
Pharyngeal oedema		1		1		
Pulmonary embolism	1	1			1	1
Pulmonary oedema	1	1			1	1
Pyrexia	1	3	1	3		
Respiratory tract oedema		1				1
Shock	1	1			1	1
Swollen tongue		1		1		
Unresponsive to stimuli	1	1			1	1
Vaccination site pain		1		1		
Vasculitis	1	1			1	1
Viral sepsis	1	1			1	1
Vomiting	2	2	1	1	1	1
	31	58	13	33	18	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Asthenia		2		2		
Confusional state		1		1		
COVID-19		6				6
C-reactive protein increased	1	1	1	1		
Diarrhoea		1		1		
Dizziness		1		1		
Drug ineffective		1				1
Dyspnoea	1	3	1	1		2
Face oedema		1				1
Facial paresis		2				2
Fatigue		3		3		
Fibrin D dimer increased		1		1		
Gait disturbance		1		1		
Gait inability		1		1		
Gastric haemorrhage		1				1
Guillain-Barre syndrome		1				1
Headache		1		1		
Hypertension	1	1	1	1		
Hyponatraemia	1	2	1	2		
Malaise		1		1		
Muscular weakness	1	2		1	1	1
Myalgia	1	2	1	2		
Myelitis		1				1
Myocardial infarction		1				1
Nausea		1		1		
Oxygen saturation decreased		2				2
Pulmonary embolism	3	5			3	5
Pyrexia		1		1		
Rash erythematous		1		1		
Sialoadenitis		1				1
Sluggishness		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary retention	1	1			1	1
Vaccination failure		1				1
Vomiting		1		1		
	10	54	5	27	5	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Arthralgia	2	9	2	9		
Back pain		1		1		
Chills	3	7	3	7		
Contusion		1		1		
COVID-19	1	1			1	1
Dizziness		1		1		
Drug ineffective	1	1			1	1
Dysgeusia		1		1		
Facial paralysis		1				1
Fatigue	1	5	1	5		
Headache	2	5	2	5		
Hypoaesthesia	2	3	2	3		
Influenza		1		1		
Influenza like illness		2		2		
Insomnia	1	1	1	1		
Malaise	1	6	1	6		
Migraine		1		1		
Myalgia	3	11	3	11		
Nasopharyngitis		1		1		
Nausea	1	1	1	1		
Pain		2		2		
Paraesthesia		1		1		
Pyrexia	1	4	1	4		
Rash		1		1		
Swollen tongue		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling		1		1		
Vomiting	1	1	1	1		
	22	79	20	76	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**CZECH REPUBLIC**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acute respiratory failure	1	1			1	1
Anaesthesia oral		1				1
Anaphylactic reaction		3				3
Angina pectoris		1				1
Angioedema	1	1			1	1
Anxiety		1		1		
Arthralgia	4	22	3	19	1	3
Asthenia		7		4		3
Back pain	1	3	1	3		
Blister	1	1			1	1
Blood pressure systolic increased		1		1		
Bradycardia		1				1
Burning sensation		1				1
Chest pain		1				1
Chills	5	22	4	18	1	4
Choking sensation		1				1
Circulatory collapse		1				1
Cough	1	1			1	1
COVID-19	1	2			1	2
Decreased appetite	1	1			1	1
Dermatitis allergic	1	1			1	1
Diarrhoea	1	4	1	4		
Dizziness	1	6	1	4		2
Drug ineffective	1	2			1	2
Dry mouth	1	1			1	1
Dry skin	1	1			1	1
Dysphagia		1				1
Dyspnoea	3	7	1	2	2	5
Dysstasia	1	1			1	1
Ear discomfort		2		1		1
Eczema	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enterococcal infection	1	1			1	1
Erythema	1	3		2	1	1
Eye movement disorder		1		1		
Eye pain	1	1	1	1		
Facial paralysis		1				1
Fatigue	3	22	2	19	1	3
Feeling hot		4		3		1
Flushing		1		1		
Gastric ulcer	1	1			1	1
Grunting		1				1
Headache	2	28	2	26		2
Hot flush	2	5	1	2	1	3
Hyperaesthesia	1	1	1	1		
Hyperhidrosis		1		1		
Hypersensitivity	4	8	2	3	2	5
Hypertension		2		1		1
Hypoacusis		1				1
Hypoaesthesia oral		1				1
Hypotension		1		1		
Immunoglobulins increased		1		1		
Influenza		1		1		
Influenza like illness	3	6	2	5	1	1
Insomnia		1				1
Irritability		1		1		
Joint range of motion decreased	1	1	1	1		
Joint swelling	1	1	1	1		
Joint warmth		1		1		
Lip swelling		1				1
Loss of consciousness	1	2			1	2
Lymphadenopathy	2	6	2	4		2
Lymph node pain		1		1		
Malaise		3		3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Maternal exposure during pregnancy		1		1			
Menstrual disorder		1		1			
Migraine	1	1	1	1			
Mucosal disorder		1					1
Multiple organ dysfunction syndrome		1					1
Muscle spasms	1	1			1		1
Muscle twitching		1		1			
Muscular weakness		1		1			
Musculoskeletal disorder		1		1			
Musculoskeletal stiffness		2		2			
Myalgia	5	20	4	17	1		3
Nausea	1	7	1	5			2
Neck pain	1	2		1	1		1
Neuropathy peripheral		1					1
Oedema peripheral		1					1
Oxygen saturation decreased	1	1			1		1
Pain		3		1			2
Pain in extremity	1	4	1	4			
Pallor		5		3			2
Paraesthesia		3		1			2
Paraesthesia oral		1					1
Paresis	1	1			1		1
Peripheral coldness		1		1			
Peripheral nerve palsy	1	1			1		1
Peripheral swelling		1					1
Pharyngeal oedema		1					1
Pharyngeal swelling		1					1
Photopsia		1					1
Photosensitivity reaction		1		1			
Presyncope		1		1			
Product administered at inappropriate site		1		1			
Pruritus	3	6	1	1	2		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	1	1			1	1
Pyrexia	7	35	3	24	4	11
Rash	3	5		2	3	3
Rash macular		2				2
Rash pruritic		3				3
Rash pustular		1		1		
Respiratory depression		1				1
Respiratory disorder		1				1
Rhinorrhoea	1	2		1	1	1
SARS-CoV-2 antibody test negative	1	1			1	1
Seizure		1				1
Shock		1				1
Skin burning sensation	2	2			2	2
Skin disorder		1				1
Somnolence		3		2		1
Swelling face	1	3			1	3
Syncope	2	3			2	3
Tachycardia	1	5		2	1	3
Tachypnoea	1	1			1	1
Tension headache		1		1		
Tongue oedema		1				1
Urticaria	1	1			1	1
Vaccination site erythema	1	8		3	1	5
Vaccination site haematoma		1				1
Vaccination site induration		1		1		
Vaccination site oedema	1	4	1	1		3
Vaccination site pain	1	17	1	13		4
Vaccination site pruritus	1	3	1	3		
Vaccination site rash	2	2	1	1	1	1
Vaccination site reaction		1		1		
Vaccination site swelling	2	5	1	1	1	4
Vaccination site urticaria		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth		2				2
Vertigo		3		1		2
Vestibular neuronitis		1				1
Vision blurred	1	1	1	1		
Vomiting	1	4	1	4		
	98	415	44	247	54	168

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	3	1	1	1	2
Abdominal pain	2	4		1	2	3
Abdominal pain upper		2		1		1
Acute vestibular syndrome		1				1
Ageusia	1	3		1	1	2
Airway burns		2				2
Akinesia	1	1			1	1
Allergy to vaccine		4		1		3
Alopecia		2		1		1
Altered state of consciousness		1				1
Anal incontinence		1		1		
Anaphylactic reaction	1	5			1	5
Angioedema		1				1
Anosmia	1	4		2	1	2
Antibody test abnormal		1		1		
Anxiety		3		1		2
Aphonia		1				1
Apnoea	1	1			1	1
Application site coldness		1				1
Application site erythema		1				1
Arrhythmia		2				2
Arthralgia	20	65	15	48	5	17
Asthenia	7	32	6	26	1	6
Asthma		1				1
Axillary mass	1	1	1	1		
Axillary pain	2	6	2	6		
Back pain	1	10		8	1	2
Blindness		1				1
Blood pressure increased	3	5		1	3	4
Blood pressure systolic increased		2		1		1
Body temperature decreased		1		1		
Body temperature increased	1	3		2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bone pain		1		1			
Bradycardia		1					1
Breast pain		3		1			2
Breast swelling	1	2		1	1		1
Burning sensation	1	2	1	2			
Burning sensation mucosal		2		2			
Cerebral venous sinus thrombosis	1	1			1		1
Chest discomfort	1	5	1	1			4
Chest pain	3	8	2	5	1		3
Chills	15	79	12	67	3		12
Circulatory collapse		2					2
Cold sweat		1		1			
Confusional state		1		1			
Conjunctivitis allergic	1	1	1	1			
Cough	1	6	1	6			
COVID-19	6	14	1	4	5		10
C-reactive protein increased		3		1			2
Decreased appetite	2	5	2	4			1
Deep vein thrombosis	2	2			2		2
Depression	1	2			1		2
Dermatitis		1					1
Dermatitis allergic	4	5		1	4		4
Diarrhoea	5	17	4	14	1		3
Diplopia		1					1
Discomfort	1	1	1	1			
Disease recurrence	1	3	1	1			2
Disturbance in attention		3		2			1
Dizziness	7	18	4	12	3		6
Drug hypersensitivity	2	3		1	2		2
Drug ineffective		3					3
Drug interaction	1	1			1		1
Dry mouth	1	2		1	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysaesthesia		1				1
Dysgeusia	3	3	2	2	1	1
Dyskinesia	1	1			1	1
Dyspepsia	2	5		2	2	3
Dysphagia	3	7		1	3	6
Dyspnoea	5	26	1	7	4	19
Ear discomfort		3		1		2
Ear pain	1	1	1	1		
Eczema herpeticum		1				1
Epistaxis		1		1		
Erythema	2	13	1	8	1	5
Erythema nodosum	1	1			1	1
Extrasystoles		1		1		
Eye irritation	1	2			1	2
Eyelid oedema	1	1			1	1
Eye pain	1	4		3	1	1
Eye swelling	1	1			1	1
Face oedema		1				1
Facial paralysis	1	2			1	2
Facial paresis		3				3
Fatigue	18	95	14	79	4	16
Febrile convulsion		1				1
Feeling abnormal		2		2		
Feeling cold	2	3	2	3		
Feeling hot	2	7		2	2	5
Flatulence	1	1	1	1		
Fluid intake reduced		1		1		
Flushing		2				2
Foetal death		1				1
Formication		1		1		
Frequent bowel movements		1		1		
Gastroenteritis		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal hypermotility		1				1
Gastrooesophageal reflux disease		1				1
Gaze palsy		1				1
Generalised oedema		1		1		
General physical health deterioration	1	1			1	1
Groin pain	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Haematochezia		2				2
Haematoma	1	1			1	1
Haemoptysis	1	1			1	1
Haemorrhage		1				1
Hallucinations, mixed	1	1			1	1
Headache	20	96	15	77	5	19
Head discomfort		1				1
Heart rate increased	1	1			1	1
Herpes simplex	1	1			1	1
Herpes zoster	1	1			1	1
Hordeolum	1	1			1	1
Hot flush	1	6		5	1	1
Hyperacusis	1	1			1	1
Hyperaemia		1		1		
Hyperglycaemia		1				1
Hyperhidrosis	1	8	1	6		2
Hypersensitivity	7	17	1	3	6	14
Hypersomnia	1	2			1	2
Hypertension	5	12	1	5	4	7
Hyperventilation		1		1		
Hypoacusis	1	2	1	2		
Hypoaesthesia		7		5		2
Hypoaesthesia oral		1		1		
Hypokinesia		1		1		
Hypophagia		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	8		2	1	6
Illusion		1		1		
Impaired work ability		1				1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration	1	2	1	2		
Inflammation		1		1		
Influenza like illness	16	41	13	31	3	10
Injection site erythema		1				1
Insomnia	3	5	3	4		1
Joint instability		1				1
Joint range of motion decreased		2		2		
Joint stiffness		1		1		
Joint swelling		1		1		
Lacrimation increased	1	1			1	1
Laryngospasm	1	1			1	1
Ligament sprain		1				1
Limb discomfort	3	3	1	1	2	2
Limb immobilisation		1		1		
Lip dry	1	1	1	1		
Lip swelling	1	2			1	2
Localised oedema	1	4			1	4
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities		1		1		
Lymphadenitis		3		1		2
Lymphadenopathy	4	44	2	21	2	23
Lymph node pain		11		8		3
Lymphoedema		1		1		
Malaise	3	13	3	12		1
Mass	1	2		1	1	1
Menstruation delayed		1		1		
Migraine	3	6	1	2	2	4
Mobility decreased	1	3		2	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Monoplegia		2					2
Mucosal dryness		1					1
Multiple sclerosis		1					1
Multiple sclerosis relapse		1					1
Muscle spasms	1	1			1		1
Muscle spasticity		1		1			
Muscle twitching		1		1			
Muscular weakness	2	6	1	4	1		2
Musculoskeletal chest pain	1	1	1	1			
Musculoskeletal pain		1		1			
Musculoskeletal stiffness		6		4			2
Myalgia	11	48	9	36	2		12
Mydriasis		1					1
Myelitis		1					1
Myocarditis		1					1
Myosclerosis		1					1
Nasal congestion	1	1	1	1			
Nasal oedema		1		1			
Nausea	12	52	9	45	3		7
Neck pain		1		1			
Night sweats		2		2			
Nodule	1	1			1		1
Nuchal rigidity		1		1			
Nystagmus		1		1			
Oedema		1		1			
Oedema peripheral	1	3		1	1		2
Off label use		7		7			
Oral discomfort	1	1	1	1			
Oral herpes	1	1	1	1			
Oral mucosal blistering		1		1			
Oral pruritus		1		1			
Oropharyngeal discomfort		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	2	6	1	4	1	2
Overdose		2		2		
Pain	2	9	1	8	1	1
Pain in extremity	14	42	11	35	3	7
Pain of skin		2		2		
Palatal swelling	2	2			2	2
Pallor	2	2	1	1	1	1
Palpitations	2	11		4	2	7
Paraesthesia	6	29		9	6	20
Paraesthesia mucosal		1				1
Paraesthesia oral	8	16		1	8	15
Paralysis	1	1			1	1
Paresis		1				1
Paresis cranial nerve		1				1
Parosmia	1	1			1	1
Peripheral coldness	2	5	1	4	1	1
Peripheral swelling	1	4	1	2		2
Petechiae	1	1			1	1
Pharyngeal oedema		1				1
Pharyngeal swelling	2	3			2	3
Photophobia	2	4	1	3	1	1
Photopsia		1		1		
Poor quality product administered		1		1		
Presyncope	2	8		1	2	7
Product administered at inappropriate site		2		2		
Productive cough		1		1		
Product preparation error		1		1		
Product use issue		5		5		
Pruritus	3	16	2	5	1	11
Pulmonary embolism	1	1			1	1
Pulmonary sensitisation		2		1		1
Puncture site oedema		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	20	101	9	59	11	42
Rash	5	27		9	5	18
Rash macular	3	5		1	3	4
Rash maculo-papular		1				1
Rash pruritic	1	2		1	1	1
Renal pain	1	1	1	1		
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory tract oedema		1				1
Restlessness		1		1		
Retching	4	6	2	3	2	3
Rhinitis	1	1	1	1		
Rhinorrhoea		3		2		1
Salivary hypersecretion		1				1
SARS-CoV-2 antibody test negative		1				1
SARS-CoV-2 test positive	1	2		1	1	1
Seizure	1	3			1	3
Sensation of foreign body		3				3
Shock		1				1
Skin burning sensation	2	2	2	2		
Skin discolouration		1		1		
Skin disorder	1	1			1	1
Skin exfoliation	1	2	1	1		1
Skin reaction		1		1		
Somnolence	2	9	1	4	1	5
Sopor		1				1
Spinal pain	2	2			2	2
Supraventricular tachycardia		1				1
Swelling		4		3		1
Swelling face	2	9		1	2	8
Swollen tongue	3	4			3	4
Syncope	1	5			1	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	3	12		8	3	4
Tachypnoea		1				1
Taste disorder	1	1			1	1
Tension headache		2		1		1
Throat irritation	3	4	1	2	2	2
Throat tightness	1	4		1	1	3
Thrombophlebitis superficial	1	1			1	1
Tinnitus	4	8	3	3	1	5
Tongue discomfort	1	2	1	1		1
Tongue oedema	1	1			1	1
Toothache	1	1	1	1		
Tooth infection		1				1
Transverse sinus thrombosis	1	1			1	1
Tremor	2	7	1	6	1	1
Troponin I increased		1				1
Urinary incontinence	1	1			1	1
Urinary tract inflammation		1				1
Urticaria	2	7		1	2	6
Vaccination complication		2		1		1
Vaccination failure	3	5			3	5
Vaccination site atrophy		1		1		
Vaccination site bruising		1				1
Vaccination site discomfort		2		1		1
Vaccination site erythema	7	43	4	24	3	19
Vaccination site haematoma	1	1	1	1		
Vaccination site induration	1	5	1	2		3
Vaccination site joint movement impairment	1	2		1	1	1
Vaccination site mass		2				2
Vaccination site movement impairment	1	5	1	4		1
Vaccination site oedema	3	21	1	10	2	11
Vaccination site pain	13	77	9	54	4	23
Vaccination site papule		1				1

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Age Range

**31 - 50 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	2	9		5	2	4
Vaccination site rash		3		1		2
Vaccination site reaction		2		2		
Vaccination site swelling	6	21	3	12	3	9
Vaccination site warmth		8		5		3
Vertigo	6	22	2	15	4	7
Viral infection		1		1		
Vision blurred	3	9		5	3	4
Visual field defect	1	2			1	2
Visual impairment		1				1
Vomiting	7	24	6	16	1	8
	451	1,774	217	1049	234	725

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		5		2		3
Abdominal pain upper		2		1		1
Abscess of salivary gland		1				1
Allergy to vaccine		1				1
Anaphylactic reaction	2	3			2	3
Angina pectoris		2				2
Anosmia	1	1			1	1
Anuria		1				1
Anxiety		3		2		1
Apathy	1	2		1	1	1
Aphasia	1	1			1	1
Aphthous ulcer	1	2			1	2
Arthralgia	6	34	3	20	3	14
Asthenia	6	19	3	10	3	9
Atrial flutter		1				1
Attention deficit hyperactivity disorder	1	1	1	1		
Axillary pain		2				2
Back pain		1		1		
Blood pressure decreased	1	1			1	1
Blood pressure increased		2		2		
Body temperature increased		3		1		2
Bone pain	1	1			1	1
Bronchospasm	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort	3	8	1	3	2	5
Chest pain		1				1
Chills	5	35	4	30	1	5
Circulatory collapse	1	2			1	2
Coordination abnormal		1				1
Cough	4	9	4	8		1
COVID-19	6	9		2	6	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19 pneumonia		3				3
Deafness neurosensory		1				1
Deafness unilateral		1				1
Decreased appetite		4		3		1
Depression		1		1		
Dermatitis	1	1	1	1		
Dermatitis allergic	1	2			1	2
Diarrhoea	1	9		4	1	5
Disease recurrence	1	1			1	1
Disturbance in attention	2	3			2	3
Diverticulitis		1				1
Dizziness		4		4		
Drug eruption		2				2
Drug ineffective	4	6			4	6
Dry eye		1				1
Dry mouth		1		1		
Dry skin		1				1
Dysgeusia		1				1
Dyspepsia		1				1
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	7	16	2	4	5	12
Ear discomfort		2		1		1
Ear pain		2		2		
Ear swelling		1				1
Epistaxis	2	3		1	2	2
Erythema	3	8	1	4	2	4
Eye haemorrhage	1	1			1	1
Eye inflammation		1		1		
Eye irritation	1	1			1	1
Eyelid function disorder		1				1
Eyelid oedema	1	2			1	2

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	1	2	1	1		1
Eye pruritus		1		1		
Eye swelling		1				1
Facial pain		1				1
Facial paralysis	2	3			2	3
Facial paresis	1	2			1	2
Fatigue	12	47	11	35	1	12
Fear	1	1	1	1		
Feeling abnormal		2		1		1
Feeling hot		1		1		
Flatulence		1				1
Food intolerance		1				1
Functional gastrointestinal disorder		1		1		
Gait disturbance		1		1		
Gingival pain	1	1	1	1		
Headache	5	39	5	31		8
Herpes dermatitis	1	1			1	1
Herpes zoster		3				3
Hot flush	1	3		1	1	2
Hyperglycaemia	1	2		1	1	1
Hyperhidrosis	1	7	1	6		1
Hypersensitivity	3	9	1	3	2	6
Hypertension	4	6		1	4	5
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Hypokalaemia	1	2			1	2
Hypotension		5		2		3
Hypoxia		1				1
Immune system disorder		1				1
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration		2		2		
Infection	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	10	20	9	14	1	6
Injected limb mobility decreased		2		2		
Insomnia	1	6	1	5		1
Ischaemic stroke		1				1
Joint range of motion decreased		1				1
Joint stiffness		1				1
Joint swelling		2		2		
Lagophthalmos		1		1		
Laryngeal oedema		1				1
Leukocytosis		1		1		
Leukopenia		1				1
Ligament pain	1	1	1	1		
Lip oedema		1				1
Lip swelling		1				1
Livedo reticularis	1	1	1	1		
Loss of consciousness	1	5			1	5
Lymphadenitis		1				1
Lymphadenopathy	2	21	1	6	1	15
Lymph node pain		2		2		
Malaise	1	6		4	1	2
Migraine		3		2		1
Migraine with aura		1		1		
Muscle atrophy		1				1
Muscle spasms	1	2	1	1		1
Muscular weakness	2	4	1	3	1	1
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	4	35	4	23		12
Myocardial infarction		1				1
Nasal congestion	2	2	2	2		
Nasal discomfort		1				1
Nausea	3	16	1	11	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	1	4		3	1	1
Nervousness		1				1
Neutropenia		1				1
Ocular discomfort		2				2
Ocular hyperaemia		1		1		
Oedema	1	1	1	1		
Oedema mouth		1				1
Oedema peripheral		3		1		2
Off label use		2		2		
Oral discomfort		2				2
Oral herpes	1	1			1	1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	2	1	2		
Overdose	1	1	1	1		
Pain	1	2	1	2		
Pain in extremity	7	19	4	9	3	10
Palpitations	1	5		2	1	3
Paraesthesia	2	17	1	8	1	9
Paraesthesia oral	2	6			2	6
Paralysis		1				1
Paraparesis		1				1
Parosmia		1		1		
Peripheral coldness		3		3		
Peripheral swelling	1	4		1	1	3
Pharyngeal swelling		2				2
Photophobia		1		1		
Pneumonia	1	1			1	1
Presyncope		3				3
Product preparation error	1	1	1	1		
Product use issue		1		1		
Pruritus	1	6		3	1	3
Pulmonary pain	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulpitis dental	1	1			1	1
Pulse abnormal		1		1		
Purpura	1	1			1	1
Pyrexia	10	58	3	30	7	28
Radiculitis brachial		1				1
Rash	3	7	1	2	2	5
Rash erythematous		1				1
Rash macular		1				1
Rash maculo-papular		1				1
Rash pruritic		2				2
Red blood cell sedimentation rate increased		1		1		
Renal transplant failure	1	1			1	1
Retching		1				1
Rhinalgia	1	1	1	1		
Rhinitis	1	2	1	2		
Rhinorrhoea	2	3	2	3		
SARS-CoV-2 test positive		1		1		
Seizure	1	2			1	2
Sensation of foreign body	1	1			1	1
Sinus pain	1	1	1	1		
Sinus tachycardia	1	1			1	1
Skin burning sensation	1	1			1	1
Skin mass		1		1		
Sleep deficit		1				1
Sleep disorder		1				1
Sneezing		1		1		
Somnolence	2	4	1	3	1	1
Spinal disorder		1				1
Spinal pain		3		1		2
Sputum purulent	1	1			1	1
Suspected COVID-19	1	1			1	1
Swelling face	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swollen tongue		2
Syncope		3
Tachycardia	4	11
Tachypnoea	1	3
Tendon pain	1	1
Throat tightness		2
Tinnitus		2
Tongue oedema		2
Toothache		2
Tremor	2	4
Urinary incontinence		1
Urinary tract infection		1
Urticaria	1	2
Vaccination complication		1
Vaccination failure	2	2
Vaccination site atrophy		1
Vaccination site bruising		1
Vaccination site discomfort		1
Vaccination site erythema	4	20
Vaccination site extravasation	1	1
Vaccination site haematoma		1
Vaccination site induration		1
Vaccination site joint pain		2
Vaccination site lymphadenopathy		1
Vaccination site oedema	2	6
Vaccination site pain	7	30
Vaccination site paraesthesia		1
Vaccination site pruritus		1
Vaccination site reaction		3
Vaccination site swelling		2
Vaccination site urticaria	1	1
Vaccination site warmth		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
			3
1	4	3	7
	2	1	1
		1	1
			2
			2
	1		1
	1	2	3
			1
			1
	1	1	1
	1		
		2	2
			1
	1		
	1		
2	8	2	12
1	1		
			1
			1
	2		
	1		
	3	2	3
5	22	2	8
	1		
	1		
	1		2
	2		
		1	1
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular pain		1				1
Vertigo	1	9		5	1	4
Vision blurred	2	5			2	5
Vomiting	1	10		4	1	6
Wheezing		1		1		
	216	880	94	446	122	434

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	2		
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Acne	1	1	1	1		
Ageusia		1		1		
Akathisia	1	1	1	1		
Allergic oedema	1	1			1	1
Allergy to vaccine	1	1			1	1
Altered state of consciousness	2	3			2	3
Anaphylactic reaction	1	1			1	1
Anosmia	1	2	1	2		
Apathy	1	1	1	1		
Aphthous ulcer	1	1			1	1
Application site erythema	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	4	13	4	10		3
Asthenia	7	9	5	7	2	2
Asthma		1		1		
Atrial fibrillation	2	2			2	2
Back pain	3	7	2	6	1	1
Bacterial rhinitis		1				1
Bacterial test positive	1	1	1	1		
Blister	1	1			1	1
Blood pressure fluctuation		1		1		
Blood pressure increased	1	2			1	2
Blood pressure systolic increased	1	1			1	1
Blood urine present	1	1	1	1		
Body temperature increased	1	2	1	2		
Bradypnea		1		1		
Brain oedema	1	1			1	1
Bronchitis		1				1
Bundle branch block right	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	2
		1	1
		1	1
		5	6
		1	1
6	16	1	1
			1
			1
1	1	1	1
	1		
2	3	1	1
	1	4	5
			1
		1	1
		1	1
4	7	1	2
	1		
1	3	1	2
		1	1
	2		
		1	1
		1	1
		1	1
		1	1
2	3		
1	2	5	8
1	1		
2	2		
		1	1
1	1		

Burning sensation 1 1  
 Cardiac arrest 1 2  
 Cardiac failure 1 1  
 Cardio-respiratory arrest 1 1  
 Cerebrovascular accident 5 6  
 Chest pain 1 1  
 Chills 7 17  
 Coma 1 1  
 Communication disorder 1 1  
 Confusional state 2 2  
 Constipation 1 1  
 Cough 3 4  
 COVID-19 4 6  
 COVID-19 pneumonia 1 1  
 Cranial nerve palsies multiple 1 1  
 Deafness unilateral 1 1  
 Decreased appetite 5 9  
 Dehydration 1 1  
 Diarrhoea 2 5  
 Disease recurrence 1 1  
 Dizziness 2 2  
 Dizziness postural 1 1  
 Drug hypersensitivity 1 1  
 Drug ineffective 1 1  
 Dry throat 1 1  
 Dysarthria 1 1  
 Dyspepsia 2 3  
 Dyspnoea 6 10  
 Dyspnoea exertional 1 1  
 Ear discomfort 2 2  
 Epilepsy 1 1  
 Epistaxis 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	4		2
		2	2
1	1		
1	1		
		1	1
		1	1
		1	1
		2	2
11	20	5	7
	1		
	1		
	1		
	1		
		2	2
1	1		
1	1		
		1	1
		1	1
4	14		
1	1		
		1	1
		1	2
		1	1
		2	2
2	3		
	2	4	6
			1
1	1	6	8
		2	2
		1	1
1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	3			1	3
Inappropriate schedule of product administration		1		1		
Induration		1		1		
Influenza like illness	10	13	6	9	4	4
Injection site pain		1		1		
Insomnia	2	2	1	1	1	1
Ischaemic stroke	1	2			1	2
Joint effusion		1				1
Laboratory test abnormal	1	1	1	1		
Lacrimation increased	1	1	1	1		
Lethargy	1	1	1	1		
Leukocytosis	1	1	1	1		
Lip swelling	1	3		1	1	2
Loss of consciousness	1	1			1	1
Lymphadenitis	1	1			1	1
Lymphadenopathy	2	2	2	2		
Malaise	2	4	1	2	1	2
Migraine		1				1
Mobility decreased		2		2		
Monoparesis	1	1			1	1
Movement disorder	1	1			1	1
Muscle tightness	1	1	1	1		
Muscle twitching	1	1			1	1
Muscular weakness	1	1			1	1
Musculoskeletal stiffness	3	3	1	1	2	2
Myalgia	4	6	3	5	1	1
Myositis	1	1			1	1
Narcolepsy	2	2			2	2
Nausea	3	12	2	10	1	2
Neuralgia		1				1
Neuropathy peripheral	1	3			1	3
Oedema		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oedema peripheral		1				1	
Off label use		2		2			
Oral discomfort	1	1	1	1			
Overdose		1		1			
Oxygen saturation decreased	1	1			1	1	
Pain	4	4	3	3	1	1	
Pain in extremity	9	12	8	11	1	1	
Palpitations		1				1	
Paraesthesia	5	8		1	5	7	
Paraesthesia oral	3	4			3	4	
Peripheral swelling	1	3	1	2		1	
Petechiae	1	1			1	1	
Pharyngeal paraesthesia		1				1	
Pneumonia	2	2			2	2	
Polyarthritis		1				1	
Poor quality product administered		65		65			
Productive cough		1				1	
Product preparation error		65		65			
Product use issue		1		1			
Pruritus	1	7	1	3		4	
Pulmonary embolism		1				1	
Pulmonary oedema	1	1			1	1	
Pyrexia	12	26	8	20	4	6	
Rash	3	6	1	3	2	3	
Rash macular	2	2			2	2	
Rash pruritic	1	2	1	1		1	
Renal failure	1	1			1	1	
Renal impairment	1	1			1	1	
Renal pain	1	1	1	1			
Respiration abnormal		1				1	
Respiratory failure	1	1			1	1	
Rheumatoid arthritis	1	1			1	1	

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinitis	1	1	1	1		
Rhinorrhoea		1		1		
Scab	1	2	1	2		
Seizure	1	1			1	1
Sinus bradycardia		1		1		
Somnolence	4	6	2	3	2	3
Sputum discoloured	1	1			1	1
Sudden death		2				2
Swelling	1	1	1	1		
Swelling face	1	3			1	3
Swelling of eyelid	1	1			1	1
Syncope	4	6			4	6
Tachycardia	1	2			1	2
Throat irritation		1				1
Throat tightness	1	1			1	1
Tongue discomfort		1		1		
Tongue oedema	2	2			2	2
Toothache	1	1	1	1		
Tremor	1	1			1	1
Urinary tract infection	1	1			1	1
Urinary tract inflammation	1	1	1	1		
Vaccination failure	2	2			2	2
Vaccination site cellulitis	1	1			1	1
Vaccination site erythema		2		1		1
Vaccination site hypersensitivity		1				1
Vaccination site induration	2	2	1	1	1	1
Vaccination site joint movement impairment		1				1
Vaccination site mass		1				1
Vaccination site oedema	2	2	2	2		
Vaccination site pain	5	12	5	11		1
Vaccination site pruritus	2	3	2	2		1
Vaccination site pustule	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		3		3		
Vaccination site warmth	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vertigo	1	3		2	1	1
Vision blurred	3	3			3	3
Vomiting	1	7	1	5		2
Yellow skin	1	1			1	1
	294	638	135	404	159	234

\* I=Interval, C=Cumulative  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		1		2
Abdominal pain lower	1	1			1	1
Abdominal pain upper	1	2	1	2		
Abnormal dreams		2		2		
Acute kidney injury		1				1
Acute myocardial infarction	1	1			1	1
Acute respiratory failure		1				1
Altered state of consciousness	1	1			1	1
Amnesia		1				1
Anaemia		3		1		2
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	1			1	1
Aneurysm	1	1			1	1
Angina pectoris	1	1			1	1
Anxiety	1	3	1	3		
Aortic arteriosclerosis		1				1
Aortic stenosis	1	1			1	1
Apathy		3				3
Aphasia	2	3	1	1	1	2
Aphthous ulcer		1				1
Arrhythmia		2				2
Arteriosclerosis		1				1
Arthralgia	12	17	8	12	4	5
Asthenia	4	14	4	9		5
Atrial fibrillation	1	3			1	3
Back pain	1	1	1	1		
Balance disorder	1	1			1	1
Basal ganglia haemorrhage		1				1
Blindness		1				1
Blood chloride increased		1		1		
Blood glucose increased		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood lactic acid increased		1		1			
Blood pressure abnormal	1	1			1		1
Blood pressure decreased	1	1			1		1
Blood pressure diastolic increased		1		1			
Blood pressure fluctuation		1					1
Blood pressure increased		4		2			2
Blood urine present	1	1	1	1			
Bradycardia		2					2
Bradyphrenia		1					1
Brain oedema		1					1
Breast pain	1	1	1	1			
Cardiac arrest	1	1			1		1
Cardiac disorder	1	1			1		1
Cardiac failure	2	3			2		3
Cardiac failure congestive	1	1			1		1
Cardiomyopathy		1					1
Cardio-respiratory arrest		1					1
Carpal tunnel syndrome	1	1			1		1
Cerebral haemorrhage		1					1
Cerebral ischaemia		1					1
Cerebral thrombosis	1	1			1		1
Cerebrovascular accident	2	7			2		7
Chest discomfort	2	4	1	2	1		2
Chest pain		3		2			1
Chills	5	16	5	13			3
Circulatory collapse	1	2			1		2
Coagulopathy		1					1
Cognitive disorder	1	1			1		1
Concussion		1					1
Condition aggravated		1		1			
Confusional state		5					5
Constipation	1	2		1	1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	2	3			2	3
Cough	2	7		3	2	4
COVID-19	3	8	1	1	2	7
COVID-19 pneumonia		3				3
C-reactive protein increased		2		1		1
Cyanosis		1				1
Cystitis noninfective		1		1		
Deafness		1				1
Deafness neurosensory	1	1			1	1
Death	1	3			1	3
Decreased activity	1	2	1	2		
Decreased appetite	6	13	5	9	1	4
Dehydration		1				1
Delirium		3				3
Dementia	1	1			1	1
Dermatitis allergic		1				1
Diarrhoea	1	7		4	1	3
Disorganised speech	1	1			1	1
Disorientation	2	7		2	2	5
Dizziness	4	8	3	7	1	1
Drug eruption	2	2			2	2
Drug ineffective	2	4			2	4
Duodenal ulcer		1				1
Dysarthria		2		1		1
Dysphemia	1	1			1	1
Dyspnoea	4	11		2	4	9
Dyspnoea at rest		1				1
Dyspnoea exertional		1				1
Dysuria	1	1			1	1
Ear discomfort		1				1
Ear pruritus		1				1
Eating disorder		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram abnormal	2	2	1	1	1	1
Epilepsy		1				1
Epistaxis	1	2			1	2
Erysipelas	1	2			1	2
Erythema	2	3	1	2	1	1
Escherichia infection		1				1
Eyelid oedema		1				1
Eye pruritus		1				1
Eye swelling		1		1		
Facial paralysis	1	2			1	2
Fall	2	8		4	2	4
Fatigue	7	25	6	19	1	6
Feeling abnormal	1	1	1	1		
Feeling hot	2	2	1	1	1	1
Flank pain	1	1	1	1		
Formication		1				1
Gait disturbance	2	6		2	2	4
Gait inability	1	3		1	1	2
Gallbladder disorder	1	1	1	1		
Gastric ulcer	1	1			1	1
Gastrointestinal disorder	1	2	1	2		
Gastrointestinal necrosis		1				1
General physical health deterioration	4	8	2	3	2	5
Glomerular filtration rate decreased		1		1		
Gout		1		1		
Haematoma	1	2	1	1		1
Haemorrhage intracranial	1	1			1	1
Hallucination		1				1
Headache	7	11	6	10	1	1
Head discomfort		1		1		
Heart rate increased	1	3			1	3
Heart rate irregular		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparesis	1	1			1	1
Hemiplegia	1	2			1	2
Hepatic function abnormal		1				1
Hepatic infarction		1				1
Hepatitis		1				1
Herpes simplex		1				1
Herpes zoster	4	7			4	7
Hyperhidrosis	2	5	2	4		1
Hyperphagia		1		1		
Hyperpyrexia	1	1			1	1
Hypersensitivity	3	5	1	2	2	3
Hypersomnia		1				1
Hypertension	3	7		1	3	6
Hypoacusis	1	1			1	1
Hypoaesthesia		2				2
Hypoglycaemia		1		1		
Hypokalaemia	1	3			1	3
Hypokinesia		1		1		
Hypotension	1	5			1	5
Hypotonia		1		1		
Hypotonic-hyporesponsive episode	1	1			1	1
Hypoxia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		1		1		
Inflammation		1				1
Influenza like illness	7	11	7	7		4
Insomnia	2	4	1	2	1	2
International normalised ratio increased		2		1		1
Intestinal infarction		1				1
Jaundice		1		1		
Joint swelling	2	2	1	1	1	1
Jugular vein distension		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Klebsiella infection		1					1
Lacrimation increased		1		1			
Language disorder		1					1
Leukopenia	1	1			1		1
Localised oedema	1	1			1		1
Logorrhoea		1		1			
Loss of consciousness	1	2			1		2
Lymphadenopathy	1	3		1	1		2
Lymph node pain		1					1
Malaise		3		2			1
Melaena		1					1
Memory impairment		1					1
Mental disorder		1		1			
Mesenteric arterial occlusion		1					1
Mesenteric vascular insufficiency		1					1
Monoparesis		1					1
Multiple organ dysfunction syndrome		1					1
Muscle spasms		1		1			
Muscle twitching	1	1			1		1
Muscular weakness		3		2			1
Myalgia	2	5	2	5			
Myocardial infarction	2	2			2		2
Nasopharyngitis	1	1	1	1			
Nausea	5	12	5	10			2
Nervousness		1		1			
Night sweats	1	2		1	1		1
Nystagmus	1	1	1	1			
Oedema peripheral	3	4	3	3			1
Oropharyngeal pain	2	2	2	2			
Oxygen saturation decreased		3		2			1
Pain	2	7	1	4	1		3
Pain in extremity	3	11	1	8	2		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor	1	1	1	1		
Palpitations	1	3			1	3
Pancreatic infarction		1				1
Paraesthesia	1	3	1	2		1
Patient uncooperative	1	1	1	1		
Peripheral coldness		1				1
Peripheral swelling	1	2	1	1		1
Petechiae	1	1			1	1
Pneumonia		3				3
Pneumonitis	1	1			1	1
Polyarthrits	2	2			2	2
Posture abnormal	1	1	1	1		
Productive cough	1	2			1	2
Prolonged expiration		1		1		
Prostate cancer		1				1
Pruritus	4	6	1	2	3	4
Psychomotor hyperactivity	1	1			1	1
Pulmonary embolism		1				1
Pulmonary pain		1		1		
Pyrexia	18	39	11	24	7	15
Quadripareisis		1				1
Radiculopathy		1				1
Rash	2	5		1	2	4
Rash erythematous	1	2			1	2
Rash macular	1	1			1	1
Rash maculo-papular	1	2			1	2
Rash pruritic	2	4	1	1	1	3
Rash vesicular	1	1	1	1		
Renal disorder		1		1		
Renal failure		2				2
Renal impairment		1				1
Respiratory acidosis		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Respiratory failure		2				2	
Respiratory tract oedema	1	1			1	1	
Restlessness	1	3	1	3			
Rheumatoid arthritis	1	1			1	1	
Rhinitis	1	2	1	2			
SARS-CoV-2 test positive		1				1	
Sepsis		2				2	
Sitting disability		1				1	
Skin burning sensation	1	1	1	1			
Sleep disorder		1		1			
Sleep talking		1		1			
Somnolence		4		4			
Speech disorder	1	4		2	1	2	
Splenic infarction		1				1	
Splenic infection		1				1	
Stridor		1		1			
Sudden death		1				1	
Swelling		1				1	
Swelling face	1	6			1	6	
Swelling of eyelid		1				1	
Syncope	1	4			1	4	
Tachycardia		1		1			
Tachypnoea		1				1	
Tenderness	1	2	1	1		1	
Tension headache	1	1			1	1	
Thirst		1		1			
Thrombocytopenia		1				1	
Thrombosis	1	1			1	1	
Tinnitus	2	2			2	2	
Tongue oedema		2				2	
Transient ischaemic attack	1	2			1	2	
Tremor	1	4		1	1	3	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Truncus coeliacus thrombosis		1					1
Urinary tract infection	1	2		1	1		1
Urinary tract infection enterococcal		1					1
Urinary tract inflammation		1					1
Urogenital infection bacterial	1	1			1		1
Urosepsis		1					1
Urticaria	1	1			1		1
Vaccination failure		2					2
Vaccination site anaesthesia		1					1
Vaccination site discomfort		1		1			
Vaccination site erythema	3	4	1	1	2		3
Vaccination site mass		1		1			
Vaccination site oedema		2		2			
Vaccination site pain	1	8	1	7			1
Vaccination site pruritus	1	2	1	2			
Vaccination site swelling	2	3	1	1	1		2
Vaccination site urticaria	1	1			1		1
Vena cava thrombosis		1					1
Ventricular tachycardia		1					1
Vertigo	1	5		4	1		1
Visual impairment		2		1			1
Vomiting	4	13	3	10	1		3
Wheezing		1		1			
White coat hypertension	1	1	1	1			
	260	708	116	312	144		396

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		1				1
Alanine aminotransferase increased		1		1		
Amnesia		1				1
Angina pectoris		1		1		
Anosmia		1		1		
Apathy		1				1
Aphasia		1		1		
Arthralgia	3	12	3	11		1
Aspartate aminotransferase increased		1		1		
Asthenia	3	8	3	8		
Axillary pain		1		1		
Back pain	1	1	1	1		
Body temperature increased		1		1		
Bradycardia		1				1
Burning sensation	1	1	1	1		
Chest discomfort	1	3	1	3		
Chest pain		1		1		
Chills	2	13	2	12		1
Circulatory collapse	1	1			1	1
Cold sweat		1		1		
Condition aggravated		1				1
Confusional state		1		1		
Cough		3		3		
COVID-19	3	8		3	3	5
Decreased appetite		2		2		
Decreased interest		1		1		
Diplopia		1		1		
Drug ineffective	1	2			1	2
Dry mouth		1		1		
Dysphagia		1		1		
Dyspnoea		3		1		2
Exposure via breast milk		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	1	2	1	2		
Facial pain		1		1		
Fatigue	1	12	1	11		1
Feeling abnormal		2		2		
Hallucination		1				1
Headache	3	13	3	13		
Hot flush		1		1		
Hyperhidrosis		1		1		
Hypersensitivity		1		1		
Inappropriate schedule of product administration		1		1		
Insomnia		1		1		
Local reaction		1		1		
Loss of personal independence in daily activities		1		1		
Lymphadenopathy	1	1			1	1
Metrorrhagia		1		1		
Migraine		1		1		
Mucosal dryness		1		1		
Myalgia		2		1		1
Nasal congestion		1		1		
Oedema peripheral	1	1	1	1		
Oesophageal irritation		1		1		
Oral pruritus		1		1		
Orbital oedema	1	1			1	1
Oropharyngeal discomfort		1		1		
Pain		3		3		
Pain in extremity	2	5	2	5		
Pain in jaw	1	1	1	1		
Pain of skin		1				1
Palpitations	1	1	1	1		
Paraesthesia	1	1	1	1		
Paralysis		1				1
Petechiae	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Poor quality product administered		17		17		
Poor quality sleep		1		1		
Product preparation error		16		16		
Product preparation issue		1		1		
Pruritus	1	1	1	1		
Pyrexia	4	16	4	14		2
Rhinorrhoea		2		2		
Sleep disorder		1		1		
Somnolence		2		2		
Spinal pain	1	2	1	2		
Swelling		1		1		
Swelling face	1	1	1	1		
Tachycardia		1		1		
Taste disorder		1		1		
Throat tightness		1		1		
Toothache		1		1		
Vaccination failure	2	2			2	2
Vaccination site discolouration		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site oedema		1		1		
Vaccination site pain	2	8	2	8		
Vaccination site swelling		1		1		
Vertigo	2	3	2	3		
Viral infection		1				1
	45	225	35	195	10	30

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**DENMARK**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Dyspnoea		1				1
Erythema		1		1		
Oxygen saturation decreased		1				1
Peripheral swelling		1		1		
Vaccination site pain		1		1		
		6		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper	1	3		1	1	2
Angioedema		1				1
Anxiety		1		1		
Arthralgia		10		7		3
Arthritis reactive		1				1
Asthenia		1				1
Axillary pain		1		1		
Blood pressure increased		3		2		1
Breath sounds abnormal		1				1
Bursitis		1				1
Cerebrovascular accident		1				1
Chest discomfort	1	3		2	1	1
Chest pain	1	2		1	1	1
Chills	1	10	1	6		4
Cold sweat		1		1		
Cough		5		4		1
COVID-19		1				1
C-reactive protein increased		1				1
Deep vein thrombosis		1				1
Derealisation		1		1		
Diarrhoea	1	4	1	2		2
Diplopia	1	2			1	2
Discomfort		1				1
Disease recurrence		1		1		
Dizziness	1	23		10	1	13
Drug ineffective		1				1
Dyspepsia		1				1
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	2	8	1	3	1	5
Dyspnoea exertional		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorder		1		1		
Eczema	1	1	1	1		
Erythema		1		1		
Eye pain		2		2		
Face oedema		1				1
Fall		1				1
Fatigue	1	21	1	15		6
Feeling cold		3		1		2
Feeling hot		1		1		
Feeling of body temperature change		2				2
Flushing		1				1
Gastrooesophageal reflux disease		1		1		
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration		2				2
Headache	6	55	5	39	1	16
Heart rate increased		1		1		
Hot flush		1		1		
Hyperacusis		1				1
Hyperchlorhydria		1		1		
Hypersensitivity		4				4
Hypersomnia		1		1		
Hypertension		1		1		
Hyperventilation		2				2
Hypoacusis		2		2		
Hypoaesthesia		1				1
Hypokalaemia		1				1
Hypotonia	1	1	1	1		
Idiopathic intracranial hypertension	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1				1
Influenza		2		1		1
Influenza like illness		3		3		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling		1				1
Lethargy		1		1		
Limb discomfort		2		1		1
Loss of consciousness		2				2
Lymphadenitis		1				1
Lymphadenopathy		7		5		2
Lymphangitis	1	1			1	1
Malaise		17		9		8
Maternal exposure during pregnancy		1		1		
Migraine		1		1		
Muscle tightness		1				1
Muscular weakness	1	3	1	2		1
Myalgia		23		18		5
Nasal congestion		1		1		
Nausea	1	22	1	13		9
Obstructive airways disorder		1				1
Odynophagia		2		2		
Off label use		1		1		
Oral mucosal blistering		1		1		
Oropharyngeal pain		8		8		
Pain	1	2			1	2
Pain in extremity		7		5		2
Pain of skin		1				1
Palpitations	1	5	1	3		2
Panic attack		1				1
Paraesthesia		2		1		1
Paraesthesia oral		1				1
Pericarditis	1	1			1	1
Pharyngeal swelling		1		1		
Photophobia		1				1
Photopsia		1				1
Presyncope		3				3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue		1		1		
Pruritus		2		1		1
Pyrexia	2	36	2	26		10
Rash		4		3		1
Rash erythematous		2				2
Rash pruritic	1	2			1	2
Renal colic		1		1		
Rhinalgia		1		1		
Rhinorrhoea		2		1		1
Seizure	1	2			1	2
Sensory disturbance		2		2		
Somnolence		1		1		
Stomatitis		1		1		
Stridor		1				1
Swelling		1		1		
Swelling face		2				2
Syncope		2				2
Tachycardia		2		1		1
Temporomandibular joint syndrome		1				1
Tenderness		3		1		2
Throat tightness		1		1		
Thrombosis	1	1			1	1
Tinnitus		1		1		
Tremor		3		2		1
Tunnel vision		1				1
Urticaria		5		2		3
Vaccination site abscess		1				1
Vaccination site discolouration		1				1
Vaccination site erythema	1	9	1	8		1
Vaccination site induration		1		1		
Vaccination site nodule		1		1		
Vaccination site pain	4	34	4	30		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		3		3		
Vaccination site rash		1				1
Vaccination site reaction		1		1		
Vaccination site swelling	1	14	1	12		2
Vaccination site thrombosis		1				1
Vaccination site warmth		3		3		
Vaginal discharge		1		1		
Vaginal haemorrhage		1		1		
Vision blurred		3				3
Visual impairment		1				1
Vlth nerve paralysis	1	1			1	1
Vomiting	1	7	1	7		
Vulvovaginal pain		1		1		
Vulvovaginal pruritus		1		1		
	39	503	23	311	16	192

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension		1		1		
Abdominal pain	2	8	1	6	1	2
Abdominal pain upper		2		1		1
Abortion missed	1	2			1	2
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome		1				1
Ageusia		1		1		
Allergy to vaccine		1				1
Anaphylactic reaction	1	11			1	11
Anaphylactic shock	1	3			1	3
Angioedema		1				1
Anosmia		1		1		
Appendicitis		1				1
Arthralgia	2	17	1	10	1	7
Asthenia	1	6		2	1	4
Asthma	1	3		1	1	2
Atrial fibrillation	1	3			1	3
Axillary pain		2		2		
Back pain		2		2		
Blood bilirubin decreased		1		1		
Blood glucose increased		1		1		
Blood potassium decreased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased		2				2
Blood pressure fluctuation		1		1		
Blood pressure increased	1	5		1	1	4
Body temperature increased		1		1		
Burning sensation	1	4	1	3		1
Cardiovascular disorder	1	1			1	1
Cerebrovascular accident		2				2
Chest discomfort		9		4		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	3		1	1	2
Chills		26		22		4
Choking sensation		1				1
Chorioretinitis		1				1
Cold sweat	1	5		3	1	2
Colitis	1	1	1	1		
Condition aggravated		1				1
Conjunctival hyperaemia		1		1		
Coordination abnormal		2				2
Coronary artery thrombosis	1	1			1	1
Cough	3	14		7	3	7
C-reactive protein increased	2	4	1	1	1	3
Death	1	1			1	1
Decreased appetite		1		1		
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness		1				1
Derealisation		2		2		
Dermatitis allergic		1				1
Diarrhoea	4	16	3	12	1	4
Discomfort	1	7	1	2		5
Disease recurrence		1		1		
Disorientation		1				1
Disturbance in attention		2		1		1
Dizziness	5	62	3	41	2	21
Dizziness exertional		1		1		
Dizziness postural		1				1
Dry eye		1		1		
Dry mouth		2		1		1
Dry skin		1		1		
Dry throat	1	1	1	1		
Dysaesthesia		1		1		
Dysgeusia	1	2		1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	1	4	1	2		2
Dysphonia		2		1		1
Dyspnoea		21		9		12
Dyspnoea at rest		1				1
Dyspnoea exertional		1		1		
Electrocardiogram ST segment depression		1				1
Epistaxis		1				1
Erythema	1	16	1	10		6
Eyelid oedema		1		1		
Eye pain		3		3		
Eye pruritus		4		4		
Eye swelling		1		1		
Facial pain		1		1		
Facial paralysis	1	1			1	1
Fatigue	10	75	6	57	4	18
Feeling abnormal		2		2		
Feeling cold		5		4		1
Feeling drunk		1		1		
Feeling hot		15		9		6
Flushing		5		1		4
Gastrooesophageal reflux disease		1		1		
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	1			1	1
Groin pain		1		1		
Haematology test abnormal	1	1			1	1
Hand dermatitis		1		1		
Headache	11	123	10	97	1	26
Head discomfort		1				1
Heart rate decreased		2		2		
Heart rate increased	4	8	2	5	2	3
Hot flush		1		1		
Hyperhidrosis	1	6		2	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	1	15	1	6		9
Hypertension	1	7	1	3		4
Hyperventilation		2				2
Hypoacusis	1	2			1	2
Hypoaesthesia	2	4	2	3		1
Hypoglycaemia		1		1		
Hypokalaemia		1				1
Hypotension		1				1
Influenza		2		1		1
Influenza like illness	1	10		5	1	5
Initial insomnia		1		1		
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Insomnia	1	5	1	5		
Lacrimation increased		1		1		
Lethargy		1		1		
Leukopenia		1				1
Limb discomfort		4		2		2
Lip pruritus		1				1
Lip swelling		2				2
Loss of consciousness		1				1
Loss of control of legs		1				1
Lymphadenitis		1		1		
Lymphadenopathy		14		10		4
Lymph node pain		4		4		
Lymphopenia		1				1
Malaise	3	48		32	3	16
Maternal exposure during pregnancy	1	2	1	1		1
Meniere's disease		1				1
Migraine	1	4		1	1	3
Mobility decreased	1	1	1	1		
Monoplegia		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Motor dysfunction		1					1
Muscle discomfort		1		1			
Muscle fatigue	2	3	2	3			
Muscle spasms		2		1			1
Muscle tightness		1		1			
Muscle twitching		1					1
Muscular weakness	1	4	1	1			3
Musculoskeletal discomfort		1					1
Musculoskeletal stiffness		1					1
Myalgia	2	53	1	41	1		12
Mydriasis		1		1			
Myelitis		1					1
Myocarditis		1					1
Nasal congestion		3		3			
Nasal discomfort		1					1
Nasal obstruction		1		1			
Nasal pruritus	1	2	1	1			1
Nasopharyngitis		2		2			
Nausea	5	61	5	44			17
Neck pain	1	4	1	4			
Night sweats		1		1			
Obliterative bronchiolitis		1					1
Odynophagia		1					1
Off label use		3		3			
Oral discomfort		1					1
Oral fungal infection		1		1			
Oropharyngeal discomfort		3		2			1
Oropharyngeal pain	1	6	1	4			2
Pain	2	10	2	7			3
Pain in extremity	2	17	2	17			
Pain of skin		2		2			
Pallor	1	8		2	1		6

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	1	15	1	8		7
Paraesthesia	1	23		14	1	9
Paraesthesia oral	2	8	2	6		2
Pericarditis	1	1			1	1
Periorbital swelling		1				1
Peripheral swelling	1	3	1	1		2
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		4		1		3
Photophobia		1				1
Photopsia		2		1		1
Pleuritic pain	1	1	1	1		
Pneumonia		2				2
Postmenopausal haemorrhage		1				1
Presyncope	2	12	2	5		7
Productive cough		1		1		
Product use issue		3		3		
Pruritus	1	28	1	19		9
Pulmonary embolism	2	2			2	2
Pulse abnormal	1	1			1	1
Pyrexia	5	88	3	65	2	23
Rash	1	19	1	11		8
Rash erythematous	1	13		9	1	4
Rash pruritic	1	6		5	1	1
Renal pain		1				1
Respiratory failure		3				3
Respiratory tract infection bacterial		1				1
Restlessness		4		4		
Rhinitis		1		1		
Rhinorrhoea		1		1		
Seasonal allergy		1		1		
Seizure		2				2
Sensation of foreign body		2				2

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory disturbance	1	3	1	3		
Sensory loss		1				1
Sinus tachycardia		2		2		
Sleep disorder	1	1	1	1		
Sneezing		3		3		
Swelling	1	3	1	3		
Swelling face	1	8	1	3		5
Swelling of eyelid		1		1		
Swollen tongue		6		1		5
Syncope	1	6			1	6
Tachycardia	1	4			1	4
Tachypnoea		1				1
Taste disorder		2		1		1
Tenderness		2		2		
Throat irritation	2	8	1	4	1	4
Throat tightness		2				2
Thrombosis	2	2			2	2
Tinnitus	1	2			1	2
Tongue pruritus		2				2
Tonic convulsion		1				1
Tonsillar hypertrophy		1		1		
Transient ischaemic attack		1				1
Transplant failure		1				1
Tremor		9		4		5
Upper respiratory tract infection		1		1		
Urinary incontinence		1				1
Urticaria	4	17	3	12	1	5
Vaccination complication		2		1		1
Vaccination site discomfort		1		1		
Vaccination site erythema	4	15	4	14		1
Vaccination site haematoma		2		2		
Vaccination site haemorrhage		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration		1		1		
Vaccination site inflammation		3		3		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	9	100	9	93		7
Vaccination site paraesthesia		3		3		
Vaccination site pruritus	2	5	2	4		1
Vaccination site rash		4		2		2
Vaccination site swelling	3	24	3	21		3
Vaccination site warmth	2	10	2	9		1
Vaginal haemorrhage	1	1			1	1
Vasodilatation		1				1
Visual impairment		1		1		
Vomiting	1	12	1	8		4
Wheezing		1				1
Wound complication		1		1		
	157	1,446	97	953	60	493

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abdominal pain upper		1		1		
Abdominal wall abscess		1				1
Acute myocardial infarction		1				1
Adrenal insufficiency		1				1
Alanine aminotransferase increased		1		1		
Altered state of consciousness	1	1			1	1
Amnesia	1	2			1	2
Anaphylactic reaction		4				4
Anaphylactic shock		3				3
Angioedema		2				2
Anxiety	1	3			1	3
Arthralgia	3	19		12	3	7
Arthritis		1		1		
Asthenia		4		1		3
Asthma		1				1
Atrial fibrillation	2	2			2	2
Auricular swelling		1		1		
Axillary pain		2		2		
Back pain		6		5		1
Blood lactate dehydrogenase abnormal		1		1		
Blood pressure systolic increased	1	2			1	2
Body temperature increased	1	5		4	1	1
Bradycardia		1				1
Breast pain		1		1		
Bronchitis		1				1
Burning sensation		2		1		1
Cardiac arrest	1	1			1	1
Cardiogenic shock		1				1
Cerebral thrombosis	1	1			1	1
Chest discomfort		9		2		7
Chest pain	2	3			2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		22		15		7
Chronic obstructive pulmonary disease		1				1
Clonic convulsion		1				1
Condition aggravated		2				2
Coronary artery thrombosis	1	1			1	1
Cough	1	3	1	2		1
COVID-19	2	3	1	1	1	2
C-reactive protein increased	2	5		1	2	4
Crying		1				1
Cystitis		1		1		
Decreased appetite		1		1		
Deep vein thrombosis	3	3			3	3
Derealisation	1	2		1	1	1
Dermatitis allergic		1				1
Diarrhoea	1	8		6	1	2
Discomfort		1		1		
Disturbance in attention	1	2		1	1	1
Dizziness	4	37	3	15	1	22
Dizziness postural		1				1
Dry mouth		3		3		
Dysaesthesia		1				1
Dysarthria		1				1
Dysgeusia		2		1		1
Dysphagia		2				2
Dysphonia		2		1		1
Dyspnoea	5	26		6	5	20
Dyspnoea exertional	1	4		2	1	2
Dysuria	1	1			1	1
Ear discomfort		2		2		
Ear pruritus		1				1
Electrocardiogram QT prolonged		1				1
Epistaxis		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Erysipelas		1					1
Erythema		13		7			6
Eye irritation		1		1			
Eyelid ptosis		1					1
Eye pain		2		2			
Eye pruritus		1					1
Facial paresis		1					1
Faeces soft		1		1			
Fall		1					1
Fatigue	5	48	1	36	4		12
Feeling abnormal	1	1			1		1
Feeling cold		2		2			
Feeling hot	1	7	1	1			6
Feeling of body temperature change		1					1
Fibrin D dimer increased	2	2	1	1	1		1
Flatulence		1		1			
Flushing	1	3	1	3			
Generalised tonic-clonic seizure		1					1
Glossodynia		1		1			
Groin pain	1	1	1	1			
Haematoma		1		1			
Haemolysis		1					1
Headache	12	84	5	61	7		23
Head discomfort		2		2			
Head injury		1					1
Heart rate abnormal		1		1			
Heart rate increased	1	3	1	3			
Hot flush		1		1			
Hyperacusis		1		1			
Hyperhidrosis		2		1			1
Hypersensitivity		3					3
Hypersomnia	2	2			2		2

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		6		3		3
Hyperventilation		1				1
Hypoaesthesia		1				1
Hypoaesthesia oral		2				2
Hypophagia		1		1		
Hypotension	1	3			1	3
Idiopathic pulmonary fibrosis	1	1			1	1
Illrd nerve paresis		1				1
Immune-mediated hepatitis	1	1			1	1
Immune thrombocytopenia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Infection	1	2	1	2		
Influenza	1	3		1	1	2
Influenza like illness	1	5		4	1	1
Joint stiffness		1				1
Joint swelling		4		2		2
Joint warmth		1		1		
Lacrimation increased		1		1		
Limb discomfort		2		1		1
Lip swelling	1	2			1	2
Loss of consciousness	1	3			1	3
Lymphadenopathy		4		2		2
Malaise	4	35	3	19	1	16
Memory impairment	1	1			1	1
Migraine	1	2	1	2		
Mobility decreased		2		2		
Monoplegia		1				1
Multimorbidity	1	1			1	1
Muscle fatigue		1		1		
Muscle spasms		2		2		
Muscle twitching		1		1		
Muscular weakness		3		1		2

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myalgia	4	31
Nasal congestion		1
Nasal pruritus		1
Nasopharyngitis		1
Nausea	3	43
Neck pain		2
Nervous system disorder		1
Neuralgia		1
Obstructive airways disorder	1	1
Ocular hyperaemia		1
Oedema peripheral	1	2
Oesophageal spasm		1
Off label use	1	3
Oral discomfort		1
Oral mucosal eruption		1
Oral pruritus		1
Oropharyngeal pain	1	5
Oxygen saturation decreased	2	5
Pain		10
Painful respiration		1
Pain in extremity	2	17
Pain of skin		1
Pallor		1
Palpitations		6
Paraesthesia	1	11
Paraesthesia mucosal		1
Paraesthesia oral	1	5
Periarthritis		2
Periorbital swelling	1	2
Peripheral coldness	1	2
Peripheral swelling		4
Pharyngeal oedema		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	22	4	9
	1		
			1
	1		
3	30		13
	2		
			1
			1
		1	1
	1		
	1	1	1
	1		
	1		
	4	1	1
1	1	1	4
	10		
	1		
	14	2	3
			1
			1
	5		1
	6	1	5
			1
	2	1	3
	2		
	1	1	1
		1	2
	3		1
			1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia		1				
Pharyngeal swelling	1	5		1	1	5
Pharyngitis		1				1
Photophobia	2	3		1	2	2
Photosensitivity reaction	1	1	1	1		
Pleural effusion		1				1
Pneumonia	1	1			1	1
Poor quality sleep		1		1		
Presyncope	2	8	1	3	1	5
Productive cough	2	2			2	2
Product use issue		3		3		
Pruritus		9		7		2
Pulmonary embolism	4	5			4	5
Pulmonary pain		1		1		
Pyrexia	9	62	2	43	7	19
Rash		9		6		3
Rash erythematous		4		3		1
Rash macular		1		1		
Rash morbilliform		1		1		
Rash papular		1		1		
Rash pruritic	1	2		1	1	1
Rash vesicular		1		1		
Respiration abnormal		1				1
Respiratory arrest	1	1			1	1
Respiratory failure	1	1			1	1
Restlessness		3		2		1
Rheumatoid factor increased	1	1			1	1
Rhinorrhoea		2		2		
Salivary gland enlargement		1		1		
Salivary gland pain		1		1		
Salivary hypersecretion		1				1
Sensory disturbance		3		2		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis	1	1			1	1
Skin burning sensation		1				1
Sleep disorder		1		1		
Sneezing		3		3		
Somnolence		2		1		1
Speech disorder		1				1
Sputum discoloured	1	1			1	1
Sudden cardiac death		1				1
Sudden death		1				1
Swelling		2		2		
Swelling face		5		3		2
Swelling of eyelid		1				1
Swollen tongue		4		1		3
Syncope	1	5			1	5
Tachycardia		2		1		1
Taste disorder		1		1		
Tenderness	1	3		1	1	2
Throat irritation		2		1		1
Throat tightness		2		1		1
Thrombocytopenia	2	2			2	2
Thrombosis	1	2			1	2
Tinnitus		3		3		
Tongue discomfort		1		1		
Toxicity to various agents		1				1
Tracheal stenosis	1	1			1	1
Tremor		3		1		2
Tunnel vision		1				1
Type I hypersensitivity		1				1
Urticaria		9		7		2
Vaccination site discomfort		1		1		
Vaccination site erythema	1	6	1	6		
Vaccination site hypoaesthesia		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation		1		1		
Vaccination site irritation		2		1		1
Vaccination site movement impairment		1		1		
Vaccination site pain	5	48	3	44	2	4
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site swelling		6		6		
Vaccination site warmth		2		2		
Vertigo		2		1		1
Viral infection		1		1		
Vomiting	1	9		5	1	4
Wound infection	1	1			1	1
	140	967	35	568	105	399

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	3			2	3
Abdominal pain lower		1				1
Abdominal pain upper		1				1
Abdominal tenderness		1				1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Altered state of consciousness	1	1			1	1
Anaphylactic reaction	1	2			1	2
Angina pectoris		1				1
Angioedema		1				1
Anti-glomerular basement membrane disease	1	1			1	1
Anxiety		1		1		
Appendicitis		1				1
Arthralgia	1	4		2	1	2
Asthenia		1				1
Back pain		1		1		
Balance disorder	1	2			1	2
Blood albumin decreased		1		1		
Blood chloride increased		1		1		
Blood creatinine increased		1				1
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure decreased		1		1		
Blood urea decreased		1				1
Bradycardia	1	2			1	2
Bronchospasm	1	2			1	2
Calcium ionised increased		1		1		
Cardiac arrest	2	3			2	3
Cardiac failure	1	1			1	1
Cardiovascular disorder	1	1			1	1
Cerebrovascular accident	5	6			5	6
Chest discomfort	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	2			1	2
Chills	1	2		1	1	1
Chronic obstructive pulmonary disease	2	4			2	4
Colitis	1	1			1	1
Condition aggravated		2				2
Confusional state	2	3			2	3
Coordination abnormal		1				1
Cough		2		1		1
COVID-19	1	4	1	2		2
C-reactive protein increased		1				1
Death	2	3			2	3
Decreased appetite	1	1			1	1
Deep vein thrombosis	2	2			2	2
Dehydration	1	1			1	1
Delirium	1	3			1	3
Depressed level of consciousness	1	2			1	2
Diarrhoea	2	3			2	3
Diplopia	1	1			1	1
Discomfort		1				1
Disseminated intravascular coagulation	1	1			1	1
Dizziness	1	4		1	1	3
Drug ineffective		1				1
Dysarthria	2	2			2	2
Dysphagia	1	1			1	1
Dysphonia		2		2		
Dyspnoea	9	14	1	1	8	13
Epilepsy	2	2			2	2
Epistaxis	1	1			1	1
Erythema	1	2		1	1	1
Eyelid ptosis		1				1
Face oedema		1				1
Facial paresis		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	1			1	1
Fatigue	4	15	1	8	3	7
Feeling cold	1	3		1	1	2
Feeling hot		1				1
Fluid intake reduced	1	1			1	1
Foaming at mouth		2		1		1
Gait disturbance	1	2		1	1	1
Gastric ulcer	1	1			1	1
Gastrointestinal necrosis	1	1			1	1
Gastrooesophageal reflux disease	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	4			1	4
Glomerular filtration rate decreased		1				1
Guillain-Barre syndrome		1				1
Haemoglobin decreased		1				1
Haemorrhage intracranial		1				1
Headache	5	16	1	7	4	9
Heart rate increased	1	2			1	2
Heart rate irregular	1	1			1	1
Hemiparesis	3	4			3	4
Herpes zoster		2		1		1
Hyperhidrosis	1	3		2	1	1
Hypersensitivity	1	1	1	1		
Hypersomnia		1				1
Hypertension	1	1			1	1
Hypoaesthesia		1				1
Hypotension	2	4		1	2	3
Illness		1		1		
Inappropriate schedule of product administration	1	2	1	2		
Infarction	1	1			1	1
Influenza		3		3		
Influenza like illness	1	4		2	1	2

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intestinal ischaemia	1	1			1	1
Joint stiffness		1		1		
Lacrimation increased		1		1		
Lethargy		1		1		
Limb discomfort	1	2		1	1	1
Livedo reticularis	1	1			1	1
Lung disorder	1	1			1	1
Lymphadenopathy		2		1		1
Malaise	7	16		4	7	12
Mesenteric artery thrombosis	1	1			1	1
Metabolic acidosis	1	1			1	1
Metabolic alkalosis		1		1		
Micturition urgency		1				1
Mobility decreased	1	1			1	1
Monoparesis		1				1
Muscle spasms	1	1			1	1
Muscular weakness	1	2			1	2
Myalgia	1	8		5	1	3
Nausea	3	8		2	3	6
Neck pain	1	1			1	1
Neutrophil count increased		1		1		
Oedema	1	1			1	1
Oedema peripheral	2	4	1	2	1	2
Off label use	1	2	1	2		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		1				1
Pain	1	2			1	2
Pain in extremity	2	3		1	2	2
Pain of skin		1				1
Pallor		1		1		
Pancreatitis acute		1				1
Paraesthesia oral	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Paresis		1					1
Parkinson's disease		1					1
Peripheral swelling	2	2			2		2
Pharyngeal swelling		1					1
Pneumonia	2	5			2		5
Pneumonia bacterial		1					1
Pneumonitis		1					1
Presyncope		2					2
Prolonged expiration		1					1
Pruritus	1	2	1	2			
Pulmonary arterial hypertension		1					1
Pulmonary embolism	6	7			6		7
Pulmonary fibrosis		1					1
Pulmonary oedema	2	3			2		3
Pyrexia	2	16	1	9	1		7
Rash	3	6	3	5			1
Rash pruritic		1		1			
Renal failure	1	1			1		1
Respiratory acidosis	2	2			2		2
Respiratory distress	1	1			1		1
Respiratory failure	2	3			2		3
Restlessness	1	1			1		1
Rheumatoid arthritis	1	1			1		1
Rhinorrhoea	1	2		1	1		1
Sensory disturbance	1	1			1		1
Sensory loss		1					1
Skin abrasion	1	1			1		1
Sleep disorder	1	1	1	1			
Somnolence	1	5	1	4			1
Speech disorder	1	2		1	1		1
Splenic infarction	1	1			1		1
Staphylococcal infection		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death		1				1
Swelling face		1				1
Swollen tongue	1	1			1	1
Syncope	1	2			1	2
Tachypnoea		1				1
Tenderness	1	2		1	1	1
Therapeutic response unexpected		1		1		
Thrombocytopenia	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	2	2			2	2
Transient ischaemic attack	1	1			1	1
Tremor	2	2			2	2
Urinary tract infection	1	1			1	1
Urosepsis	1	1			1	1
Urticaria	4	5	1	1	3	4
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	1	5	1	4		1
Vaccination site haematoma		1		1		
Vaccination site pain	2	8	2	7		1
Vaccination site swelling		3		2		1
Vaccination site warmth		1		1		
Vasculitis	1	1	1	1		
Ventricular tachycardia	1	1			1	1
Vertigo		1				1
Vomiting	3	5	1	1	2	4
Weight increased	1	1	1	1		
Wound		1				1
	176	403	23	122	153	281

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	4		1	1	3
Abdominal pain upper		2		1		1
Acute kidney injury		3				3
Acute leukaemia		1				1
Acute myocardial infarction	1	2			1	2
Acute respiratory failure		1				1
Aggression	1	2			1	2
Altered state of consciousness		2				2
Amnesia	2	3			2	3
Anaemia		2		1		1
Anaphylactic reaction	1	3			1	3
Angioedema		2				2
Aphasia	2	2			2	2
Appendicitis		1				1
Arthralgia	1	2			1	2
Aspiration		1				1
Asthenia	3	11	1	3	2	8
Atrial fibrillation	2	4			2	4
Atrial flutter		2				2
Back pain		1				1
Bacteraemia		1				1
Bacterial infection		1				1
Basilar artery occlusion	1	1			1	1
Blood count abnormal		1		1		
Blood creatine phosphokinase increased		1				1
Blood potassium increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased		1				1
Blood pressure systolic increased		1		1		
Blood sodium decreased		1		1		
Blood uric acid abnormal		1		1		
Bradycardia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm	1	1			1	1
Carbon monoxide poisoning	1	1			1	1
Cardiac arrest	4	4			4	4
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis	1	2			1	2
Cerebrovascular accident	7	8			7	8
Chest discomfort		1				1
Chest pain	2	7		2	2	5
Chills	1	2			1	2
Chronic obstructive pulmonary disease	1	2			1	2
Circulatory collapse		1				1
Cognitive disorder	1	1			1	1
Coma		1				1
Condition aggravated	1	6			1	6
Confusional state	3	9		1	3	8
Conjunctival haemorrhage		1				1
Contusion	1	1			1	1
Cough	1	2			1	2
COVID-19	1	13	1	1		12
C-reactive protein increased	1	6	1	3		3
Death	5	12			5	12
Decreased appetite		4				4
Deep vein thrombosis	2	2			2	2
Dehydration		1				1
Delirium	2	5			2	5
Delusion		1				1
Dementia	1	1			1	1
Depressed level of consciousness	2	8			2	8
Diarrhoea	1	6		2	1	4
Discomfort	2	3			2	3
Disturbance in attention	2	2			2	2
Dizziness	1	12		8	1	4

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Drug ineffective		6					6
Drug interaction		1					1
Dysarthria		1					1
Dyspnoea	9	27		3	9		24
Dyspnoea exertional	1	1	1	1			
Dysstasia		1					1
Emphysema	1	1			1		1
Epistaxis		1					1
Erythema		6		4			2
Facial paralysis	2	3			2		3
Facial paresis	2	2			2		2
Fall	3	6			3		6
Fatigue	4	19		5	4		14
Feeling abnormal		2		1			1
Feeling hot		3		3			
Femur fracture		1					1
Fibrin D dimer increased	1	1			1		1
Fluid intake reduced		2		1			1
Flushing		2		1			1
Gait disturbance	1	1			1		1
General physical health deterioration	3	9			3		9
Haematemesis	1	1			1		1
Haematochezia	1	1			1		1
Haematuria	1	2	1	1			1
Haemodynamic instability	1	1			1		1
Haemoglobin decreased		2					2
Haemorrhagic diathesis	1	1			1		1
Hallucination, visual		1					1
Headache	3	10		1	3		9
Head injury		1					1
Heart rate decreased		1		1			
Hemiparesis	1	2			1		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiplegia	2	2			2	2
Hot flush		3		3		
Hyperglycaemia		1				1
Hyperhidrosis	1	4		3	1	1
Hypersensitivity		1				1
Hypertension	1	4			1	4
Hypertonia		1				1
Hypoglycaemia		1				1
Hypophagia		1		1		
Hypotension		3				3
Hypothermia		2				2
Hypoxia		1				1
Ileus paralytic		1				1
Immune-mediated adverse reaction		1				1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration		2		2		
Infection		1				1
Influenza		1				1
Influenza like illness		2		2		
Ketoacidosis		1				1
Leukocytosis		1		1		
Livedo reticularis		1				1
Loss of consciousness		1				1
Loss of control of legs		1				1
Lung disorder	1	1			1	1
Lung infiltration	1	1			1	1
Lymphopenia	1	2	1	1		1
Malaise	3	19	1	7	2	12
Melaena	1	1			1	1
Mobility decreased		2				2
Monoparesis	1	1			1	1
Muscle discomfort		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscle spasms		1					1
Musculoskeletal stiffness		1					1
Myalgia	1	3			1		3
Myelosuppression		1					1
Myocardial infarction	1	1			1		1
Nausea	3	13	1	4	2		9
Neck pain	1	2			1		2
Obstructive airways disorder		1					1
Oedema		1					1
Oedema peripheral	1	1			1		1
Off label use		1		1			
Oral pruritus		1		1			
Oropharyngeal pain	1	1			1		1
Oxygen saturation decreased	1	1			1		1
Pain		3		1			2
Painful respiration		1		1			
Pain in extremity	1	2		1	1		1
Pallor		1					1
Palpitations		2					2
Pancytopenia	1	1			1		1
Paraesthesia		1		1			
Paralysis	1	1			1		1
Parosmia		1		1			
Phlebitis deep	1	1			1		1
Pleural effusion		1					1
Pneumonia	5	12			5		12
Pneumonia aspiration		1					1
Pruritus	1	4	1	3			1
Pulmonary arterial pressure increased	1	1	1	1			
Pulmonary embolism	6	9			6		9
Pulmonary fibrosis	1	1			1		1
Pulmonary oedema		3					3

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	4	21		2	4	19
Rales		1				1
Rash		2		2		
Rash macular		1		1		
Rash pruritic		1		1		
Renal failure		3				3
Respiration abnormal	1	1			1	1
Respiratory acidosis		2				2
Respiratory arrest	1	2			1	2
Respiratory failure	1	7			1	7
Respiratory rate decreased		1				1
Restlessness		2		1		1
Retinal vascular thrombosis	1	1			1	1
Rhabdomyolysis		1				1
SARS-CoV-2 test positive		1				1
Scratch		1				1
Sensation of foreign body	2	2			2	2
Sepsis		1				1
Septic shock		1				1
Severe acute respiratory syndrome		1				1
Skin haemorrhage	1	1			1	1
Skin lesion		1		1		
Somnolence	1	4		2	1	2
Splenic haemorrhage	1	1			1	1
Stress cardiomyopathy		1				1
Sudden death	1	2			1	2
Swelling		2		1		1
Swelling face		3		1		2
Syncope	2	3			2	3
Systemic immune activation	2	2			2	2
Systemic inflammatory response syndrome		1				1
Taste disorder		1		1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tenderness	1	2	1	2		
Thinking abnormal		1				1
Thrombocytopenia		1				1
Thrombocytosis	1	1			1	1
Thrombosis	3	4			3	4
Tremor	2	3			2	3
Troponin I increased		2		1		1
Troponin increased	1	2			1	2
Unresponsive to stimuli	1	1			1	1
Urinary tract infection		2				2
Urinary tract infection bacterial		1				1
Urine odour abnormal	1	1			1	1
Urticaria		3		3		
Vaccination site necrosis		1				1
Vaccination site pain		2		2		
Vaccination site swelling		1		1		
Vision blurred		1		1		
Vomiting	1	15	1	4		11
White matter lesion		1		1		
	166	571	12	116	154	455

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Anaphylactic reaction	3	3			3	3
Arthralgia		1		1		
Chills		2		2		
Contusion		1		1		
COVID-19	1	1			1	1
Discomfort		1		1		
Drug ineffective	1	1			1	1
Dysphonia		1		1		
Dyspnoea		2		2		
Exposure via breast milk		1		1		
Exposure via skin contact		1		1		
Fatigue		3		3		
Feeling abnormal		1		1		
Gastrointestinal disorder		1		1		
General physical health deterioration	1	2	1	2		
Headache		5		4		1
Hepatic enzyme increased	1	2	1	2		
Hypoaesthesia		1		1		
Immunisation reaction		1		1		
Incorrect route of product administration		1		1		
Influenza like illness		3		2		1
Injection site erythema		1		1		
Injection site pain		1		1		
Injection site swelling		1		1		
Lymphadenopathy	1	2	1	2		
Malaise		1		1		
Myalgia		4		3		1
Pain	1	2	1	2		
Paraesthesia		1		1		
Product administration error		1		1		
Product preparation issue		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		2		2		
Reaction to excipient	2	2			2	2
Respiratory disorder		1		1		
Underdose		2		2		
Urticaria		1				1
Vaccination site erythema		1		1		
Vaccination site pain		2		1		1
Vaccination site pruritus		1		1		
Vaccination site swelling		2		2		
Vaccination site warmth		1		1		
	11	66	4	54	7	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**ECUADOR**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased		1		1
Chills	1	1	1	1
Diarrhoea		2		2
Dizziness		2		2
Face oedema		1		1
Fatigue	1	1	1	1
Lip oedema		1		1
Vaccination site pain	1	1	1	1
Vomiting		1		1
	3	11	3	11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Cough	1	1	1	1		
COVID-19		2		1		1
Depressed mood		1		1		
Diarrhoea	1	1	1	1		
Discomfort	1	2	1	2		
Eye pain		1		1		
Headache	1	1	1	1		
Limb discomfort	1	1	1	1		
Lung infiltration	1	1	1	1		
Myalgia	1	1	1	1		
Oropharyngeal pain		1		1		
Pyrexia	2	3	2	3		
SARS-CoV-2 test positive		1		1		
Vaccination site pain	1	2	1	2		
	11	20	11	19		1

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
Laryngitis		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thrombotic stroke	1	1	1	1
	1	1	1	1

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Blood pressure increased	1	1	1	1		
COVID-19	1	4			1	4
Diarrhoea		1		1		
Discomfort	2	2	2	2		
Drug ineffective	1	4			1	4
Fatigue	1	1	1	1		
Laryngitis		1		1		
Lymphadenitis	1	1	1	1		
Musculoskeletal disorder		1		1		
Pain	1	1	1	1		
Pyrexia	3	3	3	3		
Suspected COVID-19		1				1
Tracheitis		1		1		
Vaccination site pain	2	3	2	3		
	14	26	11	16	3	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**EGYPT**

Age Range

**Unknown**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ESTONIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		2		2		
Asthenia		3		2		1
Bradycardia		1				1
Chest pain	1	1	1	1		
Chills	2	6	2	6		
COVID-19	3	3			3	3
Dizziness	2	3	2	2		1
Dyspnoea	1	1	1	1		
Ear disorder	1	1	1	1		
Exposure during pregnancy		1		1		
Fatigue	1	4	1	4		
Feeling hot	1	1	1	1		
Flushing		1		1		
Headache		7		7		
Hyperhidrosis	1	1	1	1		
Hypoaesthesia		1		1		
Hypopnoea		1				1
Hypotension		1				1
Immunisation reaction		1				1
Insomnia	1	1	1	1		
Intranasal paraesthesia		1		1		
Malaise		3		1		2
Maternal exposure during pregnancy		2		2		
Migraine with aura		1		1		
Muscular weakness		1		1		
Myalgia	1	3	1	3		
Nausea		2		1		1
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	2	1	2		
Paraesthesia		3		3		
Paraesthesia oral		1		1		
Pharyngeal paraesthesia		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	2	9	2	9		
Retching		1				1
Speech disorder		1				1
Syncope	2	2			2	2
Vaccination failure	3	3			3	3
Vaccination site erythema		2		2		
Vaccination site oedema		2		2		
Vaccination site pain	1	8	1	8		
Visual impairment		1				1
Vomiting	1	1	1	1		
	26	92	18	72	8	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Acute disseminated encephalomyelitis		1				1
Acute myocardial infarction	1	1			1	1
Anxiety		1				1
Aphonia	1	1			1	1
Arthralgia	3	6	3	6		
Asthenia	2	9	2	6		3
Asymptomatic COVID-19		1				1
Back pain		3		1		2
Balance disorder	1	1	1	1		
Blood creatine phosphokinase increased		1		1		
Body temperature decreased	1	1	1	1		
Chest pain	2	3	2	2		1
Chills	3	6	3	6		
Cognitive disorder		1		1		
COVID-19	9	10			9	10
Death	1	1			1	1
Demyelination		1				1
Diarrhoea		2		2		
Disease recurrence		1				1
Dizziness	3	7	3	6		1
Drug hypersensitivity		1				1
Drug ineffective	1	2			1	2
Dysgeusia		3		2		1
Dyspepsia	1	1	1	1		
Dysphagia	1	1			1	1
Dyspnoea	3	6	2	4	1	2
Dysuria		1				1
Ear pain	1	1	1	1		
Exposure during pregnancy	2	3	2	3		
Facial nerve disorder		1		1		
Facial pain	1	2	1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall		1		1		
Fatigue	1	7	1	6		1
Feeling hot		1		1		
Fracture		1				1
Headache	5	18	5	16		2
Heart rate increased		1				1
Hyperhidrosis	2	2	2	2		
Hypersensitivity		1		1		
Hypertension		2		1		1
Hypoaesthesia		2		2		
Hypothermia	2	3			2	3
Immunisation anxiety related reaction		4		4		
Insomnia	2	3	2	3		
Laryngeal oedema	1	1			1	1
Lymphadenopathy	1	3	1	3		
Malaise		4		4		
Maternal exposure during pregnancy		1		1		
Mouth swelling		1				1
Muscular weakness		1		1		
Musculoskeletal stiffness		1				1
Myalgia	3	6	3	6		
Myelitis transverse		1				1
Nasal congestion		1		1		
Nausea	2	5	2	4		1
Neck pain		2				2
Nervousness		1				1
Ocular discomfort	1	1	1	1		
Pain	1	2	1	1		1
Pain in extremity	1	3	1	3		
Paraesthesia	1	12	1	9		3
Paraesthesia oral		1		1		
Peripheral swelling	1	1	1	1		

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling		1		1		
Photopsia	1	1	1	1		
Pruritus	1	1	1	1		
Pulmonary oedema	1	1			1	1
Pyrexia	3	13	3	12		1
Rhinorrhoea	2	2	2	2		
Seizure		1				1
Somnolence		6		5		1
Spinal cord injury		1				1
Sputum increased	1	1	1	1		
Syncope	1	4			1	4
Syringe issue		1		1		
Tachycardia	1	3	1	3		
Tendon pain	1	1	1	1		
Thrombophlebitis	1	1	1	1		
Type I hypersensitivity		1				1
Underdose		1		1		
Urinary retention		1				1
Vaccination failure	8	9			8	9
Vaccination site erythema		3		3		
Vaccination site induration		1		1		
Vaccination site oedema	1	3	1	3		
Vaccination site pain	2	15	2	15		
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site swelling		2		2		
Ventricular extrasystoles		1				1
Vision blurred	1	2	1	2		
	88	256	60	181	28	75

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain upper		1				1	
Arthralgia	1	3	1	3			
Asthenia	3	7	3	6		1	
Blood pressure increased		1				1	
Bone pain		1				1	
Chest discomfort		1		1			
Chest pain		1				1	
Chills	3	9	3	8		1	
Chronic obstructive pulmonary disease	1	1			1	1	
Cold sweat		1				1	
Cough		2		2			
COVID-19	4	5			4	5	
Decreased appetite		1		1			
Diplopia	1	1	1	1			
Disease recurrence	1	1	1	1			
Dizziness	1	4	1	2		2	
Drug ineffective	1	2			1	2	
Dysgeusia		2		1		1	
Dysphagia		1		1			
Dyspnoea		1		1			
Extensive swelling of vaccinated limb		1		1			
Fatigue	1	2	1	2			
Headache	2	7	2	5		2	
Hypersensitivity		3				3	
Hypertension		2		2			
Hypoaesthesia oral		1		1			
Hypoglycaemia	1	1			1	1	
Hypotension		1				1	
Hypothermia	1	2			1	2	
Illrd nerve disorder	1	1			1	1	
Immunisation anxiety related reaction		5		4		1	
Insomnia	1	1	1	1			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
	2		
	1		
1	1		
1	2		1
1	5		2
	1		
	1		
			1
	1		
	2		
			1
	1		
	1		
1	2		
	1		
			1
	1		
			1
			1
	1		
3	7		
			1
	1	1	1
	1		
1	3		
		1	1
		2	3
			1
1	1		1
1	1		

Laryngeal oedema		1
Lip swelling		1
Lymphadenopathy		2
Malaise		1
Muscular weakness	1	1
Myalgia	1	3
Nausea	1	7
Off label use		1
Oral herpes		1
Oropharyngeal discomfort		1
Oropharyngeal pain		1
Pain in extremity		2
Pallor		1
Palpitations		1
Panic attack		1
Paraesthesia	1	2
Paraesthesia oral		1
Peripheral sensory neuropathy		1
Pharyngeal hypoaesthesia		1
Pneumonia		1
Presyncope		1
Product use issue		1
Pyrexia	3	7
Respiration abnormal		1
Respiratory failure	1	1
Restlessness		1
Somnolence	1	3
Suspected COVID-19	1	1
Syncope	2	3
Throat tightness		1
Tinnitus	1	2
Tremor	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal nerve disorder	1	1			1	1
Vaccination failure	4	4			4	4
Vaccination site erythema		1		1		
Vaccination site pain	1	5	1	5		
Vomiting		1		1		
	43	139	25	87	18	52

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Arthralgia	2	3	2	3		
Asthenia	2	2	2	2		
Balance disorder		1		1		
Cardiac failure congestive	1	1			1	1
Cerebral infarction	1	1			1	1
Condition aggravated	1	1	1	1		
COVID-19	5	6		1	5	5
C-reactive protein increased	1	1	1	1		
Death	1	1			1	1
Decreased appetite	1	1	1	1		
Deep vein thrombosis	1	1			1	1
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	2	4	2	4		
Fatigue		1		1		
Headache	2	3	2	3		
Hypertensive heart disease	1	1			1	1
Immunisation anxiety related reaction		1		1		
Increased appetite		1		1		
Joint range of motion decreased	1	1	1	1		
Joint stiffness	1	1	1	1		
Joint swelling	1	1	1	1		
Myalgia	1	2	1	2		
Nausea	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity		1		1		
Palpitations		2		2		
Psoriasis		1				1
Pulmonary embolism	1	1			1	1
Pyrexia	4	6	4	6		
Respiratory failure	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory symptom		1		1		
Restlessness		2		2		
Rhinorrhoea	1	1	1	1		
Supraventricular tachycardia		1				1
Tremor		1		1		
Type IV hypersensitivity reaction	1	1			1	1
Vaccination failure	4	4			4	4
Vaccination site erythema	1	1	1	1		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site oedema	1	2	1	2		
Vaccination site pain		2		2		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	1	2	1	2		
Vaccine breakthrough infection	1	1			1	1
	49	74	30	53	19	21

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Asthenia	1	2	1	1		1
Blindness unilateral	1	1			1	1
Bone contusion		1				1
Bone pain		1		1		
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Chills		2		2		
Contusion		1				1
Cough	1	1	1	1		
COVID-19	2	2			2	2
COVID-19 pneumonia	1	1			1	1
Facial paralysis		1				1
Fall		1		1		
Haematoma		1		1		
Headache		2		2		
Hypoaesthesia		1		1		
Hypoaesthesia oral		1		1		
Loss of consciousness		1				1
Malaise		2		1		1
Musculoskeletal pain		1		1		
Myalgia		1		1		
Nausea		1		1		
Paraesthesia		1		1		
Pulmonary embolism		1				1
Pyrexia	1	3	1	2		1
Respiratory failure	1	1			1	1
Retinal vascular thrombosis	1	1			1	1
Rhinitis	1	1	1	1		
Road traffic accident		1		1		
Syncope		2				2
Vaccination failure	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Wound		1				1	
	11	41	4	21	7	20	

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Dysgeusia		1		1		
Headache		1		1		
Influenza like illness	1	1	1	1		
Muscle spasms		1		1		
Oral herpes		1		1		
Vaccination site pain		5		5		
	3	12	1	10	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FINLAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		3		1		2
Abdominal pain upper		1				1
Abortion spontaneous	1	1			1	1
Allergy to vaccine		1				1
Ankylosing spondylitis		1				1
Appendicitis		1				1
Arrhythmia		1				1
Arthralgia	1	8		2	1	6
Asthenia	1	7		1	1	6
Axillary pain		4		2		2
Back pain		2				2
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure increased		2		1		1
Breast cyst		1				1
Breath sounds abnormal		1				1
Bronchitis		2				2
Burning sensation		2				2
Cervical spinal stenosis		1				1
Chest discomfort		3				3
Chest pain		2		1		1
Chills	1	6		2	1	4
Choking sensation		1				1
Confusional state		1				1
Cough		4				4
C-reactive protein increased		1				1
Diarrhoea		2		2		
Disease recurrence		1				1
Dizziness	1	4		1	1	3
Dysarthria		1				1
Dysphagia		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	9			1	9
Dysuria		1				1
Erythema		4		1		3
Erythema of eyelid		1				1
Eyelid oedema		1				1
Eye pain		2				2
Face oedema		3		1		2
Facial pain		1				1
Facial paralysis		1				1
Fatigue	1	14		4	1	10
Feeling abnormal		2		1		1
Feeling cold		2		1		1
Feeling hot	1	6		2	1	4
Flank pain		2				2
General physical health deterioration		2				2
Headache		20		3		17
Heart rate increased		5		1		4
Heart rate irregular		1				1
Hemianaesthesia		1				1
Herpes zoster		3		1		2
Hyperaesthesia		1				1
Hyperhidrosis		1				1
Hypersensitivity	1	4			1	4
Hypersomnia		1		1		
Hypoaesthesia	1	12		2	1	10
Hypoaesthesia oral		2				2
Hypokalaemia		2				2
Hypothermia		1				1
Illness		1				1
Impaired work ability		2				2
Incorrect route of product administration		1		1		
Increased upper airway secretion		2				2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza		1				1
Insomnia		1				1
Joint range of motion decreased		1				1
Joint stiffness		1		1		
Localised oedema		2		1		1
Loss of consciousness		2				2
Loss of control of legs		1				1
Lymphadenopathy		10		4		6
Lymph node pain		2		1		1
Lymph nodes scan abnormal		1				1
Malaise		7		1		6
Malignant lymphoid neoplasm		1				1
Migraine	1	4		1	1	3
Mobility decreased		1				1
Muscle fatigue		1				1
Muscle spasms		2		1		1
Muscle twitching		3		2		1
Muscular weakness	1	4			1	4
Musculoskeletal pain		1		1		
Musculoskeletal stiffness		3		2		1
Myalgia	1	16		3	1	13
Myocarditis		1				1
Narcolepsy	1	1			1	1
Nasal congestion		1				1
Nasal oedema		1				1
Nasopharyngitis		2				2
Nausea		11		3		8
Neck pain	1	2			1	2
Neuralgia		4		1		3
Night sweats		1		1		
Nuchal rigidity		1		1		
Oedema peripheral		1				1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pruritus		1				1
Oropharyngeal oedema		1		1		
Oropharyngeal pain	1	2			1	2
Pain		3		1		2
Pain in extremity		14		4		10
Pain of skin		1				1
Pallor		1		1		
Palpitations	1	3			1	3
Paraesthesia	1	6		2	1	4
Paraesthesia oral		1				1
Pharyngeal hypoaesthesia		2				2
Pharyngeal oedema		4				4
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1				1
Photophobia		1				1
Pneumonia		2				2
Presyncope	1	1			1	1
Productive cough		1				1
Pruritus		1		1		
Pulmonary pain		2				2
Pyrexia	3	26		8	3	18
Rash macular		1				1
Salivary hypersecretion		1				1
SARS-CoV-2 test negative		1				1
Sensation of foreign body		1		1		
Sensory disturbance		1		1		
Somnolence	1	2			1	2
Stridor		1				1
Syncope		3				3
Tendon pain		1				1
Throat irritation		2				2
Thrombocytosis		1				1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema		1				1
Tremor		2		1		1
Urticaria	1	3		1	1	2
Vaccination site abscess		1				1
Vaccination site bruising		1				1
Vaccination site erythema		7		3		4
Vaccination site haematoma		1		1		
Vaccination site hyperaesthesia		2				2
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		1		1
Vaccination site mass		1				1
Vaccination site movement impairment		1		1		
Vaccination site oedema		5		4		1
Vaccination site pain	1	13		7	1	6
Vaccination site swelling		1				1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	5		2	1	3
Vestibular neuronitis		1				1
Vision blurred		1				1
Vomiting		4				4
Wheezing		1				1
	26	416		100	26	316

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2				2
Abdominal distension	1	2		1	1	1
Abdominal pain		3		1		2
Abdominal pain lower		1				1
Abdominal pain upper		2				2
Abdominal symptom		1				1
Accommodation disorder		1		1		
Allergy to vaccine		1				1
Anaphylactic reaction	2	9			2	9
Anaphylactic shock		2				2
Anxiety		1				1
Aphonia		3		1		2
Apnoea		1				1
Arrhythmia	1	14			1	14
Arthralgia	4	37	1	11	3	26
Arthritis reactive	1	1			1	1
Asthenia	3	31		5	3	26
Asthenopia		1				1
Axillary pain		8		4		4
Back pain	1	12		7	1	5
Blister	1	3		2	1	1
Blood pressure decreased	1	3			1	3
Blood pressure fluctuation		1				1
Blood pressure increased	1	12		1	1	11
Blood pressure systolic decreased		1				1
Body temperature decreased		1				1
Body temperature fluctuation		1				1
Body temperature increased		1				1
Bone pain		2				2
Borrelia infection		1				1
Breast pain		1				1
Breast swelling		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast tenderness		1				1
Burning sensation		3		1		2
Central nervous system inflammation	1	1			1	1
Chest discomfort	1	9		4	1	5
Chest pain		3				3
Chills	1	20		7	1	13
Clumsiness		2		2		
Cognitive disorder		1				1
Cold sweat		2		1		1
Condition aggravated		1				1
Confusional state		2		1		1
Conjunctival hyperaemia	1	1			1	1
Contusion		1		1		
Coordination abnormal	1	1	1	1		
Corneal infection	1	1			1	1
Cough	3	11	1	2	2	9
COVID-19	2	2			2	2
C-reactive protein increased		2		1		1
CSF immunoglobulin increased	1	1			1	1
Deafness unilateral		1				1
Decreased appetite	3	4			3	4
Deep vein thrombosis		1				1
Delusion		1		1		
Demyelination	1	1			1	1
Depressed level of consciousness		1				1
Derealisation		1		1		
Diarrhoea	1	9		3	1	6
Diplopia	1	1	1	1		
Discomfort		4		1		3
Diverticulitis		1				1
Dizziness	5	36	1	13	4	23
Dry eye		1				1

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth		3				3
Dysarthria	2	2	1	1	1	1
Dysgeusia	1	3		1	1	2
Dyskinesia		1		1		
Dyspepsia	1	1			1	1
Dysphagia		1				1
Dysphonia	1	4		1	1	3
Dyspnoea	3	37		5	3	32
Dyspnoea exertional		3				3
Dysstasia		2				2
Dysuria		1		1		
Ear canal erythema		1		1		
Ear discomfort		2		2		
Ear pain		5		5		
Ear pruritus		1		1		
Eczema		1				1
Encephalitis		1				1
Eosinophil count increased		1				1
Epilepsy		1				1
Epistaxis		1		1		
Erythema	1	24	1	8		16
Erythema of eyelid	1	1			1	1
Exercise tolerance decreased	1	2			1	2
Extensive swelling of vaccinated limb		2		2		
Extrasystoles		5		3		2
Eye haematoma		1				1
Eye infection	1	1			1	1
Eyelid irritation		1				1
Eyelid oedema		3				3
Eye movement disorder		1		1		
Eye pain	1	3			1	3
Face oedema		5				5

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial pain		1				1
Facial paralysis	1	4			1	4
Facial paresis		1				1
Fall		3				3
Fatigue	4	53		14	4	39
Fear		1		1		
Feeling abnormal	2	5		1	2	4
Feeling cold	1	9		2	1	7
Feeling hot		12		3		9
Female genital tract fistula		1				1
Flatulence		1		1		
Flushing		6		2		4
Food allergy		2				2
Food aversion		1				1
Gait disturbance		2		1		1
Gait inability		1				1
Gastric disorder		1		1		
General physical health deterioration	1	5		1	1	4
Glossodynia		1				1
Haematochezia		1				1
Haematoma		2		2		
Hallucination, auditory		1				1
Headache	4	68		20	4	48
Head discomfort	1	4			1	4
Head injury		2		1		1
Heart rate decreased		1				1
Heart rate increased	2	13		1	2	12
Helplessness		1		1		
Hemianaesthesia		11				11
Hemiparaesthesia		1				1
Herpes ophthalmic	1	1			1	1
Herpes virus infection		1		1		

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 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Herpes zoster		2		2			
Herpes zoster cutaneous disseminated		1					1
Herpes zoster oticus		1					1
Hot flush		1					1
Hyperacusis	1	1			1		1
Hyperaesthesia		3					3
Hyperhidrosis	1	8		3	1		5
Hypersensitivity		8					8
Hypersomnia		1					1
Hypertension	1	2			1		2
Hypoacusis	1	2		1	1		1
Hypoaesthesia	3	15	2	8	1		7
Hypoaesthesia oral		6		3			3
Hypoaesthesia teeth		1		1			
Hypokalaemia		3					3
Hypothermia		2					2
Impaired work ability	4	12		1	4		11
Inappropriate schedule of product administration	1	1	1	1			
Incorrect route of product administration	1	3	1	3			
Increased upper airway secretion		1					1
Inflammation	1	1			1		1
Influenza	1	1			1		1
Influenza like illness	2	3			2		3
Initial insomnia		1					1
Insomnia	1	5		3	1		2
International normalised ratio decreased	2	2	1	1	1		1
Irritability		2					2
Joint range of motion decreased		1		1			
Keratitis	1	1			1		1
Laryngeal pain		1					1
Limb discomfort	1	2	1	2			
Lip oedema	1	1	1	1			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
	1		1
			1
			1
			1
1	12	3	17
1	2		3
1	10	3	20
			1
			1
	3		3
		2	6
			1
		1	1
			1
			3
			2
			1
	1		1
			3
1	2	2	11
			1
			1
	1	3	5
1	8	5	39
	1		
	2	1	2
			1
	1	1	4
1	13	4	28
			6

Lip pain		1
Lip pruritus		1
Localised oedema		2
Loss of consciousness		1
Loss of personal independence in daily activities		1
Lung disorder		1
Lymphadenopathy	4	29
Lymph node pain	1	5
Malaise	4	30
Meniere's disease		1
Menstrual disorder		1
Middle insomnia		6
Migraine	2	6
Mouth swelling		1
Muscle disorder	1	1
Muscle fatigue		1
Muscle spasms		3
Muscle spasticity		2
Muscle strain		1
Muscle tightness		2
Muscle twitching		4
Muscular weakness	3	13
Musculoskeletal discomfort		1
Musculoskeletal pain		1
Musculoskeletal stiffness	3	6
Myalgia	6	47
Mydriasis		1
Nasal congestion	1	4
Nasal oedema		1
Nasopharyngitis	1	5
Nausea	5	41
Neck pain		6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neuralgia		6		1		5	
Neurological symptom	1	1			1	1	
Neutropenia		1				1	
Nodule	1	2	1	2			
Ocular hyperaemia		2				2	
Oedema peripheral	1	4		1	1	3	
Oral herpes		1		1			
Oral pruritus		3				3	
Oropharyngeal discomfort		2				2	
Oropharyngeal oedema		1				1	
Oropharyngeal pain		8		4		4	
Oxygen saturation decreased		1				1	
Pain	3	18		2	3	16	
Pain in extremity	6	49	4	19	2	30	
Pain of skin		3		1		2	
Pallor		3				3	
Palpitations	2	16		6	2	10	
Papule		1		1			
Paraesthesia	2	20	1	6	1	14	
Paraesthesia oral		10		5		5	
Paranasal sinus discomfort		1				1	
Paraparesis		1				1	
Peak expiratory flow rate decreased		1				1	
Perichondritis		1		1			
Peripheral coldness		1				1	
Pharyngeal hypoaesthesia		2		1		1	
Pharyngeal oedema		1		1			
Pharyngeal paraesthesia		1				1	
Pharyngeal swelling	1	4			1	4	
Photophobia		2				2	
Presyncope		2		1		1	
Pruritus	2	9		3	2	6	

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary pain	1	4		1	1	3
Pyrexia	9	72	1	20	8	52
Rash	2	10	1	3	1	7
Rash erythematous		2		1		1
Rash pruritic		2		2		
Rectal ulcer		1				1
Red blood cell sedimentation rate increased		1				1
Respiratory arrest		1				1
Respiratory rate increased	1	1			1	1
Respiratory tract irritation		1				1
Rhinitis		2				2
Rhinorrhoea		2		1		1
Rinne tuning fork test abnormal		1		1		
SARS-CoV-2 test negative	1	1			1	1
Scab	1	1			1	1
Secretion discharge		1				1
Seizure		2				2
Sensation of foreign body	1	6		1	1	5
Sinus disorder		1				1
Sinus tachycardia		2				2
Skin reaction	1	1	1	1		
Skin sensitisation	1	1			1	1
Skin striae	1	1			1	1
Skin warm	1	1			1	1
Sneezing	1	1			1	1
Somnolence		1				1
Speech disorder	1	2			1	2
Spinal pain		1		1		
Sputum discoloured	1	1			1	1
Stiff tongue		1				1
Stridor		1				1
Suffocation feeling		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling		3
Swelling face		1
Swelling of eyelid		2
Swollen tongue		1
Syncope	1	9
Tachycardia		6
Throat irritation		6
Throat tightness		5
Thrombophlebitis superficial		1
Thrombosis	1	1
Tinnitus		4
Tongue discolouration	1	1
Tongue discomfort	1	2
Tongue disorder		1
Tongue erythema	1	1
Tongue oedema		2
Transient aphasia	1	1
Tremor		7
Trigeminal palsy	1	1
Tympanic membrane hyperaemia		1
Type IV hypersensitivity reaction		1
Urinary tract infection		2
Urticaria	1	17
Vaccination failure	2	2
Vaccination site bruising		1
Vaccination site erythema		19
Vaccination site haematoma		2
Vaccination site hyperaesthesia		2
Vaccination site induration		3
Vaccination site joint movement impairment		1
Vaccination site mass		3
Vaccination site movement impairment		6

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		1
	1		
			2
			1
		1	9
	1		5
	2		4
			5
			1
		1	1
	3		1
		1	1
		1	2
			1
		1	1
			2
		1	1
	1		6
		1	1
	1		
	1		
			2
	4	1	13
		2	2
			1
	13		6
	2		
			2
	3		
	1		
	1		2
	1		5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema		12		11		1
Vaccination site pain	1	35		16	1	19
Vaccination site plaque		1		1		
Vaccination site pruritus		6		4		2
Vaccination site rash		1		1		
Vaccination site reaction	1	3		2	1	1
Vaccination site swelling		5		1		4
Vaccination site warmth		7		5		2
Vaginal infection		1				1
Vertigo		3		1		2
Viral infection		2				2
Vision blurred		2		1		1
Visual impairment	1	1			1	1
Vomiting	3	15	2	5	1	10
Vulvovaginal inflammation		1				1
Weber tuning fork test abnormal		1		1		
Wheezing	1	3			1	3
Wrong technique in product usage process		1		1		
	182	1,467	31	427	151	1040

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain		1		1		
Abdominal pain lower	1	3	1	2		1
Abdominal pain upper		3		1		2
Abdominal symptom		1		1		
Ageusia		1				1
Amnesia		1				1
Anaesthesia		1		1		
Anaphylactic reaction		5				5
Anaphylactic shock		1				1
Arthralgia	2	12		7	2	5
Arthritis		1				1
Asthenia	1	8		4	1	4
Asthenopia		1				1
Atrial fibrillation		1				1
Autoimmune arthritis	1	1			1	1
Axillary pain		2				2
Back pain	1	5	1	3		2
Blepharitis		1				1
Blood pressure decreased		1		1		
Blood pressure diastolic increased		1				1
Blood pressure increased		2				2
Bone pain		1		1		
Burning sensation		3		2		1
Cerebral infarction	1	1			1	1
Chest discomfort		1				1
Chest pain		1		1		
Chills	1	11		6	1	5
Cognitive disorder		2		1		1
Condition aggravated		1				1
Cough		3				3
Crohn's disease		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		1				
Deep vein thrombosis	1	1			1	1
Delusion		1		1		
Diarrhoea		3		3		
Diplopia	1	1	1	1		
Disease recurrence	1	3			1	3
Disturbance in attention		1				1
Dizziness		9		2		7
Dysphagia		3		1		2
Dyspnoea	2	10		2	2	8
Dyspnoea exertional	1	1			1	1
Ear discomfort		1		1		
Ear pain		1				1
Erythema		6		3		3
Erythema multiforme		1				1
Eyelid oedema		1		1		
Eye pain		4		3		1
Face oedema	1	2			1	2
Facial pain		1		1		
Facial paralysis		2				2
Facial paresis		1				1
Fall		1		1		
Fatigue	4	22		10	4	12
Feeding disorder		1				1
Feeling abnormal		5				5
Feeling cold		2		1		1
Feeling hot		5		3		2
Fixed eruption		2		2		
Flushing		2				2
Foaming at mouth		1				1
Gait disturbance		3		1		2
Gingival swelling		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Grip strength decreased		1				1
Groin pain		1				1
Hallucination		1				1
Hallucination, auditory		1				1
Headache	2	29	1	13	1	16
Head discomfort		3		2		1
Heart rate increased		1				1
Hemianaesthesia	1	6			1	6
Hemiparaesthesia		2				2
Hemiparesis	1	1			1	1
Herpes zoster		3		3		
Hot flush		1				1
Hyperhidrosis		1				1
Hypersensitivity	1	3		1	1	2
Hypertension		1				1
Hypoaesthesia	4	8		4	4	4
Hypoaesthesia oral	1	5	1	2		3
Hypotension		1				1
Hypothermia		1				1
Immune thrombocytopenia	1	1			1	1
Impaired reasoning		1				1
Impaired work ability	1	2			1	2
Incorrect route of product administration		6		6		
Insomnia		2				2
Iritis		1				1
Irritability postvaccinal		1		1		
Joint effusion		1				1
Joint range of motion decreased		1		1		
Joint swelling	1	1	1	1		
Limb injury	1	1			1	1
Lip oedema	1	1	1	1		
Lip pain		1		1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
			1
			1
	3		5
			1
	2		5
	1		
			1
			1
		1	1
			1
			1
	1		1
			1
			1
			1
			1
1	3		
	13	4	15
	3	2	8
1	2		1
	1		1
			1
	1		
			1
	1		
	1		
	2		
	1		
	1		
	2		
	1		2
	2		1
		1	4
2	7		7
			1

Lip swelling		2
Loss of consciousness		1
Loss of personal independence in daily activities		1
Lymphadenopathy		8
Lymph node pain		1
Malaise		7
Memory impairment		1
Mental impairment		1
Migraine		1
Migraine with aura	1	1
Mouth swelling		1
Muscle twitching		1
Muscular weakness		1
Musculoskeletal disorder		2
Musculoskeletal pain		1
Musculoskeletal stiffness	1	3
Myalgia	4	28
Nausea	2	11
Neck pain	1	3
Neuralgia		2
Noninfective sialoadenitis		1
Nuchal rigidity		1
Obstruction		1
Ocular discomfort		1
Off label use		1
Oral discomfort		2
Oral mucosal blistering		1
Oropharyngeal discomfort		3
Oropharyngeal pain		3
Pain	1	4
Pain in extremity	2	14
Pallor		1

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	2	7		3	2	4
Paraesthesia oral	1	7	1	4		3
Peak expiratory flow rate decreased		1				1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	1	1			1	1
Photophobia		1		1		
Photopsia	1	2			1	2
Photosensitivity reaction		1				1
Polyarthrits	1	1			1	1
Polymyalgia rheumatica	1	1			1	1
Presyncope		2				2
Product use issue		1		1		
Pruritus		4		4		
Pyrexia	3	27		12	3	15
Rash erythematous	1	3		1	1	2
Rash macular		2		1		1
Rash pruritic	2	2	1	1	1	1
Respiratory rate decreased		1				1
Respiratory tract infection		1				1
Retinal haemorrhage	1	1			1	1
Retinal tear		1				1
Retinal vein thrombosis	1	1			1	1
Rhinorrhoea		1		1		
Salivary gland enlargement		1				1
Seizure	1	1			1	1
Self-injurious ideation		1				1
Sensation of foreign body	1	2			1	2
Sialoadenitis		1				1
Skin warm		1		1		
Snoring		1				1
Somnolence		1		1		
Speech disorder		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sudden hearing loss		1					1
Swelling	1	3		1	1		2
Swelling face		2					2
Synovial fluid white blood cells positive		1					1
Tachycardia	1	2			1		2
Tendon pain	1	1			1		1
Throat irritation		2					2
Tinnitus		1		1			
Tongue discomfort		1		1			
Toothache		1		1			
Transient aphasia		1					1
Tremor		1					1
Trismus	1	1	1	1			
Ulcerative keratitis		1					1
Urticaria		4		2			2
Vaccination site erythema	1	4	1	3			1
Vaccination site haematoma		2		2			
Vaccination site hyperaesthesia		1					1
Vaccination site macule		1		1			
Vaccination site mass		2		1			1
Vaccination site movement impairment		1					1
Vaccination site oedema		1		1			
Vaccination site pain	1	13	1	9			4
Vaccination site swelling		1		1			
Vaccination site warmth		2		1			1
Vision blurred		1					1
Visual impairment	1	4		1	1		3
Vomiting	2	4		2	2		2
	72	518	16	213	56		305

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Alanine aminotransferase increased		1				1
Anaphylactic reaction	1	1			1	1
Anuria	2	2			2	2
Aortitis	1	1			1	1
Apnoea		1				1
Arrhythmia	1	2			1	2
Arthralgia	3	3			3	3
Asthenia	2	2	1	1	1	1
Atrial fibrillation	1	1			1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood pressure decreased	1	2			1	2
Blood pressure increased	4	6			4	6
Cardiac arrest	1	1			1	1
Cardiac failure	1	2			1	2
Cardiac flutter	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebrovascular accident		1				1
Cerebrovascular disorder	1	1			1	1
Chest discomfort	1	2			1	2
Chest pain		1				1
Chest X-ray abnormal	1	1			1	1
Chills	2	2			2	2
Cholelithiasis		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse	1	1			1	1
Cold sweat		1				1
Coma scale abnormal		1				1
Contusion	1	1			1	1
Coronary artery thrombosis	1	1			1	1
Cough	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased		2				2
Cyanosis		1				1
Decreased appetite	2	2			2	2
Deep vein thrombosis		1				1
Dehydration	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea	1	2			1	2
Disease recurrence	1	1			1	1
Dizziness	3	4			3	4
Dysarthria	3	4			3	4
Dysmetria	1	1			1	1
Dyspnoea	4	6			4	6
Ear discomfort	1	1			1	1
Epilepsy		1				1
Erythema	2	2			2	2
Extrasystoles		1				1
Face oedema	1	1			1	1
Facial paralysis		1				1
Fall	1	2			1	2
Fatigue	1	4			1	4
Feeling cold	1	1			1	1
Gastrointestinal necrosis	1	1			1	1
Gastrointestinal viral infection	1	1			1	1
Gaze palsy		1				1
General physical health deterioration	2	3			2	3
Giant cell arteritis	1	1			1	1
Haemodynamic instability	1	1			1	1
Headache	2	3			2	3
Heart rate increased		3				3
Hemiparesis	1	1			1	1
Hemiplegia	1	1			1	1
Herpes zoster	1	1			1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
			1
		2	2
			1
		1	1
			1
		1	2
		1	1
		3	4
		3	4
		1	1
		4	6
		1	1
			1
		2	2
			1
		1	1
			1
		1	2
		1	4
		1	1
		1	1
		1	1
		2	3
		1	1
		1	1
		2	3
			3
		1	1
		1	1
		1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperlactacidaemia	1	1			1	1
Hypersensitivity	1	1			1	1
Hyperventilation		1				1
Hypoaesthesia	1	2			1	2
Hyposmia	1	1	1	1		
Hypotonia	1	2			1	2
Inflammatory marker increased		1				1
Insomnia	1	1			1	1
Intestinal ischaemia	1	1			1	1
Jaundice		1				1
Lethargy	1	1			1	1
Lip oedema	1	1			1	1
Lung disorder	1	1			1	1
Malaise	2	3			2	3
Mesenteric artery thrombosis	1	1			1	1
Middle insomnia	1	1			1	1
Monoparesis		1				1
Movement disorder		1				1
Muscle spasms		1				1
Muscular weakness	2	3			2	3
Myalgia		1				1
Myocardial infarction		1				1
Nausea	3	5		2	3	3
Neck pain	1	2			1	2
Neuritis	1	1			1	1
Neurological symptom		1				1
Oedema peripheral		1				1
Oxygen saturation decreased	1	1			1	1
Pain	1	1			1	1
Pain in extremity	4	5			4	5
Pain of skin		1				1
Pallor		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Paraesthesia	2	3
Paresis	1	1
Pelvic venous thrombosis		1
Pharyngeal oedema	1	1
Platelet disorder	1	1
Pneumonia	1	2
Porphyria	1	1
Productive cough		1
Pulmonary embolism	3	4
Pulmonary haemorrhage	1	1
Pyrexia	2	9
Rales		1
Rash	1	1
Renal failure	1	1
Respiratory arrest		1
Resuscitation	1	1
Retinal vascular thrombosis	1	1
Right ventricular failure	2	2
Seizure		1
Sensory loss		1
Skull fractured base		1
Slow speech		1
Somnolence		1
Spinal pain		1
Sudden death		2
Swollen tongue	1	1
Syncope	1	1
Throat tightness	1	1
Thrombosis	1	2
Thrombotic cerebral infarction	1	1
Tongue oedema	1	1
Transient ischaemic attack		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	3
		1	1
			1
		1	1
		1	1
		1	2
		1	1
			1
		3	4
		1	1
		2	9
			1
		1	1
		1	1
			1
		1	1
		1	1
		2	2
			1
			1
			1
			1
			2
		1	1
		1	1
		1	1
		1	2
		1	1
		1	1
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urine porphobilinogen increased	1	1			1	1
Vaccination site hypoaesthesia		1				1
Vaccination site movement impairment		1				1
Vaccination site pain	1	2			1	2
Venous thrombosis	1	1			1	1
Ventricular fibrillation	1	1			1	1
Vertigo	1	1			1	1
Vomiting	2	6		2	2	4
White blood cell count increased	1	1			1	1
	125	215	2	6	123	209

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	4			1	4
Acute myocardial infarction		1				1
Amaurosis fugax	1	1			1	1
Aphasia	1	2			1	2
Apnoea		1				1
Areflexia		1				1
Arrhythmia	1	2			1	2
Arthralgia	1	4			1	4
Arthritis reactive		1				1
Asthenia	3	5			3	5
Asthma		1				1
Atrial fibrillation	2	3			2	3
Bacterial test positive	2	3			2	3
Balance disorder		1				1
Bedridden		1				1
Blood creatine increased	1	1			1	1
Blood creatinine increased		1				1
Blood glucose decreased	1	1			1	1
Blood glucose increased		1				1
Blood lactic acid decreased		1		1		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic decreased		1				1
Blood pressure increased		1				1
Blood uric acid increased		1				1
Body temperature decreased		1				1
Body temperature increased		1		1		
Breath sounds abnormal		1		1		
Burning sensation	1	1			1	1
Cardiac failure	1	4			1	4
Cardiac hypertrophy	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral infarction	2	7			2	7
Cerebrovascular accident		1				1
Chest discomfort	1	2		1	1	1
Chest pain	1	2			1	2
Chills	1	3			1	3
Circulatory collapse	1	1			1	1
Coma scale abnormal		1				1
Condition aggravated		2				2
Confusional state	1	3		1	1	2
Congestive cardiomyopathy		1				1
Cough		2		1		1
C-reactive protein increased		8		1		7
CREST syndrome		1				1
CSF protein increased		1				1
Cystitis	1	1			1	1
Deafness unilateral	2	2			2	2
Death	1	11			1	11
Decreased appetite	1	2			1	2
Deep vein thrombosis	1	1			1	1
Delirium	1	1			1	1
Dementia Alzheimer's type		4				4
Depressed level of consciousness		4				4
Diarrhoea	2	4		1	2	3
Diverticulitis	1	1			1	1
Dizziness	3	8			3	8
Dysarthria	2	4			2	4
Dysphagia		4		1		3
Dysphonia		1		1		
Dyspnoea	4	19		2	4	17
Eating disorder	1	1	1	1		
Eczema		1				1
Electrocardiogram ST segment depression	1	1			1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram T wave inversion	1	1			1	1
Encephalitis		1				1
Epilepsy		2				2
Epistaxis	1	2			1	2
Erysipelas		2				2
Erythema		1				1
Eye disorder		1				1
Eyelid ptosis		1				1
Face oedema		1				1
Facial paralysis	1	6			1	6
Fall	3	6			3	6
Fatigue	5	21		5	5	16
Feeling abnormal	1	2			1	2
Feeling cold		1				1
Feeling drunk	1	1			1	1
Feeling hot	1	1			1	1
Fibrin D dimer increased	1	1	1	1		
Fluid intake reduced		1				1
Gait disturbance	1	2			1	2
Gaze palsy		1				1
General physical health deterioration	4	18		1	4	17
Haematoma	1	1			1	1
Haematuria	1	1			1	1
Haemoglobin decreased	1	2			1	2
Headache	3	9			3	9
Head discomfort		1				1
Heart rate decreased		1		1		
Heart rate irregular	1	2			1	2
Hemiparesis	1	3			1	3
Hemiplegia	1	1			1	1
Herpes zoster	2	3			2	3
Hip fracture	1	1			1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperhidrosis		1					1
Hypernatraemia		1					1
Hypersensitivity		1					1
Hypertension		4		1			3
Hypoacusis	2	2	2	2			
Hypoaesthesia	1	1			1		1
Hyponatraemia	1	1			1		1
Hypophagia		1					1
Hyporeflexia		1					1
Hypotension	2	2			2		2
Hypotonia		1					1
Incorrect route of product administration		1		1			
Increased tendency to bruise	1	1			1		1
Increased upper airway secretion		2					2
Infection	1	2			1		2
Influenza	1	1	1	1			
Insomnia		2					2
International normalised ratio decreased	1	1			1		1
Intervertebral disc disorder		1		1			
Joint injury	1	1			1		1
Limb injury	1	1			1		1
Lip oedema		1		1			
Loss of consciousness	1	3			1		3
Loss of control of legs		2					2
Lymphadenopathy		1		1			
Lymph node pain		1					1
Macular oedema	1	1			1		1
Malaise	4	8		1	4		7
Memory impairment	1	1			1		1
Migraine		1					1
Mobility decreased	1	2			1		2
Mouth haemorrhage	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscle twitching		1					1
Muscular weakness	2	6		1	2		5
Musculoskeletal stiffness	2	2	1	1	1		1
Myalgia	1	7			1		7
Myocardial infarction		1					1
Nasal pruritus		1		1			
Nasopharyngitis	1	2			1		2
Nausea	3	8	1	2	2		6
Neck pain		1		1			
Neuralgia	1	1	1	1			
Nodule	1	1			1		1
Obstruction		1					1
Oedema peripheral	1	2	1	1			1
Ophthalmic vein thrombosis	1	1			1		1
Opisthotonus		1					1
Oral disorder		1					1
Oropharyngeal pain		2		2			
Osteoarthritis		1		1			
Oxygen saturation decreased		1					1
Pain	2	4			2		4
Painful respiration		1					1
Pain in extremity	2	4			2		4
Peak expiratory flow rate decreased		1					1
Peripheral embolism	1	1			1		1
Peripheral swelling	1	1	1	1			
Petit mal epilepsy	1	1			1		1
Pharyngeal oedema		1					1
Pigmentary glaucoma	1	1			1		1
Pneumonia	1	6			1		6
Pneumonia aspiration		1					1
Poor quality sleep	1	1			1		1
Post procedural haemorrhage	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Productive cough		1					1
Pseudomonal sepsis	1	1			1		1
Pulmonary embolism	4	5			4		5
Pulmonary infarction		1					1
Pulmonary oedema		1					1
Pyelonephritis		2					2
Pyrexia	1	18		2	1		16
Rash		1					1
Rash macular		1					1
Rectal haemorrhage	1	1			1		1
Red blood cells urine	1	1			1		1
Red blood cells urine positive	1	1			1		1
Reduced facial expression	1	1	1	1			
Retinal vascular occlusion	1	1			1		1
Retinal vein thrombosis	1	1			1		1
Rheumatoid arthritis		1					1
Rhonchi		1					1
SARS-CoV-2 test negative	1	1			1		1
Secretion discharge		1		1			
Somnolence	1	1			1		1
Strabismus		1					1
Stress	1	1			1		1
Stupor		1					1
Subcutaneous abscess		1					1
Sudden death		1					1
Suffocation feeling	1	1			1		1
Swelling		2		1			1
Swelling face		1					1
Syncope	2	2			2		2
Tachycardia	1	1			1		1
Throat irritation		1		1			
Thrombosis	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1			1	1
Transient ischaemic attack	1	1			1	1
Tremor	2	4			2	4
Troponin I increased	1	1			1	1
Unresponsive to stimuli		2				2
Urinary retention	1	1			1	1
Urinary tract infection	3	4	1	1	2	3
Urogenital haemorrhage	1	1			1	1
Urticaria	1	1			1	1
Vaccination site erythema		1				1
Vaccination site pain		1				1
Vaccination site reaction		1				1
Venous thrombosis	1	1			1	1
Vertigo		1				1
Visual acuity reduced	1	1			1	1
Visual impairment		1				1
Vomiting	1	8		2	1	6
Weight decreased		1		1		
Wheezing		2		1		1
White blood cell count increased		2				2
White blood cells urine	1	1			1	1
White blood cells urine positive	1	1			1	1
	160	464	12	53	148	411

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Arrhythmia	1	2			1	2
Arthralgia		4		4		
Asthenia		2				2
Atrial fibrillation	1	1			1	1
Balance disorder		1				1
Blood pressure decreased		1				1
Blood pressure increased		1		1		
Cerebral infarction	2	2			2	2
Cheilitis		1		1		
Chest pain		1				1
Chills		3		2		1
COVID-19	1	1			1	1
Death		1				1
Dizziness	1	4			1	4
Drug ineffective	1	1			1	1
Ear pain		1		1		
Epistaxis		1				1
Erythema		1				1
Eye irritation		1		1		
Facial pain		1		1		
Fatigue	1	7		5	1	2
Feeling cold		1				1
Feeling hot		2		1		1
Gait disturbance		1				1
Headache	2	6	1	5	1	1
Head discomfort	1	1	1	1		
Heart rate irregular		1		1		
Hemianaesthesia		1				1
Hemihyperaesthesia		1				1
Hemiparesis	1	1			1	1
Hypoaesthesia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypopnoea		1				1
Increased upper airway secretion		1				1
Lymphadenopathy		2		2		
Malaise	1	3	1	2		1
Maternal exposure during pregnancy		1		1		
Mental impairment	1	1			1	1
Mobility decreased		1		1		
Musculoskeletal stiffness		1		1		
Myalgia		4		4		
Nausea	1	3	1	3		
Off label use	1	2	1	2		
Oral mucosal blistering		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		3		2		1
Pneumonia	1	1			1	1
Poor quality product administered		12		12		
Product preparation error		12		12		
Product quality issue	1	1	1	1		
Pruritus		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia		3		3		
SARS-CoV-2 test negative		1		1		
Tremor		1				1
Vaccination site erythema		2		2		
Vaccination site hyperaesthesia		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		3		3		
Vaccination site pruritus		1		1		
Vaccination site warmth		1		1		
	20	122	6	83	14	39

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FRANCE**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1				1
Asthenia	1	1			1	1
COVID-19		1		1		
C-reactive protein increased		1				1
Dysphonia		1				1
Dyspnoea		1				1
Exposure via breast milk	1	4		3	1	1
Face oedema		1				1
Myalgia		1				1
Nasal congestion		1				1
Pyrexia	1	2			1	2
Respiratory disorder		1				1
Rhinorrhoea		1				1
Vaccination site pain		1				1
	3	18		4	3	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		2		1
Abdominal pain upper		3		1		2
Abortion spontaneous	2	2			2	2
Allergy to vaccine		1				1
Anaphylactic reaction	1	6			1	6
Angioedema		2				2
Anxiety		1				1
Arthralgia	1	4	1	2		2
Asthenia	10	28	5	12	5	16
Asthmatic crisis		1				1
Auditory disorder		1				1
Autoimmune haemolytic anaemia		1				1
Back pain		1				1
Balance disorder		1				1
Blister	1	1			1	1
Blood pressure decreased		3				3
Blood pressure fluctuation	1	1	1	1		
Body temperature increased		1				1
Bone pain		1				1
Cerebral thrombosis	1	1			1	1
Chest discomfort		1				1
Chest pain		2				2
Chills	3	8	2	2	1	6
Coordination abnormal		1		1		
Costovertebral angle tenderness		1				1
Cough		4				4
COVID-19	5	6			5	6
C-reactive protein increased		1				1
Deafness neurosensory		1				1
Decreased appetite		2		1		1
Diabetes mellitus	1	1			1	1
Diabetic ketoacidosis	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Diarrhoea		4		1			3
Discomfort	3	6		1		3	5
Disease recurrence		2		1			1
Disturbance in attention		1		1			
Dizziness	5	13		3		5	10
Drooling		1		1			
Drug ineffective	2	3				2	3
Dysphagia		1		1			
Dyspnoea		4					4
Dyspnoea exertional		1					1
Dysuria		1		1			
Ear pain	1	1				1	1
Epilepsy		1					1
Epistaxis	1	2		1		1	1
Epstein-Barr virus infection		1					1
Erythema		2					2
Eyelid oedema		1					1
Face oedema	1	3				1	3
Facial paralysis	1	2				1	2
Factor II mutation	1	1	1	1			
Faeces soft		1		1			
Fatigue	2	5		1		2	4
Febrile convulsion		1					1
Feeling cold	1	2				1	2
Feeling drunk		1		1			
Fine motor skill dysfunction	1	1	1	1			
Formication		1					1
Gait disturbance		1					1
Gait inability		1					1
Gastrointestinal disorder		2					2
Gastrointestinal pain	1	1	1	1			
Generalised tonic-clonic seizure		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematemesis	1	1			1	1
Haemoglobin decreased	1	1			1	1
Haemorrhagic diathesis	1	1			1	1
Headache	8	28	4	11	4	17
Head injury	1	1			1	1
Hepatocellular injury		1				1
Hot flush		2		1		1
Hyperhidrosis	3	5	1	1	2	4
Hypersensitivity	1	5		2	1	3
Hypertension	2	5	1	1	1	4
Hyperthermia		5		2		3
Hypoaesthesia	2	3			2	3
Hypotension	3	4			3	4
Hypothermia		1				1
Immune thrombocytopenia	1	1			1	1
Impaired work ability		1				1
Incorrect route of product administration		1		1		
Infection		2				2
Influenza		1		1		
Influenza like illness	8	26		3	8	23
Injected limb mobility decreased	1	2			1	2
Insomnia		5		1		4
Intercostal neuralgia		1				1
Ischaemic stroke	1	1			1	1
Laryngeal oedema		1				1
Limb discomfort	1	2			1	2
Lip oedema		1				1
Loss of consciousness		4		1		3
Lymphadenitis		1		1		
Lymphadenopathy	3	6	3	4		2
Lymphopenia		1				1
Malaise	5	20		4	5	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
1	1		
			1
1	1		
	1		1
			2
2	6	2	6
3	17	1	7
	1		1
	3		3
6	19	4	12
	2		2
1	1	1	1
1	3	1	1
	1		1
	1		1
	2		1
1	1		
1	1	1	1
	1		
	1		1
2	7		3
3	8	1	3
	1		1
1	2	1	2
2	9	2	7
	1		
	4		4
	1		
	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	1	1			1	1
Petit mal epilepsy		1				1
Pharyngeal paraesthesia		1				1
Phonophobia		1		1		
Poor quality product administered		1		1		
Posterior reversible encephalopathy syndrome	1	1			1	1
Presyncope		2		1		1
Product temperature excursion issue		1		1		
Product use issue	1	1	1	1		
Protein C increased	1	1			1	1
Pruritus	1	6	1	2		4
Pulmonary embolism	1	2			1	2
Pyrexia	1	18		6	1	12
Rash		2		1		1
Rash erythematous	1	1			1	1
Rash papular	1	1			1	1
Rash pruritic	1	1			1	1
Renal colic	1	1			1	1
Restlessness		1				1
Rhinalgia	1	1			1	1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive	1	1	1	1		
Shock		1				1
Sinus tachycardia		1				1
Skin plaque	1	1	1	1		
Skin reaction		1				1
Somnolence	2	2			2	2
Speech disorder	1	2			1	2
Suffocation feeling		1				1
Supraventricular tachycardia		2				2
Tachyarrhythmia		1				1
Tachycardia	2	11	2	2		9

\* I=Interval, C=Cumulative  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea		1				1
Taste disorder		1		1		
Thirst		1				1
Thrombocytopenia	1	1			1	1
Tonsillitis	1	1			1	1
Transient ischaemic attack	1	1			1	1
Tremor	1	3			1	3
Type 1 diabetes mellitus	1	1			1	1
Type II hypersensitivity		1				1
Urinary incontinence	1	1			1	1
Urticaria		4		1		3
Vaccination complication		2		2		
Vaccination failure	3	3			3	3
Vaccination site discolouration		1				1
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site lymphadenopathy		1				1
Vaccination site oedema		1		1		
Vaccination site pain	7	24	1	6	6	18
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1				1
Vaccination site swelling		1				1
Venous thrombosis limb	1	1			1	1
Vertigo	4	7	2	4	2	3
Vision blurred		1				1
Visual field defect	1	1			1	1
Vomiting	6	14	1	4	5	10
Wheezing	1	2			1	2
White blood cell count decreased	1	1			1	1
	164	554	42	154	122	400

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	2	1	2		
Abdominal pain	4	21	2	6	2	15
Abdominal pain lower	1	1			1	1
Abdominal pain upper	2	5		1	2	4
Abortion spontaneous	4	7			4	7
Acute coronary syndrome	3	3			3	3
Acute febrile neutrophilic dermatosis		1				1
Acute myocardial infarction		1				1
Acute respiratory failure		1				1
Acute vestibular syndrome		2		1		1
Adrenal insufficiency	1	1			1	1
Ageusia	3	3	2	2	1	1
Aggression		1				1
Agitation		1				1
Alanine aminotransferase increased		1		1		
Allergy to vaccine		1				1
Amaurosis		1				1
Amenorrhoea	1	1			1	1
Anaemia		1				1
Anaphylactic reaction	2	7			2	7
Anaphylactic shock	1	3			1	3
Anaphylactoid reaction		2				2
Angina pectoris	1	3			1	3
Angioedema	4	12			4	12
Ankylosing spondylitis		2				2
Anosmia	1	2	1	1		1
Antinuclear antibody positive		1				1
Anxiety	1	5		2	1	3
Anxiety disorder		1		1		
Aphasia		2		1		1
Aphonia		1				1
Aphthous ulcer		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apnoea		1				1
Appendicitis		1				1
Arrhythmia	2	7			2	7
Arterial disorder	1	1			1	1
Arthralgia	8	50	3	20	5	30
Arthritis		2				2
Arthritis reactive		1				1
Aspartate aminotransferase increased		1		1		
Asthenia	24	157	6	49	18	108
Asthma	1	5			1	5
Asthmatic crisis		2				2
Ataxia		1				1
Atrial fibrillation	3	5			3	5
Aura		2				2
Autoimmune hepatitis	1	1			1	1
Autoimmune thyroiditis		1				1
Axillary pain		6		4		2
Back pain	2	7	1	2	1	5
Balance disorder	1	3			1	3
Behaviour disorder		1				1
Blood alkaline phosphatase increased		1		1		
Blood glucose fluctuation		1		1		
Blood glucose increased	1	2	1	1		1
Blood pressure abnormal		1				1
Blood pressure decreased	1	6		1	1	5
Blood pressure increased	1	4	1	2		2
Blood pressure systolic increased		1				1
Blue toe syndrome		1		1		
Body temperature increased		4				4
Bone pain		1				1
Bone swelling		1		1		
Bradycardia	2	4			2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast induration	1	1			1	1
Breast mass	1	1			1	1
Breast pain		2				2
Burning sensation	1	4	1	2		2
Bursitis	1	1			1	1
Cardiac discomfort	1	1			1	1
Cardiac failure	1	1			1	1
Cardio-respiratory arrest	1	2			1	2
Cerebellar infarction		1				1
Cerebral haemorrhage	1	1			1	1
Cerebral ischaemia		1				1
Cerebrovascular accident		1				1
Cervicobrachial syndrome		1		1		
Chest discomfort	3	15		5	3	10
Chest pain	6	28		1	6	27
Chest X-ray abnormal		1				1
Chillblains		1				1
Chills	12	83	4	28	8	55
Choking		1				1
Chromaturia		1				1
Cold sweat	2	3	1	1	1	2
Colitis ulcerative	1	1			1	1
Condition aggravated	3	9			3	9
Confusional state	2	4			2	4
Conjunctival haemorrhage		2				2
Conjunctivitis	1	3		2	1	1
Contraindicated product administered	1	1			1	1
Cough	4	16	2	4	2	12
COVID-19	16	41	4	14	12	27
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased		5		3		2
Cytomegalovirus infection	1	1			1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cytomegalovirus test positive		1				
Deafness unilateral	1	2		1	1	2
Death	1	2			1	2
Decreased appetite	1	12		6	1	6
Deep vein thrombosis	2	3			2	3
Dehydration		1				1
Delirium		1				1
Dermo-hypodermatitis		1				1
Diabetes mellitus inadequate control	2	3			2	3
Diabetic ketoacidosis		1				1
Diarrhoea	3	40	1	12	2	28
Diarrhoea haemorrhagic		1				1
Diplegia		1				1
Diplopia	2	2			2	2
Discomfort	2	10	1	5	1	5
Disease recurrence	3	11		1	3	10
Disorientation	1	1			1	1
Disturbance in attention	1	4		1	1	3
Dizziness	15	50	2	13	13	37
Drug hypersensitivity		1				1
Drug ineffective	5	18			5	18
Dry mouth		2				2
Dysaesthesia	1	3		2	1	1
Dysarthria		2		1		1
Dysgeusia	2	10		2	2	8
Dyskinesia	1	1			1	1
Dyspepsia		3				3
Dysphagia	4	10	3	4	1	6
Dysphonia	1	1			1	1
Dyspnoea	6	32		5	6	27
Dyspnoea exertional	1	3		1	1	2
Dysstasia		2		1		1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysuria		1		1		
Ear infection		1				1
Ear pain	3	9	1	3	2	6
Ear swelling	2	2			2	2
Eating disorder		1		1		
Eczema		1		1		
Electrocardiogram abnormal		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment elevation		1				1
Encephalitis viral		1				1
Enterocolitis haemorrhagic	1	1			1	1
Eosinophilic bronchitis	1	1			1	1
Epilepsy		2				2
Epistaxis	3	4		1	3	3
Epstein-Barr virus test positive		1		1		
Eructation		2				2
Erythema	5	24		8	5	16
Erythema multiforme		2				2
Erythema nodosum	1	2		1	1	1
Euphoric mood		1		1		
Extensive swelling of vaccinated limb	1	7	1	6		1
Extrasystoles		1				1
Eye haemorrhage	1	1			1	1
Eyelid oedema		4		3		1
Eye oedema		1		1		
Eye pain	1	3	1	2		1
Face injury	1	1			1	1
Face oedema	4	8		1	4	7
Facial pain		1				1
Facial paralysis	10	22			10	22
Facial paresis		1		1		
Fall	2	8			2	8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	20	93	3	33	17	60
Fat tissue increased		1		1		
Feeling abnormal	1	3		1	1	2
Feeling cold		3		1		2
Feeling drunk		1				1
Feeling hot	2	10		3	2	7
Feeling of body temperature change		1		1		
Fibrin D dimer increased		1				1
Fibroma		1		1		
Flushing	3	8	1	2	2	6
Focal dyscognitive seizures		1				1
Food craving	1	1			1	1
Formication	1	3		1	1	2
Frostbite		1		1		
Gait disturbance	1	2		1	1	1
Gait inability	2	2			2	2
Gastrointestinal disorder		1		1		
Gastrointestinal motility disorder		1				1
Gastrointestinal pain		1				1
Gastrooesophageal reflux disease		2				2
Generalised anxiety disorder		1				1
General physical health deterioration		1				1
Genital haemorrhage	1	1			1	1
Genital herpes	1	1			1	1
Gingival bleeding	1	1			1	1
Gingivitis		1				1
Glomerulonephritis		1				1
Glossitis	1	1	1	1		
Glossodynia	1	1	1	1		
Gout		1				1
Guillain-Barre syndrome		1				1
Haematemesis	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematoma	1	2		1	1	1
Haemophagocytic lymphohistiocytosis		1				1
Haemorrhagic stroke	1	1			1	1
Haemorrhoids thrombosed		1				1
Hair colour changes		1		1		
Hallucination	1	3			1	3
Hallucination, auditory		1				1
Hallucination, olfactory		1				1
Hallucination, visual		1				1
Headache	47	201	15	64	32	137
Head injury		1				1
Heart rate decreased	1	1	1	1		
Heart rate increased		4		1		3
Heart rate irregular	1	1			1	1
Hemiparaesthesia		2				2
Hemiparesis	2	4			2	4
Hepatic steatosis	1	1	1	1		
Hepatitis viral		1				1
Hepatocellular injury	2	2			2	2
Herpes simplex		1		1		
Herpes zoster	4	14		3	4	11
Herpes zoster reactivation		1		1		
Hormone level abnormal	1	1			1	1
Hot flush	2	14		5	2	9
Hyperacusis	1	1	1	1		
Hyperaesthesia	1	5	1	1		4
Hyperbilirubinaemia		2				2
Hyperglycaemia		1				1
Hyperhidrosis	5	23		5	5	18
Hyperleukocytosis		1				1
Hypersensitivity	2	21		2	2	19
Hypersensitivity vasculitis		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersomnia	1	1			1	1
Hypertension	28	75	4	6	24	69
Hypertensive crisis	7	15			7	15
Hyperthermia	1	13		3	1	10
Hyperthyroidism		1				1
Hyperventilation		2		1		1
Hypoacusis		3				3
Hypoaesthesia	9	18	2	8	7	10
Hypoaesthesia oral	1	4			1	4
Hypoglycaemia	1	5		1	1	4
Hypokalaemia		1				1
Hypokinesia	1	2			1	2
Hypoperfusion		1				1
Hypotension	7	23	1	4	6	19
Hypothermia		4				4
Hypotonia	1	2			1	2
Hypoventilation		1				1
Immune thrombocytopenia	1	2			1	2
Impaired work ability	3	12	1	3	2	9
Inappropriate schedule of product administration		2		1		1
Incorrect route of product administration	1	4		3	1	1
Induration	1	2		1	1	1
Infection	1	1			1	1
Inflammation	1	2	1	1		1
Influenza	5	17	2	3	3	14
Influenza like illness	39	167	4	21	35	146
Injected limb mobility decreased	2	10	1	3	1	7
Injection site erythema		1		1		
Injection site pain		2		2		
Injection site paraesthesia		1		1		
Injection site pruritus	1	3	1	3		
Injection site reaction		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	4	10		3	4	7
Intracranial pressure increased		1				1
Iridocyclitis		1				1
Irritability		1				1
Ischaemic stroke	2	3			2	3
Joint swelling	1	2			1	2
Joint warmth	1	1			1	1
Labile blood pressure		1				1
Lacrimation increased		2		1		1
Lactic acidosis		1				1
Laryngeal discomfort		1				1
Laryngeal oedema	2	5			2	5
Laryngitis		1				1
Larynx irritation		1				1
Left ventricular hypertrophy		1				1
Lichen planus		1				1
Limb discomfort	2	4	1	3	1	1
Lip oedema		3		1		2
Lipoma		1				1
Lip pain		1				1
Lip pruritus		1				1
Lip swelling		3				3
Livedo reticularis		1				1
Localised oedema		2				2
Local reaction	1	1	1	1		
Logorrhoea		1				1
Loss of consciousness	4	14			4	14
Loss of personal independence in daily activities	1	2			1	2
Lung disorder		2				2
Lymphadenitis	2	4	1	2	1	2
Lymphadenopathy	9	54	3	24	6	30
Lymphangitis	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymph node pain	1	3
Lymphoedema		2
Macroglossia	1	2
Malaise	17	70
Maternal exposure during pregnancy		2
Memory impairment	1	3
Meningitis		1
Menorrhagia		1
Metrorrhagia		2
Microembolism		1
Middle insomnia	2	2
Migraine	1	11
Migraine with aura	1	4
Mobility decreased	2	5
Mononeuropathy multiplex	1	1
Morning sickness		1
Motor dysfunction	3	5
Movement disorder		1
Mucosal pain		1
Mucous stools		1
Muscle contractions involuntary		1
Muscle contracture		4
Muscle fatigue		2
Muscle spasms		3
Muscle tightness		1
Muscular weakness	3	10
Musculoskeletal chest pain		2
Musculoskeletal pain	1	2
Musculoskeletal stiffness	9	39
Myalgia	17	107
Myocardial infarction		2
Myocarditis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		2
	2		
		1	2
3	18	14	52
	1		1
		1	3
			1
			1
			2
			1
		2	2
	3	1	8
	3	1	1
1	1	1	4
		1	1
	1		
	1	3	4
			1
	1		
	1		
			1
	1		3
	1		1
	2		1
	1		
	3	3	7
			2
1	2		
4	14	5	25
3	37	14	70
			2
			1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Myoclonus		1					1
Myositis	1	2			1		2
Nasopharyngitis	1	2	1	2			
Nausea	23	108	7	36	16		72
Near death experience	1	1			1		1
Neck injury	1	1			1		1
Neck pain	4	7	1	3	3		4
Nephropathy	1	1			1		1
Nerve injury		1					1
Neuralgia	1	16		5	1		11
Neuritis	1	1			1		1
Neuromuscular pain		1					1
Neuromyopathy		2					2
Neuropathy peripheral	1	2			1		2
Neutropenia		1					1
Neutrophil count decreased		1		1			
Neutrophil count increased		1		1			
Night sweats	1	3	1	2			1
Noninfective chorioretinitis		1					1
N-terminal prohormone brain natriuretic peptide increased		1		1			
Nystagmus		1					1
Ocular discomfort		1		1			
Ocular hyperaemia	1	1			1		1
Odynophagia	1	3	1	2			1
Oedema	1	3		1	1		2
Oedema peripheral		3					3
Off label use		4		4			
Oral dysaesthesia	2	3	1	2	1		1
Oral pain		2		2			
Oral pruritus		2					2
Oropharyngeal discomfort	1	2	1	1			1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal oedema		1				1
Oropharyngeal pain	2	6	2	5		1
Orthostatic hypotension		3				3
Otitis externa		1		1		
Overdose		1		1		
Oxygen saturation decreased		2				2
Pain	7	57	2	17	5	40
Pain in extremity	7	27		5	7	22
Pain in jaw	1	1			1	1
Pain of skin		1				1
Palatal oedema		4				4
Pallor		4				4
Palpitations	8	20	3	10	5	10
Pancreatitis acute	1	3			1	3
Panic attack	1	1			1	1
Paraesthesia	17	60	2	20	15	40
Paraesthesia oral	1	12		4	1	8
Paralysis		1				1
Paresis		1				1
Pelvic pain	1	4			1	4
Periarthritis		1				1
Pericardial effusion		1				1
Pericarditis	2	7			2	7
Peripheral coldness		2				2
Peripheral ischaemia		1				1
Peripheral sensory neuropathy	1	1			1	1
Peripheral swelling	2	5			2	5
Pernio-like erythema		2		2		
Petechiae	1	1			1	1
Pharyngeal paraesthesia		2		1		1
Pharyngitis	1	1	1	1		
Phlebitis	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Phonophobia		1				1
Photophobia		4				4
Photosensitivity reaction		1		1		
Piloerection		1				1
Pneumonia		1				1
Pneumonitis		1		1		
Pneumothorax	1	1			1	1
Polydipsia		2		1		1
Polyneuropathy	1	2			1	2
Polyp	1	1	1	1		
Poor quality product administered		12		12		
Post herpetic neuralgia		1		1		
Presyncope	2	11		1	2	10
Proctitis	1	1	1	1		
Product administered at inappropriate site		1				1
Productive cough		1				1
Product preparation issue		3		3		
Product temperature excursion issue		12		12		
Product use issue		3		3		
Pruritus	3	19		6	3	13
Psychomotor hyperactivity		1				1
Psychomotor skills impaired		2		1		1
Pulmonary embolism	1	5			1	5
Pulmonary pain	1	1			1	1
Purpura	1	2			1	2
Pyrexia	15	135	4	39	11	96
Radial nerve palsy	1	1			1	1
Rash	4	17	1	7	3	10
Rash erythematous		2				2
Rash macular		2				2
Rash maculo-papular	1	3		1	1	2
Rash papular		3		1		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic		1				1
Raynaud's phenomenon	1	2		1	1	1
Rectal haemorrhage		1				1
Red blood cell sedimentation rate increased		2		2		
Renal pain	1	1			1	1
Respiratory depression		2				2
Respiratory disorder		2				2
Respiratory distress		1				1
Respiratory tract infection		1				1
Respiratory tract oedema		1				1
Restlessness	1	1			1	1
Retinal vein occlusion	2	2			2	2
Rhabdomyolysis	1	1			1	1
Rheumatic disorder	1	1			1	1
Rheumatoid arthritis	1	2			1	2
Rhinitis	1	4	1	3		1
Rhinorrhoea		2				2
Rotator cuff syndrome		1				1
Salivary hypersecretion		2		1		1
SARS-CoV-2 antibody test positive		3		3		
SARS-CoV-2 test positive	2	3	1	1	1	2
Scleral disorder	1	1			1	1
Scleritis		1				1
Sedation	1	1	1	1		
Seizure	1	2			1	2
Sensorimotor disorder		1				1
Sensory disturbance		2		1		1
Sensory loss		3		2		1
Shoulder injury related to vaccine administration	1	1			1	1
Sinus pain		1				1
Sinus tachycardia	1	6	1	1		5
Sjogren's syndrome	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Skin discolouration		1					1
Skin induration	1	1			1		1
Skin lesion		1					1
Skin mass		1					1
Skin plaque		2		1			1
Skin reaction	2	3	2	3			
SLE arthritis		1					1
Sleep disorder	3	6	1	2	2		4
Sluggishness		1		1			
Somnolence	1	1			1		1
Speech disorder	1	3			1		3
Stress		3		2			1
Subileus		1					1
Sudden hearing loss	3	3			3		3
Supraventricular extrasystoles	1	1			1		1
Supraventricular tachycardia		1					1
Suspected COVID-19	1	2	1	1			1
Swelling		2		2			
Swelling face		1					1
Swelling of eyelid	1	1			1		1
Swollen tongue		2					2
Syncope	2	12			2		12
Synovial cyst		1					1
Systemic lupus erythematosus		1					1
Tachyarrhythmia		1		1			
Tachycardia	9	55	1	9	8		46
Tachypnoea		1					1
Tendon disorder		1					1
Tendonitis	1	3			1		3
Tetany		1					1
Therapeutic response unexpected	1	1	1	1			
Thermohypoaesthesia		1		1			

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Thirst		1					1
Throat irritation		2		1			1
Throat tightness	2	2			2		2
Thrombocytopenia		1					1
Thrombocytopenic purpura		1					1
Thrombophlebitis superficial	5	6	1	1	4		5
Thrombosis	1	2			1		2
Tinnitus	5	10	1	2	4		8
Tongue discomfort		1					1
Tongue movement disturbance		1					1
Tongue oedema	2	4	1	2	1		2
Tongue paralysis	1	1			1		1
Tonic clonic movements	1	2			1		2
Tonsillitis		1					1
Toxicity to various agents		1					1
Toxic skin eruption		1					1
Transaminases increased		1					1
Transient ischaemic attack	2	2			2		2
Tremor	4	13	1	4	3		9
Trigeminal neuralgia	1	1			1		1
Troponin increased	1	4		1	1		3
Type 1 diabetes mellitus	1	1			1		1
Type I hypersensitivity		2					2
Type III immune complex mediated reaction	1	1			1		1
Ulnar nerve palsy	1	1			1		1
Underdose		2		2			
Urinary incontinence	2	2			2		2
Urticaria	4	20	2	6	2		14
Vaccination complication		1					1
Vaccination failure	11	12			11		12
Vaccination site erythema	3	11	1	7	2		4
Vaccination site exfoliation		1					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site granuloma	1	1			1	1
Vaccination site haematoma	1	2			1	2
Vaccination site hyperaesthesia		1				1
Vaccination site hypersensitivity		3		3		
Vaccination site induration	1	5	1	5		
Vaccination site inflammation	1	4		1	1	3
Vaccination site joint pain		1				1
Vaccination site movement impairment	1	7		2	1	5
Vaccination site nodule		2				2
Vaccination site oedema	1	3		1	1	2
Vaccination site pain	15	117	5	56	10	61
Vaccination site paraesthesia		5		4		1
Vaccination site pruritus	2	6	1	3	1	3
Vaccination site rash	1	2		1	1	1
Vaccination site reaction	2	3			2	3
Vaccination site recall reaction		1		1		
Vaccination site swelling	2	5		2	2	3
Vaccination site warmth	1	4	1	1		3
Vaginal haemorrhage		1				1
Vascular purpura		1		1		
Vascular stenosis	1	1			1	1
Vasculitis		1				1
Venous thrombosis		1				1
Venous thrombosis limb	1	1			1	1
Ventricular arrhythmia	1	1			1	1
Ventricular extrasystoles	1	5	1	1		4
Ventricular tachycardia		1				1
Vertigo	6	26	1	8	5	18
Vertigo positional		1				1
Vestibular disorder		1				1
Vestibular neuronitis		1				1
Vision blurred	3	6			3	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual field defect		1				1
Visual impairment	2	4	1	1	1	3
Vomiting	7	49	1	8	6	41
Weight decreased		2		1		1
White blood cell count decreased		1		1		
	814	3,479	160	973	654	2506

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension		4		1		3
Abdominal pain	7	47	3	20	4	27
Abdominal pain upper	1	12		4	1	8
Abdominal rigidity		2				2
Abnormal sensation in eye	1	1	1	1		
Accommodation disorder		1				1
Acne	1	1	1	1		
Activated partial thromboplastin time prolonged		1				1
Activated partial thromboplastin time shortened	1	1			1	1
Acute coronary syndrome	2	4			2	4
Acute myocardial infarction	1	2			1	2
Acute pulmonary oedema	1	1			1	1
Acute respiratory failure		4				4
Acute sinusitis	1	1	1	1		
Acute vestibular syndrome	1	2			1	2
Adrenal mass	1	1	1	1		
Ageusia	1	5	1	3		2
Agitation	1	1			1	1
Air embolism	1	1			1	1
Alanine aminotransferase increased		3		3		
Alexia		1				1
Allergy to vaccine		1		1		
Altered state of consciousness	1	1			1	1
Amaurosis fugax		1				1
Amnesia		1				1
Anaemia macrocytic	1	1			1	1
Anaesthesia oral		4		2		2
Anaphylactic reaction	3	16			3	16
Anaphylactic shock		2				2
Angina pectoris	1	4			1	4
Angioedema	3	15			3	15

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ankylosing spondylitis	1	3
Anosmia	1	4
Anxiety		1
Aortic arteriosclerosis		1
Aortic dissection		2
Apathy		2
Aphasia	1	3
Aphonia		1
Aphthous ulcer		2
Arrhythmia	5	13
Arrhythmia supraventricular		1
Arthralgia	23	107
Arthritis		1
Arthrodesis	1	1
Aspartate aminotransferase increased		2
Asphyxia		1
Asthenia	34	247
Asthma	2	5
Asthmatic crisis	1	2
Asymptomatic COVID-19	2	3
Ataxia	2	2
Atrial fibrillation	4	17
Atrial flutter	1	2
Atypical pneumonia		1
Autoimmune thyroiditis	1	2
Axillary pain		7
Back pain	5	23
Balance disorder	1	12
Basedow's disease	1	1
Bed rest	1	1
Blastocystis infection		1
Blindness unilateral		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
1	2		2
			1
			1
			2
	1		1
		1	3
			1
	1		1
		5	13
			1
6	40	17	67
			1
1	1		
	2		
			1
17	90	17	157
		2	5
		1	2
	1	2	2
1	1	1	1
		4	17
		1	2
			1
		1	2
	4		3
2	9	3	14
	1	1	11
		1	1
		1	1
			1
			1

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
			1
		1	1
		1	1
1	3		
			1
	1	2	6
			1
1	3		10
	1	1	1
	1		
			1
1	2		1
1	1		
	1		
		2	8
		1	1
		1	1
1	1		1
	1		
		2	1
1	1		
			3
			2
		4	7
			1
	1		
			1
	1		2
1	3	1	3
	1		1
2	4	2	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cardiac fibrillation		1					1
Cardiogenic shock		1					1
Cardio-respiratory arrest	2	6			2		6
Cardiovascular disorder		1					1
Carotid artery occlusion	1	1			1		1
Cataract	1	1			1		1
Cell death	1	1			1		1
Cellulitis		1					1
Cerebral artery stenosis		1					1
Cerebral haematoma	1	1			1		1
Cerebral hyperperfusion syndrome		1					1
Cerebral thrombosis		1					1
Cerebrovascular accident	3	5			3		5
Cervical radiculopathy		1		1			
Chest discomfort	1	22		11	1		11
Chest pain	8	43	2	11	6		32
Chillblains		2		2			
Chills	17	132	7	50	10		82
Choking		1					1
Choking sensation		1		1			
Cholestatic liver injury		1					1
Chondrocalcinosis	1	1			1		1
Chronic obstructive pulmonary disease		2					2
Circulatory collapse		1					1
Clumsiness		1					1
Cognitive disorder		1		1			
Cold sweat	1	3	1	1			2
Colitis		1		1			
Complex regional pain syndrome		1		1			
Condition aggravated	5	18	1	4	4		14
Conduction disorder		1					1
Confusional state	5	7	1	2	4		5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage	2	6			2	6
Conjunctival irritation		1		1		
Conjunctivitis		2				2
Constipation	1	2	1	1		1
Coordination abnormal	1	1			1	1
Coronary artery disease	1	1			1	1
Coronary artery stenosis		2				2
Cough	9	33	5	15	4	18
COVID-19	11	64	3	18	8	46
COVID-19 pneumonia		3				3
C-reactive protein increased	3	10	1	4	2	6
Cutaneous vasculitis		1				1
Cyanosis		1				1
Cystic lymphangioma		1				1
Cystitis	1	1			1	1
Cytomegalovirus infection		1				1
Daydreaming	2	2			2	2
Deafness		4				4
Deafness unilateral		3				3
Death	1	4			1	4
Decreased appetite	4	25	1	9	3	16
Deep vein thrombosis	3	6			3	6
Dehydration		1		1		
Delirium		3				3
Delusion		1		1		
Demyelination		1				1
Depressed level of consciousness	1	3			1	3
Depression		2		1		1
Dermal cyst		1				1
Dermatitis exfoliative generalised		1				1
Diabetes insipidus		1				1
Diabetes mellitus inadequate control	2	3			2	3

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
3	18	6	38
		1	1
1	1	1	3
1	4	1	12
	1	1	16
			1
1	2	3	4
		1	2
1	1		
8	24	6	54
			1
	1		
		1	1
		5	30
1	3		1
	1		1
	1		1
	3	2	5
		1	2
1	8	2	5
		1	1
	2		
			2
	2		
	2		2
1	8	1	6
			3
	4	1	4
3	12	4	44
			2
1	2	3	5
	1		1
		1	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Ear discomfort		1					1
Ear disorder	1	2	1	2			
Ear pain	3	6	2	3	1		3
Ear swelling		1		1			
Eczema		2		1			1
Electrocardiogram repolarisation abnormality		1					1
Electrocardiogram ST segment depression		1					1
Electrocardiogram ST-T segment abnormal		1					1
Electrocardiogram T wave abnormal		1		1			
Emphysema		1					1
Eosinophil count increased		1		1			
Epilepsy	2	4			2		4
Epistaxis	1	5	1	1			4
Epstein-Barr virus infection reactivation		1					1
Erectile dysfunction	1	2			1		2
Eructation		1					1
Erysipelas	2	3			2		3
Erythema	3	32	1	15	2		17
Escherichia test positive	1	1	1	1			
Extensive swelling of vaccinated limb	1	4	1	4			
Extrasystoles	5	8			5		8
Extremity necrosis	1	1			1		1
Eye contusion		1		1			
Eye haemorrhage		1					1
Eye injury	1	1			1		1
Eye irritation		1		1			
Eyelid disorder		2		1			1
Eyelid function disorder		1					1
Eyelid myoclonus	1	1			1		1
Eyelid oedema	1	6		1	1		5
Eyelid ptosis		1					1
Eye movement disorder	1	1	1	1			

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pain	2	5
Eye swelling	1	3
Face oedema	2	10
Facial pain		5
Facial paralysis	12	31
Facial paresis	1	3
Fall	4	13
Familial mediterranean fever		1
Fatigue	32	135
Fear	1	1
Feeling abnormal	3	11
Feeling cold	2	12
Feeling drunk		4
Feeling hot	1	9
Feeling of body temperature change	2	2
Flank pain	1	1
Flushing	1	3
Formication	1	6
Functional gastrointestinal disorder	1	2
Gait disturbance	1	9
Gait inability	3	4
Gamma-glutamyltransferase increased	2	4
Gastric pH decreased	1	1
Gastritis		1
Gastrointestinal disorder		4
Gastrointestinal hypermotility		1
Gastrointestinal inflammation		1
Gastrointestinal motility disorder	1	1
Gastrointestinal pain		2
Gastrooesophageal reflux disease		1
Gaze palsy	1	1
Generalised onset non-motor seizure		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		3
	1	1	2
	1	2	9
	2		3
		12	31
1	2		1
3	4	1	9
			1
14	58	18	77
1	1		
2	6	1	5
1	5	1	7
	2		2
	4	1	5
		2	2
		1	1
	1	1	2
	3	1	3
		1	2
	2	1	7
		3	4
2	4		
1	1		
			1
			4
	1		
			1
1	1		
	2		
	1		
		1	1
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised tonic-clonic seizure	2	2			2	2
General physical health deterioration	2	5			2	5
Genital herpes	1	1			1	1
Gingival discomfort		1				1
Glomerular filtration rate decreased		1				1
Groin pain		1		1		
Gross motor delay		1				1
Guillain-Barre syndrome	1	1			1	1
Haemarthrosis	1	1			1	1
Haematochezia		2				2
Haematoma	2	4			2	4
Haematuria	1	2			1	2
Haemolytic anaemia	1	1			1	1
Haemorrhoids		1				1
Hallucination	1	2			1	2
Hallucination, visual	1	1			1	1
Headache	58	319	20	128	38	191
Head discomfort		4		3		1
Head injury		2				2
Heart rate increased	1	9	1	5		4
Heart rate irregular		1				1
Heart sounds abnormal		1				1
Hemianopia	1	2			1	2
Hemianopia homonymous		1				1
Hemiparaesthesia		1				1
Hemiparesis		1				1
Henoch-Schonlein purpura		1		1		
Hepatic enzyme increased	1	2	1	1		1
Hepatic infarction	1	1			1	1
Hepatitis cholestatic	1	2			1	2
Hepatitis infectious mononucleosis		1				1
Hepatocellular injury	1	5			1	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatomegaly	1	1			1	1
Herpangina	1	1	1	1		
Herpes ophthalmic	1	2			1	2
Herpes pharyngitis	1	1			1	1
Herpes simplex		3		1		2
Herpes zoster	6	25		10	6	15
Hoffmann's sign		1		1		
Horner's syndrome		1				1
Hot flush	1	16		8	1	8
Hyperaesthesia	1	2	1	1		1
Hyperaesthesia eye		1		1		
Hyperhidrosis	6	27	3	8	3	19
Hyperkalaemia	1	1			1	1
Hyperleukocytosis		1				1
Hypersensitivity	4	32	1	16	3	16
Hypersomnia		1		1		
Hypertension	28	141	2	24	26	117
Hypertensive crisis	11	31			11	31
Hypertensive encephalopathy		1				1
Hypertensive urgency		1				1
Hyperthermia	3	14	1	4	2	10
Hyperthyroidism	1	1			1	1
Hypertrophic cardiomyopathy		1				1
Hyperventilation		1		1		
Hypoaesthesia	5	15	3	6	2	9
Hypoaesthesia oral		3		1		2
Hypokalaemia	1	4			1	4
Hypokinesia		3		1		2
Hypotension	6	27	2	6	4	21
Hypotensive crisis		1				1
Hypothermia		3				3
Hypothyroidism	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypotonia		1		1			
Illness		3					3
Immune thrombocytopenia	2	2			2		2
Immunodeficiency	1	1			1		1
Immunoglobulins increased	1	1	1	1			
Impaired work ability	1	8			1		8
Inappropriate schedule of product administration	2	3	2	3			
Incorrect dose administered		1		1			
Incorrect route of product administration	2	6	2	6			
Induration		1					1
Infection	1	2	1	2			
Infectious mononucleosis		1					1
Inflammation	4	8	2	2	2		6
Inflammatory pain	1	2			1		2
Influenza	4	24	1	4	3		20
Influenza like illness	42	204	5	30	37		174
Initial insomnia		1					1
Injected limb mobility decreased	2	13		2	2		11
Injection site pain		1		1			
Injection site rash		1					1
Injection site reaction		1		1			
Inner ear disorder		1					1
Insomnia	3	27		9	3		18
International normalised ratio abnormal		1					1
Intervertebral disc disorder	1	1	1	1			
Intervertebral disc protrusion	1	1	1	1			
Intestinal ischaemia	1	1			1		1
Irritability		1		1			
Ischaemia		1					1
Ischaemic stroke	3	6			3		6
Joint ankylosis		1					1
Joint effusion	1	2		1	1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased	1	2			1	2
Joint stiffness		4		1		3
Joint swelling	4	5	1	2	3	3
Jugular vein thrombosis		1				1
Lacrimation increased	1	4	1	3		1
Lacunar infarction		1				1
Laryngeal discomfort	2	3		1	2	2
Laryngeal dyspnoea		1				1
Laryngeal oedema	1	4			1	4
Laryngitis allergic		1				1
Left ventricular dilatation	1	2	1	2		
Left ventricular hypertrophy		1				1
Leukoencephalopathy		1				1
Leukopenia	3	4	1	1	2	3
Ligament sprain		1				1
Limb discomfort	3	4	1	2	2	2
Lipase increased		2		2		
Lip haematoma	1	1			1	1
Lip haemorrhage	1	1			1	1
Lip oedema	1	5			1	5
Lipoma		1				1
Lip swelling		1				1
Livedo reticularis		1				1
Localised oedema		2		1		1
Local reaction	1	2	1	2		
Loss of consciousness	9	24			9	24
Loss of libido	1	1	1	1		
Lung disorder	1	2	1	1		1
Lung opacity		1				1
Lyme disease		1				1
Lymphadenitis	1	3	1	2		1
Lymphadenopathy	5	48	2	22	3	26

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphangitis	1	1			1	1
Lymph node pain		3		1		2
Lymphocyte count decreased		1				1
Lymphopenia	4	5	2	2	2	3
Macroglossia		1				1
Macule		1		1		
Madarosis		1				1
Malaise	19	103	8	29	11	74
Malnutrition		1		1		
Mean cell volume decreased		1		1		
Medication error		1		1		
Memory impairment	2	4			2	4
Meningeal disorder		1				1
Meningitis aseptic		1				1
Meningoencephalitis herpetic	1	1			1	1
Mental fatigue		1				1
Mental impairment		1				1
Mesenteric vein thrombosis	1	1			1	1
Metamorphopsia		1		1		
Middle insomnia		4		3		1
Migraine	1	13	1	6		7
Migraine with aura		1				1
Mitral valve incompetence		1				1
Mobility decreased	1	5	1	2		3
Monoclonal gammopathy	1	1			1	1
Monoclonal immunoglobulin increased		1				1
Mononucleosis syndrome		1				1
Monoparesis	1	2			1	2
Monoplegia	1	2			1	2
Motor dysfunction	6	7			6	7
Mouth ulceration	1	2	1	2		
Muscle contractions involuntary		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle contracture	1	2
Muscle fatigue	2	2
Muscle rigidity		1
Muscle spasms	2	9
Muscular weakness	6	11
Musculoskeletal chest pain		3
Musculoskeletal disorder		1
Musculoskeletal stiffness	5	35
Myalgia	29	161
Myalgia intercostal		1
Myasthenia gravis	1	1
Mydriasis		1
Myelitis		1
Myocardial infarction		4
Myocardial ischaemia		3
Myocardial necrosis marker increased		1
Myocarditis		3
Myoclonus	1	1
Myokymia		1
Myositis		1
Nasal congestion		2
Nasal herpes		1
Nasopharyngitis		5
Nausea	25	155
Neck pain	3	15
Neoplasm		1
Nerve compression	1	1
Nerve conduction studies abnormal	1	1
Nervousness		1
Nervous system disorder		1
Neuralgia	2	13
Neuritis		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	1	1
1	1	1	1
	1		
1	3	1	6
1	3	5	8
	2		1
	1		
	4	5	31
10	66	19	95
			1
		1	1
			1
			1
			4
			3
			1
			3
		1	1
	1		
	1		
	2		
			1
	3		2
10	56	15	99
2	5	1	10
			1
1	1		
1	1		
			1
			1
	2	2	11
	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neurological symptom		1					1
Neuropathy peripheral	1	1			1		1
Neutropenia	1	2			1		2
Neutrophil count decreased		1					1
Neutrophil count increased	1	1	1	1			
Neutrophilia	1	2	1	2			
Neutrophilic dermatosis		1					1
Nightmare		1		1			
Night sweats		3					3
Nitrite urine present	1	1	1	1			
Nocturia	1	1	1	1			
Noninfective gingivitis		1					1
Normochromic anaemia	1	1			1		1
Normochromic normocytic anaemia	1	1	1	1			
Nystagmus		1					1
Obstructive airways disorder		1		1			
Occipital neuralgia	1	2			1		2
Ocular discomfort	1	4	1	4			
Ocular hyperaemia		3					3
Oedema		3		1			2
Oedema mouth		1					1
Oedema mucosal		1		1			
Oedema peripheral	2	6		1	2		5
Oesophageal pain		1					1
Oesophageal spasm		1					1
Off label use		7		7			
Oliguria		1		1			
Ophthalmic herpes zoster	1	4			1		4
Optic neuritis	1	1			1		1
Oral herpes		1					1
Oral pain		2		2			
Oral pruritus		1		1			

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Age Range

**51 - 64 years**

*Preferred Term*

*Interval Total #  
Spontaneous AE*      *Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	2		
1	5		
			1
		1	2
2	2		
			1
	4		
1	3	3	8
		1	1
5	36	11	40
			1
4	26	8	38
		1	2
	1	1	2
			1
			8
2	9	2	14
		1	1
		2	3
	1		1
2	15	13	44
		1	1
	3	1	3
			1
		1	1
	2		
		1	1
			1
			1
			1
			1
			1
			1
			1
			1
			1
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericarditis		4				4
Periorbital haematoma	1	1			1	1
Peripheral artery thrombosis	2	2			2	2
Peripheral ischaemia	1	1			1	1
Peripheral swelling	3	10	1	3	2	7
Peripheral venous disease	1	1			1	1
Persistent depressive disorder		1				1
Persistent postural-perceptual dizziness	1	1			1	1
Petechiae	1	3		2	1	1
Petit mal epilepsy		3				3
Phaeochromocytoma		1				1
Pharyngeal disorder		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		2				2
Pharyngeal swelling		1		1		
Phlebitis	1	2			1	2
Phlebitis superficial	1	1	1	1		
Photophobia	1	7	1	2		5
Photopsia	1	2		1	1	1
Platelet count decreased	1	1			1	1
Pleural effusion	1	1	1	1		
Pneumonia		4				4
Pneumonia aspiration	1	5			1	5
Pollakiuria	1	1	1	1		
Polyarthrits	1	1			1	1
Polychondritis	1	1			1	1
Polyneuropathy	1	2			1	2
Poor quality product administered		23		23		
Portal vein thrombosis	1	1			1	1
Presyncope	5	16	1	8	4	8
Priapism		1				1
Product administration error		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Productive cough		1		1			
Product preparation error		1		1			
Product preparation issue		6		6			
Product temperature excursion issue		23		23			
Product use issue		6		6			
Proteinuria		1					1
Pruritus		25		12			13
Pseudodementia		1					1
Psoriasis	1	1			1		1
Psoriatic arthropathy		1					1
Psychomotor skills impaired		1		1			
Pulmonary alveolar haemorrhage	1	1			1		1
Pulmonary embolism	7	13			7		13
Pulmonary infarction	1	1			1		1
Pulmonary oedema		2					2
Pulpitis dental		1					1
Pyrexia	39	227	17	88	22		139
Rales		2					2
Rash	3	24	1	13	2		11
Rash erythematous	1	6	1	3			3
Rash macular		2					2
Rash maculo-papular		5		4			1
Rash papular		2		2			
Rash pruritic		4		3			1
Rash pustular	1	1			1		1
Rash vesicular		1		1			
Raynaud's phenomenon		1		1			
Rebound effect		1					1
Rectal haemorrhage		1					1
Red blood cells urine positive		1					1
Renal colic	1	1			1		1
Renal cyst haemorrhage		1					1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Renal failure		1					1
Renal impairment		1					1
Renal infarct	1	1			1		1
Renal pain		1					1
Respiratory disorder	1	4			1		4
Respiratory distress	1	3			1		3
Respiratory failure	1	2			1		2
Respiratory rate increased		1		1			
Restlessness		3		2			1
Retinal artery occlusion	2	3			2		3
Rheumatic fever	1	1			1		1
Rheumatoid arthritis	2	5			2		5
Rhinitis		2		1			1
Rhinorrhoea		6		2			4
Rhonchi		1					1
Road traffic accident		1					1
Rotator cuff syndrome		1		1			
Salivary hypersecretion		2		1			1
SARS-CoV-2 antibody test negative	1	3	1	3			
SARS-CoV-2 antibody test positive		1		1			
SARS-CoV-2 test positive	3	5	1	3	2		2
Sciatica	1	3	1	1			2
Seizure		4					4
Sense of oppression		1					1
Sensorimotor disorder		1					1
Sensory disturbance	2	4	1	1	1		3
Sensory loss	1	1	1	1			
Sepsis	1	1			1		1
Septic shock	1	1			1		1
Sinus arrest		1					1
Sinusitis	1	2			1		2
Sinus tachycardia	3	5		1	3		4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sjogren's syndrome	2	2			2	2
Skin disorder		1		1		
Skin mass		1		1		
Skin plaque		1		1		
Skin reaction		1				1
Skin warm		2		2		
Sleep apnoea syndrome		1		1		
Sleep disorder	1	4	1	1		3
Sleep disorder due to general medical condition, insomnia type		2		1		1
Snoring		1		1		
Somnolence	2	11	1	3	1	8
Speech disorder	1	2			1	2
Spinal osteoarthritis		1		1		
Spinal pain		3				3
Splenic infarction	1	1			1	1
Spondylitis		1				1
Staphylococcal bacteraemia	1	1			1	1
Status epilepticus		1				1
Status migrainosus		1				1
Stomatitis		1				1
Stress cardiomyopathy		1				1
Subarachnoid haemorrhage	1	1			1	1
Subdural haematoma		1				1
Sudden death		2				2
Sudden hearing loss		1				1
Sudden onset of sleep		1				1
Suffocation feeling		5		2		3
Suicidal ideation		1				1
Sunburn		1				1
Supraventricular extrasystoles		2				2
Supraventricular tachycardia		3				3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Suspected COVID-19		1					1
Swelling		1					1
Swelling face		1		1			
Swollen tongue		3		2			1
Syncope		7					7
Synovial cyst		1					1
Tachyarrhythmia		1					1
Tachycardia	14	74	5	24	9		50
Tachypnoea		4					4
Target skin lesion		1					1
Temporal lobe epilepsy	1	1			1		1
Tendon disorder		1					1
Tendonitis		3		2			1
Tendon pain		2		2			
Tenosynovitis		1		1			
Tension		2					2
Tension headache		1					1
Thermal burns of eye		1					1
Thirst		3		2			1
Throat irritation		4		2			2
Throat tightness		2					2
Thrombocytopenia	6	7	1	1	5		6
Thrombocytosis	1	1	1	1			
Thrombophlebitis	4	4	1	1	3		3
Thrombophlebitis superficial	2	2	1	1	1		1
Thrombosed varicose vein	1	1			1		1
Thrombosis	1	3			1		3
Thrombosis mesenteric vessel	1	1			1		1
Thyroid mass		1		1			
Tinnitus	4	25	1	5	3		20
Tongue biting	1	1	1	1			
Tongue coated	1	1			1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tongue oedema		2		1			1
Tonsillar hypertrophy		1		1			
Toothache		1					1
Torticollis		1					1
Toxicity to various agents	1	1			1		1
Transient global amnesia		1					1
Transient ischaemic attack	1	5			1		5
Tremor	1	17		4	1		13
Trismus		1		1			
Underdose		5		5			
Urinary retention		1					1
Urinary tract discomfort	1	1	1	1			
Urine odour abnormal	1	1	1	1			
Urticaria	6	26	1	13	5		13
Urticaria chronic		1					1
Uveitis		1					1
Vaccination complication	1	3		1	1		2
Vaccination failure	10	11			10		11
Vaccination site abscess		1		1			
Vaccination site bruising		1		1			
Vaccination site cellulitis		1					1
Vaccination site coldness		1		1			
Vaccination site discharge		1					1
Vaccination site discomfort		1					1
Vaccination site erythema	1	22	1	12			10
Vaccination site haematoma	1	5	1	4			1
Vaccination site haemorrhage		1					1
Vaccination site hypersensitivity		12		12			
Vaccination site induration	2	7	2	5			2
Vaccination site infection	1	1			1		1
Vaccination site inflammation	1	16	1	9			7
Vaccination site joint movement impairment		1					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site joint pain		1				1	
Vaccination site mass	1	1	1	1			
Vaccination site movement impairment	2	9		5	2	4	
Vaccination site nodule		1		1			
Vaccination site oedema		9		2		7	
Vaccination site pain	28	176	10	94	18	82	
Vaccination site papule		1		1			
Vaccination site paraesthesia		4		1		3	
Vaccination site pruritus	1	13	1	7		6	
Vaccination site rash		1				1	
Vaccination site reaction	1	8	1	5		3	
Vaccination site swelling		11		8		3	
Vaccination site thrombosis		1				1	
Vaccination site urticaria		1		1			
Vaccination site warmth	1	9		5	1	4	
Vagus nerve disorder		1				1	
Vascular purpura	1	3		1	1	2	
Vasodilatation		1		1			
Vena cava thrombosis	1	1			1	1	
Venous thrombosis	1	2			1	2	
Venous thrombosis limb	1	1			1	1	
Ventricular extrasystoles	1	3		1	1	2	
Ventricular fibrillation	2	4			2	4	
Ventricular tachycardia		1				1	
Vertigo	7	50	3	14	4	36	
Vertigo positional	1	6			1	6	
Vestibular disorder	1	3	1	2		1	
Vestibular neuronitis	2	6			2	6	
Viral infection		2		1		1	
Vision blurred	1	6		3	1	3	
Visual acuity reduced		3				3	
Visual impairment		5				5	

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	18	60	6	14	12	46
Von Willebrand's factor activity decreased		1				1
Walking disability		2				2
Weight decreased	4	7	1	1	3	6
Wheezing		1				1
White blood cell count increased		1				1
Withdrawal hypertension		1		1		
	1,108	5,374	324	1797	784	3577

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal distension	1	1	1	1		
Abdominal pain	3	12	1	4	2	8
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	3	7		2	3	5
Acne		1		1		
Acquired haemophilia	1	1			1	1
Activated partial thromboplastin time abnormal	1	1			1	1
Acute abdomen		1				1
Acute coronary syndrome	1	4			1	4
Acute kidney injury	3	7			3	7
Acute myeloid leukaemia		1				1
Acute myocardial infarction		1				1
Acute pulmonary oedema	2	4			2	4
Acute respiratory distress syndrome	3	6			3	6
Acute respiratory failure	1	2			1	2
Acute vestibular syndrome	1	1			1	1
Aggression	1	1			1	1
Agitation	3	5		1	3	4
Alanine aminotransferase increased		1				1
Albuminuria		1				1
Altered state of consciousness	1	2			1	2
Amaurosis fugax		1				1
Amnesia	2	2			2	2
Amyotrophy	1	1			1	1
Anaemia	1	6		2	1	4
Anaphylactic reaction	2	2			2	2
Anaphylactic shock	2	2			2	2
Angina pectoris	1	4			1	4
Angina unstable		1				1
Angioedema	7	15		1	7	14
Anterograde amnesia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anti-neutrophil cytoplasmic antibody positive vasculitis		1					1
Antisynthetase syndrome		1					1
Anxiety	2	7		2	2		5
Aortic valve incompetence	1	1			1		1
Apathy		1		1			
Aphasia	3	7		1	3		6
Aphthous ulcer	1	2		1	1		1
Appendicitis		1					1
Appendicitis perforated	1	1			1		1
Application site warmth		1		1			
Arrhythmia	8	22			8		22
Arrhythmia supraventricular		1					1
Arterial thrombosis	2	2			2		2
Arteriosclerosis	1	1			1		1
Arteriosclerosis coronary artery	1	1			1		1
Arthralgia	9	28	4	12	5		16
Arthritis	3	5	1	2	2		3
Arthritis reactive	3	3			3		3
Arthropathy		1		1			
Aspartate aminotransferase increased		1					1
Asthenia	35	86	10	31	25		55
Asthma	1	2			1		2
Asthmatic crisis	1	3			1		3
Asymptomatic COVID-19	3	4	1	1	2		3
Ataxia	2	3	2	2			1
Atelectasis		1					1
Atrial fibrillation	12	27			12		27
Atrioventricular block	3	4			3		4
Atrioventricular block second degree	1	1			1		1
Autoimmune thyroiditis		1					1
Back pain	3	10	1	4	2		6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bacterial infection		1					1
Bacterial pyelonephritis		1					1
Bacterial sepsis	1	1			1		1
Balance disorder	2	3	1	1	1		2
B-cell lymphoma	1	1			1		1
Behaviour disorder	2	2			2		2
Benign prostatic hyperplasia	1	1	1	1			
Bilirubin conjugated increased		1		1			
Blindness	1	1			1		1
Blister		2					2
Blood alkaline phosphatase increased	1	1	1	1			
Blood bilirubin abnormal	1	1	1	1			
Blood bilirubin increased		1		1			
Blood bilirubin unconjugated increased		1		1			
Blood glucose increased	1	3	1	2			1
Blood lactate dehydrogenase increased	1	1	1	1			
Blood loss anaemia	1	1			1		1
Blood parathyroid hormone increased	1	1	1	1			
Blood pressure decreased		3		2			1
Blood pressure fluctuation	1	1	1	1			
Blood pressure inadequately controlled		1					1
Blood pressure increased		5		2			3
Blood pressure systolic decreased	1	2	1	1			1
Blood pressure systolic increased	1	2			1		2
Blood thyroid stimulating hormone increased	2	2	1	1	1		1
Blood uric acid increased		1		1			
Body temperature increased	1	2			1		2
Bone abscess		1					1
Bone pain	1	1			1		1
Bradycardia	5	13			5		13
Bradyphrenia		1					1
Brain natriuretic peptide increased	1	1			1		1

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Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
			1
1	1		2
2	3	1	1
			1
		4	9
1	1	1	1
		7	12
			1
1	1	1	1
4	13	4	13
2	2	2	2
2	2	2	2
1	1	1	1
1	1	1	1
1	1		2
2	2	2	2
3	5	3	5
11	15	11	15
1	1	1	1
1	2	1	1
7	13	4	7
11	26	9	23
10	31	8	16
1	3	1	3
	1		
1	5	1	5
2	2	2	2
1	1	1	1
1	1	1	1

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cluster headache	1	1			1	1
Cold sweat	1	3	1	3		
Coma	2	5			2	5
Condition aggravated	9	16	1	1	8	15
Confusional state	3	7			3	7
Congestive cardiomyopathy		1				1
Conjunctival haemorrhage	2	6			2	6
Conjunctival hyperaemia	1	1	1	1		
Conjunctivitis		1				1
Constipation	2	3	2	3		
Coronary artery disease		1				1
Coronary artery occlusion	1	1			1	1
Coronavirus infection		1		1		
Cough	6	17	2	6	4	11
COVID-19	18	52	3	7	15	45
COVID-19 pneumonia	4	7			4	7
C-reactive protein increased	8	14	3	7	5	7
Crohn's disease	1	1			1	1
Cutaneous lupus erythematosus	1	1			1	1
Cyanosis		2				2
Deafness	1	2			1	2
Deafness unilateral	2	5			2	5
Death	6	21			6	21
Decreased appetite	7	14	4	6	3	8
Decreased interest		1				1
Decubitus ulcer	2	3	1	1	1	2
Deep vein thrombosis	14	14			14	14
Defect conduction intraventricular	1	1			1	1
Dehydration	2	4	1	1	1	3
Delirium		2				2
Depressed level of consciousness		2				2
Dermabrasion		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis bullous	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Dermatomyositis	1	2			1	2
Dermo-hypodermitis	2	3			2	3
Diabetes mellitus	1	3			1	3
Diabetes mellitus inadequate control	3	4			3	4
Diabetic ketosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	8	32	2	13	6	19
Diplopia	2	7			2	7
Discomfort	5	10	1	1	4	9
Disease recurrence	9	19			9	19
Disorientation	2	4	1	1	1	3
Disseminated intravascular coagulation	1	1			1	1
Diverticulitis	1	2			1	2
Dizziness	7	25	2	9	5	16
Dizziness postural		2				2
Drop attacks		1				1
Drug eruption	1	1	1	1		
Drug ineffective	7	22			7	22
Drug interaction	1	1	1	1		
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry mouth	2	2	1	1	1	1
Dysaesthesia	1	2	1	1		1
Dysarthria	4	6	1	1	3	5
Dysgeusia	1	2		1	1	1
Dysgraphia	1	1			1	1
Dyskinesia		1				1
Dyslipidaemia		1		1		
Dysmetria	1	1			1	1
Dyspepsia		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	1	1	1	1		
Dyspnoea	8	29	2	6	6	23
Dyspnoea at rest	1	3			1	3
Dyspnoea exertional	3	8			3	8
Dysstasia		3				3
Ear haemorrhage	1	1	1	1		
Ear pain	2	3	1	1	1	2
Eczema		1				1
Electric shock		1				1
Electrocardiogram QRS complex prolonged	1	1			1	1
Electrocardiogram T wave inversion		1				1
Electroencephalogram abnormal		1				1
Embolic stroke	1	1			1	1
Encephalitis	1	1			1	1
Enlarged uvula		1				1
Enterococcal infection		1				1
Eosinophilia	2	4			2	4
Epilepsy	1	6			1	6
Epistaxis	3	6	1	4	2	2
Erectile dysfunction		1				1
Eructation		1				1
Erysipelas	1	3			1	3
Erythema	9	21	2	10	7	11
Erythema nodosum	1	1			1	1
Erythema of eyelid		1				1
Escherichia urinary tract infection	1	2			1	2
Extrapyramidal disorder	1	1	1	1		
Extrasystoles	2	6	2	3		3
Eye haemorrhage		3				3
Eye irritation	1	2		1	1	1
Eyelid haematoma		1		1		
Eyelid oedema	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Eyelid ptosis		1		1			
Face injury	1	1		1		1	
Face oedema	1	6			1	6	
Facial asymmetry	1	1			1	1	
Facial pain		1				1	
Facial paralysis	15	28			15	28	
Facial paresis		1				1	
Faeces discoloured		2		2			
Faeces soft		1		1			
Fall	9	16	1	2	8	14	
Fatigue	23	65	13	40	10	25	
Fear of death		1				1	
Feeling abnormal		3		1		2	
Feeling cold	1	4		2	1	2	
Feeling drunk	2	3			2	3	
Feeling hot	2	5		1	2	4	
Feeling of body temperature change		1		1			
Femur fracture		1				1	
Fibrin D dimer increased	2	3			2	3	
Flatulence	2	2	1	1	1	1	
Flushing	1	2		1	1	1	
Focal dyscognitive seizures	1	1			1	1	
Food aversion	1	1			1	1	
Gait disturbance	3	5	3	4		1	
Gait inability		1		1			
Gamma-glutamyltransferase increased	2	4	2	3		1	
Gastroenteritis		1				1	
Gastrointestinal disorder	1	1	1	1			
Gastrointestinal haemorrhage	1	2			1	2	
Gastrointestinal motility disorder		1		1			
Gastrointestinal pain	1	1			1	1	
Gastrointestinal sounds abnormal		1		1			

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal wall thickening	1	1	1	1		
Gastroesophageal reflux disease		1		1		
Gaze palsy		1				1
Generalised tonic-clonic seizure	2	4			2	4
General physical health deterioration	6	9		1	6	8
Giant cell arteritis	3	3			3	3
Glycosylated haemoglobin increased		1		1		
Gout	1	1	1	1		
Guillain-Barre syndrome	1	2			1	2
Haematemesis		1				1
Haematochezia		1				1
Haematoma	2	3		1	2	2
Haematoma muscle	1	1			1	1
Haematuria		1				1
Haemodynamic instability	1	1	1	1		
Haemoglobin decreased	2	2	2	2		
Haemophagocytic lymphohistiocytosis	1	1			1	1
Haemoptysis	1	2			1	2
Haemorrhage		1				1
Haemorrhagic stroke	2	2			2	2
Haemothorax		1				1
Hallucination	1	1			1	1
Hallucination, auditory		1				1
Headache	25	76	4	22	21	54
Head discomfort		1		1		
Head injury	1	4			1	4
Heart rate decreased		1		1		
Heart rate increased		2				2
Heart rate irregular		1				1
Heart sounds abnormal		1				1
Hemianaesthesia		1				1
Hemianopia homonymous	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiapraxia	1	1			1	1
Hemiparesis	1	4			1	4
Hemiplegia	2	3			2	3
Hepatic cyst	1	1			1	1
Hepatic cyst infection		1				1
Hepatic enzyme increased		1				1
Hepatic haematoma		1				1
Hepatic pain		1		1		
Hepatitis		1				1
Hepatitis acute	1	1			1	1
Hepatitis B	1	1			1	1
Hepatocellular injury	1	5			1	5
Hepatojugular reflux	1	1	1	1		
Hepatomegaly		1				1
Herpes virus infection	1	1	1	1		
Herpes zoster	15	31	1	11	14	20
Herpes zoster meningoencephalitis	2	2			2	2
Hot flush	2	7	2	4		3
Hyperaesthesia		2		2		
Hyperbilirubinaemia	2	2			2	2
Hyperchloraemia	1	1			1	1
Hyperglycaemia	3	7	1	2	2	5
Hyperglycinaemia		1				1
Hyperhidrosis		13		6		7
Hyperkalaemia	2	2			2	2
Hyperleukocytosis	1	3			1	3
Hypernatraemia	2	2	1	1	1	1
Hypersensitivity	3	9		2	3	7
Hypersomnia	1	1	1	1		
Hypertension	44	109	2	8	42	101
Hypertensive crisis	17	48			17	48
Hyperthermia	2	7	1	3	1	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthyroidism		2				2
Hypertrophic cardiomyopathy	1	1			1	1
Hypervitaminosis B12		1				1
Hypoacusis	3	5		2	3	3
Hypoaesthesia	3	3	3	3		
Hypocalcaemia		1				1
Hypogammaglobulinaemia	1	1			1	1
Hypoglycaemia	1	2			1	2
Hypokalaemia		1				1
Hyponatraemia	1	1	1	1		
Hypophagia		1		1		
Hypotension	10	25	2	4	8	21
Hypothermia	1	3			1	3
Hypotonia	1	2			1	2
Hypovolaemic shock	1	1			1	1
Hypoxia	1	9			1	9
Illrd nerve paralysis		1				1
Illusion	1	1			1	1
Immune thrombocytopenia	1	2			1	2
Impaired driving ability	1	1			1	1
Inappropriate schedule of product administration	2	2	2	2		
Incoherent	1	1			1	1
Incorrect route of product administration		1		1		
Increased bronchial secretion		1				1
Infarction	1	1			1	1
Inflammation	5	7	2	3	3	4
Influenza	3	7	2	3	1	4
Influenza like illness	13	36	7	15	6	21
Injected limb mobility decreased	2	4		2	2	2
Injection site erythema		2		2		
Injection site pain		2		2		
Injection site swelling		1		1		

\* I=Interval, C=Cumulative  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Inner ear disorder		1		1			
Insomnia	8	14	4	9	4	5	
International normalised ratio increased	1	2			1	2	
Interstitial lung disease	1	1			1	1	
Intestinal ischaemia	2	2			2	2	
Intestinal obstruction		1				1	
Intracardiac thrombus		1				1	
Ischaemic stroke	15	27			15	27	
Jaundice		1				1	
Joint effusion		2		1		1	
Joint stiffness	1	1			1	1	
Joint swelling		1		1			
Jugular vein thrombosis	1	1			1	1	
Klebsiella infection		1				1	
Language disorder	1	2			1	2	
Laryngeal dyspnoea		1				1	
Laryngeal oedema	1	1			1	1	
Laryngitis		1				1	
Leukocytosis		2		1		1	
Leukocyturia	1	1	1	1			
Leukoencephalopathy	2	3			2	3	
Leukopenia	1	1			1	1	
Limb discomfort		1		1			
Lip erosion		1				1	
Lip oedema		2				2	
Lip pain	1	1			1	1	
Lip swelling		2		1		1	
Lithiasis		1		1			
Livedo reticularis	1	3		1	1	2	
Liver function test increased	1	1			1	1	
Liver injury		1				1	
Loss of consciousness	11	25			11	25	

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Low density lipoprotein increased		1				1
Lung disorder	4	6	2	2	2	4
Lymphadenopathy	5	10	1	5	4	5
Lymphadenopathy mediastinal	1	1	1	1		
Lymphoedema	2	2	1	1	1	1
Lymphopenia	3	5	1	1	2	4
Malaise	19	61	9	21	10	40
Malignant hypertension		1				1
Malnutrition		1				1
Meningorrhagia	1	1			1	1
Metamorphopsia	1	1			1	1
Middle insomnia	2	2			2	2
Migraine	2	2			2	2
Migraine with aura		1				1
Mobility decreased	2	2			2	2
Monoclonal gammopathy	1	1			1	1
Monoparesis		3		1		2
Monoplegia		1				1
Moraxella infection		1				1
Motor dysfunction	1	3			1	3
Mouth haemorrhage		1		1		
Multiple organ dysfunction syndrome	2	3			2	3
Muscle fatigue		1		1		
Muscle rigidity		1		1		
Muscle spasms		3		1		2
Muscular weakness	6	7	4	4	2	3
Musculoskeletal disorder		1				1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	6		3	1	3
Mutism		1				1
Myalgia	8	34	2	13	6	21
Myasthenia gravis crisis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myelodysplastic syndrome	1	1
Myocardial infarction	3	6
Myocardial necrosis marker increased		1
Myoclonus		2
Nasopharyngitis	1	2
Nausea	16	46
Near death experience		1
Neck pain	2	4
Needle issue		1
Nephrotic syndrome	1	1
Nervous system disorder	1	3
Neuralgia	5	6
Neuralgic amyotrophy	1	1
Neurological decompensation		1
Neuromuscular pain		1
Neuropathy peripheral	1	1
Neutropenia	3	4
Nightmare	1	1
Night sweats	1	1
Normal pressure hydrocephalus	1	1
N-terminal prohormone brain natriuretic peptide increased	1	1
Obstruction gastric		1
Ocular myasthenia		1
Odynophagia	1	1
Oedema		2
Oedema genital	1	1
Oedema peripheral	7	13
Off label use	1	3
Ophthalmic herpes zoster	5	6
Optic ischaemic neuropathy	1	2
Oropharyngeal pain	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		3	6
			1
			2
1	2		
4	22	12	24
			1
2	3		1
	1		
		1	1
		1	3
2	2	3	4
		1	1
			1
	1		
		1	1
		3	4
		1	1
1	1		
		1	1
		1	1
		1	1
3	4	4	9
1	3		
		5	6
		1	2
	2	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Orthopnoea		1				1
Osteoarthritis	1	2	1	1		1
Overdose	1	3	1	3		
Oxygen saturation decreased	5	18		2	5	16
Pain	5	23	2	10	3	13
Pain in extremity	5	18	2	11	3	7
Pain in jaw	2	3			2	3
Pallor	2	5		1	2	4
Palpitations	3	14		4	3	10
Pancreatitis acute	1	1			1	1
Paraesthesia	6	14	2	4	4	10
Paraesthesia oral	1	2		1	1	1
Paralysis	1	2			1	2
Paresis		1				1
Parkinsonism		1				1
Partial seizures		2				2
Pemphigoid	2	3			2	3
Pericardial effusion	4	5			4	5
Pericarditis	6	7			6	7
Periorbital oedema		1				1
Periorbital pain		1				1
Peripheral coldness		2		2		
Peripheral embolism	1	1			1	1
Peripheral ischaemia	3	4			3	4
Peripheral swelling	2	4	1	2	1	2
Peripheral venous disease	1	1	1	1		
Persecutory delusion	1	1			1	1
Petechiae	1	1	1	1		
Phlebitis	2	3	1	2	1	1
Phlebitis superficial	1	1	1	1		
Photophobia		1				1
Photopsia		2				2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count increased		1				1
Pleural effusion	2	2	1	1	1	1
Pleurisy	1	1			1	1
Pneumonia	5	6			5	6
Pneumonia aspiration	1	7			1	7
Pneumonia bacterial	2	3			2	3
Pneumonia moraxella		1				1
Pneumonia pneumococcal		1				1
Pneumothorax	1	1			1	1
Pollakiuria		1		1		
Polyarthritits	1	1			1	1
Polymyalgia rheumatica	1	1			1	1
Poor quality product administered		28		28		
Presyncope	1	4	1	1		3
Productive cough	1	2		1	1	1
Product preparation error	1	1	1	1		
Product preparation issue	1	3	1	3		
Product temperature excursion issue		26		26		
Product use issue		2		2		
Prostatitis	2	3	1	1	1	2
Proteinuria		1				1
Prothrombin level abnormal	1	1			1	1
Pruritus	6	18	1	4	5	14
Psychomotor retardation		1				1
Pulmonary congestion		1				1
Pulmonary embolism	31	44			31	44
Pulmonary hypertension	1	1			1	1
Pulmonary oedema	1	3			1	3
Purpura	3	3	1	1	2	2
Pyelonephritis	1	1			1	1
Pyrexia	23	98	7	38	16	60
Quadripareisis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rales	2	2			2	2
Rash	3	9			3	9
Rash erythematous	1	4		1	1	3
Rash macular	1	1			1	1
Rash maculo-papular	2	4		1	2	3
Rash papular		1				1
Rash pruritic	4	4	1	1	3	3
Rectal haemorrhage	1	2			1	2
Renal failure	2	3			2	3
Respiratory alkalosis		2				2
Respiratory arrest		1				1
Respiratory disorder		1				1
Respiratory distress	3	8			3	8
Respiratory failure	1	4			1	4
Respiratory tract infection		1				1
Restlessness		1				1
Retinal fovea disorder	1	1			1	1
Retinal vein occlusion	1	1			1	1
Retrograde amnesia	1	1			1	1
Rhabdomyolysis	2	3			2	3
Rheumatoid arthritis	1	4			1	4
Rheumatoid factor increased	1	1			1	1
Rhinitis		2		2		
Rhinorrhoea		2		1		1
Rhonchi		1				1
Rib fracture	1	2			1	2
Road traffic accident	2	4	1	1	1	3
Romberg test positive		1		1		
SARS-CoV-2 antibody test negative	1	4	1	4		
SARS-CoV-2 test false positive	1	1	1	1		
SARS-CoV-2 test positive	3	4			3	4
Seizure	2	13			2	13

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sense of oppression	1	1			1	1
Sensorimotor disorder		1				1
Sensory loss	2	4		1	2	3
Sepsis	3	5			3	5
Septic shock		3				3
Serum ferritin increased		1		1		
Serum sickness	1	1			1	1
Shock haemorrhagic	2	2			2	2
Sinus disorder		1				1
Sinusitis		1				1
Sinus tachycardia	3	5	1	2	2	3
Skin discolouration		1		1		
Skin exfoliation		1				1
Skin fissures		1				1
Skin hyperpigmentation	1	1			1	1
Skin lesion	1	4		1	1	3
Sleep disorder		2		1		1
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		
Somnolence	3	8	1	6	2	2
Speech disorder		3		1		2
Spinal cord infarction	1	1			1	1
Spinal cord ischaemia	1	1			1	1
Spinal pain	1	1	1	1		
Staphylococcal bacteraemia	1	2			1	2
Staphylococcal sepsis	1	1			1	1
Staring		1				1
Status epilepticus	2	4			2	4
Stereotypy		1				1
Sternal fracture	1	1			1	1
Stertor		1				1
Stress		2		2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stress cardiomyopathy	1	2			1	2
Subarachnoid haemorrhage	2	2			2	2
Sudden death	7	18			7	18
Sudden hearing loss	2	2			2	2
Sudden onset of sleep	1	1			1	1
Superinfection	1	1			1	1
Supraventricular extrasystoles		2				2
Supraventricular tachycardia	2	3			2	3
Suspected COVID-19		1				1
Swelling face	1	3		1	1	2
Syncope	3	9			3	9
Tachyarrhythmia	1	1			1	1
Tachycardia	13	44	3	13	10	31
Tachycardia paroxysmal	1	1			1	1
Tachypnoea	2	4			2	4
Tenderness		1		1		
Tendonitis		2				2
Terminal state		1				1
Testicular pain	1	1	1	1		
Thirst	2	2	1	1	1	1
Throat irritation	2	3	1	2	1	1
Thrombocytopenia	6	9			6	9
Thrombophlebitis	5	5			5	5
Thrombophlebitis superficial	2	2	1	1	1	1
Thrombosis	2	2			2	2
Tinnitus	3	7	1	2	2	5
Tongue biting	1	1			1	1
Tongue haematoma		2		2		
Tonic clonic movements		4				4
Tonic convulsion	1	2			1	2
Torticollis	1	1	1	1		
Toxic skin eruption	1	1			1	1

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Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
		4	8
1	5	5	12
			1
1	2	2	4
			1
		1	1
1	5		
			1
		1	2
		1	1
		1	1
	4	1	9
			1
		16	19
			1
	1		
1	1	1	1
4	9		2
			1
	2		
			1
3	4	2	2
1		1	4
			1
1	1		1
			1
2	3		1
9	24	6	15
			1
1	3		3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	1	4		3	1	1
Vaccination site swelling	2	4	1	2	1	2
Vaccination site urticaria		2		1		1
Vaccination site warmth	1	5		3	1	2
Varicella virus test positive	1	1			1	1
Varicose vein	1	1	1	1		
Vascular encephalopathy		1				1
Vascular purpura		1				1
Vasculitis		1		1		
Vein rupture		1				1
Venous thrombosis limb	2	2			2	2
Ventricular extrasystoles		2				2
Ventricular fibrillation		1				1
Ventricular hypokinesia	1	1			1	1
Ventricular tachycardia	1	4			1	4
Vertigo	9	25	4	7	5	18
Vertigo positional	1	3			1	3
Viral infection		1		1		
Vision blurred	2	2			2	2
Visual acuity reduced	1	1			1	1
Visual field defect	1	1			1	1
Visual impairment	1	5		1	1	4
Vitamin D deficiency		1				1
Vlth nerve paralysis		1				1
Vomiting	9	27	1	8	8	19
Weight increased	1	2	1	1		1
Wheezing		1				1
White blood cell count decreased	1	1			1	1
White blood cell count increased	1	2		1	1	1
Withdrawal hypertension		1				1
Wrong technique in product usage process		1		1		
Yellow skin		1		1		

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Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
255	828	1013	2285

1,268

3,113

255

828

1013

2285

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal mass	1	1	1	1		
Abdominal pain	3	11	1	4	2	7
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	3	7		2	3	5
Abnormal behaviour	2	3	2	2		1
Abnormal faeces		1		1		
Accidental overdose		1		1		
Acidosis hyperchloraemic		1				1
Acquired haemophilia	1	1			1	1
Acute coronary syndrome	3	9			3	9
Acute kidney injury	4	16			4	16
Acute myeloid leukaemia	1	1			1	1
Acute myocardial infarction	1	1			1	1
Acute pulmonary oedema	3	18			3	18
Acute respiratory distress syndrome	2	11			2	11
Acute respiratory failure	1	9			1	9
Acute vestibular syndrome		1				1
Adrenocortical insufficiency acute		1				1
Adult failure to thrive		1				1
Adverse event	1	1	1	1		
Aerococcus urinae infection		1				1
Aerophagia	1	1			1	1
Affective disorder	1	1	1	1		
Age-related macular degeneration	1	1			1	1
Ageusia	1	2	1	2		
Aggression	3	4	1	1	2	3
Agitation	2	12	1	5	1	7
Agnosia	1	1			1	1
Agranulocytosis	1	2			1	2
Allergy to vaccine		2		1		1
Altered state of consciousness	1	11			1	11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amaurosis	1	1			1	1
Amnesia	2	4	1	1	1	3
Amnesic disorder		2				2
Anaemia	3	5			3	5
Anaesthesia		1				1
Anaphylactic reaction	2	8			2	8
Anaphylactic shock	1	6			1	6
Aneurysm ruptured		1				1
Angina pectoris	1	2			1	2
Angina unstable	1	1			1	1
Angioedema	7	15			7	15
Anticoagulation drug level below therapeutic	2	2	1	1	1	1
Anuria		2				2
Anxiety	2	7	1	3	1	4
Aortic bruit		1		1		
Aortic stenosis	1	1			1	1
Aortic valve calcification	1	1			1	1
Aortic valve incompetence	2	3			2	3
Apathy	3	4	2	2	1	2
Aphasia	3	13	1	4	2	9
Aplasia		1				1
Aplastic anaemia	1	1			1	1
Apnoea		1				1
Arrhythmia	9	26			9	26
Arrhythmia supraventricular	1	3			1	3
Arteriosclerosis		1				1
Arteriovenous fistula thrombosis		1				1
Arthralgia	2	12		4	2	8
Arthritis		1				1
Aspartate aminotransferase increased		1		1		
Aspiration	2	4			2	4
Asthenia	40	138	10	38	30	100

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	1	1			1	1
Asymptomatic COVID-19	13	15	1	1	12	14
Ataxia	4	4	2	2	2	2
Atrial fibrillation	27	56			27	56
Atrial flutter	2	4	1	1	1	3
Atrial thrombosis	1	1			1	1
Atrioventricular block		3		1		2
Atrioventricular block complete		3				3
Axillary pain		1		1		
Axillary vein thrombosis	1	1	1	1		
Back pain	4	7	2	3	2	4
Bacterial sepsis	1	1			1	1
Bacterial test positive	1	2		1	1	1
Balance disorder	1	5	1	2		3
Bedridden		1		1		
Behaviour disorder	3	7		1	3	6
Benign breast neoplasm		1		1		
Benign prostatic hyperplasia	1	1			1	1
Beta 2 microglobulin increased		1		1		
Bipolar disorder		1				1
Bladder dilatation	1	1			1	1
Blindness	1	1			1	1
Blindness transient	1	1			1	1
Blindness unilateral	2	3			2	3
Blood albumin decreased	1	1	1	1		
Blood alkaline phosphatase increased		1		1		
Blood bicarbonate decreased		1				1
Blood calcium decreased	1	1	1	1		
Blood creatine phosphokinase increased		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	1	2	1	2		
Blood lactate dehydrogenase increased		1		1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood potassium increased	1	1	1	1		
Blood pressure abnormal	1	1	1	1		
Blood pressure decreased	1	3			1	3
Blood pressure diastolic decreased	1	3		2	1	1
Blood pressure fluctuation	1	3		1	1	2
Blood pressure increased	1	7			1	7
Blood pressure systolic decreased		1		1		
Blood pressure systolic increased	2	4	1	1	1	3
Blood sodium decreased	1	1	1	1		
Blood sodium increased	1	3		1	1	2
Blood thyroid stimulating hormone decreased	1	1	1	1		
Blood thyroid stimulating hormone increased		1		1		
Body temperature decreased		2		1		1
Body temperature increased	1	1			1	1
Bone pain		1				1
Bradycardia	7	23			7	23
Brain contusion	1	1			1	1
Brain hypoxia	1	1			1	1
Brain natriuretic peptide increased	2	3	2	2		1
Brain scan abnormal		1				1
Brain stem haemorrhage		1				1
Breast swelling		1		1		
Breath sounds abnormal	1	1			1	1
Bronchiolitis	1	2			1	2
Bronchitis		6				6
Bronchopneumopathy		3				3
Bronchospasm		4				4
Bundle branch block		1				1
Bundle branch block left		2				2
Bundle branch block right		4		2		2
Burning sensation		2		1		1
Burn oral cavity	1	1			1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	2	11			2	11
Cardiac discomfort		1				1
Cardiac failure	24	70			24	70
Cardiac failure acute	1	4			1	4
Cardiac failure congestive	2	3			2	3
Cardiac fibrillation	1	1			1	1
Cardiac flutter		2				2
Cardiac tamponade	1	1			1	1
Cardiogenic shock	1	4			1	4
Cardiomegaly		1				1
Cardiopulmonary failure	2	3			2	3
Cardio-respiratory arrest	5	17			5	17
Cardio-respiratory distress	1	1			1	1
Cardiovascular disorder	1	3			1	3
Carotid artery stenosis	1	1			1	1
Carotid artery thrombosis	1	1			1	1
Cell death	2	2			2	2
Central nervous system lesion		1				1
Cerebellar ataxia	1	1	1	1		
Cerebellar haematoma	1	1			1	1
Cerebellar infarction		1				1
Cerebellar stroke		1				1
Cerebellar syndrome	1	3			1	3
Cerebral amyloid angiopathy		1				1
Cerebral atrophy		1				1
Cerebral disorder		1				1
Cerebral haematoma	2	5			2	5
Cerebral haemorrhage	2	6			2	6
Cerebral infarction	3	4			3	4
Cerebral venous thrombosis	2	2			2	2
Cerebrovascular accident	8	27			8	27
Cervicobrachial syndrome		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort		6		1		5
Chest injury		1				1
Chest pain	6	25	3	7	3	18
Chest X-ray abnormal	1	1			1	1
Chills	5	14	2	5	3	9
Choking	2	3			2	3
Cholecystitis	1	3			1	3
Cholestasis	1	2			1	2
Chronic kidney disease	1	1			1	1
Chronic obstructive pulmonary disease		8		2		6
Circadian rhythm sleep disorder	1	1	1	1		
Circulatory collapse		3				3
Clinomania	1	1	1	1		
Clonus		2		1		1
Cognitive disorder	1	3		1	1	2
Colitis	1	2			1	2
Coma	4	10			4	10
Coma scale abnormal	1	1			1	1
Condition aggravated	6	18		5	6	13
Confusional state	14	26	4	5	10	21
Conjunctival haemorrhage		1				1
Conjunctival oedema	1	1	1	1		
Conjunctivitis	1	1	1	1		
Conjunctivitis bacterial	1	1			1	1
Constipation	1	4	1	4		
Contusion	1	2	1	2		
Coronary artery insufficiency	1	1			1	1
Coronary artery stenosis	2	2			2	2
Coronavirus infection		2		1		1
Cough	11	19	5	7	6	12
COVID-19	96	160	10	19	86	141
COVID-19 pneumonia	7	11			7	11

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased	7	18	4	10	3	8
Creatinine renal clearance decreased		1				1
Crepitations	1	3	1	2		1
Culture urine positive	1	1	1	1		
Cyanosis	2	7	1	2	1	5
Cystitis klebsiella		1				1
Deafness	1	1			1	1
Death	14	79			14	79
Decreased appetite	7	17	5	10	2	7
Deep vein thrombosis	15	22			15	22
Deformity		1		1		
Dehydration	11	20	4	6	7	14
Delirium	1	2			1	2
Delusion	1	3		1	1	2
Dementia	1	3			1	3
Dependent rubor	1	1			1	1
Depressed level of consciousness	2	11			2	11
Dermatitis bullous		2				2
Dermo-hypodermatitis	1	2			1	2
Diabetes mellitus	4	5			4	5
Diabetes mellitus inadequate control		2				2
Diabetic coma		1				1
Diabetic hyperosmolar coma	1	1			1	1
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	20	56	6	18	14	38
Diarrhoea haemorrhagic	2	3			2	3
Diarrhoea infectious	2	2			2	2
Diplopia		2				2
Discomfort	4	16	3	6	1	10
Disease progression		1				1
Disease recurrence	8	21			8	21

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disorientation	5	12	2	3	3	9
Disturbance in attention	2	4	1	1	1	3
Diverticulum intestinal	1	1			1	1
Dizziness	10	23	4	11	6	12
Dropped head syndrome		1				1
Drug ineffective	29	51	1	1	28	50
Drug interaction	1	1			1	1
Dry mouth		2		2		
Dry skin	1	1	1	1		
Dysarthria	3	10		1	3	9
Dysgeusia	1	2		1	1	1
Dyskinesia	1	2	1	2		
Dyslipidaemia		1		1		
Dyspepsia		1		1		
Dysphagia	1	6		1	1	5
Dysphonia	1	3		2	1	1
Dyspnoea	26	71	5	8	21	63
Dyspnoea at rest	1	2			1	2
Dyspnoea exertional	3	5	2	3	1	2
Dysstasia	1	2			1	2
Dysuria	1	2	1	1		1
Ear discomfort		1		1		
Ear infection		1				1
Ear pain		2		1		1
Eating disorder		1				1
Eczema	1	1			1	1
Eczema nummular	1	1			1	1
Ejection fraction decreased		1				1
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram T wave inversion		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Embolism		1				1	
Embolism venous		1					1
Encephalitis		1					1
Endocrine ophthalmopathy	1	1			1		1
Enuresis		1					1
Eosinophilia		1					1
Epilepsy	8	15			8		15
Epistaxis	4	9	1	2	3		7
Erysipelas	2	4			2		4
Erythema	2	14	1	6	1		8
Erythema multiforme	1	1			1		1
Erythrosis		1		1			
Escherichia bacteraemia		1					1
Escherichia infection	1	1			1		1
Escherichia test positive		1		1			
Escherichia urinary tract infection	1	1			1		1
Exophthalmos	1	1			1		1
Exposure to SARS-CoV-2		1					1
Extensive swelling of vaccinated limb		1					1
Extensor plantar response		1					1
Extradural haematoma		1					1
Extrapyramidal disorder	2	2			2		2
Extrasystoles	3	3			3		3
Extremity necrosis	1	1	1	1			
Eye discharge	1	1			1		1
Eye disorder		1					1
Eye haemorrhage		1					1
Eye injury		1					1
Eyelid oedema	1	3			1		3
Eyelid ptosis		1					1
Eye oedema		1					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	1	2	1	1		1
Eye swelling	1	1			1	1
Face oedema	5	11	1	1	4	10
Facial asymmetry		1				1
Facial bones fracture	2	2			2	2
Facial paralysis	9	29			9	29
Facial paresis		1				1
Faecaloma	1	2			1	2
Faecal vomiting		2				2
Failure to thrive		1				1
Fall	19	52	4	11	15	41
Fatigue	14	48	8	24	6	24
Fear		1				1
Feeling abnormal		3		1		2
Feeling cold		3		2		1
Feeling hot	1	2		1	1	1
Femoral neck fracture		1				1
Femur fracture	1	3			1	3
Fibrin D dimer increased		2				2
Flank pain		1		1		
Fluid retention		1				1
Flushing		3		1		2
Foaming at mouth		1				1
Food aversion		1		1		
Fracture	1	1			1	1
Functional gastrointestinal disorder		1				1
Gait disturbance	3	8	1	3	2	5
Gait inability		1				1
Gamma-glutamyltransferase increased	1	2		1	1	1
Gangrene	1	1			1	1
Gastric volvulus		1				1
Gastroenteritis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal disorder	2	4	1	2	1	2
Gastrointestinal haemorrhage		1				1
Generalised oedema		1				1
Generalised tonic-clonic seizure	2	4			2	4
General physical health deterioration	12	37	6	9	6	28
Genital herpes zoster	1	1			1	1
Giant cell arteritis	3	5			3	5
Gingival discomfort	1	1	1	1		
Glaucoma	1	1			1	1
Glomerular filtration rate decreased	1	4	1	1		3
Glossitis		1				1
Goitre		1		1		
Gout		2		1		1
Guillain-Barre syndrome	1	1			1	1
Guttate psoriasis		1		1		
Haemarthrosis		1				1
Haematemesis	2	4			2	4
Haematochezia	1	2			1	2
Haematoma	3	7	1	1	2	6
Haematoma muscle	1	1			1	1
Haematuria	2	3			2	3
Haemodynamic instability		1		1		
Haemoglobin decreased	1	5		2	1	3
Haemoglobinuria		1				1
Haemolytic anaemia	1	1			1	1
Haemophagocytic lymphohistiocytosis	2	2			2	2
Haemoptysis	1	3			1	3
Haemorrhagic disorder	1	1			1	1
Haemorrhagic stroke	5	15			5	15
Haemorrhagic transformation stroke		1				1
Hallucination		7				7
Hallucination, auditory	3	3			3	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucinations, mixed		2				2
Hallucination, visual	8	9			8	9
Headache	11	49	4	19	7	30
Head discomfort		1				1
Head injury	5	11	1	1	4	10
Heart rate decreased	3	6	1	3	2	3
Heart rate increased	1	2	1	2		
Heart rate irregular	1	2			1	2
Heart sounds abnormal		2		1		1
Hemianopia		1				1
Hemiparesis	4	7			4	7
Hemiplegia	7	16			7	16
Hepatic function abnormal	1	2	1	2		
Hepatic lesion		1		1		
Hepatic steatosis	1	1			1	1
Hepatitis acute	1	1			1	1
Hepatocellular injury	3	4			3	4
Herpes ophthalmic		1				1
Herpes simplex test positive	1	1	1	1		
Herpes zoster	8	34		10	8	24
Herpes zoster cutaneous disseminated	1	1			1	1
High-pitched crying		1		1		
Hippocampal atrophy		1				1
Hostility	1	1			1	1
Hot flush	3	8	1	3	2	5
Humerus fracture	1	1			1	1
Hypercalcaemia	1	1	1	1		
Hypercapnia	1	2			1	2
Hypercholesterolaemia		1		1		
Hyperferritinaemia	1	1			1	1
Hyperglycaemia	2	4	1	3	1	1
Hyperhidrosis		3				3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperkalaemia		4				4
Hyperlactacidaemia	1	1			1	1
Hyperleukocytosis	6	13			6	13
Hypernatraemia	1	5		2	1	3
Hypersensitivity		6		3		3
Hypersensitivity vasculitis	1	1			1	1
Hypersomnia	1	3	1	1		2
Hypertension	60	135	3	13	57	122
Hypertensive crisis	17	55			17	55
Hyperthermia	6	23	3	7	3	16
Hyperthyroidism		1				1
Hypertonia	1	2			1	2
Hyperuricaemia	1	1	1	1		
Hypoacusis		1				1
Hypoaesthesia	1	3	1	1		2
Hypoalbuminaemia	1	1			1	1
Hypoglycaemia		4				4
Hypokalaemia	1	1			1	1
Hypoperfusion		1		1		
Hypotension	8	60	4	15	4	45
Hypothermia		5				5
Hypotonia	2	3	1	1	1	2
Hypovolaemic shock		1				1
Hypoxia	3	13			3	13
Illrd nerve paralysis		1				1
Ill-defined disorder		1				1
Illness	1	1	1	1		
Immune thrombocytopenia	1	2			1	2
Inappropriate schedule of product administration	3	9	2	8	1	1
Incoherent	5	5	3	3	2	2
Incontinence	1	1			1	1
Incorrect dose administered		4		4		

Spontaneous			
Nonserious		Serious	
I	C	I	C
			4
		1	1
		6	13
	2	1	3
	3		3
		1	1
1	1		2
3	13	57	122
		17	55
3	7	3	16
			1
		1	2
1	1		
			1
1	1		2
		1	1
			4
		1	1
	1		
4	15	4	45
			5
1	1	1	2
			1
		3	13
			1
			1
1	1		
		1	2
2	8	1	1
3	3	2	2
		1	1
	4		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Incorrect route of product administration		1		1			
Increased bronchial secretion	1	2		1		1	2
Infarction	1	3				1	3
Infection	1	3	1	1			2
Inflammation	7	15	3	7	4		8
Influenza	1	5	1	2			3
Influenza like illness	7	29	2	5	5		24
Injected limb mobility decreased		1					1
Injection site hyperaesthesia		1		1			
Insomnia	3	3	3	3			
Insulin-requiring type 2 diabetes mellitus		1					1
International normalised ratio abnormal		2		1			1
International normalised ratio increased	2	4				2	4
Interstitial lung disease	2	5				2	5
Intervertebral disc compression		1					1
Intestinal ischaemia	2	2				2	2
Intestinal obstruction		1					1
Intracardiac thrombus	1	1				1	1
Intracranial haematoma		1					1
Iron deficiency anaemia		1					1
Ischaemic cardiomyopathy		1					1
Ischaemic limb pain	1	1				1	1
Ischaemic stroke	20	44				20	44
Jaundice		3					3
Jaundice cholestatic	1	1				1	1
Joint dislocation	1	1				1	1
Joint effusion	1	1				1	1
Joint injury		1					1
Jugular vein distension		1					1
Klebsiella infection		1					1
Laboratory test abnormal		1					1
Lacrimation increased		1					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lactic acidosis		1					1
Lactobacillus infection		1					1
Lacunar stroke	2	2			2		2
Language disorder		1					1
Large intestine infection	1	2			1		2
Laryngeal discomfort		1					1
Laryngeal oedema		1					1
Left atrial dilatation	1	1			1		1
Left ventricular dysfunction	1	1			1		1
Left ventricular end-diastolic pressure increased		1					1
Left ventricular failure	1	3			1		3
Leukocytosis	1	1	1	1			
Leukocyturia	1	3	1	2			1
Leukoencephalopathy		1					1
Limb discomfort		1		1			
Lip oedema	1	6		2	1		4
Lip swelling	1	1			1		1
Listless		1					1
Livedo reticularis	2	5	2	2			3
Lividity		1					1
Localised oedema	2	4	1	2	1		2
Loss of consciousness	10	35			10		35
Loss of personal independence in daily activities	6	7	2	2	4		5
Lower respiratory tract congestion	2	5			2		5
Lower respiratory tract infection		1					1
Lung abscess		1					1
Lung disorder	5	24	1	3	4		21
Lung opacity		1					1
Lyme disease	1	1			1		1
Lymphadenitis		2		1			1
Lymphadenopathy		3		2			1
Lymphocyte count decreased	1	1	1	1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphopenia	2	7	2	4		3
Macular oedema	1	1			1	1
Major depression	1	1			1	1
Malaise	22	86	8	23	14	63
Malnutrition	1	1			1	1
Mass		1				1
Mean cell volume decreased	1	1			1	1
Melaena		1				1
Memory impairment		1		1		
Meniere's disease	1	1			1	1
Meningitis	1	1			1	1
Meningitis aseptic		1				1
Meningoencephalitis herpetic	1	1			1	1
Meningoradiculitis	1	1			1	1
Mental impairment	1	2			1	2
Metastases to peritoneum		1				1
Miosis		1				1
Mitral valve calcification	1	2			1	2
Mitral valve disease		1				1
Mitral valve incompetence	2	3			2	3
Mitral valve stenosis	1	1			1	1
Mobility decreased	1	2	1	2		
Monocytosis	2	2	1	1	1	1
Motor dysfunction	1	4		1	1	3
Mouth haemorrhage	1	1			1	1
Movement disorder	2	4		1	2	3
Mucosal discolouration	1	1			1	1
Multiple organ dysfunction syndrome	2	3			2	3
Muscle contracture		1		1		
Muscle disorder		1		1		
Muscle spasms	1	2		1	1	1
Muscle strength abnormal		1				1

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			Nonserious		Serious		
			I	C	I	C	
Muscle tightness		1		1			
Muscular weakness	2	6			2	6	
Musculoskeletal discomfort		1		1			
Musculoskeletal stiffness	4	8		1	4	7	
Mutism	1	1	1	1			
Myalgia	4	16	1	4	3	12	
Myasthenia gravis	1	1			1	1	
Myasthenia gravis crisis	1	1			1	1	
Mydriasis	1	4	1	2		2	
Myelocytosis		1				1	
Myelofibrosis		1				1	
Myocardial infarction	5	23			5	23	
Myocardial ischaemia		2				2	
Myocardial necrosis		1				1	
Myocarditis	1	1			1	1	
Myoclonus	1	1			1	1	
Nasal congestion		1		1			
Nausea	9	36	2	9	7	27	
Near death experience		1				1	
Necrosis	1	1			1	1	
Necrotising colitis	1	1			1	1	
Nervous system disorder	1	1	1	1			
Neuralgia		2		1		1	
Neurological decompensation	1	1	1	1			
Neurological examination abnormal		1				1	
Neutropenia		1				1	
Neutrophil count abnormal		1				1	
Neutrophil count decreased		1				1	
Neutrophil count increased	1	3	1	2		1	
Neutrophilia		1		1			
Nocturnal dyspnoea	1	1			1	1	
Noninfective gingivitis		1		1			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Normocytic anaemia		1					1
N-terminal prohormone brain natriuretic peptide increased	1	3			1		3
Nystagmus		1		1			
Ocular hyperaemia	1	2			1		2
Ocular vascular disorder	1	1			1		1
Oedema	2	4	1	2	1		2
Oedema peripheral	8	19	1	2	7		17
Off label use	3	7	2	6	1		1
Ophthalmic herpes zoster	4	12			4		12
Oral discomfort	1	1	1	1			
Oral disorder		1		1			
Oral fungal infection	1	1	1	1			
Orbital haematoma		1					1
Oropharyngeal pain		3		2			1
Otitis externa	1	2	1	1			1
Overdose		2		2			
Oxygen saturation abnormal		1					1
Oxygen saturation decreased	16	81	4	7	12		74
Pain	5	16	2	6	3		10
Pain in extremity	10	16	3	5	7		11
Pain in jaw	1	5		2	1		3
Pain of skin		1					1
Pallor	3	8		1	3		7
Palpitations	3	7	1	3	2		4
Pancreatitis acute		1					1
Pancytopenia		2					2
Panic attack		1		1			
Paraesthesia	3	3			3		3
Paralysis	2	3			2		3
Parkinson's disease	1	1			1		1
Parophthalmia	1	1			1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Partial seizures	1	3			1	3
Peau d'orange		1		1		
Pelvic fracture		1				1
Pemphigoid	1	1			1	1
Periarthritis		1				1
Pericardial effusion	1	1			1	1
Pericardial haemorrhage	1	1			1	1
Pericarditis	2	3			2	3
Periorbital pain	1	1	1	1		
Periorbital swelling	1	1			1	1
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness	2	5	2	4		1
Peripheral ischaemia	3	4		1	3	3
Peripheral swelling	1	1			1	1
Persecutory delusion		1		1		
Petechiae	1	3	1	3		
Petit mal epilepsy	3	4			3	4
Pharyngitis	1	1	1	1		
Phlebitis	8	9	4	4	4	5
Platelet count decreased	1	3	1	2		1
Pleural effusion	3	4			3	4
Pneumococcal sepsis		1				1
Pneumonia	8	23			8	23
Pneumonia aspiration	5	16			5	16
Pneumonia bacterial	1	1			1	1
Pneumonitis		3				3
Pneumoperitoneum		1				1
Pneumothorax		1				1
Polyarthritis		1				1
Polymyalgia rheumatica	1	1			1	1
Polyneuropathy		1				1
Polyserositis	1	1			1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Poor quality product administered		54		54		
Prerenal failure	1	2			1	2
Presyncope	3	7	1	4	2	3
Productive cough	1	4		1	1	3
Product preparation error		2		2		
Product temperature excursion issue		53		53		
Product use issue		2		2		
Progressive supranuclear palsy	1	1			1	1
Prostatitis	1	1	1	1		
Proteinuria		1		1		
Prothrombin time shortened	2	2	1	1	1	1
Pruritus	3	12	1	8	2	4
Psoriasis	1	1			1	1
Psychomotor skills impaired	1	1			1	1
Pulmonary arterial hypertension	1	2			1	2
Pulmonary arterial pressure increased	1	2			1	2
Pulmonary artery dilatation	1	1			1	1
Pulmonary congestion		1				1
Pulmonary embolism	32	46			32	46
Pulmonary infarction	2	3			2	3
Pulmonary oedema	4	8			4	8
Pulmonary sepsis		1				1
Pulse abnormal		1		1		
Pulse absent	1	3	1	2		1
Pupils unequal		1		1		
Purpura	2	4	1	1	1	3
Pyelonephritis	3	4			3	4
Pyrexia	28	113	8	27	20	86
Quadriplegia	1	2			1	2
Rales	4	9	1	1	3	8
Rash		7		4		3
Rash erythematous	3	6	1	2	2	4

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash macular	1	2		1	1	1
Rash maculo-papular	1	3			1	3
Rash pruritic		3		2		1
Rash vesicular	1	2			1	2
Recalled product administered	1	1	1	1		
Rectal haemorrhage	2	4			2	4
Renal cyst	1	1			1	1
Renal failure	5	15			5	15
Renal impairment		2				2
Respiration abnormal	1	2			1	2
Respiratory acidosis	1	1			1	1
Respiratory alkalosis	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory depression		2				2
Respiratory disorder	1	6		1	1	5
Respiratory distress	5	27			5	27
Respiratory failure		7				7
Respiratory fatigue		1				1
Respiratory rate decreased	1	1			1	1
Respiratory rate increased	1	2	1	1		1
Respiratory tract congestion		1				1
Respiratory tract infection		1				1
Respiratory tract infection bacterial	1	1			1	1
Restlessness	1	5	1	3		2
Retinal artery occlusion	1	2			1	2
Retinal vein occlusion	2	3			2	3
Rhabdomyolysis	1	1			1	1
Rheumatoid arthritis		1				1
Rhinitis	2	2	1	1	1	1
Rhinorrhoea	2	3	1	1	1	2
Rhonchi		1		1		
Rib fracture		1				1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Right ventricular dilatation	1	1			1	1
Road traffic accident	1	1			1	1
Salivary gland disorder		1		1		
SARS-CoV-2 antibody test negative		1		1		
SARS-CoV-2 antibody test positive		1		1		
SARS-CoV-2 test positive	9	17	2	3	7	14
Seizure	4	6			4	6
Seizure anoxic		1				1
Sensorimotor disorder	1	1	1	1		
Sensory disturbance	1	1			1	1
Sensory loss	1	3			1	3
Sepsis		4				4
Septic shock		2				2
Shock		4				4
Sialoadenitis		1				1
Sinus bradycardia		2				2
Sinus tachycardia		2				2
Skin discolouration	1	1	1	1		
Skin exfoliation		1		1		
Skin lesion	2	2	2	2		
Skin necrosis	1	1			1	1
Skin ulcer	1	2		1	1	1
Skin warm		1		1		
Sleep apnoea syndrome	1	1			1	1
Sleep talking		1		1		
Somnolence	7	21	3	10	4	11
Speech disorder	3	10		1	3	9
Spinal compression fracture		2				2
Spinal cord infarction	1	1			1	1
Status epilepticus	1	3			1	3
Stereotypy		1				1
Stomatitis	1	1	1	1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
	1		
	1		
	1		
2	3	7	14
		4	6
			1
1	1		
		1	1
		1	3
			4
			2
			4
			1
			2
			2
1	1		
	1		
2	2		
		1	1
	1	1	1
	1		
		1	1
	1		
3	10	4	11
	1	3	9
			2
		1	1
		1	3
			1
1	1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Stress		1		1			
Subclavian vein thrombosis	1	1		1	1	1	
Subdural haematoma	2	2			2	2	
Subileus		1				1	
Sudden death	8	37			8	37	
Suffocation feeling		1				1	
Superinfection	1	1			1	1	
Superinfection bacterial	1	1			1	1	
Superior vena cava syndrome		1				1	
Supraventricular tachyarrhythmia		1				1	
Supraventricular tachycardia		1				1	
Suspected COVID-19	1	2			1	2	
Swelling		3		2		1	
Swelling face	1	2			1	2	
Swollen tongue		1				1	
Syncope	3	11			3	11	
Systemic inflammatory response syndrome	2	2			2	2	
Systolic hypertension		1				1	
Tachyarrhythmia		2		1		1	
Tachycardia	15	54	5	11	10	43	
Tachypnoea	1	6	1	2		4	
Tendon rupture	1	1			1	1	
Tension		3		3			
Therapeutic response unexpected		1		1			
Thirst		1		1			
Throat irritation		1		1			
Throat tightness		1				1	
Thrombocytopenia	3	11			3	11	
Thrombolysis	1	1			1	1	
Thrombophlebitis superficial	2	4	1	2	1	2	
Thrombosis	5	5			5	5	
Thyroid disorder		1		1			

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroxine free decreased	1	1	1	1		
Tinnitus	3	3	3	3		
Tongue biting		1				1
Tongue coated		1				1
Tongue discolouration		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue oedema		2				2
Tonic clonic movements		1				1
Tooth abscess		2		1		1
Toothache		1		1		
Tooth infection		1		1		
Torticollis		1				1
Transcription medication error		1		1		
Transient global amnesia		1				1
Transient ischaemic attack	10	20			10	20
Tremor	1	11	1	5		6
Trigeminal neuralgia		1				1
Tri-iodothyronine free decreased	1	1	1	1		
Trismus		1		1		
Troponin increased	1	4	1	1		3
Tumour perforation		1				1
Underdose		1		1		
Unresponsive to stimuli		2				2
Urinary incontinence	2	2	1	1	1	1
Urinary retention	3	3			3	3
Urinary tract candidiasis		1				1
Urinary tract infection	1	7		1	1	6
Urinary tract infection bacterial	1	2			1	2
Urine odour abnormal	1	1	1	1		
Urosepsis		1				1
Urticaria	3	9	2	4	1	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination complication		1					1
Vaccination failure	79	89			79		89
Vaccination site eczema		1					1
Vaccination site erythema		11		9			2
Vaccination site haematoma	1	3			1		3
Vaccination site induration		3		2			1
Vaccination site inflammation	1	6	1	3			3
Vaccination site joint pain		1		1			
Vaccination site oedema		2					2
Vaccination site pain	3	22	2	12	1		10
Vaccination site paraesthesia		1					1
Vaccination site pruritus		1		1			
Vaccination site rash		2		1			1
Vaccination site reaction		2		1			1
Vaccination site swelling		2		2			
Vaccination site urticaria		1		1			
Vascular purpura	1	3			1		3
Vascular stent thrombosis	1	1			1		1
Vasoplegia syndrome	1	1			1		1
Vein rupture	1	1			1		1
Vena cava thrombosis	1	1			1		1
Venous oxygen saturation decreased	1	2			1		2
Venous thrombosis		1					1
Venous thrombosis limb	2	2	1	1	1		1
Ventricular extrasystoles	3	4		1	3		3
Ventricular failure	1	1			1		1
Ventricular hypokinesia	1	1			1		1
Ventricular tachycardia		1					1
Vertigo	3	11	1	3	2		8
Vertigo positional	1	1			1		1
Vestibular disorder		1					1
Vestibular neuritis		1					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vestibulitis		1				1	
Viral infection		1		1			
Vision blurred	2	6		2	2	4	
Visual acuity reduced		1				1	
Visual acuity reduced transiently	1	1			1	1	
Visual brightness		1				1	
Visual impairment		6		2		4	
Vitamin D deficiency	1	1	1	1			
Vlth nerve paralysis	1	2			1	2	
Vitreous floaters		1				1	
Vomiting	18	68	5	20	13	48	
Weight decreased	3	5			3	5	
Weight increased	2	2			2	2	
Wheezing	3	3	1	1	2	2	
White blood cell count decreased	1	2	1	1		1	
White blood cell count increased		1		1			
White matter lesion		1				1	
Wound	1	1			1	1	
Wrong patient received product		1		1			
	1	1	1	1			
	1,648	4,527	307	961	1341	3566	

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Accidental overdose		1		1		
Ageusia	1	1			1	1
Allergy to vaccine	1	1	1	1		
Anosmia	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia		3		2		1
Asthenia	1	10	1	8		2
Asthma	1	1	1	1		
Asymptomatic COVID-19	2	9			2	9
Blood pressure decreased		1		1		
Bone pain		1				1
Bradycardia		1				1
Breast abscess		1				1
Chest pain		2		1		1
Chills		5		4		1
Circumstance or information capable of leading to medication error	1	1	1	1		
Condition aggravated		1		1		
Cough		2		1		1
COVID-19	11	83	2	6	9	77
C-reactive protein increased		1		1		
Diplopia	1	1	1	1		
Disease recurrence		1				1
Drug ineffective	9	85			9	85
Dysgeusia		1		1		
Erythema		1		1		
Exposure during pregnancy	1	1			1	1
Exposure via skin contact		1		1		
Extrasystoles	1	1	1	1		
Eyelid irritation		1		1		
Facial paralysis	1	1			1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall		3				3
Fatigue		9		9		
Feeling abnormal	1	1	1	1		
Functional gastrointestinal disorder		1				1
Gait inability		1		1		
General physical health deterioration		2				2
Haemorrhagic stroke	1	1			1	1
Headache	1	10		6	1	4
Herpes zoster		4		3		1
Hot flush		2		2		
Hypertension		6		4		2
Hypertensive crisis		1				1
Hypotension		1				1
Hypoxia		1				1
Immune thrombocytopenia		1				1
Inappropriate schedule of product administration		5		5		
Incorrect route of product administration	1	2	1	2		
Influenza		1		1		
Influenza like illness	3	5		1	3	4
Injection site pain		1		1		
Injection site swelling		1		1		
Intercepted product preparation error		1		1		
Limb discomfort		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	1	2		1	1	1
Maternal exposure during pregnancy		1		1		
Migraine	1	1	1	1		
Monoplegia	1	1			1	1
Musculoskeletal stiffness		2		2		
Myalgia		5		2		3
Nausea		4		2		2
Needle issue	1	2	1	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
No adverse event	2	2	2	2		
Occipital neuralgia		1				1
Occupational exposure to product		2		2		
Off label use		6		6		
Ophthalmic herpes zoster		1				1
Overdose	1	1	1	1		
Pain		3		3		
Pain in extremity	1	4	1	4		
Pancreatitis		1				1
Paraesthesia	2	2	1	1	1	1
Paraesthesia oral		1		1		
Periarthritis		1				1
Poor quality product administered	2	70	2	70		
Product administered at inappropriate site		1		1		
Product complaint		15		15		
Product contamination physical		1		1		
Product label confusion	1	1	1	1		
Product packaging quantity issue		1		1		
Product physical issue		1		1		
Product preparation error		6		6		
Product preparation issue	1	7	1	7		
Product quality issue	1	1	1	1		
Product storage error	1	1	1	1		
Product temperature excursion issue		49		49		
Product use issue		2		2		
Pulmonary embolism	1	2			1	2
Pulmonary pain		1		1		
Pyrexia	3	18	2	15	1	3
Rash		1		1		
Renal artery stenosis		1				1
Retinal vein occlusion		1				1
Rheumatic disorder		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 antibody test negative	1	6	1	6		
SARS-CoV-2 test positive	1	3	1	1		2
Serology negative	1	1	1	1		
Sluggishness		1		1		
Small for dates baby	1	1			1	1
Suspected COVID-19		1				1
Tachycardia	1	3	1	1		2
Tinnitus		1		1		
Underdose		14		14		
Vaccination failure	1	1			1	1
Vaccination site dysaesthesia		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hypersensitivity		2		2		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1				1
Vaccination site pain		9		9		
Vomiting		1		1		
Wrong technique in product usage process		3		3		
	66	559	29	324	37	235

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Country Where Event Occurred

**FRENCH POLYNESIA**

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Arthralgia		1		1
Asthenia		2		2
Cardiopulmonary failure		1		1
Confusional state		1		1
Dermatitis bullous		1		1
Dermatosis		1		1
Dyspnoea		1		1
Dysstasia		1		1
Haemoptysis		1		1
Hyperaesthesia		1		1
Hyperthermia		1		1
Memory impairment		1		1
Movement disorder		1		1
Oxygen saturation decreased		1		1
Pulmonary embolism		1		1
Staphylococcal sepsis		1		1
Toxic epidermal necrolysis		1		1
		19		19

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**FRENCH SOUTHERN TERRITORIES**

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**GEORGIA**

Age Range

**Unknown**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Pneumonia	1	1	1	1
Sepsis	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**GERMANY**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic shock		1				1	
Chills		1		1			
Diarrhoea	1	1	1	1			
Dizziness		1					1
Dyspnoea	1	3	1	1			2
Erythema		1					1
Exposure via breast milk		4		4			
Flushing		1					1
Haemorrhage	1	1			1		1
Headache	1	2	1	2			
Hypersensitivity		1					1
Hypoaesthesia		1		1			
Hypotension		1					1
Hypotonia	1	1	1	1			
Incorrect route of product administration	1	1	1	1			
Lymphopenia		1		1			
Malaise		1					1
Multiple sclerosis		1					1
Muscle spasms	1	1	1	1			
Myalgia	1	1	1	1			
Off label use		2		2			
Pain in extremity	1	2	1	2			
Paraesthesia	1	1	1	1			
Product administered to patient of inappropriate age		1		1			
Product use issue		1		1			
Pustule	1	1	1	1			
Pyrexia	2	3	2	2			1
SARS-CoV-2 antibody test	1	1	1	1			
Seizure	1	1			1		1
Sensory loss		1		1			
Thrombocytopenia		1					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
	20	46	18	32	2	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	1	6			1	4		2
Abdominal pain lower		2				2		
Abdominal pain upper	1	3			1	2		1
Abnormal faeces	1	4			1	4		
Abortion spontaneous		2						2
Abscess		1						1
Acne		1				1		
Acute myocardial infarction		1						1
Ageusia		1						1
Agranulocytosis		1						1
Alopecia	1	1					1	1
Altered state of consciousness				1				
Anaphylactic reaction	1	16					1	16
Anaphylactic shock	1	1		1			1	1
Anaphylactoid reaction		1						1
Angina pectoris		1						1
Angioedema		1						1
Anorectal disorder	1	1					1	1
Anosmia		2				1		1
Apathy	1	1			1	1		
Appendicitis				1				
Arrhythmia	2	3					2	3
Arthralgia	8	18		9	8	16		2
Arthritis reactive		1						1
Asthenia	12	28			12	25		3
Asthma	1	5			1	3		2
Autonomic nervous system imbalance		1						1
Axillary pain	1	2			1	2		
Back pain	3	7			3	6		1
Bladder dysfunction	1	1					1	1
Blister	1	1					1	1
Blood potassium decreased		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood pressure decreased		2				1		1
Blood pressure increased	1	3			1	3		
Body temperature increased	2	4			2	4		
Breast pain				1				
Bronchial obstruction	1	1					1	1
Bronchitis bacterial		1						1
Bronchospasm		1						1
Burning sensation	2	5			1	1	1	4
Capillary nail refill test abnormal		1				1		
Cardiovascular disorder		4				1		3
Cardiovascular insufficiency	1	2					1	2
Cerebrovascular accident		1						1
Chest discomfort	1	2			1	1		1
Chest pain	2	3			2	3		
Chills	21	47		13	18	39	3	8
Circulatory collapse	2	11					2	11
Condition aggravated		1				1		
Confusional state		1						1
Conjunctival haemorrhage		2						2
Conjunctivitis		1						1
Cough	1	7		1	1	5		2
COVID-19	1	10			1	2		8
COVID-19 pneumonia		1						1
Craniocerebral injury	1	1					1	1
Cyanosis	1	2			1	1		1
Deafness	1	1					1	1
Deep vein thrombosis		1						1
Depressed level of consciousness		1						1
Depression	2	2			2	2		
Diarrhoea	10	19		5	10	16		3
Discomfort				2				
Disease recurrence	1	2				1	1	1

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 \* AE=Adverse Event  
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Age Range

18 - 30 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Disturbance in attention	2	4
Dizziness	16	47
Drug eruption		1
Drug ineffective		6
Dry mouth	1	3
Dysaesthesia		1
Dysgeusia	1	1
Dysphagia	1	1
Dysphonia		1
Dyspnoea	6	23
Dyspnoea exertional	1	2
Dysuria	1	2
Ear pain	1	2
Eating disorder		1
Emotional disorder		1
Enanthema		1
Enteritis		1
Epilepsy		1
Epistaxis		1
Epstein-Barr virus infection reactivation		3
Erysipelas		1
Erythema	1	12
Extrapyramidal disorder	1	2
Eyelid oedema		1
Eye pain		1
Facial paralysis		3
Facial paresis	1	5
Fall	1	1
Fatigue	22	64
Feeling cold	2	7
Feeling hot		6
Feeling of body temperature change		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
	18	15	31	1	16
					1
					6
		1	3		
					1
		1	1		
		1	1		
					1
	2	5	10	1	13
				1	2
				1	2
		1	2		
			1		
					1
					1
					1
			1		
					3
					1
	2	1	8		4
			1	1	1
					1
			1		
					3
		1	5		
				1	1
	20	20	58	2	6
		2	5		2
			4		2
			1		

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 \* AE=Adverse Event  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flank pain		1
Flatulence	1	2
Flushing	2	8
Frequent bowel movements		1
Gastrointestinal disorder		1
Gastrointestinal pain		
General physical health deterioration		2
Genital herpes		1
Groin pain		1
Haematoma		1
Haemoptysis	1	2
Headache	39	99
Head discomfort	1	1
Head injury	2	2
Heart rate increased	1	4
Hemiparaesthesia		1
Hemiparesis		1
Herpes zoster	2	5
Hot flush	2	4
Hyperhidrosis	4	9
Hypersensitivity	2	14
Hypertension		7
Hyperthermia		1
Hyperventilation		3
Hypoacusis		2
Hypoaesthesia	3	9
Hypoaesthesia oral		2
Hypoglycaemia		1
Hypokinesia		1
Hypotension	4	11
Hypothyroidism	1	1
Hypotonia	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2		
		2	5		3
			1		
					1
	1				
			1		1
			1		
			1		
		1	2		
	23	36	85	3	14
		1	1		
				2	2
			3	1	1
					1
					1
			3	2	2
		2	4		
		3	8	1	1
	1	1	3	1	11
			2		5
					1
			1		2
			1		1
	1	2	7	1	2
					2
			1		
			1		
		3	5	1	6
				1	1
		2	2		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Illness	1	1
Immune thrombocytopenia	2	2
Inappropriate schedule of product administration	1	2
Incorrect route of product administration	3	8
Influenza	2	2
Influenza like illness	5	16
Insomnia	1	1
Intestinal obstruction	1	1
Irregular breathing		1
Joint swelling		1
Lacrimation increased		1
Limb discomfort	3	9
Lip swelling		1
Local reaction	1	5
Loss of consciousness		2
Lymphadenitis	2	4
Lymphadenopathy	6	12
Lymph node pain	3	7
Lymphopenia	1	1
Malaise	8	17
Maternal exposure during pregnancy		2
Mental impairment		1
Middle insomnia		1
Migraine	1	3
Mobility decreased		3
Monocytosis		1
Monoplegia	1	1
Mouth swelling		1
Movement disorder		1
Multiple sclerosis relapse	1	1
Muscle mass	1	1
Muscle spasms	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	2
		1	2		
		3	8		
		2	2		
		5	16		
		1	1		
				1	1
					1
			1		
		2	7	1	2
					1
		1	4		1
					2
		2	2		2
		6	12		
		3	7		
				1	1
	21	8	13		4
			2		
					1
			1		
		1	3		
			2		1
					1
				1	1
			1		1
				1	1
		1	1		
		1	1		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle strain		
Muscle tightness		
Muscle twitching	1	2
Muscular weakness		5
Musculoskeletal stiffness		1
Myalgia	13	32
Myocarditis	1	8
Nasal congestion		2
Nasopharyngitis		4
Nausea	13	34
Neck pain	1	3
Neuralgic amyotrophy		1
Neurodermatitis		1
Neutropenia		1
Obstructive airways disorder	1	1
Oedema		1
Oesophageal irritation		1
Off label use	2	7
Oligoarthritis		1
Oral candidiasis	1	1
Oral pain		1
Oropharyngeal blistering		1
Oropharyngeal pain	2	5
Otitis media		1
Oxygen saturation decreased		1
Pain	5	11
Pain in extremity	20	49
Palatal swelling		1
Palpitations	5	14
Panic attack		1
Panic disorder	1	1
Paraesthesia	6	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				
	1				
		1	2		
			3		2
			1		
	11	12	29	1	3
				1	8
			2		
	1		3		1
	16	12	27	1	7
		1	3		
					1
			1		
					1
				1	1
					1
					1
		2	7		
					1
				1	1
					1
					1
		2	5		
			1		
			1		
		5	10		1
		18	45	2	4
					1
	1	3	7	2	7
					1
		1	1		
	1	5	8	1	7

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia oral	1	2
Paralysis	1	2
Pericarditis		1
Peripheral circulatory failure		1
Peripheral swelling	3	4
Peripheral vascular disorder	1	7
Petechiae	2	2
Pharyngeal swelling		1
Pneumonia		1
Polyarthritis		1
Polydipsia	1	1
Polyneuropathy	1	1
Polyuria	1	1
Poor quality product administered		5
Poor quality sleep	1	1
Presyncope	3	9
Product temperature excursion issue		5
Product use issue	1	5
Pruritus	5	14
Pulmonary embolism		3
Pulse waveform abnormal		1
Pustule	1	1
Pyrexia	22	51
Rash	5	20
Rash erythematous	1	2
Rash macular		1
Rash papular	1	1
Rash pruritic	2	5
Rash vesicular		1
Respiration abnormal	1	1
Respiratory distress	5	15
Respiratory tract oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
				1	2
					1
					1
		3	3		1
		1	3		4
		1	1	1	1
	1				1
					1
				1	1
				1	1
			4		1
				1	1
		2	5	1	4
			4		1
		1	5		
	1	3	7	2	7
					3
			1		
	1	1	1		
	13	21	44	1	7
	2	3	8	2	12
		1	2		
			1		
		1	1		
		2	4		1
			1		
		1	1		
				5	15
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restlessness	1	2
Retching		1
Rhinorrhoea	1	1
SARS-CoV-2 antibody test positive		5
SARS-CoV-2 test positive	1	2
Seizure		7
Sensation of foreign body	1	6
Sensory disturbance	5	6
Sensory loss		1
Shock	1	1
Sinusitis		1
Sinus tachycardia	1	3
Skin burning sensation	1	1
Skin disorder		1
Skin irritation	1	1
Skin laceration	1	1
Skin reaction	1	1
Somatic symptom disorder		1
Somnolence	1	4
Spinal cord ischaemia	1	1
Spinal pain	1	1
Status epilepticus		1
Stridor		2
Sudden hearing loss		1
Supraventricular tachycardia		1
Swelling	1	6
Swelling face		4
Swollen tongue		1
Syncope	6	15
Tachycardia	7	21
Tachypnoea		1
Tension headache	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		
		1	1		
			5		
		1	1		1
					7
		1	1		5
		4	5	1	1
					1
				1	1
			1		
		1	1		2
		1	1		
					1
		1	1		
				1	1
		1	1		
					1
			2	1	2
				1	1
				1	1
					1
					2
					1
			1		
		1	4		2
			1		3
					1
				6	15
	1	6	12	1	9
					1
		1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Therapeutic response unexpected	1	1
Thirst		1
Throat irritation	2	3
Throat tightness	1	5
Thrombocytopenia	1	1
Tinnitus	1	1
Tongue coated	1	1
Tongue pruritus		1
Tremor		9
Type 1 diabetes mellitus	1	2
Urticaria	3	10
Vaccination failure		1
Vaccination site bruising		1
Vaccination site discomfort		1
Vaccination site erythema	2	5
Vaccination site granuloma	1	1
Vaccination site haematoma		2
Vaccination site hypersensitivity	1	1
Vaccination site inflammation		
Vaccination site movement impairment		1
Vaccination site pain	34	86
Vaccination site paraesthesia		2
Vaccination site pruritus	1	3
Vaccination site rash	1	2
Vaccination site reaction	2	3
Vaccination site swelling	6	16
Vaccination site urticaria		1
Vaccination site warmth	1	3
Vertebral wedging		1
Vertigo		5
Viral rash	1	1
Visual field defect		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
	1		1		
	1	2	3		
		1	1		4
				1	1
				1	1
		1	1		
					1
			1		8
				1	2
	1	3	6		4
					1
			1		
			1		
		2	5		
		1	1		
			1		1
	1	1	1		
			1		
	21	33	84	1	2
			2		
		1	3		
		1	2		
		2	3		
	6	6	15		1
			1		
		1	3		
					1
			5		
		1	1		
					1

\* I=Interval, C=Cumulative  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Visual impairment		4							4
Vomiting	3	10		5	2	5	1		5
Vulvitis	1	1					1		1
Vulvovaginal discomfort	1	1					1		1
Vulvovaginal mycotic infection	1	1					1		1
Vulvovaginal pain	1	1					1		1
Weight decreased	1	1					1		1
Wheezing		2							2
White blood cell count decreased		1				1			
	492	1,445		210	394	960	98		485

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	1			1	1		
Abdominal pain	3	7		1	2	6	1	1
Abdominal pain upper	1	9				5	1	4
Abnormal faeces	1	7			1	7		
Abortion missed		1						1
Abortion spontaneous	1	1					1	1
Accidental overdose	1	9			1	7		2
Acute myeloid leukaemia	1	1					1	1
Acute myocardial infarction		2						2
Ageusia	1	3			1	3		
Agitation		1				1		
Allergy to vaccine		1						1
Allodynia	1	1			1	1		
Alopecia areata		1				1		
Amnesia	1	5				1	1	4
Anaphylactic reaction	4	46					4	46
Anaphylactic shock		5						5
Anaphylactoid reaction		1						1
Angina pectoris		7						7
Angioedema	4	14					4	14
Anosmia	1	2			1	2		
Anxiety	2	4			2	2		2
Aphasia		3				1		2
Application site vesicles		1						1
Arrhythmia	1	18					1	18
Arteriosclerosis		1				1		
Arthralgia	11	33		8	11	27		6
Ascites		1						1
Aspiration		2						2
Asthenia	17	43			17	37		6
Asthma	5	9			5	6		3
Ataxia		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atrial fibrillation	1	2
Atypical pneumonia		1
Autoimmune thyroiditis	1	1
Axillary pain	1	4
Back pain	2	5
Basedow's disease	1	1
Bladder discomfort	1	2
Bladder pain		1
Blepharitis		1
Blister	1	3
Blood count abnormal	1	1
Blood glucose decreased		1
Blood glucose increased		1
Blood methaemoglobin present		1
Blood potassium decreased		1
Blood pressure abnormal		1
Blood pressure decreased		4
Blood pressure fluctuation		2
Blood pressure increased	3	12
Blood sodium decreased		1
Blood thyroid stimulating hormone increased		1
Body temperature decreased	1	1
Body temperature increased	4	13
Bone pain	5	9
Bowel movement irregularity		1
Bradycardia		1
Brain death	1	1
Bronchial obstruction		1
Bundle branch block right		1
Burning sensation	3	4
Bursitis	1	1
Cardiac arrest		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
				1	1
		1	4		
		2	5		
				1	1
		1	2		
			1		
			1		
		1	3		
				1	1
			1		
			1		
			1		1
			1		
	1		1		3
			2		
	2	3	5		7
			1		
			1		
		1	1		
		4	12		1
		5	9		
			1		
					1
				1	1
					1
		2	3	1	1
	1	1	1		
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac discomfort		1
Cardiac failure		2
Cardiomyopathy		1
Cardiovascular disorder	4	13
Cardiovascular insufficiency		3
Cerebellar ataxia		1
Cerebellar syndrome		2
Cerebral infarction		3
Cerebral venous sinus thrombosis	3	4
Cerebral venous thrombosis		1
Cerebrovascular accident	2	2
Cervix haematoma uterine	1	1
Chest discomfort	1	8
Chest pain	4	12
Chest X-ray abnormal		1
Chills	33	82
Circulatory collapse	1	6
Cold sweat	1	5
Colitis ulcerative		1
Condition aggravated	1	3
Conjunctivitis	1	2
Coronary artery thrombosis		1
Coronavirus infection		1
Cough	2	20
COVID-19	6	25
C-reactive protein increased	1	1
Cyanosis	1	3
Deafness	1	3
Deafness bilateral		1
Deafness transitory		1
Deafness unilateral		1
Death	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
					1
		4	9		4
					3
					1
					2
					3
				3	4
					1
				2	2
				1	1
		1	5		3
		4	7		5
					1
	8	30	71	3	11
	1			1	6
				1	5
					1
			1	1	2
		1	2		
					1
			1		
		2	14		6
		2	8	4	17
		1	1		
		1	2		1
				1	3
					1
					1
				1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased appetite	2	6
Deep vein thrombosis	3	4
Depressed level of consciousness	1	3
Depression	1	1
Dermatitis allergic	2	6
Dermatitis atopic		1
Diabetes mellitus		1
Diaphragmalgia		1
Diarrhoea	12	37
Digestive enzyme abnormal	1	1
Diplopia	3	4
Discomfort		
Disease recurrence	1	1
Disorientation		2
Disturbance in attention	2	6
Dizziness	21	79
Dizziness postural		1
Drug ineffective	5	14
Dry eye		1
Dry mouth	2	5
Dysaesthesia	1	4
Dysarthria	1	2
Dysgeusia	2	5
Dyspepsia	1	2
Dysphagia	2	6
Dysphonia	1	8
Dyspnoea	8	51
Dyspnoea at rest		1
Dyspnoea exertional	1	5
Ear discomfort		3
Ear pain	1	1
Eczema	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		
				3	4
				1	3
		1	1		
		1	3	1	3
			1		
					1
			1		
	5	12	32		5
		1	1		
		2	2	1	2
	1				
		1	1		
			1		1
		2	5		1
	17	19	57	2	22
					1
				5	14
			1		
			1	2	4
		1	3		1
		1	1		1
		2	4		1
		1	2		
			1	2	5
		1	7		1
		6	24	2	27
					1
		1	4		1
			1		2
		1	1		
		3	4		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Electrocardiogram ST segment depression		1
Embedded device	1	1
Epilepsy	1	6
Episcleritis		1
Epistaxis		2
Erythema	5	25
Evans syndrome		1
Exercise tolerance decreased		
Extrasystoles		1
Eye irritation	1	4
Eyelid oedema		1
Eye pain	1	3
Eye pruritus		4
Eye swelling		1
Face oedema		1
Facial nerve disorder		2
Facial pain	2	2
Facial paralysis	3	14
Facial paresis	1	6
Fatigue	45	130
Fear		1
Feeling abnormal	4	7
Feeling cold	3	8
Feeling hot	9	14
Feeling jittery		
Feeling of body temperature change	2	5
Fibrin D dimer increased		1
Flatulence		1
Flushing	6	22
Gait disturbance	1	4
Gastrointestinal pain		1
Generalised tonic-clonic seizure		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	6
			1		
	1		2		
		5	17		8
					1
	1				
					1
		1	3		1
					1
		1	3		
			2		2
			1		
					1
			1		1
		2	2		
				3	14
		1	3		3
	23	43	122	2	8
					1
		4	7		
		3	6		2
		7	10	2	4
	1				
		2	5		
					1
	1		1		
		5	9	1	13
			2	1	2
					1
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
General physical health deterioration		1
Gingivitis	2	2
Guillain-Barre syndrome		1
Haematemesis		1
Haematochezia	2	2
Haematocrit decreased		1
Haematoma		2
Haematuria		1
Haemoglobin decreased		1
Haemorrhage	2	3
Hallucination	1	2
Headache	66	186
Head discomfort	2	4
Heart rate increased		4
Hemiparaesthesia	1	2
Hemiparesis		1
Hepatic enzyme increased		2
Hepatic pain		1
Herpes dermatitis		1
Herpes simplex	1	1
Herpes zoster		6
Herpes zoster meningitis	1	1
Herpes zoster oticus		1
HIV test positive	1	1
Hordeolum		1
Hot flush	4	7
Hunger		1
Hyperacusis	1	1
Hyperaesthesia	1	2
Hyperhidrosis	2	5
Hypersensitivity	10	32
Hypersensitivity vasculitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				2	2
					1
				2	2
			1		
			2		
			1		
			1		
				2	3
				1	2
	21	63	159	3	27
		2	3		1
			1		3
				1	2
					1
					2
			1		
			1		
		1	1		
			4		2
				1	1
					1
				1	1
			1		
		2	5	2	2
			1		
		1	1		
		1	2		
	1	2	5		
	3	8	11	2	21
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersomnia		1
Hypertension	5	25
Hypertensive crisis	2	8
Hyperthyroidism	1	1
Hypertonia		1
Hyperventilation	1	7
Hypoaesthesia	4	17
Hypoaesthesia oral	3	6
Hypotension	2	14
Hypothermia	1	2
Hypotonia	1	4
Hypoxia		1
Idiopathic intracranial hypertension		1
Immune thrombocytopenia		1
Impaired work ability		1
Inappropriate schedule of product administration	1	4
Incorrect route of product administration	13	22
Infection		2
Influenza	2	2
Influenza like illness	12	35
Injected limb mobility decreased	1	1
Injection site pain	2	2
Insomnia	2	3
Joint range of motion decreased	1	2
Keratoconus	1	1
Lacrimation increased		5
Laryngeal oedema		3
Laryngospasm		1
Limb discomfort	2	8
Lipid metabolism disorder		1
Lip swelling		3
Livedo reticularis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	3	4	11	1	14
				2	8
			1	1	1
		1	3		4
	1	4	15		2
		3	6		
		2	6		8
				1	2
		1	3		1
					1
					1
			1		
		1	4		
		13	22		
			1		1
		2	2		
		12	34		1
		1	1		
		2	2		
		2	2		1
		1	2		
				1	1
			3		2
					3
					1
		2	6		2
			1		
					3
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction	3	4
Loss of consciousness		3
Lower respiratory tract congestion		1
Lung disorder	1	2
Lymphadenitis	1	2
Lymphadenopathy	15	32
Lymphangitis		1
Lymph node pain	1	7
Lymphoedema	1	1
Malaise	11	27
Maternal exposure during pregnancy		5
Memory impairment		1
Meningitis aseptic		1
Meningitis viral		1
Menstruation irregular		1
Mental disorder	1	1
Microembolism		1
Migraine	2	5
Mobility decreased	1	3
Monoplegia		1
Mouth swelling		1
Movement disorder	1	2
Multiple sclerosis		1
Multiple sclerosis relapse		1
Muscle spasms		3
Muscle spasticity		1
Muscle tightness		1
Muscle twitching	2	4
Muscular weakness		6
Musculoskeletal chest pain	1	3
Musculoskeletal disorder	1	1
Musculoskeletal pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	1	2
					3
			1		
		1	2		
		1	2		
		15	29		3
					1
		1	7		
		1	1		
	25	9	20	2	7
			4		1
			1		
					1
					1
			1		
		1	1		
					1
		2	4		1
		1	3		
					1
					1
			3		
					1
			1		
		2	3		1
			5		1
		1	1		2
		1	1		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal stiffness	1	1
Myalgia	27	67
Myasthenia gravis		1
Myocardial infarction		1
Myocarditis	2	3
Myoglobin blood increased		1
Myosclerosis		2
Nasal congestion		2
Nasopharyngitis	1	8
Nausea	20	60
Neck pain	5	16
Nervous system disorder		1
Neuralgia	2	3
Neurodermatitis		1
Neuropathy peripheral	1	2
Neutropenia	1	1
Night sweats		1
Nodule		1
Nystagmus		1
Obstructive airways disorder		1
Ocular discomfort	1	3
Ocular hyperaemia		4
Ocular icterus	1	1
Odynophagia		
Oedema peripheral		1
Off label use	1	5
Optic neuritis		2
Optic neuropathy		1
Oral herpes		3
Oral mucosa erosion		1
Oral mucosal eruption	1	1
Oropharyngeal pain	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
	15	27	59		8
					1
					1
				2	3
					1
					2
			1		1
		1	7		1
	18	18	47	2	13
		5	15		1
					1
		2	3		
			1		
				1	2
				1	1
			1		
			1		
					1
					1
			2	1	1
			3		1
		1	1		
	1				
					1
		1	5		
					2
					1
			2		1
			1		
		1	1		
	1	2	5		2

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Oropharyngeal swelling	1	1
Orthopnoea		1
Orthostatic hypotension	1	1
Orthostatic intolerance	1	2
Overdose	1	1
Oxygen saturation decreased		2
Pain	4	15
Pain in extremity	31	90
Pain of skin	1	1
Palpitations	7	27
Panic reaction	1	1
Paraesthesia	11	41
Paraesthesia oral	4	8
Paralysis		1
Paresis	1	1
Parosmia	1	2
Pemphigus	1	1
Performance status decreased		1
Pericardial effusion	1	1
Perioral dermatitis		1
Peripheral circulatory failure	2	3
Peripheral coldness	1	2
Peripheral swelling	2	3
Peripheral vascular disorder	3	11
Personality change		2
Petechiae	1	3
Pharyngeal hypoaesthesia		2
Pharyngeal oedema		1
Pharyngeal swelling	1	6
Photopsia		1
Photosensitivity reaction		1
Pleocytosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	1		
		1	1		1
				1	1
					2
		4	12		3
		28	80	3	10
		1	1		
	2	5	21	2	6
				1	1
	2	7	19	4	22
		4	6		2
					1
		1	1		
		1	1		1
				1	1
			1		
		2	2		1
		1	2		
		1	2	1	1
	1	3	6		5
			1		1
		1	2		1
			2		
					1
			1	1	5
			1		
			1		
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pleural effusion		1
Pneumonia		1
Poisoning	1	1
Pollakiuria	1	2
Polyneuropathy		1
Poor quality product administered	3	17
Poor quality sleep		1
Pregnancy with contraceptive device	1	1
Presyncope	1	5
Product dose omission issue		1
Product storage error	2	2
Product temperature excursion issue	3	17
Product use issue		2
Protein urine present		1
Prurigo		1
Pruritus	11	28
Pruritus allergic		2
Psychological factor affecting medical condition		1
Pulmonary embolism	3	5
Pulmonary pain		2
Pulmonary sarcoidosis	1	1
Pupils unequal		1
Pyrexia	30	99
Rash	4	20
Rash erythematous	1	2
Rash macular		1
Rash maculo-papular	1	2
Rash pruritic	4	5
Rash pustular	1	1
Rash vesicular		2
Raynaud's phenomenon		1
Red blood cell count decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
		1	2		
					1
		3	16		1
			1		
				1	1
		1	5		
			1		
		2	2		
		3	16		1
			2		
			1		
			1		
		9	17	2	11
			1		1
				3	5
			1		1
				1	1
					1
	8	28	82	2	17
	1	2	8	2	12
		1	2		
			1		
		1	2		
		4	5		
		1	1		
			2		
			1		
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Red blood cell sedimentation rate increased	1	1
Renal pain		2
Respiration abnormal		1
Respiratory distress	6	35
Respiratory failure		1
Respiratory rate increased	1	1
Respiratory symptom		1
Resting tremor		1
Restlessness	2	3
Retching	1	2
Retinal disorder		1
Retinopathy		1
Retrograde amnesia		1
Reversible cerebral vasoconstriction syndrome		1
Rheumatic disorder		1
Rheumatoid arthritis		2
Rhinalgia		1
Rhinorrhoea	2	6
SARS-CoV-2 antibody test negative	1	2
SARS-CoV-2 antibody test positive	2	12
SARS-CoV-2 test positive		2
Scratch		1
Seasonal allergy	1	1
Seizure	1	4
Sensation of foreign body		6
Sensory disturbance	4	15
Sensory level abnormal		2
Sinusitis		1
Sinus tachycardia		2
Skin burning sensation	1	1
Skin discolouration	1	3
Skin lesion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		1
			1		
				6	35
					1
		1	1		
			1		
					1
		2	3		
		1	2		
					1
					1
					1
					1
					1
			1		
		2	6		
		1	2		
		2	12		
			2		
			1		
		1	1		
				1	4
			2		4
		3	12	1	3
			2		
			1		
					2
		1	1		
		1	2		1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin swelling	1	1
Sleep disorder		2
Sneezing		3
Somnolence	2	7
Speech disorder	2	3
Spinal pain		1
Stomatitis	2	2
Stress		2
Stridor		3
Subarachnoid haemorrhage		1
Sudden death		1
Sudden hearing loss		3
Sudden visual loss		1
Superinfection bacterial	2	2
Supraventricular extrasystoles	1	2
Swelling	3	9
Swelling face	2	3
Swollen tongue	2	6
Syncope	2	14
Tachyarrhythmia		2
Tachycardia	10	47
Tachycardia induced cardiomyopathy		1
Tachypnoea		2
Taste disorder	1	4
Tenderness	1	1
Tension headache		1
Tetany		1
Thirst	1	2
Throat irritation	3	9
Throat tightness	3	11
Thrombocytopenia		1
Thrombophlebitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		
			3		
		2	5		2
			1	2	2
			1		
				2	2
			2		
					3
					1
					1
					3
					1
				2	2
			1	1	1
		3	8		1
	1	1	1	1	2
		2	3		3
	1			2	14
			1		1
	5	10	24		23
					1
			1		1
		1	2		2
		1	1		
					1
					1
		1	2		
		3	8		1
		2	6	1	5
					1
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombophlebitis superficial	1	1
Thrombosis	2	3
Thyroiditis acute		1
Tinnitus		4
Tonic convulsion		1
Tonsillitis bacterial		2
Transient ischaemic attack	1	1
Tremor	6	14
Trichoglossia		1
Trigeminal neuralgia	1	1
Underdose		1
Urticaria	5	11
Vaccination failure		1
Vaccination site dermatitis		1
Vaccination site discomfort		2
Vaccination site dysaesthesia		1
Vaccination site erythema	10	18
Vaccination site haematoma	1	2
Vaccination site hyperaesthesia		1
Vaccination site hypoaesthesia		1
Vaccination site induration	2	6
Vaccination site joint movement impairment		2
Vaccination site joint pain		2
Vaccination site lymphadenopathy	1	1
Vaccination site movement impairment	3	6
Vaccination site oedema	1	1
Vaccination site pain	56	147
Vaccination site papule	1	1
Vaccination site paraesthesia	2	3
Vaccination site pruritus	3	8
Vaccination site reaction	1	4
Vaccination site swelling	10	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	3
					1
			2		2
					1
					2
				1	1
		4	8	2	6
			1		
		1	1		
			1		
		4	6	1	5
					1
			1		
			2		
			1		
		10	18		
		1	2		
			1		
					1
		2	6		
			2		
			2		
		1	1		
		3	6		
		1	1		
	24	56	145		2
		1	1		
		2	3		
		3	8		
		1	4		
	4	10	19		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site urticaria	1	1			1	1		
Vaccination site warmth	2	10		1	2	10		
Vasculitis		1						1
Venous thrombosis in pregnancy	1	1					1	1
Venous thrombosis limb		1						1
Vertigo		3				2		1
Vision blurred		4				2		2
Visual field defect		1						1
Visual impairment	5	15			3	6	2	9
Vomiting	7	20		3	6	15	1	5
Weight bearing difficulty		1						1
Wheezing		3				1		2
White blood cell count increased		1						1
	903	2,924		214	745	1974	158	950

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	2			1	2		
Abdominal pain	3	8			1	4	2	4
Abdominal pain lower	1	2				1	1	1
Abdominal pain upper	1	3			1	3		
Abnormal faeces		3				2		1
Accidental overdose		5				4		1
Acute abdomen	1	2					1	2
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	1	1					1	1
Acute myocardial infarction	2	5					2	5
Acute phase reaction	1	1			1	1		
Acute respiratory distress syndrome	1	3					1	3
Acute respiratory failure		1						1
Acute stress disorder	1	1					1	1
Ageusia		3				3		
Agitation		1						1
Allergic oedema		1						1
Allergy to vaccine		2				1		1
Altered state of consciousness		1						1
Amnesic disorder	1	1					1	1
Anaesthesia		1						1
Anaphylactic reaction	1	13					1	13
Anaphylactic shock	1	4					1	4
Angina pectoris		3						3
Angioedema	2	4					2	4
Anosmia		2				2		
Anxiety		2				2		
Apathy		3				3		
Arrhythmia	1	8		1			1	8
Arterial thrombosis		2						2
Arthralgia	12	30		5	12	27		3
Arthritis	1	1					1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathy		1
Asthenia	10	32
Asthma		2
Asymptomatic COVID-19	1	2
Ataxia		1
Atrial tachycardia		1
Autonomic nervous system imbalance	1	1
Axillary pain	1	2
Back pain	3	7
Blood cholesterol increased		1
Blood glucose abnormal		1
Blood glucose increased		1
Blood immunoglobulin M increased		1
Blood pressure increased	1	8
Body temperature decreased	1	1
Body temperature increased	3	7
Bone pain	1	9
Bradycardia	1	2
Brain death		1
Brain oedema		1
Brain stem infarction	1	1
Breast pain	1	1
Bronchial disorder		1
Bronchitis		1
Bronchospasm		1
Burning sensation		3
Cardiac arrest	1	2
Cardiac discomfort	1	1
Cardiac failure	1	3
Cardiac fibrillation		1
Cardiovascular disorder		6
Cerebral haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		10	30		2
			1		1
			1	1	1
					1
		1	1		
		1	1		1
		2	6	1	1
			1		
			1		
			1		
		1	5		3
		1	1		
		3	5		2
		1	7		2
				1	2
					1
				1	1
		1	1		
			1		
			1		
					1
			1		2
				1	2
		1	1		
				1	3
					1
			2		4
					2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral infarction	1	1
Cerebral ventricle collapse		1
Cerebrovascular accident		2
Chest discomfort	1	2
Chest pain	2	5
Chills	26	44
Chronic obstructive pulmonary disease		1
Circulatory collapse	1	5
Cold sweat	3	6
Colitis ulcerative		3
Communication disorder		1
Complement factor C3 increased		1
Condition aggravated		1
Conjunctivitis		1
Constipation		1
Coronary artery disease	1	1
Coronary artery dissection	1	1
Coronary artery stenosis	1	1
Coronavirus test positive		1
Cough	5	15
COVID-19	7	37
COVID-19 pneumonia		2
Cranial nerve disorder		1
C-reactive protein increased	1	1
Creutzfeldt-Jakob disease	2	2
Cyanosis		1
Deafness	1	1
Deafness unilateral		1
Death	2	6
Decreased appetite	4	8
Deep vein thrombosis		2
Depressed level of consciousness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					2
		1	2		
		2	4		1
	4	25	39	1	5
					1
				1	5
		3	5		1
					3
			1		
			1		
					1
					1
			1		
				1	1
				1	1
				1	1
			1		
		5	11		4
	1	3	9	4	28
					2
			1		
		1	1		
				2	2
					1
				1	1
					1
				2	6
		3	5	1	3
					2
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depression		1
Diabetes mellitus inadequate control		1
Diarrhoea	8	27
Diet refusal		1
Diplopia		1
Disease recurrence		4
Disseminated intravascular coagulation		1
Disturbance in attention	1	6
Diverticulitis	1	2
Dizziness	8	49
Drug ineffective	3	22
Drug interaction		1
Dry age-related macular degeneration	1	1
Dry eye	1	1
Dry mouth	1	3
Dysaesthesia		5
Dysgeusia	2	3
Dysphagia	2	8
Dyspnoea	6	20
Dyspnoea at rest		1
Dyspnoea exertional		3
Dysstasia		1
Ear discomfort		1
Eczema		1
Embolic stroke	1	1
Encephalitis		1
Enteritis		1
Epilepsy	3	8
Epistaxis	1	1
Erythema	5	13
Extrasystoles		1
Eye haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		7	21	1	6
			1		1
					4
					1
		1	5		1
				1	2
	6	7	36	1	13
				3	22
			1		
				1	1
		1	1		
		1	2		1
			2		3
		2	2		1
		2	5		3
		2	9	4	11
					1
					3
			1		
			1		
					1
					1
				3	8
				1	1
		4	9	1	4
			1		
					2

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye irritation	1	2
Eye pain	1	1
Eye pruritus		1
Eye swelling		1
Face oedema	1	1
Facial paralysis		4
Facial paresis	1	6
Fall		2
Fatigue	26	70
Feeling abnormal		2
Feeling cold	4	5
Feeling hot		7
Fibrin D dimer increased	1	1
Flatulence	1	1
Flushing	1	4
Functional gastrointestinal disorder		1
Gait disturbance		2
Gastrointestinal motility disorder		1
Gastrointestinal necrosis		2
General physical health deterioration	1	7
Giant cell arteritis		1
Gingival swelling		1
Glomerular filtration rate decreased		1
Guillain-Barre syndrome		1
Haematochezia		1
Haematoma		3
Hallucination, auditory		1
Headache	33	104
Head discomfort	1	1
Hemiparesis	1	3
Hepatic enzyme increased	1	1
Hepatic failure		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		1	1		
					1
			1		
		1	1		
					4
			2	1	4
			1		1
	10	26	64		6
			2		
		4	5		
			3		4
		1	1		
				1	1
		1	2		2
			1		
			2		
			1		
					2
		1	3		4
					1
			1		
					1
					3
					1
	12	30	88	3	16
		1	1		
				1	3
		1	1		
					3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes virus infection		1
Herpes zoster	1	11
Herpes zoster infection neurological		1
Herpes zoster oticus		1
Huntington's disease		3
Hyperaesthesia	1	1
Hyperglycaemia		1
Hyperhidrosis	4	12
Hypersensitivity	3	15
Hypersensitivity vasculitis	1	1
Hypersomnia		1
Hypertension	3	14
Hypertensive crisis	1	4
Hypertensive emergency		1
Hyperthyroidism		1
Hypertonia		1
Hyperventilation		1
Hypoaesthesia	2	8
Hypoaesthesia oral		1
Hypoglycaemia	1	1
Hypophagia		1
Hypotension	5	9
Hypotonia	1	3
Ileectomy	1	1
Illness		1
Immune thrombocytopenia	1	2
Impaired work ability		1
Inappropriate schedule of product administration	1	6
Incorrect dose administered		1
Incorrect route of product administration	6	15
Induration		1
Infection	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			9	1	2
					1
					1
					3
		1	1		
					1
		4	11		1
		2	7	1	8
				1	1
					1
		1	5	2	9
				1	4
					1
					1
					1
		2	5		3
			1		
		1	1		
					1
		5	6		3
		1	3		
				1	1
			1		
				1	2
					1
		1	6		
			1		
		6	14		1
			1		
	1	1	2		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infective exacerbation of chronic obstructive airways disease		2
Influenza like illness	5	17
Injection site pain		1
Insomnia		1
Intestinal gangrene		1
Intestinal obstruction		1
Ischaemic cerebral infarction		1
Ischaemic stroke		1
IVth nerve disorder		1
IVth nerve paresis		1
Jaundice		1
Joint range of motion decreased		1
Joint swelling		1
Lacrimation increased		1
Language disorder		1
Laryngeal oedema		2
Left ventricular failure		1
Leukocytosis		1
Leukopenia		1
Lhermitte's sign	1	1
Limb discomfort	3	7
Lip oedema		1
Lip swelling		3
Local reaction	2	3
Loss of consciousness	2	8
Loss of personal independence in daily activities		1
Low density lipoprotein increased		1
Lung infiltration		1
Lymphadenopathy	6	10
Lymph node pain		3
Lymphopenia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		5	17		
			1		
			1		
					1
					1
					1
					1
					1
			1		
			1		
					1
			1		
					1
					2
					1
					1
					1
		1	1		
		2	5	1	2
			1		
					3
		2	3		
				2	8
			1		
			1		
					1
	1	6	9		1
			3		
					1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	4	16
Memory impairment	1	2
Meningism	1	2
Mental disorder		1
Mesenteric vein thrombosis	1	3
Microscopic polyangiitis		1
Micturition disorder	1	1
Middle insomnia		1
Migraine		2
Mobility decreased	2	2
Monoparesis		1
Monoplegia		1
Mouth swelling		1
Movement disorder	1	3
Multiple sclerosis relapse	1	2
Muscle discomfort		1
Muscle spasms	2	4
Muscle tightness	2	2
Muscle twitching	1	1
Muscular weakness		1
Musculoskeletal chest pain		3
Musculoskeletal pain	1	2
Myalgia	10	32
Myelitis	1	2
Myocardial infarction		1
Myocardial ischaemia	1	1
Myositis	1	1
Nasal congestion		1
Nasopharyngitis	2	9
Nausea	13	39
Neck pain	1	5
Nervousness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	4	4	10		6
			1	1	1
		1	1		1
			1		
				1	3
					1
		1	1		
			1		
			1		1
		2	2		
					1
					1
					1
		1	2		1
				1	2
			1		
		2	2		2
		2	2		
		1	1		
					1
			1		2
		1	2		
	8	10	29		3
				1	2
					1
				1	1
		1	1		
			1		
		2	8		1
	1	13	32		7
		1	4		1
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuralgia		2
Neuralgic amyotrophy		3
Neuritis		2
Nuchal rigidity	1	1
Obstructive airways disorder	1	1
Occipital neuralgia		1
Ocular discomfort		1
Oculogyric crisis		1
Odynophagia	1	1
Off label use	1	5
Ophthalmic vein thrombosis	2	2
Oral discomfort		1
Oral herpes		1
Oral mucosal blistering		1
Oropharyngeal blistering		1
Oropharyngeal discomfort		1
Oropharyngeal pain	1	5
Orthopnoea		1
Orthostatic hypotension	1	1
Oxygen saturation decreased		3
Pain	5	15
Painful respiration	2	2
Pain in extremity	18	47
Pallor	1	3
Palpitations		12
Panic attack		1
Paraesthesia	4	15
Paraesthesia oral	1	5
Paresis	1	5
Parosmia	1	1
Partial seizures	1	1
Pelvic pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		2
			2		
		1	1		
				1	1
			1		
			1		
					1
		1	1		
		1	5		
				2	2
			1		
			1		
			1		
					1
			1		
		1	4		1
					1
		1	1		
			1		2
		5	12		3
		2	2		
		17	41	1	6
		1	1		2
	1		6		6
					1
		3	10	1	5
		1	4		1
			1	1	4
		1	1		
				1	1
			1		

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pelvic venous thrombosis	1	1
Performance status decreased		2
Peripheral circulatory failure	2	2
Peripheral swelling		4
Peripheral vascular disorder		4
Personality change		1
Petechiae		2
Pharyngeal swelling		3
Pharyngitis	1	2
Phlebitis	1	1
Photopsia		1
Pneumonia	1	4
Pneumonia aspiration		2
Polyneuropathy		1
Poor quality product administered	2	8
Presyncope		1
Product preparation issue		1
Product storage error		1
Product supply issue		1
Product temperature excursion issue	2	8
Product use issue		2
Pruritus	4	15
Psoriasis		1
Psychomotor retardation	1	1
Pulmonary embolism	3	6
Pupillary disorder	1	1
Pyrexia	22	60
Quadripareisis		1
Radiculopathy		2
Rash	5	13
Rash macular		1
Rash maculo-papular		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
		2	2		
			2		2
			1		3
					1
			1		1
			2		1
		1	2		
		1	1		
			1		
				1	4
					2
					1
		2	8		
					1
			1		
			1		
			1		
		2	8		
			2		
	1	4	13		2
			1		
				1	1
				3	6
		1	1		
	4	21	47	1	13
					1
			1		1
	1	5	8		5
			1		
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash vesicular	1	1
Rectal polyp		1
Renal disorder		1
Renal failure		3
Renal impairment	1	1
Renal pain		1
Respiration abnormal		1
Respiratory distress	2	10
Respiratory failure		7
Respiratory rate decreased	1	1
Respiratory rate increased		1
Respiratory tract infection		1
Restlessness	1	6
Retching	1	3
Retinal artery occlusion	1	1
Retinal tear		2
Rhabdomyolysis		1
Rhinitis		2
Rhinorrhoea	1	7
SARS-CoV-2 antibody test negative	1	2
SARS-CoV-2 antibody test positive	2	8
SARS-CoV-2 test positive		3
Scratch	1	1
Secondary hypertension	1	1
Seizure	1	6
Sensation of blood flow		1
Sensation of foreign body		2
Sense of oppression		1
Sensory disturbance	3	6
Sensory level abnormal		2
Sialoadenitis		1
Sinus tachycardia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
					1
					3
				1	1
					1
			1		
				2	10
					7
		1	1		
			1		
					1
		1	5		1
		1	2		1
				1	1
					2
					1
			2		
		1	7		
		1	2		
		2	8		
			2		1
		1	1		
		1	1		
				1	6
			1		
					2
			1		
		3	6		
			1		1
					1
					1

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin abrasion		1
Skin burning sensation		1
Skin discolouration		1
Skin swelling		1
Sleep disorder	1	4
Snoring	2	2
Somnolence	4	10
Speech disorder		1
Spinal pain		1
Status epilepticus		3
Stomatitis		1
Subclavian artery thrombosis		1
Sudden death		1
Sudden hearing loss		2
Superior sagittal sinus thrombosis		1
Supraventricular extrasystoles		1
Supraventricular tachycardia		1
Suspected COVID-19		1
Swelling		3
Swelling face		9
Swollen tongue	2	4
Syncope	3	14
Tachycardia	4	15
Tachypnoea		1
Taste disorder	2	2
Tension		1
Therapeutic response unexpected	1	1
Throat irritation	1	2
Throat tightness	2	4
Thrombectomy	1	1
Thrombocytopenia		1
Thrombophlebitis superficial	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
			1		
		1	4		
		2	2		
		4	8		2
					1
					1
					3
					1
					1
					1
					2
					1
			1		
					1
					1
	2		4		5
		2	3		1
				3	14
		4	8		7
					1
			1		
		1	1		
		1	2		
		2	3		1
				1	1
					1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombosis	1	2
Tinnitus	1	2
Tongue disorder		1
Tonsillar hypertrophy	1	1
Transaminases increased		1
Transient aphasia	1	1
Transient ischaemic attack	1	2
Tremor	2	5
Trigeminal neuralgia		1
Unresponsive to stimuli	1	2
Urine odour abnormal	1	1
Urosepsis		1
Urticaria	6	8
Vaccination complication		1
Vaccination failure	2	5
Vaccination site erythema	1	6
Vaccination site hyperaesthesia		1
Vaccination site joint movement impairment		1
Vaccination site lymphadenopathy	1	1
Vaccination site pain	23	53
Vaccination site pruritus		1
Vaccination site reaction	1	3
Vaccination site swelling	4	11
Vaccination site warmth	1	4
Varicella zoster virus infection		1
Vasculitis		2
Ventricular extrasystoles	1	1
Vertigo		1
Vestibular neuronitis	1	1
Visceral venous thrombosis		1
Vision blurred		3
Visual impairment		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	1		1
			1		
		1	1		
			1		
				1	1
				1	2
		2	4		1
			1		
				1	2
		1	1		
					1
		5	7	1	1
					1
				2	5
	1	1	4		2
			1		
					1
		1	1		
	7	23	48		5
			1		
		1	2		1
	2	4	10		1
		1	3		1
			1		
			1		1
		1	1		
			1		
		1	1		
					1
			2		1
			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vitreous disorder		1							1
Vomiting	1	13			1	11			2
Wheezing		1				1			
White blood cell count increased	1	1			1	1			
	518	1,781		73	410	1118		108	663

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal discomfort		1				1			
Abdominal pain upper	1	1					1	1	
Acidosis		1							1
Acute febrile neutrophilic dermatosis	1	1					1	1	
Acute respiratory distress syndrome		1							1
Acute respiratory failure		1							1
Ageusia		1				1			
Aggression	1	1					1	1	
Allergy to vaccine		1							1
Alopecia		2				1			1
Amino acid level decreased		1				1			
Anaphylactic reaction		2							2
Angioedema		4							4
Antibody test abnormal		1				1			
Aortic aneurysm		1							1
Aortic dissection	1	1					1	1	
Aphasia	1	1					1	1	
Arrhythmia	1	3					1	3	
Arthralgia	4	4			4	4			
Aspiration		1							1
Asthenia	4	12			3	9	1	3	
Asthma	1	2					1	2	
Asymptomatic COVID-19		1							1
Atrial fibrillation		1							1
Back pain	2	2			2	2			
Balance disorder	1	2				1	1	1	
Basal ganglia haemorrhage	1	1					1	1	
Basilar artery thrombosis	1	2					1	2	
Bedridden		1							1
Blindness unilateral	1	1					1	1	
Blister		1				1			
Blood creatine phosphokinase increased		1							1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure decreased	1	1
Blood pressure increased	1	1
Blood test abnormal	1	1
Body temperature increased		2
Bone pain	1	2
Brain injury		1
Brain oedema		1
Breast pain	1	1
Bronchitis		2
Burning sensation	1	1
Cardiac arrest	2	3
Cardiac failure	1	2
Cardiovascular disorder	1	1
Cerebral haemorrhage	2	3
Cerebral infarction	3	3
Cerebral ischaemia	2	3
Cerebrovascular accident	3	6
Chest pain	2	2
Chills	3	9
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Chronic obstructive pulmonary disease		1
Circulatory collapse	1	4
Condition aggravated		1
Cor pulmonale		1
Cough		1
COVID-19	4	35
COVID-19 pneumonia		4
Cystitis haemorrhagic	1	1
Dark circles under eyes	1	1
Death	6	40
Decreased appetite		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		1	1		
			2		
		1	2		
					1
					1
		1	1		
			1		1
		1	1		
				2	3
				1	2
		1	1		
				2	3
				3	3
				2	3
				3	6
		2	2		
		3	7		2
					1
					1
				1	4
					1
					1
			1		
		1	4	3	31
					4
				1	1
		1	1		
				6	40
			1		1

\* I=Interval, C=Cumulative  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deep vein thrombosis	5	6
Dehydration		1
Delusion		1
Dementia		1
Diarrhoea	2	5
Diet refusal		1
Disease recurrence	2	2
Disturbance in attention	2	2
Dizziness	4	7
Drug ineffective	2	23
Drug interaction	1	1
Dysarthria		2
Dysgeusia		1
Dysphonia		1
Dyspnoea	4	9
Eczema		5
Encephalitis		1
Epilepsy		1
Epistaxis	2	2
Erysipelas	1	1
Erythema multiforme		1
Eye pruritus		2
Eye swelling		1
Facial paralysis		2
Fall	1	4
Fatigue	3	14
Feeling abnormal	1	1
Feeling cold		1
Feeling hot		1
Femur fracture	1	1
Flushing		1
Gait disturbance		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	6
					1
					1
					1
	1		1	2	4
					1
		1	1	1	1
		1	1	1	1
		4	6		1
				2	23
				1	1
					2
			1		
					1
		3	4	1	5
			5		
					1
					1
		2	2		
				1	1
					1
					1
					2
				1	4
		3	11		3
		1	1		
					1
			1		
				1	1
					1
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal necrosis	1	1
Gastrointestinal pain		1
General physical health deterioration		7
Genital haemorrhage	1	1
Gingival bleeding	1	1
Groin pain		1
Haematemesis		1
Haemolytic uraemic syndrome		1
Headache	2	8
Head discomfort		1
Heart rate decreased		1
Heart rate increased		1
Hemiplegia	2	2
Herpes zoster		5
Hyperhidrosis		2
Hyperkalaemia		1
Hypersensitivity	1	5
Hypersomnia	1	1
Hypertension	3	7
Hypertensive crisis		1
Hypoaesthesia		1
Hypoaesthesia oral		2
Hypotension		2
Hypotonia	2	3
Hypoventilation		1
Hypoxia	1	1
Inappropriate schedule of product administration	1	2
Incorrect route of product administration	1	5
Influenza	1	1
Influenza like illness		1
Injection site discomfort		1
Intentional product misuse	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			3		4
				1	1
				1	1
			1		
					1
					1
		2	6		2
					1
					1
				2	2
			4		1
			2		
					1
		1	1		4
		1	1		
		2	2	1	5
					1
			1		
			1		1
		1	1	1	2
					1
				1	1
		1	2		
		1	5		
				1	1
					1
			1		
		1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Internal haemorrhage	1	1
Irregular breathing		1
Ischaemic cerebral infarction	1	1
Lacrimation increased		1
Limb discomfort		1
Listless	1	1
Loss of consciousness		4
Lymphocytic infiltration		1
Malaise	2	8
Malignant melanoma		1
Mental disorder	1	2
Mesenteric vein thrombosis	1	1
Microscopic polyangiitis	1	1
Mobility decreased		1
Monoparesis	1	1
Monoplegia		1
Mouth haemorrhage	1	1
Multiple organ dysfunction syndrome		2
Muscular weakness	1	1
Musculoskeletal stiffness		1
Myalgia	1	3
Myocardial infarction	1	2
Nasopharyngitis	1	3
Nausea	1	3
Neuralgia		1
Neuralgic amyotrophy		1
Night sweats		1
Ocular hyperaemia		1
Off label use	1	2
Oliguria		1
Onychoclasia		1
Optic ischaemic neuropathy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	1
			1		
			1		
		1	1		
					4
					1
		2	4		4
					1
				1	2
				1	1
				1	1
			1		
		1	1		
					1
		1	1		
					2
				1	1
			1		
	1	1	2		1
				1	2
		1	3		
		1	1		2
			1		
			1		
		1	2		
					1
			1		
		1	2		
					1
			1		
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Oral fungal infection		1						1
Oxygen saturation decreased		1						1
Pain in extremity	1	6			1	5		1
Pallor		1				1		
Panic reaction		1				1		
Paraesthesia	1	3			1	2		1
Paraesthesia oral	1	2			1	2		
Paresis		1				1		
Parkinson's disease		1						1
Pelvic venous thrombosis	1	1					1	1
Peripheral circulatory failure	1	1					1	1
Peripheral coldness		1				1		
Peripheral vascular disorder		2						2
Personality change		1						1
Pleuritic pain	1	1			1	1		
Pneumonia		1						1
Poor quality product administered		1				1		
Product temperature excursion issue		1				1		
Pruritus	1	1			1	1		
Pulmonary artery thrombosis		1						1
Pulmonary embolism	5	6					5	6
Pulmonary haemorrhage	1	1					1	1
Pulmonary oedema		1						1
Pulmonary sepsis		1						1
Pulmonary vasculitis		1						1
Pyrexia	1	16				4	1	12
Rash		4						2
Rash macular	1	1			1	1		
Renal failure		1						1
Respiratory distress	1	7					1	7
Respiratory failure		3						3
Respiratory tract infection viral	1	1			1	1		

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 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retrograde amnesia	1	1
Rhabdomyolysis		2
Rhinorrhoea		2
Rhonchi		1
Rosacea		1
SARS-CoV-2 antibody test positive		1
SARS-CoV-2 sepsis		1
SARS-CoV-2 test positive	1	2
Seizure		4
Shock		1
Skin exfoliation	1	2
Skin warm	1	1
Sleep disorder		1
Sneezing		1
Somnolence		1
Status epilepticus		1
Subarachnoid haemorrhage	1	1
Subclavian vein thrombosis	1	1
Sudden cardiac death	1	1
Sudden death		4
Superinfection bacterial		1
Suspected counterfeit product		1
Swelling	1	1
Swelling face	1	2
Swollen tongue	1	1
Syncope	1	3
Systemic lupus erythematosus	1	1
Tachycardia		2
Taste disorder		1
Thrombophlebitis superficial	1	1
Tongue oedema		2
Transient global amnesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					2
			1		1
					1
			1		
					1
		1	1		1
					4
					1
		1	2		
		1	1		
			1		
			1		
					1
				1	1
				1	1
				1	1
					4
					1
			1		
		1	1		
		1	1		1
		1	1		
				1	3
				1	1
			1		1
		1	1		
					2
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Tremor		2				2			
Type IV hypersensitivity reaction		4				4			
Unresponsive to stimuli		2							2
Urticaria	1	2			1	1			1
Vaccination failure		4							4
Vaccination site erythema		1				1			
Vaccination site haematoma		1				1			
Vaccination site irritation		1				1			
Vaccination site pain	3	10		1	3	10			
Vaccination site swelling	1	1			1	1			
Venous thrombosis	1	1						1	1
Ventricular tachycardia		1							1
Visual impairment	2	3						2	3
Vomiting		5				4			1
Weight decreased	1	1						1	1
	165	577		3	76	208		89	369

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	2	4			1	1	1	3
Abdominal pain lower		1				1		
Abscess limb	1	1					1	1
Abscess neck	1	1					1	1
Acute abdomen		1						1
Acute coronary syndrome	2	5					2	5
Acute generalised exanthematous pustulosis	1	1					1	1
Acute kidney injury		13						13
Acute myocardial infarction	4	12					4	12
Acute respiratory distress syndrome		1						1
Acute respiratory failure	1	2					1	2
Acute right ventricular failure	1	1					1	1
Adverse event	1	1					1	1
Ageusia	1	3			1	3		
Aggression		2						2
Agitation		2						2
Alanine aminotransferase increased		1						1
Allergic oedema		1				1		
Altered state of consciousness	1	5					1	5
Amaurosis fugax		1						1
Amnesia		1						1
Anaemia	2	3				1	2	2
Anaphylactic reaction	1	10					1	10
Anaphylactic shock		2						2
Angina pectoris	2	4					2	4
Angioedema	1	8					1	8
Anosmia		1				1		
Aortic aneurysm	1	2					1	2
Aortic dissection		1						1
Apathy		5				1		4
Aphasia	2	11				2	2	9
Aphthous ulcer		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Appendicitis	1	1
Arrhythmia	4	8
Arterial occlusive disease		1
Arteriosclerosis		1
Arthralgia	7	11
Aspartate aminotransferase increased		1
Aspiration		1
Asthenia	15	31
Asthma		1
Asymptomatic COVID-19	1	2
Ataxia		5
Atrial fibrillation	2	18
Atrial flutter		1
Atrioventricular block complete	2	5
Atrioventricular block first degree		1
Autoimmune disorder		1
Automatism		1
Back pain	1	1
Basal ganglia infarction		1
Basilar artery occlusion		1
Bedridden		1
Blister		1
Blood calcium decreased	1	3
Blood creatine phosphokinase increased		1
Blood creatine phosphokinase MB increased		1
Blood creatinine increased		1
Blood disorder		1
Blood glucose decreased	1	1
Blood glucose fluctuation		1
Blood lactate dehydrogenase increased		2
Blood potassium decreased		2
Blood pressure decreased	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				4	8
					1
					1
		6	10	1	1
					1
					1
		9	15	6	16
					1
				1	2
					5
				2	18
			1		
				2	5
			1		
					1
					1
		1	1		
					1
					1
			1		
					1
			2	1	1
			1		
			1		
					1
					1
				1	1
			1		
					2
			1		1
		2	3	3	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure fluctuation		1
Blood pressure immeasurable		1
Blood pressure increased	3	5
Blood pressure systolic increased	1	1
Blood sodium decreased	1	1
Blood urine present		1
Body temperature increased	2	9
Bone pain	1	1
Bradyarrhythmia	1	1
Bradycardia		3
Bronchitis		1
Bronchitis bacterial		1
Bronchitis chronic	1	1
Bronchospasm		3
Bundle branch block right	1	1
Burning sensation		1
Bursitis	1	1
Capillary nail refill test abnormal		1
Carbon dioxide decreased	1	1
Cardiac aneurysm		1
Cardiac arrest	3	13
Cardiac death	1	1
Cardiac failure	7	32
Cardiac failure acute		1
Cardiac failure congestive		4
Cardiac fibrillation		1
Cardiogenic shock	1	7
Cardiopulmonary failure		1
Cardio-respiratory arrest		2
Cardiovascular disorder		4
Cardiovascular insufficiency	2	2
Carotid artery occlusion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1	3	4
				1	1
				1	1
					1
		2	2		7
		1	1		
				1	1
					3
					1
					1
		1	1		
			1		2
				1	1
			1		
				1	1
					1
				3	13
				1	1
				7	32
					1
					4
					1
				1	7
					1
					2
			1		3
				2	2
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral atrophy		1
Cerebral haemorrhage	1	9
Cerebral infarction	1	6
Cerebral ischaemia		3
Cerebral thrombosis	2	2
Cerebral venous sinus thrombosis	1	3
Cerebral venous thrombosis	1	1
Cerebrovascular accident	10	33
Cerebrovascular disorder		1
Chest discomfort		2
Chest pain	1	6
Chills	7	14
Cholelithiasis		1
Chronic kidney disease		2
Chronic obstructive pulmonary disease	2	5
Circulatory collapse	4	19
Clonus	1	1
Coagulopathy	1	2
Cognitive disorder		1
Cold sweat		1
Coma		2
Condition aggravated	1	3
Confusional state	3	15
Conjunctival hyperaemia	1	1
Conjunctivitis		1
Constipation		1
Contusion		2
Coordination abnormal		1
Coronavirus infection	7	10
Coronavirus test positive		1
Cough	6	12
COVID-19	25	113

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	9
				1	6
					3
				2	2
				1	3
				1	1
				10	33
					1
					2
			3	1	3
		6	11	1	3
			1		
					2
				2	5
				4	19
				1	1
				1	2
					1
					1
					2
				1	3
		1	5	2	10
				1	1
			1		
			1		
					2
					1
		7	7		3
					1
		4	8	2	4
		15	41	10	72

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19 pneumonia	3	13
Cranial nerve decompression		1
C-reactive protein increased	4	8
Crepitations		1
Cyanosis		3
Death	34	142
Decreased appetite	4	8
Deep vein thrombosis	14	17
Dehydration	1	4
Delirium	1	6
Delusion		1
Dementia	1	5
Dementia of the Alzheimer's type, with delirium		1
Depressed level of consciousness	1	3
Depressed mood		1
Depression	1	1
Dermatitis allergic	2	4
Dermatitis bullous	1	1
Diabetes mellitus		1
Diarrhoea	9	18
Diet refusal		4
Diplopia	1	1
Disease progression	1	1
Disease recurrence		1
Disorientation	1	5
Disturbance in attention	1	12
Dizziness	13	30
Dizziness postural		1
Drug ineffective	9	49
Drug interaction		1
Dry skin		1
Dry throat		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	13
					1
		3	4	1	4
					1
					3
				34	142
		3	6	1	2
				14	17
				1	4
				1	6
					1
				1	5
					1
				1	3
					1
		1	1		
		2	3		1
				1	1
					1
		7	13	2	5
					4
				1	1
				1	1
					1
		1	3		2
		1	2		10
		6	12	7	18
			1		
				9	49
			1		
			1		
			1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dysarthria		1						1
Dyskinesia		1						1
Dyslalia		1						1
Dysphagia	1	6			1	5		1
Dysphonia	1	2			1	2		
Dyspnoea	13	43			5	9	8	34
Dyspnoea exertional	3	3			1	1	2	2
Dysstasia	1	1			1	1		
Eastern Cooperative Oncology Group performance status worsened	1	1			1	1		
Eating disorder		1				1		
Effusion	1	1					1	1
Electrocardiogram QT prolonged		1						1
Electrocardiogram T wave inversion		1						1
Electrolyte depletion		1				1		
Electrolyte imbalance		1						1
Embolic cerebral infarction	1	1					1	1
Embolism	1	1					1	1
Embolism arterial		1						1
Emphysema	1	1					1	1
Encephalitis	1	1					1	1
Encephalitis autoimmune	1	1					1	1
Epilepsy		15						15
Epistaxis		1						1
Erysipelas	1	2					1	2
Erythema	6	11			5	10	1	1
Essential tremor		1						1
Eye haemorrhage		1						1
Eyelid oedema	2	2			1	1	1	1
Eye swelling		1				1		
Face oedema	1	1			1	1		
Facial paralysis	2	9					2	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
		1	5		1
		1	2		
		5	9	8	34
		1	1	2	2
		1	1		
		1	1		
			1		
				1	1
					1
			1		
					1
				1	1
				1	1
					15
					1
				1	2
		5	10	1	1
					1
					1
		1	1	1	1
			1		
		1	1		
				2	9

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Facial paresis	2	8
Factor VIII inhibition		1
Faeces discoloured		1
Fall		11
Fatigue	6	23
Febrile infection		3
Feeling abnormal	1	1
Feeling cold	1	3
Feeling drunk	1	1
Feeling hot	2	2
Femoral neck fracture		1
Femur fracture		1
Fibrin D dimer increased	1	1
Flatulence		1
Fluid retention	1	1
Flushing		2
Food refusal		3
Fracture		1
Gait disturbance		4
Gait inability		1
Gastrointestinal disorder	1	1
Gastrointestinal pain		1
Generalised tonic-clonic seizure		1
General physical condition abnormal	1	9
General physical health deterioration	7	44
Gingival bleeding		1
Gingival swelling		1
Glomerular filtration rate decreased		1
Glomerulonephritis minimal lesion		1
Gout		1
Haematemesis		2
Haematochezia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	7
					1
			1		
			1		10
	2	4	16	2	7
					3
				1	1
			2	1	1
		1	1		
		1	1	1	1
					1
					1
		1	1		
			1		
		1	1		
					2
			1		2
					1
					4
			1		
		1	1		
					1
					1
				1	9
		3	9	4	35
					1
					1
			1		
					1
			1		
					2
					1

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Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematocrit decreased		1
Haematoma		3
Haemoglobin decreased	1	4
Haemoptysis	1	1
Haemorrhage	1	2
Haemothorax		1
Hallucination		2
Hallucinations, mixed		1
Headache	9	20
Head injury		1
Heart rate decreased	1	1
Heart rate increased	2	4
Hemiparesis	4	14
Hemiplegia		2
Hepatic cirrhosis	1	1
Hepatic enzyme increased	1	1
Hepatic failure		1
Hepatitis cholestatic		2
Herpes simplex		1
Herpes simplex encephalitis		1
Herpes zoster	2	12
Herpes zoster infection neurological		1
Herpes zoster meningitis		1
Hyperaesthesia	1	1
Hypercalcaemia		2
Hyperglycaemia		1
Hyperhidrosis		3
Hyperpyrexia		1
Hypersensitivity	4	14
Hypersensitivity vasculitis	1	3
Hypersomnia		1
Hypertension	3	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		2
			1	1	3
				1	1
				1	2
					1
					2
					1
		4	7	5	13
					1
				1	1
		1	3	1	1
				4	14
					2
				1	1
		1	1		
					1
					2
					1
					1
		1	9	1	3
					1
					1
				1	1
					2
					1
					3
					1
		3	5	1	9
				1	3
			1		
		1	3	2	12

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\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hypertensive crisis		5						5
Hypoaesthesia		1						1
Hyponatraemia		5				2		3
Hypophagia	1	1					1	1
Hyporesponsive to stimuli		1						1
Hypotension	1	5				1	1	4
Hypothermia		1						1
Hypotonia	2	2					2	2
Hypoxia	1	1					1	1
Idiopathic intracranial hypertension	1	1					1	1
Illrd nerve paresis	1	1					1	1
Ileus		1						1
Ileus paralytic		2						2
Illness	1	1					1	1
Immune thrombocytopenia	1	4					1	4
Impaired healing	1	1					1	1
Inadequate aseptic technique in use of product	1	1			1	1		
Inappropriate schedule of product administration	2	6			2	6		
Incontinence		1						1
Incorrect route of product administration	2	22			2	22		
Infarction		1						1
Inflammation		2						2
Inflammatory marker increased		1						1
Influenza		1						1
Influenza like illness		4				1		3
Insomnia	1	1			1	1		
Intentional product misuse		1				1		
International normalised ratio decreased		1				1		
International normalised ratio increased		1				1		
Intestinal infarction		1						1
Intestinal ischaemia	1	2					1	2
Intracranial aneurysm		1						1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ischaemia	2	3
Ischaemic cardiomyopathy	1	1
Ischaemic cerebral infarction		2
Ischaemic stroke	2	4
Jaundice		1
Jaw clicking		1
Joint range of motion decreased		1
Joint swelling		1
Lacrimation increased	1	1
Language disorder		1
Laryngeal obstruction	1	1
Laryngeal oedema	1	1
Leukaemia	1	1
Limb discomfort		1
Lipase increased		1
Lip oedema		1
Lip swelling		2
Listless	1	2
Liver function test increased		1
Local reaction	1	3
Loss of consciousness	3	6
Lymphadenopathy		1
Lymphoedema		1
Lymphopenia		1
Malaise	2	11
Malignant pleural effusion	1	1
Marasmus		1
Memory impairment		2
Meningism		1
Meningitis		1
Metabolic acidosis		1
Metabolic disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
				1	1
					2
				2	4
					1
					1
					1
			1		
				1	1
					1
				1	1
				1	1
			1		
					1
					1
					2
		1	1		1
					1
			2	1	1
				3	6
			1		
			1		
					1
		2	7		4
				1	1
					1
					2
					1
					1
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Microcytic anaemia		2
Micturition urgency	1	1
Mobility decreased	2	5
Monoparesis	1	1
Motor dysfunction		1
Movement disorder	1	3
Multimorbidity		1
Multi-organ disorder		1
Multiple organ dysfunction syndrome	1	7
Muscle spasms	1	1
Muscle strength abnormal		1
Muscle swelling		1
Muscle twitching	1	2
Muscular weakness	1	2
Musculoskeletal discomfort	1	1
Musculoskeletal pain	1	1
Myalgia	2	7
Myocardial infarction	1	6
Myocarditis		1
Myocarditis infectious		1
Myocarditis septic		1
Myoclonus		1
Myositis		1
Nasal congestion		1
Nasopharyngitis	1	4
Nausea	12	31
Necrosis		1
Nephrotic syndrome		1
Nervous system disorder		3
Neuralgia	1	1
Neuritis		1
Nuchal rigidity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
		1	3	1	2
				1	1
					1
			1	1	2
					1
					1
				1	7
				1	1
			1		
			1		
		1	1		1
				1	2
		1	1		
				1	1
		2	6		1
				1	6
					1
					1
					1
			1		
		1	2		2
		10	18	2	13
					1
					1
					3
		1	1		
					1
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Obstructive pancreatitis	1	1
Oedema		1
Oedema peripheral		2
Off label use	2	2
Ophthalmic herpes zoster		2
Ophthalmic vein thrombosis	2	2
Oral discomfort		1
Organ failure		1
Oropharyngeal pain	1	1
Osteoporosis	1	1
Overdose		1
Oxygen saturation decreased		8
Pain	2	9
Pain in extremity	6	15
Pallor	2	3
Palpitations	1	2
Pancreatitis acute		1
Pancytopenia	2	2
Papilloedema	1	1
Paraesthesia	1	3
Paraesthesia oral	1	1
Paranoia		1
Parkinsonism		1
Partial seizures		1
Pathogen resistance		1
Pemphigus	1	1
Peripheral circulatory failure	1	2
Peripheral embolism	1	1
Peripheral swelling	1	5
Peripheral vascular disorder	2	8
Peritonitis		1
Peroneal nerve injury		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			2		
		2	2		
					2
				2	2
			1		
					1
		1	1		
		1	1		
					1
					8
		2	3		6
		5	10	1	5
				2	3
				1	2
					1
				2	2
				1	1
		1	2		1
		1	1		
					1
					1
					1
				1	1
				1	2
				1	1
		1	3		2
		1	1	1	7
					1
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Personality change	1	4
Petechiae	1	4
Pharyngeal inflammation		1
Pharyngeal swelling	1	2
Platelet count decreased		2
Pleocytosis	1	2
Pleural effusion		1
Pleurisy		1
Pneumonia	5	29
Pneumonia aspiration		1
Pneumonia bacterial		2
Pneumonia viral	1	1
Polymyalgia rheumatica	1	2
Polyneuropathy	1	1
Poor quality sleep		1
Postictal state		1
Presbycusis		1
Presyncope		1
Product administered at inappropriate site		1
Product dose omission issue	1	1
Product preparation issue		1
Proteinuria		1
Pruritus	4	7
Psoriasis		1
Psychomotor hyperactivity		2
Pulmonary embolism	27	39
Pulmonary fibrosis		1
Pulmonary hypertension	1	1
Pulmonary infarction	2	2
Pulmonary oedema	1	3
Pulmonary sepsis		1
Purpura		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
		1	1		3
			1		
				1	2
					2
				1	2
					1
					1
				5	29
					1
					2
				1	1
				1	2
				1	1
					1
					1
					1
			1		
		1	1		
			1		
					1
		3	4	1	3
					1
					2
				27	39
					1
				1	1
				2	2
				1	3
					1
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pustule		1						1
Pyramidal tract syndrome		1						1
Pyrexia	7	51		1	4	14	3	37
Quadriparesis		1						1
Rales		1						1
Rash	3	11			1	3	2	8
Rash erythematous		1				1		
Rash macular	1	1			1	1		
Rash maculo-papular		2				2		
Rash pruritic		2				1		1
Reaction to excipient		1				1		
Red blood cell count decreased		1				1		
Red blood cell sedimentation rate increased		1				1		
Renal failure	2	9					2	9
Respiratory distress	7	23					7	23
Respiratory failure		9						9
Respiratory fume inhalation disorder	1	1					1	1
Respiratory tract infection		5						5
Respiratory tract inflammation		1						1
Restlessness	1	2					1	2
Resuscitation		1						1
Retinal vein thrombosis	1	1					1	1
Rhinalgia		1				1		
Rhinitis allergic		1				1		
Rhinorrhoea	1	2			1	2		
Rhonchi		1						1
SARS-CoV-2 antibody test positive		1						1
SARS-CoV-2 test positive	3	11			3	9		2
Seizure	1	12					1	12
Sepsis		3						3
Septic arthritis staphylococcal	1	1					1	1
Septic shock		3						3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
	1	4	14	3	37
					1
		1	3	2	8
			1		
		1	1		
			2		
			1		1
			1		
			1		
				2	9
				7	23
					9
				1	1
					5
					1
				1	2
					1
				1	1
			1		
			1		
		1	2		
					1
					1
		3	9		2
				1	12
					3
				1	1
					3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Shock		1
Skin haemorrhage		1
Skin necrosis	1	1
Skin ulcer	1	1
Sleep disorder		1
Sneezing		3
Soft tissue infection		1
Somnolence	4	11
Sopor		1
Speech disorder		2
Staphylococcal sepsis		2
Status epilepticus		2
Stress		1
Stridor		1
Stupor		1
Subarachnoid haemorrhage	1	1
Subclavian vein thrombosis	1	1
Subcutaneous abscess	1	1
Subdural haematoma		1
Subileus	1	2
Sudden cardiac death		2
Sudden death	2	21
Sudden onset of sleep		1
Swelling	1	1
Swelling face	2	3
Swelling of eyelid		2
Swollen tongue		5
Syncope	7	16
Systemic inflammatory response syndrome		1
Tachyarrhythmia		2
Tachycardia		7
Tendonitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
		1	1		
			1		
			3		
					1
		2	3	2	8
					1
			1		1
					2
					2
					1
					1
					1
				1	1
				1	1
				1	1
		1	1		1
					2
				2	21
					1
		1	1		
		2	3		
			1		1
			1		4
				7	16
					1
					2
			1		6
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tendon rupture	1	1					1	1
Thalamic infarction		1						1
Therapeutic response unexpected		2				2		
Throat irritation		1				1		
Throat tightness		5				3		2
Thrombocytopenia		3						3
Thrombophlebitis	2	2			1	1	1	1
Thrombosis	5	7					5	7
Toxicity to various agents		1						1
Transaminases increased		1						1
Transient global amnesia		1						1
Transient ischaemic attack	1	2					1	2
Tremor	2	4				1	2	3
Tryptase increased		1						1
Unresponsive to stimuli	1	6					1	6
Upper gastrointestinal haemorrhage		2						2
Upper respiratory tract infection	1	5			1	1		4
Urinary tract infection	1	3				1	1	2
Urinary tract inflammation		1						1
Urticaria	1	5			1	4		1
Vaccination complication	1	3					1	3
Vaccination failure	3	10					3	10
Vaccination site erythema	2	3				1	2	2
Vaccination site haematoma		1				1		
Vaccination site hypersensitivity	1	1			1	1		
Vaccination site pain		8				5		3
Vaccination site pruritus		1						1
Vaccination site rash		2				1		1
Vaccination site reaction	1	2				1	1	1
Vaccination site swelling	2	5			1	3	1	2
Vaccination site urticaria		1				1		
Vaccination site warmth	1	2					1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Varicose vein	1	1			1	1		
Vascular dementia		1						1
Vascular encephalopathy		1						1
Venous occlusion	1	1					1	1
Venous thrombosis	1	2					1	2
Venous thrombosis limb	1	1					1	1
Ventricular extrasystoles	1	1					1	1
Ventricular fibrillation		4						4
Ventricular tachycardia	1	1					1	1
Vision blurred		1						1
Visual acuity reduced		1						1
Visual field defect		1				1		
Visual impairment	2	4					2	4
Vlth nerve paralysis	1	1					1	1
Vomiting	12	42			8	19	4	23
Weight increased	1	1			1	1		
White blood cell count decreased		1				1		
White blood cell count increased		1						1
Wound		1				1		
	603	2,172		3	200	522	403	1650

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	1	5	1	4		1
Abdominal pain lower		2		1		1
Abdominal pain upper	1	3	1	3		
Abortion spontaneous		1				1
Accidental exposure to product		1		1		
Acute kidney injury		1				1
Adverse event	1	1	1	1		
Ageusia		3		3		
Agitation		1				1
Alanine aminotransferase increased	1	1			1	1
Allergic oedema		1				1
Allergy to vaccine		1		1		
Amnesia		1				1
Anaphylactic reaction		2				2
Anaphylactic shock	1	3			1	3
Angina pectoris		1				1
Angioedema	2	3			2	3
Anosmia		1		1		
Antibody test abnormal		2		2		
Aphasia	1	3		2	1	1
Arthralgia	3	22	3	20		2
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	3	22	3	21		1
Asthenopia		1		1		
Asthma		2		2		
Asymptomatic COVID-19		1				1
Atrial fibrillation		1				1
Autoimmune thyroiditis	1	1			1	1
Axillary pain		2		2		
Back pain		4		3		1
Blister		1		1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blister infected		1		1			
Blood glucose decreased	1	2		1	1	1	
Blood glucose fluctuation	1	2	1	2			
Blood pressure decreased		1				1	
Blood pressure fluctuation	1	2	1	2			
Blood pressure increased	1	3	1	3			
Blood urine present	1	1			1	1	
Bloody discharge	1	1	1	1			
Body temperature increased	1	24	1	24			
Bone pain	1	2	1	2			
Booster dose missed		2		2			
Brain oedema	1	1			1	1	
Burning sensation	2	4	1	2	1	2	
Cardiovascular disorder	1	12	1	12			
Cellulitis		1				1	
Cerebral haemorrhage	1	1			1	1	
Cerebral infarction	1	1			1	1	
Cerebrovascular accident	2	4			2	4	
Chest discomfort		2		2			
Chest pain	1	1	1	1			
Chills	8	80	8	80			
Chronic obstructive pulmonary disease		1		1			
Circulatory collapse	2	4			2	4	
Circumoral oedema	1	1	1	1			
Circumstance or information capable of leading to medication error		2		2			
Coagulation time prolonged		1		1			
Cognitive disorder		1		1			
Condition aggravated	1	3		2	1	1	
Contusion		2		1		1	
Cough	1	4	1	4			
COVID-19	54	228	27	57	27	171	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	1		
	1		
	1		
		1	2
		3	17
	1		
	2		2
	1		
	3		
3	16		
	2		1
	2	1	1
			1
	9		
2	38	2	3
1	1		
	2	20	166
		1	1
	2	1	1
	1		
	2		
		1	1
1	11	3	7
	4		
	1		
		1	1
1	8		1
			1
	3		
	1		
	1	1	1
	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain		1		1		
Eye pruritus	1	1			1	1
Eye swelling		1		1		
Facial pain		1		1		
Facial paralysis	5	7			5	7
Facial paresis	4	8	3	6	1	2
Fall	1	2			1	2
Fatigue	10	163	7	160	3	3
Feeling abnormal	1	5	1	5		
Feeling cold		15		15		
Feeling hot	2	8		6	2	2
Feeling of body temperature change		5		5		
Femoral artery embolism		1				1
Fistula		1				1
Flushing	1	3	1	3		
Formication		1		1		
Gait disturbance		1		1		
Gait inability		1				1
Gamma-glutamyltransferase increased	1	1			1	1
Haematoma	2	2	1	1	1	1
Haematoma infection		1				1
Haemorrhage	1	1			1	1
Headache	14	203	12	199	2	4
Head discomfort	2	4	2	4		
Hemiparesis		1				1
Herpes simplex		1		1		
Herpes zoster	2	10	2	9		1
Herpes zoster oticus		1				1
Herpes zoster reactivation		1		1		
Hot flush		3		3		
Hyperaesthesia	1	2	1	2		
Hyperhidrosis		5		5		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersensitivity	4	10
Hypersensitivity vasculitis	1	1
Hypersomnia		1
Hypertension	1	4
Hypertensive crisis	1	1
Hypoaesthesia	4	11
Hypoaesthesia oral		2
Hypotension		1
Hypothermia	1	1
Illness		2
Inappropriate schedule of product administration	3	9
Incorrect dose administered		2
Incorrect route of product administration	1	3
Increased upper airway secretion		1
Infection	2	3
Inflammation	1	1
Influenza	1	2
Influenza like illness	1	12
Initial insomnia		2
Injected limb mobility decreased		1
Injection site erythema		1
Injection site pain		4
Injection site pruritus		1
Injection site rash		1
Injection site swelling		1
Insomnia		6
Intestinal haemorrhage	1	1
Iridocyclitis	2	2
Limb discomfort	2	9
Lip pain		1
Lip swelling		2
Liver function test increased		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	8	2	2
		1	1
	1		
	3	1	1
		1	1
2	9	2	2
	2		
	1		
		1	1
	2		
3	9		
	2		
1	3		
	1		
		2	3
		1	1
1	2		
1	12		
	2		
	1		
	1		
	4		
	1		
	1		
	1		
	6		
		1	1
		2	2
1	8	1	1
	1		
	2		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Localised infection		1
Local reaction	1	2
Loss of consciousness	1	2
Loss of personal independence in daily activities		1
Lymphadenopathy		24
Lymph node pain		6
Malaise	5	37
Maternal exposure during pregnancy	2	28
Maternal exposure timing unspecified		2
Medication error	1	1
Menorrhagia		1
Menstrual disorder		5
Middle insomnia		1
Migraine		1
Mobility decreased		3
Mouth swelling		1
Movement disorder		3
Muscle contractions involuntary		1
Muscle spasms		1
Muscle swelling		1
Muscle twitching	1	3
Muscular weakness		3
Musculoskeletal stiffness		1
Myalgia	5	80
Myoclonus		1
Nasal congestion	1	1
Nasopharyngitis	1	7
Nausea	4	41
Neck pain		4
Neoplasm	1	1
Nephrolithiasis	1	1
Nervous system disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	2		
		1	2
	1		
	24		
	6		
3	35	2	2
2	28		
	2		
1	1		
	1		
	5		
	1		
	1		
	2		1
	1		
			3
			1
			1
1	2		1
	3		
	1		
5	80		
	1		
1	1		
1	6		1
4	41		
	4		
		1	1
		1	1
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia		3		3		
Neuritis		1		1		
Neurodermatitis	1	2	1	2		
Night sweats	1	4	1	4		
No adverse event		4		4		
Occupational exposure to product		1		1		
Oedema		1				1
Off label use	1	11	1	11		
Oropharyngeal pain		8		8		
Pain	3	15	1	11	2	4
Pain in extremity	7	132	6	131	1	1
Pain in jaw		2		2		
Pain of skin		2		2		
Palpitations	2	7	1	6	1	1
Panic attack	1	2	1	1		1
Panic reaction		1		1		
Paraesthesia	3	14	3	14		
Paraesthesia oral	1	4	1	4		
Paralysis	1	1			1	1
Parkinsonian rest tremor		1		1		
Parkinson's disease		1				1
Pelvic fracture	1	1			1	1
Performance status decreased		1		1		
Peripheral embolism	1	2		1	1	1
Peripheral ischaemia	1	1			1	1
Peripheral swelling	1	7		6	1	1
Peripheral vascular disorder		1		1		
Petechiae	1	1			1	1
Petit mal epilepsy		1				1
Pharyngeal paraesthesia		1		1		
Pneumonia		2				2
PO2 decreased	1	1			1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polyneuropathy	1	1			1	1
Poor quality product administered		10		10		
Poor quality sleep		4		4		
Pregnancy		1		1		
Presyncope		1		1		
Product complaint	1	6	1	6		
Product dose omission issue		1				1
Product leakage		1		1		
Product preparation error		3		3		
Product preparation issue		7		7		
Product quality issue		1		1		
Product supply issue		1		1		
Product temperature excursion issue		4		4		
Product use issue		8		8		
Pruritus	2	8		5	2	3
Pseudoallergic reaction	2	2	1	1	1	1
Pulmonary embolism	5	5			5	5
Pustule		3		2		1
Pyrexia	9	108	8	105	1	3
Rash	5	17	3	14	2	3
Rash macular		1		1		
Rash papular		1		1		
Rash pruritic		2		2		
Raynaud's phenomenon	1	1	1	1		
Rectal haemorrhage		1				1
Renal disorder		1				1
Renal pain		1		1		
Respiratory distress	1	4			1	4
Respiratory failure		1				1
Rheumatic disorder	1	1	1	1		
Rhinorrhoea		6		6		
Salivary gland enlargement		2		2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 antibody test negative	2	17	2	16		1
SARS-CoV-2 antibody test positive		8		8		
SARS-CoV-2 test false positive		4		4		
SARS-CoV-2 test positive	3	31	3	19		12
Sensation of foreign body	2	4	1	1	1	3
Sensitive skin		1		1		
Sinus congestion		2		2		
Skin burning sensation		2		1		1
Skin exfoliation		1		1		
Skin reaction		1		1		
Sleep disorder		3		3		
Somnolence		1		1		
Speech disorder	1	1	1	1		
Stress		1		1		
Sudden death	1	1			1	1
Sudden hearing loss	1	3			1	3
Suspected COVID-19		3				3
Swelling	2	3	1	2	1	1
Swelling face	3	4	1	2	2	2
Swelling of eyelid		1		1		
Swollen tongue	2	2	1	1	1	1
Syncope	1	2			1	2
Tachycardia	2	10	2	7		3
Temporomandibular joint syndrome		1		1		
Tendon pain		1				1
Tenosynovitis		1		1		
Therapeutic response unexpected	3	5	3	5		
Throat irritation		2		2		
Throat tightness		1				1
Thrombocytopenia	1	1			1	1
Thrombosis	5	5			5	5
Tinnitus		2		2		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue discomfort		2		2		
Toothache		1		1		
Transaminases increased		1		1		
Tremor		2		2		
Underdose		20		20		
Urinary retention		1				1
Urticaria	3	6	1	4	2	2
Vaccination failure	6	12			6	12
Vaccination site bruising		3		3		
Vaccination site discolouration		1		1		
Vaccination site discomfort	1	5	1	5		
Vaccination site erythema	1	7	1	7		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		2		2		
Vaccination site hyperaesthesia		2		2		
Vaccination site induration	1	1	1	1		
Vaccination site lymphadenopathy		2		2		
Vaccination site movement impairment		4		4		
Vaccination site pain	4	215	4	214		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		11		11		
Vaccination site warmth		4		4		
Varicella		1		1		
Vascular occlusion	1	1			1	1
Vasculitis		1				1
Venous thrombosis	1	1			1	1
Venous thrombosis limb	1	1			1	1
Vertigo		1		1		
Viral rash		1		1		
Vision blurred	1	3		2	1	1

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Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment		2		2		
Vomiting	1	11		9	1	2
Vulvovaginal swelling	1	1	1	1		
White blood cell count decreased	1	1	1	1		
White blood cell count increased		1		1		
Wrong technique in product usage process	1	3	1	3		
	351	2,545	181	1951	170	594

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**GREECE**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Crying		1		1		
Exposure via breast milk		1		1		
Fall		1				1
Restlessness		1		1		
Skin lesion		1				1
Syncope		1				1
		<b>6</b>		<b>3</b>		<b>3</b>

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Arthralgia	1	6	1	2		4
Blood pressure abnormal	1	1			1	1
Blood pressure increased	2	2	1	1	1	1
Bronchospasm		2				2
Burning sensation	2	2	1	1	1	1
Cachexia		1				1
Chest pain		1				1
Chills		2		1		1
Cough		2		1		1
COVID-19		5		1		4
C-reactive protein increased		2		2		
CSF polymorphonuclear cell count increased	1	1			1	1
Diabetes mellitus inadequate control		2				2
Diarrhoea		1		1		
Discomfort	1	1			1	1
Dizziness	1	4	1	4		
Drug ineffective		2				2
Dry throat	1	1			1	1
Dyskinesia		1		1		
Dyspnoea	1	2			1	2
Electromyogram abnormal	1	1	1	1		
Erythema		3		2		1
Eyelids pruritus	1	1	1	1		
Fatigue	3	8	3	5		3
Fibrin D dimer increased		1		1		
Haematocrit decreased	1	1	1	1		
Haematuria		1				1
Headache	3	7	2	6	1	1
Head discomfort		1		1		
Heart rate abnormal	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Heart rate increased		1		1			
Hordeolum	1	1	1	1			
Hypersensitivity	1	3			1		3
Hypertension	1	3		1	1		2
Hypoaesthesia	2	3	2	3			
Hypotension		1		1			
Injection site pain		1		1			
Insulin resistance		1					1
Intercostal neuralgia	1	1	1	1			
Intervertebral disc degeneration	1	1	1	1			
Intervertebral disc protrusion	1	1	1	1			
Laryngospasm		1					1
Left ventricular hypertrophy		1					1
Leukocytosis	1	1	1	1			
Livedo reticularis		1		1			
Lymphadenitis	3	7	2	4	1		3
Lymphadenopathy	1	6	1	5			1
Lymph node pain		1					1
Lymphopenia		1		1			
Malaise	2	3	1	2	1		1
Migraine	1	1	1	1			
Muscle fatigue		1		1			
Muscle tightness	1	1			1		1
Musculoskeletal stiffness	1	1	1	1			
Myalgia	3	9	3	4			5
Nausea		1		1			
Neck pain	1	1			1		1
Oedema peripheral		1		1			
Oral herpes	1	2	1	2			
Oropharyngeal pain		3		2			1
Pain in extremity	2	5	2	5			
Palpitations	2	3		1	2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus		4		1		3
Pyrexia	4	11	4	7		4
Rash	1	8		4	1	4
Somnolence		1		1		
Tachycardia	4	6	1	2	3	4
Tachypnoea		1		1		
Throat irritation		1		1		
Tremor	1	1	1	1		
Vaccination failure		2				2
Vaccination site erythema		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		4		3		1
Vaccination site rash	1	1	1	1		
Vomiting	1	2	1	1		1
	60	180	39	102	21	78

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain		4		2		2
Abdominal pain upper		5		4		1
Abortion spontaneous	1	1			1	1
Ageusia		1				1
Alanine aminotransferase increased		2		2		
Allergy to vaccine		2		1		1
Anaphylactic reaction	3	9			3	9
Anaphylactic shock	1	1			1	1
Angioedema		5				5
Ankylosing spondylitis	1	1			1	1
Anosmia		2		1		1
Anxiety	1	1	1	1		
Arrhythmia	1	6			1	6
Arthralgia	3	35	1	16	2	19
Aspartate aminotransferase increased		1		1		
Asthenia	2	19	1	11	1	8
Asthmatic crisis		1				1
Asymptomatic COVID-19	1	2			1	2
Atrial fibrillation		3				3
Axillary pain	1	1			1	1
Back pain		1				1
Balance disorder		1		1		
Blepharitis		1		1		
Blepharospasm		1		1		
Blister		2		2		
Blood creatine phosphokinase increased		1		1		
Blood glucose abnormal		1				1
Blood pressure decreased		4		2		2
Blood pressure diastolic increased		1		1		
Blood pressure increased	5	23	1	11	4	12
Blood pressure systolic		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic abnormal	1	1			1	1
Blood pressure systolic increased	1	1			1	1
Body dysmorphic disorder		1				1
Bone pain		1				1
Bronchial hyperreactivity	1	1			1	1
Bronchospasm		5				5
Burning sensation	1	12		7	1	5
Bursitis		1		1		
Cachexia		3				3
Capillary disorder		1		1		
Cervical radiculopathy		1				1
Cervix erythema		1				1
Chest discomfort		5		1		4
Chest pain	3	7	1	3	2	4
Chills	6	50	5	26	1	24
Choking sensation	1	1			1	1
Cholinergic syndrome	1	4			1	4
Clonus	1	1			1	1
Complex regional pain syndrome	1	2			1	2
Condition aggravated	1	2			1	2
Confusional state	1	3		1	1	2
Cough	1	14		4	1	10
COVID-19	1	9		3	1	6
Cyanosis		2		1		1
Decreased appetite		2		2		
Defaecation urgency		1				1
Dermatitis allergic		1				1
Dermatomyositis	1	1			1	1
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea	1	11	1	8		3
Diastolic hypertension		1				1
Diplopia		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort		4		2		2
Disease recurrence	1	1			1	1
Disturbance in attention		1				1
Dizziness	6	41	3	23	3	18
Drowning		1				1
Drug ineffective	1	7			1	7
Drug interaction		1				1
Dry mouth		4		3		1
Dry throat		8		2		6
Dysarthria		1				1
Dysgeusia	1	9		4	1	5
Dyskinesia		1				1
Dyspepsia	1	1			1	1
Dysphagia	1	14	1	2		12
Dysphonia		8		2		6
Dysphoria		1				1
Dyspnoea	2	13	1	6	1	7
Ear pain		3		2		1
Eating disorder	2	2	1	1	1	1
Epigastric discomfort		1				1
Eructation	1	4		3	1	1
Erythema	4	32	1	20	3	12
Extrasystoles	1	3		2	1	1
Eye disorder	1	1	1	1		
Eyelid irritation		1				1
Eyelid oedema		2		2		
Eyelid ptosis		1				1
Eye oedema		1				1
Eye pain	1	1			1	1
Eye pruritus		1		1		
Face oedema	1	2	1	1		1
Facial paresis	3	4	1	1	2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	10	46	6	22	4	24
Feeling abnormal		1				1
Feeling hot		4		2		2
Flatulence		2				2
Flushing	3	26		11	3	15
Gait disturbance	2	4		1	2	3
Gait inability	1	1			1	1
Gamma-glutamyltransferase increased		1				1
Gastroenteritis		1				1
Gastrointestinal disorder		5		5		
Gastrointestinal hypermotility		1				1
Glossodynia	2	2			2	2
Granuloma annulare	1	1	1	1		
Guillain-Barre syndrome		2				2
Haemoptysis		1		1		
Headache	7	77	5	48	2	29
Head discomfort	1	1			1	1
Heart rate decreased		1				1
Heart rate increased	1	13		9	1	4
Heart rate irregular		1				1
Herpes zoster	1	5		1	1	4
Hot flush	1	1			1	1
Hyperhidrosis	2	13	1	11	1	2
Hypersensitivity	1	16		4	1	12
Hypersensitivity vasculitis	1	1			1	1
Hypertension		13		5		8
Hypertensive crisis		6				6
Hypertensive emergency		1				1
Hypoaesthesia	9	43	3	21	6	22
Hypoaesthesia oral		11		3		8
Hypokalaemia	1	1			1	1
Hyponatraemia	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	10		3	1	7
Hypotonia	1	3		1	1	2
Illness	1	2	1	1		1
Impaired gastric emptying	1	1			1	1
Impaired work ability		1				1
Incorrect route of product administration		1		1		
Inflammation	1	3	1	1		2
Influenza like illness		1		1		
Insomnia	2	2	1	1	1	1
Iridocyclitis	1	1			1	1
Joint effusion	1	1			1	1
Joint range of motion decreased		1		1		
Laryngeal oedema		1				1
Laryngeal pain		1				1
Laryngospasm	1	2			1	2
Lethargy		1		1		
Lichenoid keratosis	1	1	1	1		
Limb discomfort		2				2
Lip oedema		3		2		1
Lip pain	2	2			2	2
Lip swelling		1				1
Localised oedema		3		1		2
Local reaction		1		1		
Loss of consciousness		2				2
Lymphadenitis	3	10		1	3	9
Lymphadenopathy	8	21	5	7	3	14
Lymph node pain		1		1		
Malaise	3	16	2	8	1	8
Maternal exposure during pregnancy	2	2	2	2		
Mechanical urticaria		1		1		
Meningism		1		1		
Menorrhagia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Menstruation irregular		2		1			1
Middle insomnia		1		1			
Migraine		4		2			2
Mouth injury	1	1	1	1			
Mucosal dryness		1					1
Muscle discomfort		1					1
Muscle injury		1		1			
Muscle spasms		3					3
Muscle tightness		1		1			
Muscular weakness	3	6		2	3		4
Musculoskeletal discomfort		1		1			
Musculoskeletal stiffness		1					1
Myalgia	6	61	2	36	4		25
Myelitis	1	2			1		2
Myocardial infarction	1	1			1		1
Myocarditis		1					1
Nasal pruritus		1		1			
Nausea	3	29	1	20	2		9
Neck pain	2	3	2	3			
Neuritis		1					1
Ocular hyperaemia	1	1			1		1
Oedema		1					1
Off label use	1	2	1	2			
Oral herpes		1					1
Oropharyngeal pain	2	6	1	3	1		3
Oxygen saturation abnormal	1	1			1		1
Oxygen saturation decreased	1	2			1		2
Pain		10		2			8
Pain in extremity	1	15	1	12			3
Pain in jaw		1					1
Pallor	1	3		2	1		1
Palpitations		16		9			7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pancreatitis		1					1
Panic reaction		1					1
Paraesthesia	1	1			1		1
Paralysis		1					1
Paratracheal lymphadenopathy	1	1			1		1
Parosmia	1	1			1		1
Peripheral coldness	1	6			1		6
Petechiae	1	2		1	1		1
Pharyngeal oedema		1		1			
Pharyngitis		1		1			
Platelet count increased		1		1			
Polyarthritits	1	1			1		1
Polymenorrhoea		2		2			
Polyneuropathy	1	2			1		2
Poor quality sleep		1		1			
Post herpetic neuralgia		1					1
Presyncope	2	12	1	5	1		7
Product use issue	1	2	1	2			
Pruritus	6	36	3	22	3		14
Pruritus allergic		1					1
Psoriasis		1		1			
Psoriatic arthropathy		1					1
Pulse abnormal	1	1			1		1
Purpura	1	1			1		1
Pyrexia	13	80	8	44	5		36
Rash	4	32	1	12	3		20
Rash erythematous		2		2			
Rash macular		1		1			
Rash papular	1	1			1		1
Rash pruritic	1	7	1	4			3
Rhinitis	1	1	1	1			
Rhinorrhoea	1	1			1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Salivary gland pain	1	1	1	1		
Sciatica		1				1
Seizure		1				1
Sensation of foreign body		1				1
Sensory loss	1	1			1	1
Shock		1				1
Skin burning sensation	1	2		1	1	1
Skin reaction		1				1
Soft tissue swelling		1		1		
Somnolence		7		5		2
Speech disorder	1	1	1	1		
Spinal pain		2				2
Swelling	3	4	1	1	2	3
Swelling face		1				1
Syncope		4				4
Tachycardia	5	34	2	14	3	20
Taste disorder	1	1			1	1
Temporomandibular joint syndrome	1	1	1	1		
Terminal state	1	1			1	1
Thirst	1	1	1	1		
Throat irritation	2	7		3	2	4
Throat tightness		1				1
Thyroiditis	1	1			1	1
Thyroiditis acute		1				1
Tinnitus	1	5		3	1	2
Tongue discomfort		1				1
Tongue oedema		1				1
Tonsillitis	1	1	1	1		
Tremor	2	9	1	5	1	4
Trigeminal neuralgia		1				1
Urticaria		3		1		2
Uveitis	1	2			1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination failure	1	1			1	1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	1	3		2	1	1
Vaccination site hyperaesthesia		1		1		
Vaccination site hypoaesthesia	1	3		2	1	1
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment		1		1		
Vaccination site oedema		5		4		1
Vaccination site pain	5	46	3	39	2	7
Vaccination site rash		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth	1	2		1	1	1
Vertigo	1	6		4	1	2
Viral infection		1		1		
Vision blurred		1		1		
Vomiting	2	9		5	2	4
Water pollution	1	1			1	1
White blood cell count decreased		1		1		
	248	1,437	89	684	159	753

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		4		2		2
Abdominal pain upper		1		1		
Acute myocardial infarction		2				2
Acute respiratory distress syndrome		1				1
Allergy to vaccine		1				1
Alopecia		1		1		
Anaemia	2	2	1	1	1	1
Anaphylactic reaction		1				1
Anaphylactic shock		5				5
Anaphylactoid reaction		1				1
Angioedema	1	5			1	5
Anxiety		1		1		
Arrhythmia	3	3	1	1	2	2
Arthralgia		14		5		9
Arthritis		1		1		
Arthritis enteropathic		1				1
Asthenia		14		8		6
Asymptomatic COVID-19		1				1
Atrial fibrillation	2	2			2	2
Autonomic nervous system imbalance	1	1	1	1		
Axillary pain		1		1		
Back injury	1	1			1	1
Back pain		1		1		
Balance disorder		1				1
Blister		1		1		
Blood pressure abnormal		1				1
Blood pressure diastolic increased		1		1		
Blood pressure increased	1	11		5	1	6
Blood pressure systolic increased		3		1		2
Blood triglycerides increased	1	1			1	1
Body temperature increased		1		1		
Bone pain	1	3		1	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bradycardia		1					1
Brain death	1	1			1		1
Breast pain		1		1			
Bronchospasm		1					1
Burning sensation	1	9	1	7			2
Carbohydrate antigen 125 increased		1		1			
Carcinoembryonic antigen increased		1					1
Cardiac arrest	1	3			1		3
Cardiac discomfort		1					1
Cardiac failure	1	1			1		1
Cardiac valve disease		1					1
Chest pain		6		2			4
Chills	3	21	1	6	2		15
Complex regional pain syndrome		1		1			
Condition aggravated		2					2
Confusional state		2					2
Conjunctival hyperaemia		1		1			
Contusion	1	1			1		1
Cough	1	6	1	1			5
COVID-19		2					2
Deafness		1					1
Deep vein thrombosis		1					1
Dehydration	1	1			1		1
Dermatitis allergic		1					1
Diarrhoea	1	8	1	4			4
Diplegia	1	1			1		1
Diplopia		1					1
Discomfort		1		1			
Disease recurrence		1					1
Disorientation	1	1	1	1			
Diverticulitis	1	1			1		1
Dizziness	2	18	1	12	1		6

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Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Drug ineffective  
Dry eye  
Dry mouth  
Dry throat  
Dysarthria  
Dysgeusia  
Dyspepsia  
Dysphagia  
Dysphonia  
Dysphoria  
Dyspnoea  
Dysstasia  
Ear pain  
Eating disorder symptom  
Enlarged uvula  
Eructation  
Erythema  
Extrasystoles  
Eyelid oedema  
Eyelids pruritus  
Eye pruritus  
Face oedema  
Facial paralysis  
Facial paresis  
Fall  
Fatigue  
Feeling cold  
Feeling drunk  
Feeling hot  
Flushing  
Gait disturbance  
Gastrointestinal disorder

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
1	1		
2	2		1
1	1		2
			1
	2		
	1		1
	2	1	3
2	2	1	4
		1	1
	2	2	8
		1	1
			1
1	1		
			1
			1
	10		7
	1		1
			1
			1
			2
			1
			1
			1
2	13		13
1	3		
			1
	1		
			1
	1		
		1	1
	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Goitre	1	1			1	1
Guillain-Barre syndrome	1	1			1	1
Haemoptysis	2	2			2	2
Headache	3	30	2	15	1	15
Head discomfort		2		2		
Heart rate increased		6		3		3
Herpes ophthalmic	1	1			1	1
Herpes zoster		4		2		2
Hot flush		1				1
Hyperhidrosis	2	10			2	10
Hypersensitivity		5		3		2
Hypertension		9		5		4
Hypertensive crisis		7				7
Hypoacusis		1				1
Hypoaesthesia	2	15		9	2	6
Hypoaesthesia oral		6		4		2
Hyporeflexia	1	1			1	1
Hypotension		3				3
Hypothermia		1				1
Hypotonia		1		1		
Immunoglobulins increased	1	1			1	1
Incorrect route of product administration		1		1		
Inflammation		1				1
Injection site hypoaesthesia		1		1		
Injection site pain		1		1		
Insomnia		3		2		1
Irritability		1		1		
Joint stiffness		1				1
Joint swelling		1		1		
Laryngeal oedema		4				4
Laryngospasm		2				2
Leukocytosis		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema		4		1		3
Lip swelling		2		2		
Loss of consciousness		1				1
Lymphadenitis	1	5		1	1	4
Lymphadenopathy	2	7	2	6		1
Lymph node pain		1		1		
Lymphoedema		1				1
Malaise		4		2		2
Meningomyelitis herpes		1				1
Muscular weakness		3		1		2
Myalgia	1	34	1	21		13
Myocardial infarction		1				1
Nasal congestion		1		1		
Nausea	1	13	1	8		5
Neck pain		2		1		1
Nervousness		1				1
Neuralgia		1				1
Neuropathy peripheral	1	2			1	2
Nystagmus		1		1		
Ocular hyperaemia		1				1
Oedema		2		1		1
Off label use		1		1		
Oral herpes		1		1		
Oral mucosal erythema		1		1		
Oropharyngeal pain	1	2			1	2
Orthostatic hypotension		1		1		
Pain		5		1		4
Pain in extremity	1	6		4	1	2
Pain in jaw		1		1		
Palpitations	3	9		3	3	6
Paraesthesia	1	1			1	1
Parotid gland enlargement	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	1	2	1	1		1
Peripheral swelling		1		1		
Peripheral venous disease	1	1			1	1
Photophobia	1	1			1	1
Pneumonia		1				1
Presyncope		1				1
Product use issue		1		1		
Pruritus	1	13		7	1	6
Pulmonary embolism		1				1
Pulmonary mass	1	1			1	1
Pulse abnormal		1		1		
Pyrexia	5	37	3	20	2	17
Rash	2	18	2	10		8
Rash maculo-papular		3		1		2
Rash pruritic		2		1		1
Raynaud's phenomenon	1	1			1	1
Reflexes abnormal	1	1			1	1
Respiratory tract infection		1				1
Rheumatoid arthritis		2				2
Rhinitis allergic		1		1		
Rhinorrhoea		1		1		
Salivary gland enlargement	1	1			1	1
Sarcoidosis	1	1			1	1
SARS-CoV-2 test positive		1		1		
Sjogren's syndrome	1	1			1	1
Somnolence	1	7	1	4		3
Spinal pain	2	2			2	2
Stress		1		1		
Swelling		1		1		
Swelling face		1				1
Syncope		1				1
Tachycardia	1	9	1	5		4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		2				2
Teething		1				1
Temporomandibular joint syndrome		1		1		
Tension		1		1		
Throat irritation	1	4	1	4		
Thrombosis	1	2			1	2
Thyroid cyst		1				1
Thyroiditis		1		1		
Tinnitus		1				1
Tongue oedema		1				1
Tongue ulceration		1		1		
Tonsillar hypertrophy		1				1
Tremor		3		1		2
Trismus		1		1		
Urticaria		1		1		
Uveitis	1	1			1	1
Vaccination site discomfort		1		1		
Vaccination site erythema		1				1
Vaccination site irritation		1				1
Vaccination site oedema		1		1		
Vaccination site pain	1	28	1	24		4
Vaccination site pruritus		2		1		1
Vaccination site rash		1		1		
Vascular pain	1	1			1	1
Vasculitis	1	1			1	1
Ventricular arrhythmia		1				1
Vertigo		3		2		1
Vision blurred		1		1		
Vomiting	1	3			1	3
Walking disability	1	1			1	1
	102	718	35	326	67	392

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Abdominal pain upper		1		1		
Acne	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock		1				1
Angioedema	1	2			1	2
Aphasia	1	1			1	1
Arrhythmia	1	2			1	2
Arteriovenous graft thrombosis	1	1			1	1
Arthralgia	1	1	1	1		
Aspiration	1	1			1	1
Audiogram abnormal	1	1	1	1		
Back pain	2	2	1	1	1	1
Blood pressure decreased	1	1			1	1
Blood pressure increased	3	3			3	3
Brain death		1				1
Burning sensation	1	3	1	3		
Cardiac arrest	1	1			1	1
Cerebral haemorrhage		1				1
Chest discomfort	1	1			1	1
Chest pain		1		1		
Chills		3		1		2
Coma	1	1			1	1
Confusional state	1	1			1	1
Conjunctival hyperaemia		1		1		
COVID-19	1	5		2	1	3
Death	1	1			1	1
Deep vein thrombosis	2	2			2	2
Diarrhoea		1				1
Diplegia		1				1
Dizziness	2	2			2	2
Drug ineffective		2				2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia		1		1		
Dysphoria	1	1			1	1
Dyspnoea	1	4		1	1	3
Ear, nose and throat examination abnormal	1	1	1	1		
Electrocardiogram repolarisation abnormality	1	1			1	1
Enlarged uvula	1	1			1	1
Epilepsy	1	1			1	1
Episcleritis		1				1
Erythema	1	2	1	2		
Eyelid oedema	1	1	1	1		
Facial paralysis	2	2			2	2
Facial paresis	3	3	1	1	2	2
Fall		1				1
Fatigue		1		1		
Foot deformity	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Glycosylated haemoglobin decreased		1		1		
Guillain-Barre syndrome	1	2			1	2
Haematocrit decreased	1	1			1	1
Haematoma		1				1
Headache	2	4	2	3		1
Heart rate decreased	3	3			3	3
Heart rate increased		1				1
Hemiparesis	1	1			1	1
Herpes simplex reactivation	1	1	1	1		
Herpes zoster		1				1
Hyperhidrosis	1	1			1	1
Hypersensitivity	1	2		1	1	1
Hypertension	1	2		1	1	1
Hypertensive crisis		1				1
Hypoaesthesia	2	3	1	1	1	2
Hypoglycaemia		2		2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypotension		1		1			
Ischaemic cerebral infarction	1	1			1	1	
Leukaemia	1	1			1	1	
Loss of consciousness	2	3			2	3	
Lymphadenitis		1				1	
Lymphadenopathy		1		1			
Malaise	1	1	1	1			
Memory impairment		1				1	
Musculoskeletal chest pain	1	1	1	1			
Musculoskeletal stiffness	1	1	1	1			
Myalgia	1	3	1	2		1	
Nail discolouration		2		2			
Onycholysis		1		1			
Oxygen saturation decreased	1	1			1	1	
Pain		2				2	
Pain in extremity	4	4	3	3	1	1	
Paraparesis	1	1			1	1	
Parotid gland enlargement		1		1			
Periorbital swelling	1	1	1	1			
Pruritus		1		1			
Pulmonary oedema		1				1	
Pulse absent		1				1	
Pyrexia	3	8	2	5	1	3	
Rash	1	1			1	1	
Rash maculo-papular	1	1			1	1	
Salivary gland pain		1		1			
Speech disorder	1	1			1	1	
Swelling face	1	1	1	1			
Syncope	1	3			1	3	
Tachycardia	1	1			1	1	
Therapeutic response unexpected		2		2			
Tinnitus	1	1	1	1			

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema	1	2			1	2
Uveitis	2	2			2	2
Vaccination site discomfort		1		1		
Vaccination site pain	1	1	1	1		
Visual impairment	1	1	1	1		
	86	156	27	60	59	96

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		1		1
Acute myocardial infarction	1	1			1	1
Acute respiratory failure		1				1
Aggression		1				1
Agitation		1				1
Anaphylactic reaction		2				2
Angina pectoris	1	1			1	1
Angioedema	1	3			1	3
Arrhythmia		1				1
Arteriosclerosis		1				1
Arthralgia	2	6	1	3	1	3
Asthenia	2	5	1	3	1	2
Atrial fibrillation	1	1			1	1
Auscultation		1		1		
Back pain	2	3	2	3		
Blood calcium decreased		1		1		
Blood gases abnormal	1	1			1	1
Blood glucose abnormal		2		2		
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood potassium decreased		1		1		
Blood pressure decreased		1		1		
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased	4	10		4	4	6
Blood pressure systolic increased	1	1			1	1
Blood urea increased		1		1		
Bronchospasm		1				1
Burning sensation	1	2	1	1		1
Burning sensation mucosal		1				1
Bursitis	1	1			1	1
Cardiac arrest	1	4			1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Carotid artery occlusion		1					1
Central nervous system stimulation		1					1
Cerebral ischaemia	1	1			1		1
Cerebral venous thrombosis	1	1			1		1
Cerebrovascular accident	2	4			2		4
Chest discomfort	1	1			1		1
Chest pain		1					1
Chills		5		3			2
Cholelithiasis		1					1
Circumoral oedema		1					1
Communication disorder	1	1	1	1			
Complex regional pain syndrome	1	2			1		2
Confusional state		4		1			3
Constipation		1		1			
Coronary artery stenosis		1					1
Cough		3		2			1
COVID-19	3	4			3		4
Deafness unilateral		1					1
Death	1	5			1		5
Decreased appetite	1	2		1	1		1
Deep vein thrombosis	1	1			1		1
Dermatitis allergic		1					1
Diabetes mellitus inadequate control	1	1			1		1
Diarrhoea	1	3	1	2			1
Diplegia		1					1
Disease recurrence	1	2			1		2
Disorientation		1					1
Dizziness	3	7	2	3	1		4
Drug ineffective	1	2			1		2
Dysarthria	1	1			1		1
Dysphagia	2	3		1	2		2
Dysphoria		1					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	5	12		2	5	10
Dysstasia		2		1		1
Enlarged uvula	1	1			1	1
Epistaxis	1	1	1	1		
Erythema	3	5	2	3	1	2
Eye haemorrhage	1	1			1	1
Eyelid oedema	1	1	1	1		
Eye swelling		1				1
Facial paralysis	1	3			1	3
Facial paresis	2	3			2	3
Fall	1	3		2	1	1
Fatigue	5	12	2	6	3	6
Feeding disorder	1	1	1	1		
Femur fracture	1	1			1	1
Fine motor skill dysfunction		1				1
Gait disturbance	1	2		1	1	1
Gait inability		1				1
Gastrointestinal disorder		1		1		
Genital herpes zoster		1				1
Guillain-Barre syndrome	1	1			1	1
Haematochezia	1	1			1	1
Haemoglobin decreased		1		1		
Headache	2	7	1	5	1	2
Heart rate decreased		1				1
Hemiparesis		1				1
Hepatitis		1				1
Herpes dermatitis		1				1
Herpes ophthalmic		1				1
Herpes zoster	1	2	1	1		1
Hyperhidrosis		1				1
Hypersensitivity		1				1
Hypertension	2	6		1	2	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypertensive crisis		1					1
Hypertrophic cardiomyopathy		1					1
Hypoaesthesia	3	8	1	2	2		6
Hypoaesthesia oral		2					2
Hypoalbuminaemia		1		1			
Hypoglycaemia	1	2		1	1		1
Hypokalaemia	1	1			1		1
Hyponatraemia	1	2		1	1		1
Hypotension		1					1
Hypothermia	1	1			1		1
Hypotonia		2		1			1
Impaired self-care		1					1
Incorrect route of product administration	1	1	1	1			
Infection	1	1	1	1			
Insomnia		1		1			
Ischaemic stroke		1					1
Lethargy	1	3		2	1		1
Lip oedema	1	2			1		2
Loss of consciousness	1	3			1		3
Loss of personal independence in daily activities		1		1			
Lower respiratory tract infection	1	1			1		1
Lymphadenopathy	1	1			1		1
Malaise	1	4	1	3			1
Memory impairment	1	1			1		1
Migraine		2		2			
Movement disorder	1	1	1	1			
Muscle spasms	1	1			1		1
Muscular weakness	1	2			1		2
Myalgia		2		2			
Myocardial infarction		1					1
Nasopharyngitis		1		1			
Nausea		2		2			

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular hyperaemia	1	1			1	1
Oedema peripheral	2	3		1	2	2
Off label use		1		1		
Ophthalmic artery thrombosis	1	1			1	1
Oropharyngeal pain		1		1		
Orthostatic hypotension		1				1
Overdose		1		1		
Oxygen saturation decreased	2	4			2	4
Pain in extremity	3	4	3	4		
Paralysis		1				1
Paresis	1	1			1	1
Parotitis		1		1		
Peripheral swelling	1	1	1	1		
Petit mal epilepsy		1				1
Polydipsia		1		1		
Polyneuropathy	1	1			1	1
Polyuria		1		1		
Product preparation error		1		1		
Product use issue		1		1		
Protein total decreased		1		1		
Prothrombin time prolonged		1		1		
Pruritus	2	5			2	5
Pulmonary embolism	1	1			1	1
Pyrexia	9	17	7	10	2	7
Rash	2	6	2	3		3
Rash pruritic		1		1		
Renal failure	1	1			1	1
Renal impairment	1	1			1	1
Respiratory failure	1	1			1	1
Respiratory tract infection		1				1
Scleritis	1	1			1	1
Skin burning sensation		1		1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence	1	3	1	2		1
Speech disorder	1	3		2	1	1
Sputum increased	1	1			1	1
Sputum purulent		1				1
Sudden death		3				3
Suspected COVID-19		2		1		1
Swelling face		1				1
Syncope		4				4
Tachycardia		2		1		1
Tachypnoea		1		1		
Tension		1		1		
Thrombosis	1	1			1	1
Tongue oedema	1	1			1	1
Transient ischaemic attack		1				1
Tremor		2		2		
Urinary incontinence	1	2	1	1		1
Urinary tract infection	1	2			1	2
Urticaria	1	1	1	1		
Vaccination failure		1				1
Vaccination site haemorrhage		1		1		
Vaccination site pain		2		1		1
Venous thrombosis limb	1	1			1	1
Vertigo		2		1		1
Viral infection		1		1		
Vomiting	1	7	1	3		4
Wheezing		1		1		
	132	372	40	142	92	230

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Anaphylactic reaction		1				1
Anaphylactoid reaction		1				1
Arthralgia	2	6	2	5		1
Asthenia		4		4		
Asymptomatic COVID-19	2	2			2	2
Back pain		3		3		
Blister		1		1		
Blood pressure decreased		1				1
Blood pressure increased	1	6	1	5		1
Bradycardia		1				1
Bronchospasm		1				1
Burning sensation	2	3	2	3		
Catarrh		1		1		
Chest discomfort		1		1		
Chest pain	2	2	1	1	1	1
Chills	1	8	1	6		2
Circumstance or information capable of leading to medication error		2		2		
Cold sweat	1	1			1	1
Conjunctivitis		1		1		
Cough	1	5	1	5		
COVID-19		10		4		6
Cyanosis		1		1		
Deafness unilateral		1				1
Depression		1		1		
Diarrhoea		3		2		1
Discomfort		1		1		
Dizziness		13		10		3
Drug ineffective	1	7			1	7
Dry mouth		1		1		

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		2
	3		
	2		
	1		1
			2
	3		2
		1	1
	1		
	6		
	1		
1	2		
			1
	1		
1	1		
3	13		
	1		1
	1		
	3		1
	1		
	2		
	2		
2	11		2
2	3		
	1		1
	5		
1	1		
	9		2
	3		
1	13		4
1	9		4
	4		3
	1		
	1		

Dysgeusia 4

Dyskinesia 3

Dyspepsia 2

Dysphagia 2

Dysphonia 2

Dyspnoea 5

Dysstasia 1 1

Eczema 1

Erythema 6

Expired product administered 1

Eye irritation 1 2

Eyelid ptosis 1

Face oedema 1

Facial paresis 1 1

Fatigue 3 13

Fibrin D dimer increased 1

Fibromyalgia 1

Flushing 3

Gait disturbance 1

Gastrointestinal disorder 2

Headache 2 11

Heart rate increased 2 3

Hemiparesis 1

Herpes zoster 5

Hyperhidrosis 1 1

Hypersensitivity 9

Hypertension 3

Hypoaesthesia 1 13

Hypoaesthesia oral 1 9

Hypotension 4

Incomplete course of vaccination 1

Incorrect route of product administration 1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injury		1		1		
Lacrimation increased		1		1		
Laryngeal oedema		1				1
Lethargy		1				1
Limb discomfort		1		1		
Limb injury		1		1		
Liquid product physical issue		4		4		
Local reaction		1		1		
Lymphadenopathy		3		2		1
Lymph node pain		1		1		
Malaise		4		4		
Maternal exposure during pregnancy	1	2	1	2		
Menstruation delayed		1		1		
Metrorrhagia	1	2	1	2		
Migraine		1		1		
Monoparesis	1	1			1	1
Muscle spasms		1		1		
Myalgia	2	7	2	6		1
Nasal congestion	1	1	1	1		
Nausea		2		1		1
No adverse event		10		10		
Occupational exposure to product	1	1	1	1		
Ocular hyperaemia		1		1		
Oedema		1		1		
Off label use		1		1		
Oral discomfort	1	1	1	1		
Oropharyngeal discomfort		2		2		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		1		1		
Pain	1	11	1	11		
Pain in extremity	2	6	2	6		
Palpitations		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pancreatitis		1					1
Papilloedema		1					1
Paraesthesia		2		2			
Periorbital oedema	1	2	1	2			
Pollakiuria		1		1			
Poor quality product administered		5		5			
Product quality issue		1		1			
Product temperature excursion issue		1		1			
Pruritus		5		4			1
Pulmonary thrombosis		2					2
Pyrexia	4	21	4	19			2
Rash	1	8		2	1		6
Rash macular	1	1	1	1			
Rash pruritic	1	2	1	2			
Reaction to excipient		1					1
Respiratory tract infection	1	1			1		1
SARS-CoV-2 antibody test positive	1	2	1	2			
Skin irritation		1		1			
Soft tissue swelling		1					1
Somnolence		3		3			
Speech disorder		1					1
Tachycardia		10		7			3
Therapeutic response unexpected		2		2			
Tinnitus		2		2			
Tremor	1	3	1	3			
Urinary tract infection		1		1			
Urticaria		1		1			
Vaccination site bruising	1	1	1	1			
Vaccination site discomfort	1	2	1	2			
Vaccination site hypoaesthesia		1		1			
Vaccination site induration		1		1			
Vaccination site inflammation		1		1			

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Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema		1		1		
Vaccination site pain	2	19	2	19		
Vaccination site warmth		1		1		
Vasoconstriction	1	1			1	1
Vertigo	1	1	1	1		
Visual impairment	1	1			1	1
Vomiting	1	4	1	3		1
Wrong technique in product usage process		2		2		
	56	397	45	310	11	87

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Country Where Event Occurred

**GUINEA**

Age Range

**65 - 79 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Headache	1	1	1	1
Hypertension	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred  
**HOLY SEE (VATICAN CITY STATE)**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Extensive swelling of vaccinated limb		1		1
Injected limb mobility decreased		1		1
Oedema peripheral		2		2
Pain in extremity		1		1
Periorbital oedema		1		1
Vaccination site pain		1		1
		8		8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**HONG KONG**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal pain	1	1	1	1
Loss of consciousness	1	1	1	1
Syncope	1	1	1	1
	3	3	3	3

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Allergy to vaccine	1	1	1	1		
Contusion	1	1			1	1
Dizziness	4	4			4	4
Fall	1	1			1	1
Hypoaesthesia	2	2			2	2
Injury	1	1			1	1
Loss of consciousness	3	3			3	3
Nausea	1	1			1	1
Rash		1				1
Seizure	1	1			1	1
Syncope	2	2			2	2
Vomiting	1	1			1	1
	19	20	1	1	18	19

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	1	1			1	1
Allergy to vaccine	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	1			1	1
Back pain	1	1			1	1
Blood pressure increased	2	2	1	1	1	1
Burning sensation	1	1	1	1		
Chest discomfort	3	3	3	3		
Chest pain	2	2			2	2
Dizziness	5	5	2	2	3	3
Dyspnoea	1	2			1	2
Essential hypertension	1	1			1	1
Facial paralysis	1	1			1	1
Fall	1	1			1	1
Headache	2	2	1	1	1	1
Hyperhidrosis	2	2	2	2		
Hypersensitivity	1	2	1	1		1
Hypertension	1	1			1	1
Hyperventilation	2	2			2	2
Hypoaesthesia	3	3	2	2	1	1
Lip injury	1	1			1	1
Loss of consciousness	5	5			5	5
Nausea	1	1			1	1
Palpitations	7	8	2	2	5	6
Pharyngeal swelling	1	1	1	1		
Presyncope	1	1			1	1
Rash	6	7	2	2	4	5
Seizure	4	4			4	4
Syncope	2	2			2	2
Urticaria	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
	67	72	23	23	44	49

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Blood pressure increased	2	3	1	2	1	1
Cerebrovascular accident		1				1
Chest discomfort	2	3		1	2	2
Chest pain	2	3			2	3
Coronary artery disease	1	1			1	1
Dizziness	7	8	3	3	4	5
Dyspnoea	1	3	1	2		1
Facial paralysis	1	1			1	1
Fatigue		1		1		
Headache	1	1			1	1
Hypersensitivity	1	1			1	1
Hypertension	10	10	2	2	8	8
Hypoaesthesia	2	3			2	3
Loss of consciousness	1	1			1	1
Malaise		1		1		
Muscle twitching	1	1	1	1		
Muscular weakness	1	1			1	1
Nausea	1	1	1	1		
Neuralgia		1		1		
Palpitations	1	2			1	2
Paresis		1				1
Pruritus	1	1	1	1		
Pyrexia	1	1	1	1		
Rash	4	4	3	3	1	1
Syncope	1	1			1	1
	42	56	14	21	28	35

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Coronary artery disease		1				1
Dizziness	3	4	1	1	2	3
Headache	1	1	1	1		
Hypertension	2	2			2	2
Hypoaesthesia	2	2			2	2
Ischaemic stroke	1	1			1	1
Myocardial ischaemia		1				1
Palpitations	2	2			2	2
Pyrexia	1	1			1	1
Rash	1	1	1	1		
Syncope		1				1
	16	20	3	3	13	17

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Drug hypersensitivity	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1	1	1		
Arthralgia	2	2	2	2		
Asthenia	1	1	1	1		
Decreased appetite	1	1	1	1		
Dizziness	2	2	2	2		
Facial paralysis	1	1			1	1
Fatigue	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Injection site pain	1	1	1	1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	2	2	2	2		
Migraine	1	1	1	1		
Movement disorder	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Paraesthesia	1	1	1	1		
Paralysis	1	1			1	1
Rash	1	1	1	1		
Seizure	1	1			1	1
Syncope	1	1			1	1
Tremor	1	1	1	1		
Vaccination site pain	1	1	1	1		
	24	24	19	19	5	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**HUNGARY**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		4		4
Irritability		1		1
Maternal exposure during breast feeding		1		1
		6		6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abortion missed		1				1
Aphthous ulcer		1		1		
Arrhythmia		1				1
Arthralgia	1	1			1	1
Asthenia	2	7	1	6	1	1
Axillary pain		1		1		
Back pain		2		2		
Cardiomegaly	1	1			1	1
Chest discomfort		1		1		
Chest pain	1	5		4	1	1
Chills	2	6	2	6		
Confusional state		1		1		
Decreased appetite	1	1	1	1		
Diarrhoea	1	3	1	3		
Disturbance in attention	1	1			1	1
Dizziness	2	9	1	8	1	1
Drug hypersensitivity		1		1		
Dry mouth	1	2	1	2		
Dysphemia	1	1			1	1
Dyspnoea		1				1
Dyspnoea exertional	1	1			1	1
Ear discomfort		1		1		
Ear pain		1		1		
Ear pruritus		1		1		
Erythema		1		1		
Erythema multiforme		1				1
Facial pain		1		1		
Facial paresis		2		1		1
Fatigue		4		4		
Feeling hot		1		1		
Headache	2	12	1	10	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis		1		1		
Hypoaesthesia	1	3		2	1	1
Hypoaesthesia oral	1	2		1	1	1
Hypoglycaemia		1		1		
Influenza like illness		1		1		
Insomnia		2		2		
Lethargy		2		2		
Lymphadenopathy		6		5		1
Lymph node pain		2		2		
Malaise		6		5		1
Maternal exposure during pregnancy		1				1
Memory impairment	1	1			1	1
Migraine		2		2		
Musculoskeletal stiffness		1		1		
Myalgia	1	9	1	9		
Nasal congestion		1		1		
Nausea	3	8	3	8		
Neck pain		1		1		
Off label use		1		1		
Oropharyngeal pain		3		3		
Pain in extremity		7		7		
Palpitations		1		1		
Panic attack		1		1		
Peripheral coldness		1		1		
Peripheral nerve paresis		1				1
Peripheral swelling	1	1			1	1
Petechiae		1		1		
Polyarthritis		1				1
Productive cough		1		1		
Product use issue		1		1		
Pulmonary arterial pressure increased	1	1			1	1
Pulpitis dental		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	4	12	4	10		2
Rash		2		2		
Rash erythematous		1		1		
Retching		1		1		
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Sensitive skin		1		1		
Skin burning sensation		1		1		
Somnolence		1		1		
Swelling		1		1		
Tremor		2		2		
Tricuspid valve incompetence	1	1			1	1
Urticaria		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema		4		4		
Vaccination site hypoaesthesia		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain		7		7		
Vaccination site pruritus		1		1		
Vaccination site swelling		2		2		
Vaginal discharge		1		1		
Vision blurred		1		1		
Vomiting		1		1		
	31	192	16	163	15	29

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain		4		4		
Abortion	1	1			1	1
Abortion missed	1	1			1	1
Adnexa uteri pain		1		1		
Adverse event following immunisation		1		1		
Ageusia		2		2		
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema		1				1
Anosmia		4		4		
Arthralgia	1	10		9	1	1
Arthritis reactive		1				1
Asthenia	3	27	2	24	1	3
Ataxia		1		1		
Atrial fibrillation	1	1			1	1
Axillary pain		1		1		
Back pain		4		4		
Bezold-Jarisch reflex		1		1		
Blepharospasm	1	1	1	1		
Blindness		1				1
Blister		1		1		
Blood glucose increased		1		1		
Blood pressure fluctuation	1	3	1	1		2
Blood pressure increased	2	5		2	2	3
Blood thyroid stimulating hormone decreased		1		1		
Body temperature increased		1		1		
Bone pain		1		1		
Bradyphrenia		1		1		
Burning sensation		3		3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral ischaemia		1				1
Chest discomfort	1	1			1	1
Chest pain		3		3		
Chills	3	25	3	25		
Chromaturia		1		1		
Cold sweat		1		1		
Condition aggravated		1		1		
Cough	1	2		1	1	1
COVID-19	1	5		1	1	4
Cyanosis		1				1
Deep vein thrombosis		1				1
Defaecation urgency		1		1		
Depression		1		1		
Dermal cyst		1		1		
Diarrhoea	1	6	1	6		
Dizziness	4	19	3	16	1	3
Drug hypersensitivity		1		1		
Drug ineffective		1				1
Dry mouth		1				1
Dysgeusia		3		2		1
Dysphagia	1	5		1	1	4
Dysphonia	1	1			1	1
Dyspnoea		2		1		1
Ear pain		1		1		
Ear pruritus		1		1		
Epistaxis		1		1		
Erythema		2		2		
Eye oedema		1				1
Facial paralysis		1				1
Facial paresis		1		1		
Fatigue	2	17	2	17		
Fear of death		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		4		3		1
Feeling hot		3		2		1
Flushing		1				1
Gait disturbance		2		2		
Glossitis		1		1		
Guillain-Barre syndrome		1				1
Haematoma	1	1			1	1
Haemorrhage		1				1
Headache	4	34	4	31		3
Heart rate decreased		1		1		
Heart rate increased		4		3		1
Heart rate irregular	1	1	1	1		
Heat stroke		1		1		
Hemiparesis		1				1
Herpes virus infection		1		1		
Herpes zoster		3		3		
Hot flush	2	3	1	2	1	1
Hyperaesthesia		3		3		
Hyperhidrosis	1	4	1	4		
Hypersensitivity		2		2		
Hypertension	1	3	1	2		1
Hypoaesthesia	2	11	2	10		1
Hypoaesthesia oral	1	1	1	1		
Hypotension		2				2
Incorrect route of product administration		1		1		
Influenza		1		1		
Injection site discolouration		1		1		
Injection site erythema		1		1		
Injection site pain		1		1		
Injection site swelling		1		1		
Insomnia	1	2	1	2		
Intervertebral disc protrusion		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Iodine uptake decreased		1		1			
Lacrimation increased		1		1			
Lactation disorder	1	1	1	1			
Lethargy	1	1			1	1	
Lhermitte's sign		1		1			
Lymphadenitis		2		2			
Lymphadenopathy	3	20	1	15	2	5	
Lymph node pain		4		3		1	
Lymphocyte count decreased		1		1			
Macular oedema		1				1	
Malaise		13		12		1	
Maternal exposure during pregnancy		1		1			
Menstruation irregular		1		1			
Micturition urgency		1		1			
Migraine		2		1		1	
Mobility decreased		1		1			
Monocyte count increased		1		1			
Muscular weakness		1		1			
Musculoskeletal chest pain		1		1			
Musculoskeletal stiffness		1		1			
Myalgia	4	19	4	19			
Myelopathy		1				1	
Nasopharyngitis		1		1			
Nausea	1	13	1	11		2	
Neck pain		1		1			
Nipple pain		1		1			
Oedema peripheral		1				1	
Oral herpes		1		1			
Oropharyngeal pain	1	3		2	1	1	
Overdose	1	1	1	1			
Oxygen saturation decreased		1		1			
Pain		2		2			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Painful respiration		1
Pain in extremity	1	24
Pain of skin		2
Pallor	1	2
Palpitations	1	4
Paraesthesia		3
Paranasal sinus discomfort		1
Pericarditis	1	1
Peripheral swelling		3
Pharyngeal swelling	1	2
Pityriasis rosea		1
Polyarthritits		1
Productive cough		1
Product use issue		2
Pruritus	1	5
Psychiatric symptom		1
Pyrexia	4	36
Rash		2
Rash erythematous		1
Rash maculo-papular		1
Red blood cell sedimentation rate increased		1
Renal pain		2
Retching		1
Rhinorrhoea		4
SARS-CoV-2 test positive		2
Sensation of foreign body		1
Serum ferritin increased		1
Skin lesion		1
Skin sensitisation	1	1
Sleep disorder	1	2
Somnolence		3
Stress		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	23		1
	2		
1	2		
	3	1	1
	1		2
	1	1	1
	3		
	1	1	1
	1		
	1		1
	2		
1	5		
			1
4	36		
	1		1
	1		
	1		
	2		
	1		
	4		
	2		
	1		1
	1		
1	1		
1	2		
	3		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stridor		1				1
Swelling		2		2		
Syncope	1	2			1	2
Tachycardia		5		2		3
Tachypnoea		1				1
Thirst		1				1
Throat irritation		1		1		
Throat tightness		1				1
Thrombophlebitis	1	1	1	1		
Thyroiditis subacute		1		1		
Thyroxine free increased		1		1		
Tinnitus		2		2		
Tremor	1	5	1	3		2
Tri-iodothyronine free increased		1		1		
Upper respiratory tract infection		1		1		
Urinary tract pain		1		1		
Urticaria		3		3		
Vaccination failure	1	3			1	3
Vaccination site coldness		1		1		
Vaccination site erythema	1	8	1	8		
Vaccination site induration		1		1		
Vaccination site movement impairment		2		2		
Vaccination site nodule		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		27		27		
Vaccination site pruritus		1		1		
Vaccination site swelling		6		6		
Vaccination site warmth		3		3		
Visual impairment		1				1
Vomiting	1	7	1	6		1
White matter lesion		1		1		
Wound		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term

Interval Total #  
Spontaneous AE

71

Cumulative Total #  
Spontaneous AE

602

Spontaneous			
Nonserious		Serious	
I	C	I	C
46	503	25	99

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		2		2		
Abdominal pain upper		1		1		
Acute myocardial infarction		1				1
Anaphylactic reaction		2				2
Angioedema		1				1
Anxiety		1		1		
Arthralgia	2	6	2	5		1
Asphyxia		1				1
Asthenia		9		8		1
Atrial fibrillation		1				1
Axillary pain	1	2	1	2		
Blister		1		1		
Blood glucose increased		2		2		
Blood pressure decreased		1		1		
Blood pressure increased		9		7		2
Blood pressure systolic increased		1				1
Body temperature increased		1		1		
Bradycardia		1				1
Bursitis		1		1		
Cartilage injury		1				1
Chest discomfort		3		3		
Chest pain		1		1		
Chills	2	14	2	13		1
Circulatory collapse		2				2
Cold sweat		1		1		
Condition aggravated		1				1
Constipation		1		1		
Cough		3		3		
COVID-19	1	2	1	2		
Craniofacial fracture		1				1
Death		1				1
Decreased appetite		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deep vein thrombosis	1	1
Depressed mood		1
Dermatitis herpetiformis		1
Diarrhoea		2
Dizziness	1	8
Drug ineffective		1
Dry eye		2
Dysgeusia		3
Dysphagia		4
Dysphonia		1
Dyspnoea		6
Ear discomfort		1
Ear pain		1
Ear pruritus		1
Erythema		3
Extrasystoles		1
Eye inflammation		1
Eye irritation		1
Eye oedema		1
Face oedema		1
Facial paralysis		1
Fall		2
Fatigue	1	13
Feeling cold		2
Feeling of body temperature change		1
Feeling of despair		1
Flushing		4
Gait disturbance		1
Glossodynia		1
Headache	3	21
Heart rate increased	1	3
Herpes zoster		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
	1		
	2		
1	6		2
			1
	2		
	3		
	1		3
	1		
	3		3
	1		
	1		
	3		
			1
	1		
	1		
			1
			1
			1
	1		1
1	13		
	2		
	1		
	1		
	4		
	1		
	1		
3	19		2
1	3		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	2		
	1		1
	1		1
			1
	2		
	1		
1	1		
	1		
1	1		
	3		
	1		
	2		
	1		1
	1		
	1		1
	1		
	2		
	1		
	8		
	4		
	13		1
1	1		
	1		1
	1		1
	2		
	2		
	3		
	1		
	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myalgia	2	9
Nasal congestion		1
Nausea	2	11
Neoplasm progression		1
Odynophagia		1
Oedema peripheral		2
Oral herpes		1
Oropharyngeal pain		3
Oxygen consumption increased		1
Pain		1
Pain in extremity		11
Pallor		2
Palpitations		2
Peripheral coldness		1
Peripheral swelling		1
Pharyngeal oedema		1
Photopsia		1
Pneumonia		1
Poor quality sleep		1
Pruritus		5
Pulseless electrical activity		1
Pyrexia	3	23
Rash		3
Rash erythematous		3
Rash maculo-papular		2
Rash pruritic		3
Rash vesicular		1
Respiratory distress		2
Restlessness		1
Rhinorrhoea		2
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 antibody test positive		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	8		1
	1		
2	10		1
			1
	1		
	1		1
	1		
	3		
	1		
	11		
	2		
	1		1
	1		
	1		
	1		
	1		1
	1		
	4		1
			1
3	22		1
	2		1
	3		
	1		1
	3		
	1		
	1		1
	2		
	1		
	2		
	1		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
SARS-CoV-2 test positive		1					1
Sensation of foreign body		3					3
Sensitive skin		1		1			
Sensory loss		1		1			
Sinusitis		1		1			
Skin burning sensation		3		2		1	
Skin warm		1		1			
Somnolence	1	2	1	2			
Stress		1		1			
Swelling	1	1	1	1			
Swelling face		1		1			
Swelling of eyelid		1		1			
Syncope		1					1
Tachycardia		3		2			1
Taste disorder		1		1			
Tension		1		1			
Therapeutic response unexpected		1		1			
Thirst		1		1			
Throat irritation		1		1			
Thrombotic stroke		1					1
Tremor		2		2			
Urticaria		3		2			1
Vaccination site erythema	2	6	2	6			
Vaccination site haematoma		1		1			
Vaccination site haemorrhage		1		1			
Vaccination site nodule		2		2			
Vaccination site oedema		1		1			
Vaccination site pain	2	9	2	8			1
Vaccination site paraesthesia		1		1			
Vaccination site pruritus		1		1			
Vaccination site rash	1	1	1	1			
Vaccination site swelling		5		5			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth		2		2		
Varicose vein		2		2		
Vision blurred		1		1		
Visual impairment		1		1		
Vomiting	1	2	1	2		
White coat hypertension		1		1		
Wound	2	2	2	2		
	33	406	32	339	1	67

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		3		
Acute respiratory failure		1				1
Anaemia	1	1	1	1		
Asphyxia		1				1
Asthenia		7		5		2
Atrial fibrillation	1	2			1	2
Axillary mass		1		1		
Blood pressure fluctuation		1		1		
Blood pressure increased	1	3	1	2		1
Blood urine present	1	1			1	1
Bone pain	1	1	1	1		
Burning sensation	1	1	1	1		
Cardiac disorder	1	1			1	1
Cardiac failure		1				1
Cellulitis	1	1			1	1
Cervical neuritis		1		1		
Chills	2	3	2	3		
Choking	1	1			1	1
Circulatory collapse	1	1			1	1
Condition aggravated	1	2			1	2
Cough	3	5	2	4	1	1
COVID-19	6	9			6	9
COVID-19 pneumonia		1				1
C-reactive protein increased	1	1	1	1		
Cutaneous symptom		1				1
Decreased appetite		2		2		
Diarrhoea		4		4		
Discomfort	1	1	1	1		
Dizziness	1	4	1	4		
Drug ineffective	5	7			5	7
Dysphagia	1	3	1	1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia	1	1			1	1
Dyspnoea	2	4	1	3	1	1
Erysipelas	1	1			1	1
Erythema		2		1		1
Eye haemorrhage		1				1
Eye inflammation	1	1			1	1
Eye pain	1	2	1	2		
Facial paralysis		1				1
Fall		1				1
Fatigue	1	3	1	3		
Feeling abnormal		1		1		
Full blood count abnormal	1	1			1	1
Gingival pain		1		1		
Haematuria	1	1	1	1		
Haemoptysis	1	1			1	1
Headache	3	9	3	9		
Head discomfort	1	1	1	1		
Heart rate increased		1				1
Herpes zoster		4		4		
Hyperhidrosis		1		1		
Hypersensitivity		1				1
Hypertensive crisis		1				1
Hypoaesthesia	1	2	1	2		
Hypoaesthesia oral	1	1	1	1		
Hypotension		2		1		1
Illness		1		1		
Inflammation	1	1	1	1		
Lethargy		1		1		
Lip oedema		1				1
Lip swelling		1				1
Loss of consciousness		2				2
Lower limb fracture		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy		1				1
Malaise	1	3	1	3		
Megacolon		1				1
Monocytosis	1	1			1	1
Mouth swelling		1				1
Mucosal inflammation	1	1			1	1
Muscle spasms	1	1	1	1		
Myalgia	1	3	1	3		
Nausea	1	4	1	3		1
Neuralgia	1	2	1	1		1
Night sweats		1		1		
Oropharyngeal pain	3	3	1	1	2	2
Pain in extremity	1	1	1	1		
Pain of skin	1	2	1	2		
Paraesthesia		1		1		
Periorbital disorder	1	1			1	1
Petechiae	1	1			1	1
Poor quality product administered	1	1	1	1		
Product complaint	1	1	1	1		
Pyrexia	3	8	1	5	2	3
Radiculopathy		1		1		
Rash		1				1
Rash macular	1	1	1	1		
Rash pruritic		2		2		
Red blood cell sedimentation rate increased	1	1	1	1		
Respiratory failure	1	1			1	1
SARS-CoV-2 test positive	2	3		1	2	2
Sciatica		1				1
Sensation of foreign body		1				1
Skin burning sensation		1		1		
Skin discolouration	2	2	1	1	1	1
Skin haemorrhage	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin hypertrophy		1		1		
Skin ulcer	1	1			1	1
Somnolence	1	1			1	1
Spinal osteoarthritis		1		1		
Suspected COVID-19		1				1
Syncope		2				2
Throat tightness		1				1
Thrombocytopenia	1	1			1	1
Thrombophlebitis	1	1			1	1
Toothache	1	1	1	1		
Type IV hypersensitivity reaction		1				1
Vaccination failure	1	1			1	1
Vaccination site erythema		3		3		
Vaccination site inflammation		1		1		
Vaccination site mass		1		1		
Vaccination site pain	1	2	1	2		
Vasoconstriction	1	1			1	1
Vomiting		1		1		
Weight decreased	1	1			1	1
	84	203	39	114	45	89

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Aggression	1	1			1	1
Anaemia	1	1			1	1
Anal incontinence		1				1
Angina pectoris	1	1			1	1
Anuria	1	1			1	1
Arteriosclerosis		1				1
Arthralgia		1				1
Asthenia	3	11	1	2	2	9
Biliary tract disorder		1				1
Blood pressure decreased	1	1			1	1
Blood pressure increased		1		1		
Bronchitis	2	2	1	1	1	1
Burning sensation		1		1		
Capillaritis		1		1		
Cardiac disorder	1	1			1	1
Cardiac failure	1	4			1	4
Cardiomegaly	1	1	1	1		
Cardiopulmonary failure	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest discomfort	1	1	1	1		
Chest pain	1	1			1	1
Chills	1	3	1	3		
Condition aggravated	2	3	1	1	1	2
Confusional state	2	3	1	1	1	2
Cough	1	1	1	1		
COVID-19	3	4			3	4
Death	2	5			2	5
Decreased appetite		1				1
Decubitus ulcer		1				1
Dementia	1	1			1	1
Diarrhoea	1	3		2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness		1		1		
Drug ineffective	4	5			4	5
Dysphonia		1				1
Dyspnoea	1	4	1	1		3
Dysuria		1		1		
Emphysema		1				1
Erythema		1		1		
Face oedema		1				1
Fall	1	2			1	2
Fatigue	2	3	2	2		1
Feeding disorder		2				2
Feeling abnormal		1				1
Femoral neck fracture		1				1
Fibrin D dimer increased	1	1			1	1
Foaming at mouth		1				1
Gastritis erosive	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
General physical health deterioration	1	1	1	1		
Glomerular filtration rate decreased	1	1	1	1		
Haematoma	1	2			1	2
Headache	2	2	2	2		
Heart rate increased		1		1		
Hyperhidrosis		1				1
Hypersensitivity		1		1		
Hypotension		2				2
Hypotonia	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Ischaemic stroke		1				1
Left ventricular failure		1				1
Listless		1				1
Loss of consciousness	1	3			1	3
Lymphadenopathy		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	3	1	3		
Melaena	1	1			1	1
Micturition urgency		1		1		
Nausea	2	3	2	3		
Noninfective gingivitis		1		1		
Oedema blister	1	1			1	1
Off label use	1	1	1	1		
Oxygen saturation decreased		1				1
Pain		1		1		
Pain in extremity		4		3		1
Pallor		1				1
Paralysis		1				1
Peripheral swelling	1	2		1	1	1
Peripheral venous disease	1	1			1	1
Pharyngitis		1		1		
Pneumonia	2	2			2	2
Polyneuropathy		1				1
Potentiating drug interaction	1	1	1	1		
Product administered at inappropriate site		1		1		
Psychiatric symptom	1	1			1	1
Pyrexia	2	6	1	3	1	3
Renal impairment	1	1			1	1
Respiratory disorder	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Somnolence	1	3		1	1	2
Syncope	2	2			2	2
Tension	1	1	1	1		
Thrombophlebitis superficial	1	1			1	1
Tooth disorder		1				1
Transient ischaemic attack		1				1
Urinary incontinence	1	1	1	1		
Vaccination site erythema	4	6	4	6		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	5	7	5	7		
Vaccination site swelling	3	4	3	4		
Vomiting		3		1		2
	85	178	37	72	48	106

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Alanine aminotransferase increased	1	1	1	1		
Alopecia		1		1		
Angina pectoris	1	3			1	3
Antibody test negative		1		1		
Antibody test normal	1	1	1	1		
Arthralgia	1	2	1	2		
Aspartate aminotransferase increased	1	1	1	1		
Asphyxia	1	2			1	2
Asthenia	1	7	1	7		
Asthenopia	1	1	1	1		
Autoimmune thyroiditis	1	1			1	1
Back pain	2	4	2	4		
Blood glucose decreased	1	1	1	1		
Blood glucose increased		1				1
Blood pressure decreased		1		1		
Blood pressure increased	2	6		2	2	4
Breast mass	1	1			1	1
Burning sensation	1	4		3	1	1
Cerebral infarction		1				1
Chest pain	1	3	1	3		
Chills	3	8	3	8		
Cholecystitis	1	1			1	1
Chromaturia		1		1		
Chronic obstructive pulmonary disease		1		1		
Coordination abnormal	1	1	1	1		
Cough	1	1	1	1		
COVID-19	4	14		2	4	12
Decreased appetite	2	3	2	3		
Dehydration	1	1			1	1
Dermatitis allergic		1		1		
Diarrhoea	1	6		5	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
1	1		
	4		
		4	13
1	1		
1	1		
	2		
1	1	1	1
		1	1
	1		
		1	1
2	6		
	1		
	1		
			1
1	1		
1	1		
3	4		
1	5		
	3	1	1
	1		
1	1		
			1
	1		
			1
			1
4	17		
1	1		
1	1		
	3		
1	1		

Diarrhoea haemorrhagic 1

Disease recurrence 1 1

Disturbance in attention 1 1

Dizziness 4

Drug ineffective 4 13

Drug interaction 1 1

Dysgeusia 1 1

Dyspnoea 2

Ear discomfort 2 2

Ear swelling 1 1

Eczema 1

Enteritis 1 1

Erythema 2 6

Exposure during pregnancy 1

Exposure via breast milk 1

Eye haemorrhage 1

Eyelid oedema 1 1

Face oedema 1 1

Fatigue 3 4

Feeling abnormal 1 5

Feeling hot 1 4

Functional gastrointestinal disorder 1

Gamma-glutamyltransferase increased 1 1

Haematochezia 1

Haematoma 1

Haematuria 1

Haemorrhage 1

Headache 4 17

Heart rate increased 1 1

Hepatic enzyme increased 1 1

Herpes zoster 3

Hot flush 1 1

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 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	3	5	1	3	2	2
Hypoaesthesia	3	4	3	4		
Hypoaesthesia oral	1	2	1	2		
Illness		1		1		
Incorrect product formulation administered	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Induration		1		1		
Influenza like illness	1	2	1	2		
Insomnia	1	1	1	1		
Lip swelling	1	1	1	1		
Liquid product physical issue	1	1	1	1		
Lymphadenopathy	1	2	1	2		
Lymphoedema		1		1		
Malaise	7	9	7	9		
Memory impairment		1		1		
Menstruation delayed		1		1		
Migraine		1		1		
Monoplegia		1				1
Muscle fatigue		1		1		
Muscle tightness		1		1		
Muscle twitching	1	1			1	1
Muscular weakness	1	3	1	3		
Myalgia	1	7	1	7		
Nasopharyngitis		1		1		
Nausea		5		5		
Neck pain	1	1	1	1		
Neuralgia		1		1		
Off label use		1		1		
Oropharyngeal pain	1	1	1	1		
Pain	2	4	2	4		
Pain in extremity	7	13	7	13		
Pain of skin		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	1	1	1	1		
Periarthritis		1		1		
Peripheral swelling	1	2	1	2		
Pharyngeal oedema		1		1		
Pharyngeal swelling	1	1	1	1		
Pneumonia	1	1			1	1
Pollakiuria	1	1			1	1
Productive cough	1	1	1	1		
Pruritus		4		4		
Pulmonary embolism	1	1			1	1
Pyrexia	4	18	4	18		
Rash	1	3	1	3		
Rash erythematous	2	3	1	2	1	1
Rash macular		1		1		
Rash pruritic	2	2	1	1	1	1
Rhinorrhoea	1	2	1	2		
SARS-CoV-2 antibody test positive		1		1		
SARS-CoV-2 test positive		1				1
Sensitive skin		1		1		
Skin disorder		1		1		
Somnolence	1	1	1	1		
Speech disorder	1	1	1	1		
Swelling face		1		1		
Swelling of eyelid	1	1	1	1		
Swollen tongue	1	1	1	1		
Tension headache	1	1	1	1		
Tinnitus	1	2	1	2		
Tremor	1	1			1	1
Urticaria	2	3	1	2	1	1
Uveitis		1				1
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema	1	3	1	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	1	1	1	1		
Vaccination site macule	1	1	1	1		
Vaccination site movement impairment	2	3	2	3		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	3	11	3	11		
Vaccination site pruritus		1		1		
Vaccination site swelling	3	4	3	4		
Vasculitis		1		1		
Vomiting		1		1		
Wheezing	1	1			1	1
	135	330	101	264	34	66

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ICELAND**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Off label use		4		4
Product use in unapproved indication		2		2
Product use issue		3		3
Pyrexia		1		1
		10		10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Axillary pain		1		1		
Back pain		1		1		
Bone pain		1		1		
Chills		3		3		
Cough		1		1		
Decreased appetite		1		1		
Discomfort		1		1		
Disease recurrence		1		1		
Dizziness		1		1		
Dry mouth		1		1		
Dry throat		1		1		
Erythema		1		1		
Fatigue		4		4		
Feeling cold		1		1		
Feeling hot		1		1		
Headache	1	9	1	9		
Hyperhidrosis		1		1		
Hypoaesthesia		3		3		
Lymphadenopathy		3		3		
Malaise		6		5		1
Muscular weakness	1	1	1	1		
Myalgia		9		9		
Nasopharyngitis		1		1		
Nausea	1	3	1	3		
Oropharyngeal pain		2		2		
Pallor		1		1		
Pruritus		3		3		
Pyrexia		13		13		
Rash		2		2		
Rhinorrhoea		1		1		
Sensory loss		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation		1		1		
Thirst		1		1		
Vaccination site erythema		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
Vomiting		1		1		
	5	93	5	92		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		3		3		
Arthritis		1		1		
Asthenia		2		2		
Axillary pain		2		2		
Blood pressure increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Breast inflammation		1		1		
Chest discomfort		2		2		
Chest pain		2		2		
Chills	1	7	1	7		
Cold sweat		1		1		
Decreased appetite		1		1		
Delirium	2	2			2	2
Discomfort	1	1	1	1		
Dizziness	1	7	1	7		
Dyspnoea		1		1		
Erythema		2		2		
Fall	1	1	1	1		
Fatigue		8		8		
Feeling abnormal	1	2	1	2		
Feeling cold		1		1		
Fibrin D dimer increased	1	1			1	1
Headache	1	19	1	19		
Head discomfort		1		1		
Heart rate increased		1		1		
Hepatic enzyme increased		1		1		
Hot flush		1		1		
Hyperhidrosis		1		1		
Hypoaesthesia		2		2		
Influenza like illness	1	1	1	1		
Injection site pain		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	1	2	1	2		
Joint stiffness		1		1		
Joint swelling		1		1		
Limb discomfort		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	1	2	1	2		
Malaise	1	10	1	10		
Maternal exposure during pregnancy	1	1	1	1		
Memory impairment	1	1	1	1		
Migraine		1		1		
Muscle twitching		2		2		
Myalgia	1	10	1	10		
Nausea	2	8	2	8		
Ocular discomfort		1		1		
Oedema peripheral		1		1		
Oropharyngeal pain		2		2		
Pain		2		2		
Pain in extremity	2	6	1	5	1	1
Pallor		1		1		
Periorbital swelling		1		1		
Peripheral embolism	1	1			1	1
Pharyngeal swelling		1		1		
Poor quality sleep		1		1		
Pruritus		2		2		
Pyrexia	2	10	2	10		
Rash		2		2		
Sensitive skin		1		1		
Skin discolouration		1		1		
Sleep disorder	1	1			1	1
Sluggishness		1		1		
Swelling		1		1		
Syncope	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		1		1		
Tremor		1		1		
Vaccination site erythema		2		2		
Vaccination site inflammation		2		2		
Vaccination site pain	1	9	1	9		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth		1		1		
Visual impairment	1	1	1	1		
Vomiting		1		1		
	28	177	20	168	8	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Back pain		1		1
Chills		2		2
Cough		1		1
Decreased appetite		1		1
Dizziness		1		1
Dysgeusia		1		1
Dyspnoea		2		2
Fatigue		2		2
Feeling abnormal		1		1
Gastrointestinal pain		1		1
Headache		5		5
Heart rate increased		1		1
Hypersomnia		1		1
Malaise		2		2
Myalgia		5		5
Nasopharyngitis		1		1
Pruritus		1		1
Pyrexia		6		6
Sensitive skin		1		1
Vaccination site pain		4		4
		41		41

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal incontinence		1		1		
Asthenia		2		2		
Atrial fibrillation		1				1
Breath sounds abnormal		1				1
Cough		2		2		
Death		2				2
Decreased appetite		1		1		
Dyspnoea		1		1		
Fluid overload		1				1
Headache		1		1		
Hepatic enzyme increased		1				1
Hypertension		1		1		
Hypoperfusion		1				1
Malaise		1		1		
Nasopharyngitis		1		1		
Nausea		1		1		
Oxygen saturation decreased		1				1
Pneumonia		1				1
Productive cough		1		1		
Pulmonary oedema		1				1
Pyrexia		3		2		1
Respiratory arrest		1				1
Tachycardia		1				1
Urinary incontinence		1		1		
Urine flow decreased		1				1
Vaccination site pain		1		1		
Vaccination site swelling		1		1		
		32		18		14

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Aortic aneurysm		1				1
Aphasia		2		1		1
Arthralgia		1		1		
Asthenia		2		2		
Asthma		1				1
Back pain	1	1	1	1		
Balance disorder	1	1			1	1
Blood pressure decreased		1				1
Cardiac failure		2				2
Cerebrovascular accident		1				1
Chest pain		1				1
Chills		1		1		
Chronic obstructive pulmonary disease		1				1
Confusional state	1	1			1	1
Contusion		1				1
Cough		1				1
Death		4				4
Deep vein thrombosis	1	1			1	1
Delirium		1				1
Depressed level of consciousness		1				1
Disease progression		1				1
Dizziness		1		1		
Dyspnoea		2				2
Erythema		2		2		
Fatigue	1	2		1	1	1
Headache		1		1		
Hypercapnia		1				1
Hyperhidrosis		1				1
Hypoxia		2				2
Joint swelling		1		1		
Loss of consciousness		2				2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung infiltration		1				1
Malaise		7		3		4
Motor dysfunction	1	1			1	1
Myocardial infarction		1				1
Nasopharyngitis		2		2		
Noninfective sialoadenitis		1		1		
Oxygen saturation decreased		1				1
Pain in extremity	1	1			1	1
Peripheral artery thrombosis		1				1
Peripheral swelling	1	1			1	1
Personality change		1				1
Pneumonia		3				3
Pneumonia aspiration		1				1
Pyrexia		8		5		3
Respiration abnormal		1				1
Respiratory failure		1				1
Rhinorrhoea		2		2		
Salivary gland enlargement		1		1		
Sepsis		1				1
Sudden death		2				2
Syncope	1	1			1	1
Transient ischaemic attack	1	2			1	2
Vaccination site erythema		3		3		
Vaccination site inflammation		1		1		
Ventricular tachycardia	1	1			1	1
	12	90	1	30	11	60

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anencephaly	1	1			1	1
Ear pain		1		1		
Fatigue		1		1		
Headache		1		1		
Maternal exposure during pregnancy	1	1	1	1		
Myalgia		2		2		
Oropharyngeal pain		2		2		
Painful respiration		1		1		
Pain in extremity		1		1		
Pulmonary pain		1		1		
Pyrexia		2		2		
	2	14	1	13	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**INDIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Incorrect product administration duration	1	1	1	1		
	3	3	1	1	2	2

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenia	1	1	1	1
Dizziness	1	1	1	1
Fatigue	1	1	1	1
Headache	1	1	1	1
Loss of consciousness	1	1	1	1
Oxygen saturation decreased	1	1	1	1
Pain	1	1	1	1
Vaccination site pain	1	1	1	1
Vomiting	1	1	1	1
	9	9	9	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Suspected counterfeit product		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**IRAQ**

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Headache	1	1	1	1
Myalgia	1	1	1	1
Nausea	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	6	6	6	6

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
Fatigue	1	1	1	1
Insomnia	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	5	5	5	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**IRELAND**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Exposure via breast milk		1		1
Rash		1		1
Urticaria		1		1
		3		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Abdominal pain upper		1				1
Abortion spontaneous	1	1			1	1
Accidental overdose	1	1	1	1		
Ageusia		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Anosmia		1				1
Anxiety		2				2
Arthralgia	3	9	3	4		5
Asthenia	2	10	2	2		8
Axillary mass		1				1
Back pain		1				1
Blepharospasm		1				1
Blindness		1				1
Blister		1				1
Blood pressure increased		2				2
Body temperature increased		1				1
Bone pain		1		1		
Breath odour	1	1			1	1
Burning sensation		2				2
Cellulitis		1				1
Chest discomfort		1				1
Chest pain		3				3
Chills	1	8	1	1		7
Cold sweat		1				1
Confusional state		2				2
Contusion		1		1		
C-reactive protein increased		1				1
Deafness		1				1
Decreased appetite	1	3			1	3
Diarrhoea	1	6		1	1	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia		1				1
Disturbance in attention		1				1
Dizziness	1	9	1	3		6
Dysarthria		1				1
Dyskinesia	1	1	1	1		
Dysphagia		1				1
Dyspnoea		4				4
Dysstasia		1				1
Ear discomfort		1				1
Ear infection		1				1
Ear pain		1				1
Erythema		2		1		1
Exposure during pregnancy		1		1		
Eye movement disorder		1				1
Facial paralysis		2				2
Fatigue	6	19	5	8	1	11
Feeling hot		1				1
Feeling of body temperature change		1				1
Flatulence		1				1
Flushing		1				1
Gait inability		2				2
Gastroesophageal reflux disease		1				1
Hallucination	1	1			1	1
Headache	2	20	2	7		13
Heart rate increased		2				2
Herpes zoster		1				1
Hyperhidrosis		5				5
Hypersensitivity		1				1
Hypoaesthesia		2				2
Hypotension		1				1
Impaired driving ability		1				1
Impaired work ability		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammation		1				1
Influenza like illness		1		1		
Insomnia		4				4
Loss of personal independence in daily activities		1				1
Lymphadenopathy		4				4
Lymph node pain		2				2
Malaise		3				3
Mastitis		1				1
Maternal exposure during pregnancy	2	2	1	1	1	1
Menorrhagia	1	1	1	1		
Menstrual disorder	1	1	1	1		
Metrorrhagia	1	1			1	1
Migraine		1		1		
Mobility decreased		1				1
Muscle fatigue	1	1	1	1		
Muscle twitching	1	1	1	1		
Musculoskeletal stiffness	1	3	1	1		2
Myalgia	1	11	1	5		6
Myokymia		1				1
Nausea	5	19	4	8	1	11
Neck mass		1				1
Neck pain		1				1
Neuritis cranial		1				1
Neutropenia		1				1
Oligomenorrhoea	1	1	1	1		
Oral herpes		1				1
Oropharyngeal pain		1				1
Pain	1	9	1	1		8
Pain in extremity	4	11	4	5		6
Pallor		1				1
Palpitations		5				5
Paraesthesia	1	3	1	1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Photophobia		1					1
Presyncope	1	2	1	1			1
Pruritus		3					3
Pyrexia	4	15	4	5			10
Rash		5		2			3
Rash erythematous		2					2
Rash pruritic		1					1
Respiratory rate increased		1					1
Retching	1	2			1		2
Sinusitis		1					1
Skin burning sensation		1					1
Sleep disorder		1					1
Stridor		1					1
Syncope	3	5			3		5
Tachycardia		5					5
Tenderness		1					1
Tinnitus		1					1
Tremor		1					1
Urticaria		4		1			3
Urticarial vasculitis		1					1
Urticaria papular		1		1			
Vaccination error	1	1	1	1			
Vaccination site erythema		1					1
Vaccination site pain	6	11	5	6	1		5
Vaccination site pruritus		2					2
Vaccination site swelling		2					2
Vaccination site warmth		1					1
Vision blurred		1					1
Vomiting	2	14	1	2	1		12
Wheezing		2					2
	61	346	46	80	15		266

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	4	2	2	1	2
Abdominal distension	1	3	1	1		2
Abdominal infection		1				1
Abdominal pain		2				2
Abdominal pain upper		1				1
Abortion spontaneous	1	2			1	2
Ageusia		3		1		2
Allergy to vaccine		1				1
Amenorrhoea		1				1
Anaemia		1				1
Anaphylactic reaction		6				6
Anaphylactic shock		1				1
Angioedema	2	3			2	3
Anosmia		1		1		
Anxiety		1				1
Aphasia		1				1
Arthralgia	6	23	3	5	3	18
Asthenia	3	26	2	6	1	20
Asthma		1				1
Axillary pain		7		1		6
Back pain	2	14	1	2	1	12
Bedridden		1				1
Blood glucose fluctuation		1				1
Blood pH decreased	1	1			1	1
Blood pressure increased	1	4			1	4
Blood pressure systolic increased		1		1		
Blood urine present		1				1
Bloody discharge		1				1
Body temperature decreased		1				1
Body temperature increased	1	1	1	1		
Bone pain	2	4			2	4
Bradycardia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Breast pain		3					3
Breast swelling		2					2
Breast tenderness	1	1	1	1			
Burning sensation		1					1
Carbon dioxide increased	1	1			1		1
Cardiac arrest	1	1			1		1
Cerebrovascular accident		1					1
Cheilitis		1					1
Chest discomfort	2	14	1	1	1		13
Chest pain	3	12	1	1	2		11
Chills	7	32	2	4	5		28
Chromaturia	1	2	1	1			1
Cluster headache		1		1			
Cold sweat		3		1			2
Complicated appendicitis		1					1
Condition aggravated		1					1
Confusional state		1					1
Conjunctivitis	1	1	1	1			
Constipation		1					1
Corneal reflex decreased	1	1			1		1
Coronary artery occlusion	1	1			1		1
Coronary artery thrombosis	1	1			1		1
Cough	2	8	1	1	1		7
COVID-19	1	3			1		3
Decreased activity		1					1
Decreased appetite	2	7	1	1	1		6
Deep vein thrombosis	1	1			1		1
Dehydration	1	2	1	1			1
Depressed mood	1	1			1		1
Dermatitis allergic		1					1
Diarrhoea	1	9	1	1			8
Discomfort		7					7

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disease recurrence		3				3
Disorientation	1	3			1	3
Disturbance in attention		3		2		1
Dizziness	6	34	3	4	3	30
Drug ineffective		2				2
Dry eye		1				1
Dry mouth		1				1
Dry throat		2				2
Dysarthria		2				2
Dysgeusia	1	4	1	1		3
Dysphagia		1				1
Dysphonia		1				1
Dyspnoea	1	9			1	9
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional		2				2
Dysstasia		1				1
Ear pain		1				1
Emotional distress		1				1
Encephalitis		1				1
Epistaxis		1				1
Erythema	1	3	1	2		1
Erythema of eyelid		1				1
Excessive eye blinking		1				1
Exposure during pregnancy		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye irritation	1	2	1	1		1
Eyelids pruritus		1				1
Eye movement disorder		1				1
Eye pain		4				4
Eye swelling	1	1	1	1		
Facial nerve disorder		1		1		
Facial pain		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis		5
Facial paresis		1
Fatigue	10	59
Feeding disorder		1
Feeling abnormal	1	7
Feeling cold		6
Feeling drunk		2
Feeling hot	2	8
Feeling of body temperature change		1
Flank pain		3
Flushing		3
Furuncle		1
Gait disturbance	1	3
Headache	10	96
Heart rate decreased		1
Heart rate increased	1	7
Heart rate irregular	1	2
Hemiparesis		1
Herpes zoster		1
Hordeolum		1
Hyperaesthesia		1
Hyperhidrosis	1	10
Hyperpyrexia		1
Hypersensitivity		3
Hypertension	1	13
Hyperventilation		1
Hypoaesthesia	5	20
Hypoaesthesia oral	1	7
Hypoglycaemia		1
Hypopnoea		1
Hypotension	2	6
Hypotonia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			5
			1
5	15	5	44
1	1		6
	1		5
			2
	1	2	7
			1
			3
			3
			1
		1	3
5	13	5	83
			1
	1	1	6
		1	2
			1
			1
			1
1	1		9
			1
			3
		1	13
			1
3	7	2	13
1	1		6
			1
2	2		4
			1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness		2		1		1
Impaired driving ability		2				2
Impaired work ability	2	12	1	2	1	10
Inappropriate schedule of product administration		3		3		
Inflammation		1				1
Influenza		1				1
Influenza like illness	3	11	2	4	1	7
Injection site pain		1				1
Insomnia	2	10		1	2	9
Irritability	1	1			1	1
Irritable bowel syndrome		1				1
Joint range of motion decreased	1	1			1	1
Joint stiffness	1	4	1	1		3
Joint swelling		1				1
Lacrimation decreased		1				1
Lacrimation increased		1				1
Lethargy		8		1		7
Limb discomfort		4		2		2
Lip dry		1				1
Lip swelling		5				5
Loss of consciousness	1	3			1	3
Loss of personal independence in daily activities		2		1		1
Lymphadenopathy		14		1		13
Lymph node pain		2				2
Malaise	6	28	2	7	4	21
Mass		1				1
Mastitis	1	1			1	1
Maternal exposure during breast feeding		2		2		
Maternal exposure during pregnancy		3		2		1
Memory impairment		1				1
Menstrual disorder		1				1
Metrorrhagia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Micturition urgency		1		1			
Migraine		4		1			3
Mobility decreased		2					2
Mood swings	1	1			1		1
Muscle spasms		2					2
Muscle tightness		1					1
Muscle twitching		6					6
Muscular weakness		6					6
Musculoskeletal chest pain	1	1			1		1
Musculoskeletal discomfort		1					1
Musculoskeletal pain		1		1			
Musculoskeletal stiffness	2	4	2	2			2
Myalgia	4	29	2	2	2		27
Myelitis transverse		1					1
Myocarditis	1	1			1		1
Nasal congestion		3		1			2
Nausea	9	57	3	8	6		49
Neck pain	2	7	1	1	1		6
Negative thoughts	1	1			1		1
Nerve compression		1					1
Nerve injury		1					1
Nervousness		2		1			1
Nervous system disorder	1	1			1		1
Neuralgia		3					3
Nystagmus	1	1			1		1
Off label use		8		8			
Oropharyngeal discomfort		1					1
Oropharyngeal pain		6		2			4
Orthostatic hypotension	1	1			1		1
Oxygen saturation decreased		2					2
Pain	5	35	3	5	2		30
Pain in extremity	5	31	3	9	2		22

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor		6		1		5
Palpitations	1	11	1	2		9
Panic attack	1	1			1	1
Paraesthesia	2	28	2	6		22
Paraesthesia oral	1	7	1	2		5
Paranasal sinus discomfort		1				1
Periorbital oedema		1		1		
Periorbital swelling		1				1
Peripheral swelling		2				2
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal paraesthesia	2	5	2	3		2
Pharyngeal swelling		2				2
Photophobia		1				1
Pollakiuria		1				1
Poor quality product administered	1	1	1	1		
Poor quality sleep		1		1		
Presyncope	1	1	1	1		
Product preparation error	1	1	1	1		
Product use issue		5		5		
Pruritus	1	11	1	4		7
Pulmonary embolism		1				1
Pyrexia	10	52	5	9	5	43
Quality of life decreased		1				1
Rash	3	14	2	4	1	10
Rash erythematous		5		1		4
Rash macular		1				1
Rash pruritic	2	3	2	2		1
Respiration abnormal		1				1
Respiratory failure	1	1			1	1
Retching		1				1
Road traffic accident		1				1
Salivary hypersecretion		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		1				1
Sensitive skin		1				1
Sensory loss		1				1
Sinus congestion	1	1			1	1
Sinus pain		1				1
Skin burning sensation		1				1
Skin laceration	1	1	1	1		
Skin papilloma		1				1
Skin warm		1				1
Skin wrinkling		1				1
Somnolence		3				3
Speech disorder		1				1
Stress		1		1		
Stridor		2				2
Sudden onset of sleep	1	1			1	1
Suspected COVID-19		1		1		
Swelling	1	5	1	1		4
Swelling face		6		1		5
Swelling of eyelid		2		1		1
Swollen tongue		4				4
Syncope	2	9			2	9
Tachycardia	1	11	1	1		10
Taste disorder		2				2
Tenderness		1				1
Tension headache		1				1
Throat irritation	1	2	1	1		1
Throat tightness		3				3
Thrombosis		1				1
Tidal volume decreased	1	1			1	1
Tinnitus	1	2	1	1		1
Tongue disorder		1				1
Transient ischaemic attack		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	5			1	5
Trigeminal nerve disorder		2				2
Trigeminal neuralgia		1				1
Type IV hypersensitivity reaction		1				1
Unresponsive to stimuli		2				2
Upper respiratory tract infection	1	1	1	1		
Urinary incontinence		1				1
Urinary retention		1				1
Urinary tract infection		1		1		
Urine odour abnormal	1	1	1	1		
Urticaria	2	6	2	2		4
Vaccination failure	1	1			1	1
Vaccination site bruising		1				1
Vaccination site discomfort	2	2	1	1	1	1
Vaccination site erythema		4		1		3
Vaccination site inflammation		1		1		
Vaccination site irritation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site pain	8	20	8	10		10
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus		2		1		1
Vaccination site swelling		3		1		2
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth		1				1
Vaginal haemorrhage		1				1
Vertigo	1	2		1	1	1
Vision blurred		1				1
Visual impairment		2				2
Vitreous floaters		3				3
Vomiting	1	17			1	17
Weight bearing difficulty	1	1			1	1
Weight decreased		1				1

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Age Range

31 - 50 years

Preferred Term

Wheezing

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
105	242	106	1052

211

1,294

105

242

106

1052

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	2	1	1		1
Alanine aminotransferase increased		1				1
Anaphylactic reaction		1				1
Angioedema		1				1
Anxiety		2				2
Arthralgia	1	6	1	1		5
Aspiration		1				1
Asthenia		8		1		7
Back pain		3		1		2
Balance disorder		1		1		
Blindness transient		1				1
Blood bilirubin increased		1				1
Blood lactic acid increased		1				1
Blood pressure diastolic increased		1				1
Blood pressure increased		2				2
Bone pain		1		1		
Breast swelling		1				1
Burning sensation		2		1		1
Cellulitis	1	2			1	2
Chest pain		2				2
Chills	1	6			1	6
Chromaturia		1				1
Confusional state		1				1
Cough	1	3		1	1	2
COVID-19		3		1		2
C-reactive protein increased		1				1
Cyanosis		1				1
Dark circles under eyes		1				1
Deafness	1	1			1	1
Decreased appetite		1				1
Dermatitis	2	2	1	1	1	1
Diarrhoea		3		1		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia	2	2	1	1	1	1
Discomfort	1	2			1	2
Dizziness	3	15		1	3	14
Dry eye		1				1
Dysgeusia	1	2	1	1		1
Dyspnoea		4				4
Eosinophil count increased		1				1
Eye discharge		1				1
Eye pruritus		1				1
Eye swelling		1				1
Facial pain		1		1		
Facial paralysis		2				2
Faeces pale		1				1
Fatigue	3	15	1	4	2	11
Feeling abnormal		3		2		1
Feeling cold		1				1
Feeling hot		5				5
Flank pain		1				1
Flushing		3		1		2
Formication		1				1
Gait inability	1	1	1	1		
Gastric disorder		1				1
Glossodynia		1		1		
Headache	2	18	1	4	1	14
Heart rate increased	1	1			1	1
Herpes zoster reactivation		1				1
Hyperhidrosis		2				2
Hypersensitivity	1	2	1	1		1
Hypertension		4		2		2
Hypoaesthesia	1	5	1	1		4
Hypoaesthesia oral		1				1
Impaired work ability	1	3			1	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infection		1		1		
Influenza like illness		2				2
Injected limb mobility decreased		1				1
Injection site movement impairment		1				1
Injection site pain		1				1
Injury		1				1
Insomnia		3		1		2
Jaundice		1				1
Joint stiffness		1				1
Joint swelling		1				1
Lethargy		2				2
Limb discomfort	1	3			1	3
Lip discolouration		1				1
Lip swelling	1	4			1	4
Liver function test increased		1				1
Loss of consciousness		1				1
Loss of control of legs		1				1
Lower respiratory tract infection		1				1
Lymphadenopathy		3				3
Lymph node pain		2				2
Malaise		8		2		6
Metabolic acidosis		1				1
Migraine		1				1
Muscle spasms		2				2
Musculoskeletal chest pain		1				1
Myalgia	2	10	2	3		7
Mydriasis	1	1	1	1		
Myocardial infarction		1				1
Nasopharyngitis		1		1		
Nausea		9		1		8
Night sweats		1				1
Oral herpes	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pruritus	1	1	1	1		
Oxygen saturation decreased		1				1
Pain		9				9
Pain in extremity	2	7	1	2	1	5
Pain in jaw		1		1		
Palpitations		1				1
Paraesthesia		7		1		6
Paraesthesia oral	1	3	1	1		2
Periarthritis		1				1
Periorbital discomfort	1	1	1	1		
Peripheral swelling		5				5
Pneumonia		2				2
Presyncope		1				1
Product preparation issue		1		1		
Pruritus		2				2
Psychomotor hyperactivity		1				1
Pulmonary embolism		1				1
Pulmonary sepsis		1				1
Pulse abnormal		1				1
Pupils unequal	1	1	1	1		
Pyrexia	2	14	1	2	1	12
Rash		2				2
Rhinitis	1	1			1	1
Salivary hypersecretion	1	1	1	1		
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensation of foreign body		1				1
Sensory loss		1				1
Sinus pain		1		1		
Skin exfoliation		1				1
Somnolence		2				2
Supraventricular tachycardia	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected product quality issue		1		1		
Swelling		2				2
Swelling face		1				1
Swollen tongue		2				2
Syncope		4				4
Tachycardia		3				3
Throat irritation		1				1
Tinnitus	1	1	1	1		
Tongue biting		1				1
Tremor		2				2
Troponin increased		1				1
Underdose		1		1		
Urticaria		2				2
Vaccination site erythema		3		1		2
Vaccination site mass		1				1
Vaccination site warmth		2				2
Vertigo		1				1
Vision blurred		1		1		
Visual field defect		1		1		
Visual impairment		1		1		
Vomiting		4				4
Wheezing		1				1
	43	348	21	62	22	286

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute cardiac event		1				1
Agitation		1				1
Arthralgia	1	2	1	1		1
Asthenia		1				1
Back pain	1	1	1	1		
Cardiac failure	1	1			1	1
Chest pain	1	1	1	1		
Chills		2				2
Cold sweat		1				1
Confusional state	1	2			1	2
Death	1	1			1	1
Diarrhoea	1	1			1	1
Dizziness		2		1		1
Erythema		1				1
Eye movement disorder		1				1
Facial paralysis	1	2			1	2
Fatigue	1	1	1	1		
Feeling abnormal		1				1
Gait disturbance		1				1
Headache	1	2			1	2
Hyperhidrosis		1				1
Hypertension		1				1
Hypoaesthesia	1	1			1	1
Hypoglycaemia		1				1
Hypotonia		1				1
Impaired work ability		2				2
Influenza like illness	1	1	1	1		
Injected limb mobility decreased	1	1	1	1		
Loss of consciousness		1				1
Malaise	1	2			1	2
Migraine	1	1			1	1
Migraine with aura	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	1	1	1	1		
Myalgia		1				1
Nausea	1	2			1	2
Oral herpes	1	1	1	1		
Pain	1	2	1	1		1
Photopsia	1	1			1	1
Presyncope		1				1
Pyrexia		2				2
Respiratory rate increased		1				1
Retching		1				1
Sudden death		1				1
Supraventricular tachycardia		1				1
Tardive dyskinesia		1				1
Tongue movement disturbance		1				1
Unresponsive to stimuli		1				1
Vaccination site pain	1	1	1	1		
Vertigo		1		1		
	22	60	10	12	12	48

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2		1	1	1
Anaphylactic reaction		1				1
Aortic aneurysm	1	1			1	1
Aphasia	1	1			1	1
Asthenia	2	3			2	3
Atrial fibrillation	1	1			1	1
Back pain	1	1			1	1
Cardiac arrest	2	2			2	2
Cardiac failure congestive		1				1
Cerebral infarction		1				1
Cerebrovascular accident	1	1			1	1
Cerebrovascular insufficiency	1	1			1	1
Chest pain	1	1			1	1
Chills	1	2			1	2
Confusional state	1	2			1	2
COVID-19	4	4			4	4
Cyanosis		2		1		1
Death	3	8			3	8
Deep vein thrombosis	3	5			3	5
Depressed level of consciousness		2				2
Dysarthria		1				1
Dyspnoea	1	3			1	3
Dyspnoea at rest		1				1
Epistaxis	1	1			1	1
Face injury		1				1
Facial paralysis	1	2			1	2
Faeces discoloured		1				1
Fall	1	1			1	1
Fatigue		1				1
Feeling abnormal		1				1
General physical condition abnormal	1	1			1	1
General physical health deterioration	3	4			3	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Haematemesis		1					1
Haemoglobin decreased		1					1
Headache	1	1			1		1
Heart rate irregular		1					1
Hemiparesis		1					1
Hyperhidrosis		1					1
Hypopnoea		1					1
Hypotension		2					2
Hypoxia		1					1
Inappropriate schedule of product administration	1	1	1	1			
Loss of consciousness	2	4			2		4
Malaise	1	3			1		3
Melaena		1					1
Memory impairment	1	1			1		1
Myocardial infarction		1					1
Myocardial ischaemia	1	1			1		1
Off label use	1	1	1	1			
Oxygen saturation decreased	1	6			1		6
Pain		1					1
Pallor		3		1			2
Pancreatitis relapsing		1					1
Pneumonitis		1					1
Presyncope		1					1
Pruritus		1					1
Pulse abnormal		1					1
Pyrexia	1	8			1		8
Rales		1					1
Rash		1					1
Rash erythematous		1					1
Rash macular		1					1
Respiratory distress	1	1			1		1
Respiratory rate decreased	1	3			1		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract infection	2	3			2	3
Seizure	1	2			1	2
Skin discolouration		1		1		
Sudden death	1	2			1	2
Syncope	1	2			1	2
Tachycardia		1				1
Tonic clonic movements		1				1
Transient ischaemic attack	2	2			2	2
Unresponsive to stimuli		1				1
Upper gastrointestinal haemorrhage		1				1
Urticaria		2				2
Vomiting		1				1
Wheezing		1				1
	51	134	2	6	49	128

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain upper		1				1	
Accidental exposure to product	1	3	1	3			
Arthralgia	1	4	1	2			2
Asthenia	1	5	1	3			2
Asthma		1					1
Blood pressure increased	1	2			1		2
Bone pain		1					1
Burning sensation		1					1
Cellulitis		1					1
Cerebrovascular accident	1	1			1		1
Chest discomfort		3		1			2
Chillblains	1	1			1		1
Chills	1	3	1	2			1
Choking sensation		1		1			
Circumstance or information capable of leading to medication error	1	1	1	1			
Cough		1					1
COVID-19		2					2
Diarrhoea		2		1			1
Discomfort		1		1			
Disease recurrence		1					1
Dizziness	2	5	2	4			1
Drug ineffective		3					3
Dyspnoea		3		1			2
Eczema	1	1			1		1
Emotional distress		1					1
Erythema	1	1			1		1
Expired product administered	1	1	1	1			
Exposure via breast milk	1	5	1	5			
Exposure via skin contact	1	2	1	2			
Eye swelling	1	1			1		1
Facial pain		1					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis		3
Fatigue	2	8
Feeling cold		3
Feeling hot	1	5
Feeling of body temperature change		1
Flatulence		1
Haematochezia		1
Hangover		1
Headache	3	12
Heart rate increased	1	1
Hemiparesis	1	1
Hyperhidrosis		2
Hypersensitivity		1
Hypoaesthesia	1	2
Hypoaesthesia oral		2
Hypotension	1	1
Illness		1
Impaired work ability		1
Inappropriate schedule of product administration		1
Incorrect dose administered	1	1
Injury associated with device	1	2
IVth nerve paralysis		1
Lethargy		1
Lip swelling	1	2
Loss of consciousness		1
Loss of personal independence in daily activities		2
Lymphadenopathy		2
Lymph node pain		1
Malaise	1	2
Maternal exposure during pregnancy	1	3
Metrorrhagia		1
Muscle spasms		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			3
2	5		3
	1		2
	2	1	3
			1
	1		
			1
	1		
3	6		6
		1	1
		1	1
	1		1
			1
1	1		1
			2
1	1		
	1		
			1
	1		
			1
		1	2
			1
	1		1
			1
			1
1	1		1
1	3		
			1
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Musculoskeletal stiffness	1	2
Myalgia		5
Nausea	1	9
Neck pain		1
Neuralgia		1
Neuropathy peripheral		1
Night sweats		1
No adverse event	1	3
Off label use		1
Oral herpes	1	1
Oropharyngeal pain		3
Pain	2	3
Pain in extremity		4
Pallor	1	1
Panic attack		2
Paraesthesia	1	3
Paraesthesia oral	1	1
Pharyngeal swelling		1
Platelet count decreased		1
Poor quality product administered	11	11
Presyncope	1	2
Product preparation issue		5
Product temperature excursion issue	1	1
Pruritus		2
Pyrexia	1	7
Rash	2	3
Rhinitis		1
Sensory disturbance	1	1
Skin discolouration	1	1
Skin tightness		1
Somnolence		1
Supraventricular tachycardia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
	2		3
1	5		4
			1
			1
			1
	1		
1	3		
	1		
1	1		
			3
2	2		1
	3		1
1	1		
			2
1	3		
1	1		
			1
			1
11	11		
1	2		
	5		
1	1		
	1		1
1	4		3
		2	3
			1
1	1		
		1	1
			1
	1		
		1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Suspected COVID-19		1					1
Suspected product quality issue		4		4			
Swelling face	1	1			1		1
Syncope		1					1
Tachycardia		1					1
Thirst		1					1
Throat tightness		1		1			
Tremor		1		1			
Type III immune complex mediated reaction	1	1			1		1
Underdose		9		9			
Urticaria		2		1			1
Vaccination site discharge		1		1			
Vaccination site discolouration		1					1
Vaccination site erythema		1					1
Vaccination site mass		2					2
Vaccination site pain	1	3	1	2			1
Vaccination site pruritus		1					1
Vaccination site warmth		1		1			
Vaginal haemorrhage		2					2
Visual impairment		1					1
Vomiting		5		4			1
Wheezing		1					1
White blood cell count increased	1	1	1	1			
Wound		1		1			
Wrong technique in product usage process	11	11	11	11			
	74	264	58	147	16		117

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ISRAEL**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Arterial thrombosis		1				1	
Arthralgia	1	1	1	1			
Asthenia	1	2	1	2			
Chest discomfort	1	1	1	1			
Chest pain	4	5	3	3	1	2	
Chills		1		1			
Cough	1	1			1	1	
Decreased appetite	1	1	1	1			
Diarrhoea	1	1	1	1			
Dyspnoea	1	1			1	1	
Electrocardiogram abnormal		1				1	
Exposure via breast milk		3		3			
Fatigue		1		1			
Headache	2	2	2	2			
Hyperventilation	1	1	1	1			
Myalgia	1	2	1	2			
Myocarditis	9	13			9	13	
Neck pain		1		1			
Off label use		2		2			
Pain		1		1			
Pericarditis	2	5			2	5	
Product administered to patient of inappropriate age		2		2			
Productive cough	1	1	1	1			
Pyrexia	1	2	1	2			
Vomiting	2	2	2	2			
	30	54	16	30	14	24	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain upper	1	1	1	1		
Acute kidney injury		1				1
Adverse event	1	1	1	1		
Anal haemorrhage		1		1		
Angioedema		1				1
Antinuclear antibody positive	1	1	1	1		
Antiphospholipid antibodies positive	1	1			1	1
Anxiety		1		1		
Arthralgia		1		1		
Asthenia	8	20	6	18	2	2
Asthma		1				1
Asymptomatic COVID-19	1	1			1	1
Axillary pain		1		1		
Back pain	1	6	1	6		
Blood iron decreased	1	1			1	1
Blood pressure increased		1				1
Bone pain		1		1		
Breast tenderness		1		1		
Cardiogenic shock	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort		2		1		1
Chest pain	9	11	5	7	4	4
Chills	5	10	4	9	1	1
Conjunctival disorder		1				1
Cough		3		3		
COVID-19	1	2	1	2		
C-reactive protein increased		1				1
Deafness unilateral	2	2			2	2
Deep vein thrombosis	1	1			1	1
Diarrhoea	4	4	4	4		
Discomfort	1	1	1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	4	1	3	1	1
Drug ineffective	1	1			1	1
Dry throat		1		1		
Dysphonia		1		1		
Dyspnoea	2	3	2	3		
Electrocardiogram abnormal	1	1	1	1		
Electrocardiogram T wave inversion	1	1			1	1
Erythema	1	3	1	3		
Exposure to contaminated water	1	1	1	1		
Eye swelling		1		1		
Facial pain		1		1		
Facial paralysis		2				2
Fatigue	4	11	3	10	1	1
Feeling abnormal		2		1		1
Feeling cold	1	1	1	1		
Foetal death	1	1			1	1
Gait disturbance	1	1	1	1		
Gingival pain		1		1		
Haemorrhage		1				1
Headache	4	15	3	14	1	1
Heart rate increased		3		3		
Herpes zoster		1		1		
Hyperhidrosis	2	2	2	2		
Hypersensitivity		1				1
Hypoaesthesia	1	5	1	5		
Incorrect dose administered		1		1		
Infection		1		1		
Inflammation		1				1
Injection site pain		2		2		
Insomnia		1		1		
Joint noise		1		1		
Leukocytosis		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liver injury		1				1
Loss of consciousness		1				1
Loss of personal independence in daily activities		1		1		
Lung disorder		1		1		
Lymphadenopathy		2		2		
Malaise		3		3		
Maternal exposure during pregnancy	1	2		1	1	1
Movement disorder		1		1		
Multiple organ dysfunction syndrome		1				1
Muscle contractions involuntary		1		1		
Muscular weakness	1	2		1	1	1
Musculoskeletal stiffness		1		1		
Myalgia	2	6	2	6		
Myocarditis	27	36			27	36
Nasopharyngitis		1		1		
Nausea		4		4		
Neck pain		2		2		
Neuritis		1		1		
Non-Hodgkin's lymphoma		1				1
Oedema peripheral	1	1	1	1		
Off label use		1		1		
Oropharyngeal pain	1	3	1	3		
Overdose		2		2		
Pain	2	7	1	5	1	2
Pain in extremity		10		10		
Pain in jaw		1		1		
Pallor	1	1	1	1		
Palpitations	1	2		1	1	1
Paraesthesia		4		4		
Paralysis		1				1
Pericarditis	4	10			4	10
Peripheral coldness	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral swelling		1		1		
Pleuritic pain	1	1	1	1		
Premature labour	1	1			1	1
Presyncope	1	1			1	1
Product administered at inappropriate site		1		1		
Product preparation error		1		1		
Product use issue		2		2		
Pruritus		2		1		1
Pulmonary embolism	1	1			1	1
Purpura	1	1	1	1		
Pyrexia	8	20	5	16	3	4
Rash		1				1
Seizure		1				1
Shock		1				1
Sinus tachycardia		1				1
Skin discolouration	2	2	2	2		
Skin disorder		1		1		
Suffocation feeling		1				1
Systemic inflammatory response syndrome	1	7			1	7
Tachycardia		1				1
Tenderness		1		1		
Testicular pain	1	1	1	1		
Throat tightness		1		1		
Thrombosis		1				1
Tic		1		1		
Tinnitus	2	3		1	2	2
Toothache		1		1		
Tremor		1		1		
Troponin increased	1	2			1	2
Vaccination site bruising		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema		2		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint movement impairment		1		1		
Vaccination site pain	2	12	2	12		
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		2		1		1
Vaginal haemorrhage	2	3		1	2	2
Vitamin B12 decreased	1	1			1	1
Vomiting	1	1	1	1		
	130	354	62	232	68	122

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain		4				3		1
Abdominal pain upper		1				1		
Abortion spontaneous	1	2					1	2
Acute kidney injury	1	1					1	1
Acute respiratory distress syndrome	1	1					1	1
Adnexa uteri pain		1				1		
Ageusia		1				1		
Allergy to vaccine		1						1
Anaemia		1				1		
Anaesthesia oral		1				1		
Anal haemorrhage	1	1			1	1		
Anaphylactic reaction	1	3					1	3
Angina pectoris		1						1
Angioedema	1	1					1	1
Anorectal discomfort		1				1		
Anxiety	1	4			1	4		
Aphasia	1	1					1	1
Arthralgia		12				10		2
Arthritis reactive		1						1
Asthenia	5	35			2	30	3	5
Atrial fibrillation	1	3					1	3
Back pain		4				4		
Blister	1	1					1	1
Blood chloride increased		1						1
Blood creatine phosphokinase increased		1						1
Blood creatinine abnormal	1	1			1	1		
Blood glucose increased		1						1
Blood lactate dehydrogenase increased		1						1
Blood pressure abnormal	1	1					1	1
Blood pressure fluctuation	1	1					1	1
Blood pressure increased		2						2
Blood pressure systolic increased		1				1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature decreased		1
Bone pain		1
Breast inflammation		1
Cardiac arrest		2
Cerebrovascular accident	1	2
Chest discomfort	1	1
Chest pain	4	4
Chills	4	29
Choking		3
Cold sweat		1
Contusion	1	1
Coronavirus infection		1
Cough	1	4
COVID-19	5	9
Deafness	1	3
Deafness neurosensory	2	2
Death	2	6
Decreased activity		1
Decreased appetite		4
Deep vein thrombosis	1	1
Depressed mood		3
Depression		1
Diarrhoea	3	8
Discomfort		2
Disease recurrence		3
Dizziness	2	16
Drug hypersensitivity		1
Drug-induced liver injury		1
Drug ineffective	3	8
Dysgeusia		6
Dyskinesia	3	3
Dyspepsia		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
					2
				1	2
				1	1
		2	2	2	2
		2	26	2	3
					3
			1		
		1	1		
					1
			3	1	1
	1			5	9
				1	3
				2	2
				2	6
			1		
			3		1
				1	1
			2		1
					1
		3	6		2
			2		
			2		1
		1	12	1	4
					1
					1
	1			3	8
			6		
		2	2	1	1
			3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysphagia		4
Dysphemia	1	1
Dyspnoea	5	17
Dysstasia		1
Ear discomfort	3	4
Ear pain		2
Eosinophilic oesophagitis		1
Epistaxis	1	1
Erythema	1	6
Exposure during pregnancy	1	4
Exposure to SARS-CoV-2		
Extensive swelling of vaccinated limb		1
Eye disorder		1
Eye infection		1
Eye pain		1
Eye swelling		1
Facial pain		1
Facial paralysis	2	11
Fall		1
Fatigue	1	28
Feeling abnormal	1	5
Feeling cold		1
Feeling hot	1	2
Feeling of body temperature change		1
Food craving		1
Gait disturbance	1	2
Gingival bleeding	1	1
Glomerular filtration rate decreased		1
Haematochezia		1
Hangover		1
Headache	5	45
Heart rate increased		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		1
				1	1
		2	8	3	9
					1
		1	2	2	2
			2		
			1		
				1	1
		1	4		2
			3	1	1
	1				
			1		
			1		
					1
					1
					1
				2	11
			1		
		1	27		1
			4	1	1
			1		
		1	2		
			1		
			1		
				1	2
				1	1
					1
			1		
		3	38	2	7
			4		

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiparaesthesia	1	1
Hepatitis		1
Herpes virus infection	1	1
Herpes zoster	4	8
Hot flush		1
Hyperbilirubinaemia		1
Hyperhidrosis		4
Hypersensitivity	3	6
Hypersomnia		1
Hypertension		1
Hypoacusis	2	2
Hypoaesthesia	4	13
Hypoaesthesia oral		6
Illness		1
Impaired quality of life		1
Inappropriate schedule of product administration		4
Inflammation of wound	1	1
Inflammatory marker increased		1
Influenza like illness		3
Injection site pain		2
Insomnia		2
International normalised ratio increased		1
Joint swelling		2
Laryngeal inflammation		1
Laryngitis bacterial		1
Leukocytosis		1
Leukopenia		1
Limb discomfort		1
Loss of consciousness	1	2
Loss of libido		1
Loss of personal independence in daily activities	1	1
Lymphadenopathy	3	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	1		
		4	7		1
			1		
					1
			4		
		1	1	2	5
			1		
			1		
		1	1	1	1
		2	9	2	4
			5		1
			1		
			1		
			4		
		1	1		
					1
			3		
			2		
			2		
					1
			1		1
			1		
					1
					1
			1		
				1	2
			1		
		1	1		
			7	3	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphopenia		1
Malaise		8
Maternal exposure during pregnancy		3
Maternal exposure timing unspecified		1
Mean cell haemoglobin decreased		1
Menorrhagia		2
Menstrual disorder		1
Menstruation irregular	1	3
Mental disorder		1
Metrorrhagia		1
Migraine		2
Miliaria		1
Mobility decreased		2
Multiple sclerosis	1	3
Multiple sclerosis relapse		1
Muscle contractions involuntary		1
Muscle rigidity		1
Muscular weakness	1	2
Myalgia	1	29
Myocarditis	11	14
Nasopharyngitis		1
Nausea		14
Nervousness	1	1
Neuralgia		2
Neutrophil count decreased		1
Neutrophil count increased		1
No adverse event		1
Odynophagia		3
Off label use		4
Oral herpes		1
Oropharyngeal pain		5
Osteomyelitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			6		2
			3		
			1		
					1
			2		
			1		
		1	3		
			1		
			1		
			2		
			1		
					1
				1	3
					1
			1		
			1		
		1	2		
		1	27		2
				11	14
			1		
			13		1
		1	1		
			1		1
			1		
					1
			1		
			2		1
			4		
					1
			4		1
					1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Otitis media		1
Oxygen saturation decreased		1
Pain	4	12
Pain in extremity		10
Pallor		1
Palpitations		3
Paraesthesia	9	21
Paraesthesia oral	1	5
Paralysis	1	2
Parosmia		3
Pelvic pain		1
Pericarditis	3	6
Peripheral coldness		1
Peripheral swelling	1	1
Pharyngeal swelling	1	3
Pleuritic pain		1
Poor quality product administered		1
Poor quality sleep		1
Presyncope		2
Product administered at inappropriate site		1
Product use issue		2
Pruritus	1	7
Pulmonary embolism	2	3
Pulseless electrical activity		1
Pupil fixed		1
Pyrexia	6	30
Rash	1	5
Rash maculo-papular	1	1
Rash pruritic		1
Reduced facial expression		1
Respiratory arrest		1
Right ventricular enlargement		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		2	10	2	2
			9		1
			1		
			3		
		5	15	4	6
		1	4		1
				1	2
			3		
			1		
				3	6
			1		
				1	1
			1	1	2
					1
			1		
			1		
			2		
			1		
			2		
		1	5		2
				2	3
					1
					1
		3	24	3	6
		1	3		2
		1	1		
			1		
			1		
					1
			1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ruptured cerebral aneurysm		1
Sensory disturbance		1
Sensory loss		1
Sinus tachycardia		1
Sleep disorder due to general medical condition, insomnia type		1
Sneezing		2
Somnolence		2
Speech disorder		4
Stillbirth	1	1
Streptococcal infection		1
Stress		1
Suffocation feeling	1	1
Suicidal ideation		1
Swelling	1	2
Swollen tongue		2
Syncope		1
Systemic inflammatory response syndrome		1
Tachycardia		1
Taste disorder		1
Thirst		1
Throat irritation	1	1
Throat tightness		1
Tinnitus	5	6
Tongue discomfort		1
Tonsillitis	1	1
Tremor	1	2
Twin pregnancy		1
Urticaria	1	3
Uterine contractions abnormal		1
Uterine haemorrhage		1
Uterine pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		1
			1		
			1		
			1		1
			2		
			2		2
				1	1
					1
			1		
				1	1
					1
		1	2		
					2
					1
					1
			1		
			1		
				1	1
					1
		3	3	2	3
			1		
				1	1
			1	1	1
			1		
			1	1	2
			1		
					1
			1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Uveitis		1							1
Vaccination failure	2	2					2	2	
Vaccination site cellulitis		1				1			
Vaccination site erythema	1	3			1	3			
Vaccination site inflammation		1				1			
Vaccination site pain	1	31			1	31			
Vaccination site swelling		2				2			
Vaginal haemorrhage	1	5				2	1	3	
Vein discolouration	1	1			1	1			
Vertigo	1	1					1	1	
Vision blurred		2				2			
Vomiting	1	6			1	5			1
Weight decreased		2				1			1
Wrong technique in product usage process		1				1			
Yawning		2				1			1
Yellow skin		1				1			
	164	812		3	62	544	102	268	

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time shortened	1	1			1	1
Acute myocardial infarction	2	3			2	3
Allergy to vaccine		2		1		1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Anger		1		1		
Angina pectoris		2				2
Anosmia		1		1		
Anxiety	2	2			2	2
Aphonia		1				1
Aphthous ulcer		1		1		
Arrhythmia		3				3
Arthralgia	1	6	1	5		1
Asthenia		26		22		4
Asymptomatic COVID-19	1	1			1	1
Atelectasis		1				1
Atrial fibrillation	1	2			1	2
Autoimmune haemolytic anaemia		1				1
Back pain	1	4		3	1	1
Blood chloride increased		1		1		
Blood glucose increased		2		1		1
Blood pressure increased		3		2		1
Bone pain		2		2		
Burning sensation		1				1
Cardiac arrest		4				4
Cardiac failure	1	1			1	1
Cardiac flutter		1				1
Cardiac tamponade	1	1			1	1
Cerebellar haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort		1		1		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	4		3	1	1
Chills		10		9		1
Chronic obstructive pulmonary disease	1	1			1	1
Cold sweat		1		1		
Confusional state		1				1
Cough	1	2		1	1	1
COVID-19	3	8		1	3	7
C-reactive protein increased		1		1		
Crying		1				1
Death		6				6
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Diabetic ketoacidosis		1				1
Diarrhoea		1		1		
Diverticulitis		1				1
Dizziness		7		5		2
Drug hypersensitivity		1		1		
Drug ineffective	2	6			2	6
Dysarthria		1				1
Dysgeusia		1		1		
Dysmenorrhoea		1		1		
Dysphagia		1				1
Dyspnoea	3	11	1	4	2	7
Dyspnoea exertional		1		1		
Dysstasia		1		1		
Ear discomfort		1		1		
Ear pain		1		1		
Encephalitis	1	1			1	1
Epilepsy		1				1
Erythema	1	3	1	3		
Eyelid oedema		1		1		
Facial asymmetry		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial nerve disorder		1				
Facial paralysis	3	10		1		
Facial paresis	1	1			3	10
Fall	1	1			1	1
Fatigue		11	1	1		
Feeling abnormal	1	2		10		1
Feeling cold		2	1	2		
Feeling hot		2		2		
Formication		2		2		
General physical health deterioration		1				1
Guillain-Barre syndrome	1	1			1	1
Headache	1	17	1	16		1
Head discomfort		1		1		
Hepatic function abnormal		1				1
Herpes zoster	3	7	2	5	1	2
Hyperhidrosis		1		1		
Hypersensitivity	2	4		1	2	3
Hypertension		2		1		1
Hypoaesthesia	1	6	1	6		
Hypoaesthesia oral		2		1		1
Hyponatraemia	1	1			1	1
Hypotension	2	3	1	1	1	2
Immune thrombocytopenia	1	2			1	2
Inappropriate schedule of product administration		1		1		
Influenza		2		2		
Influenza like illness		4		4		
International normalised ratio decreased	1	1			1	1
Limb injury	1	1	1	1		
Lip pruritus		1		1		
Lip swelling		2		1		1
Loss of consciousness		3				3
Lung disorder	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy		1		1		
Lymphocyte count increased		1		1		
Malaise		9		7		2
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		2		2		
Mean cell volume decreased		1		1		
Mean platelet volume increased		1		1		
Menorrhagia		1		1		
Mobility decreased		1		1		
Muscle twitching		1		1		
Muscular weakness	1	3		2	1	1
Musculoskeletal stiffness		1		1		
Myalgia		12		11		1
Myocardial infarction		3				3
Myocarditis	3	3			3	3
Nasopharyngitis		2		2		
Nausea	1	10		7	1	3
Neck pain		4		4		
Oedema mouth		1				1
Ophthalmic herpes zoster	1	2			1	2
Oral discomfort	1	2	1	2		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		2		2		
Pain	1	9		6	1	3
Pain in extremity	1	12	1	12		
Palmar erythema		1		1		
Palpitations	1	4		3	1	1
Paraesthesia	1	9	1	8		1
Paraesthesia oral		3		3		
Parosmia		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral swelling		1				1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Poor quality product administered		2		2		
Product deposit		1		1		
Product packaging quantity issue		1		1		
Pruritus	1	2	1	1		1
Pulse abnormal		1				1
Purpura	1	1			1	1
Pyrexia	4	14	3	10	1	4
Rash	1	5		3	1	2
Rash macular		1		1		
Recall phenomenon	1	1	1	1		
Red blood cell count increased		1		1		
Respiratory arrest		1				1
Respiratory disorder		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 antibody test negative		2		1		1
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensory disturbance		1		1		
Sensory loss		1		1		
Skin burning sensation		1		1		
Speech disorder	1	2		1	1	1
Sudden death		1				1
Sudden hearing loss	2	2			2	2
Swelling face		1		1		
Swollen tongue		1				1
Syncope		1				1
Systemic inflammatory response syndrome		1				1
Tachycardia		4		4		
Taste disorder		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Therapeutic response unexpected		2		2		
Thirst		1				1
Thrombocytopenia	1	1			1	1
Thrombosis		1				1
Tinnitus		1				1
Tongue oedema		1				1
Transient ischaemic attack	1	1			1	1
Tremor		2		2		
Urticaria		2		1		1
Vaccination failure	2	2			2	2
Vaccination site cellulitis		1				1
Vaccination site erythema		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain		20		20		
Vaccination site paraesthesia		1		1		
Vaccination site swelling		1		1		
Ventricular fibrillation		2				2
Vertigo	1	1			1	1
Vestibular neuronitis		1				1
Vlth nerve paralysis	1	1			1	1
Vomiting	2	2			2	2
Wheezing	1	2			1	2
	77	470	19	293	58	177

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abdominal pain upper		1		1		
Acute myocardial infarction		1				1
Alcohol intolerance		1		1		
Anaemia	1	1			1	1
Anaphylactic reaction		1				1
Arthralgia		5		4		1
Arthritis	1	1	1	1		
Asthenia		11		11		
Asthma		1		1		
Atrial fibrillation	1	2			1	2
Back pain		2		2		
Blindness transient	1	1			1	1
Blood pressure decreased		1		1		
Blood pressure increased		5		4		1
Bone pain		1		1		
Cardiac arrest		2				2
Cardiac death		1				1
Cardiac disorder		1				1
Cardiac failure	1	2			1	2
Cerebral haemorrhage		1				1
Cerebrovascular accident	2	5			2	5
Cheilitis	1	1	1	1		
Chest pain	3	6	1	3	2	3
Chills	1	9	1	9		
Cholelithiasis		1		1		
Chronic lymphocytic leukaemia		1				1
Cold sweat		1		1		
Confusional state	1	1			1	1
COVID-19	1	9		2	1	7
Deafness neurosensory	2	2			2	2
Deafness unilateral	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death		12				12
Decreased appetite		2		2		
Deep vein thrombosis	1	1			1	1
Depression		1		1		
Diarrhoea		2		2		
Disseminated intravascular coagulation	1	1			1	1
Dizziness	1	9	1	8		1
Drug ineffective	1	7			1	7
Dysgeusia		2		2		
Dyspepsia		3		3		
Dyspnoea	1	9		3	1	6
Dyspnoea exertional		1		1		
Dysstasia		1				1
Ear discomfort		1		1		
Ear infection		1		1		
Ear pain		1		1		
Erythema	1	3	1	3		
Eye haemorrhage		1				1
Eye pain		1				1
Eye swelling		1				1
Facial paralysis	7	11			7	11
Facial paresis	1	1			1	1
Fall		2				2
Fatigue		8		8		
Feeling abnormal		5		2		3
Feeling cold		5		5		
Feeling hot		2		2		
Food refusal		1				1
Formication		1		1		
Gait disturbance	1	3			1	3
General physical health deterioration	1	1			1	1
Guillain-Barre syndrome	2	2			2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia		1				1
Headache		10		10		
Heart rate increased		1		1		
Hepatitis acute		1				1
Herpes zoster	1	2		1	1	1
Hip fracture		1				1
Hyperhidrosis	1	2	1	2		
Hypertension		2				2
Hypoaesthesia	1	5	1	5		
Hypoaesthesia oral	1	2	1	2		
Hypoaesthesia teeth		1		1		
Hypotension		1		1		
Hypoventilation		1				1
Illrd nerve paralysis	1	1			1	1
Illness		1		1		
Influenza		1		1		
Influenza like illness		1		1		
Insomnia		2		2		
Jaundice		1		1		
Leukocytosis	2	2			2	2
Lip disorder		1		1		
Lip swelling	1	1	1	1		
Localised infection	1	1			1	1
Loss of consciousness		2				2
Lymphocytosis		1		1		
Malaise		2		2		
Movement disorder	1	2	1	1		1
Multiple sclerosis relapse	1	2			1	2
Muscular weakness	1	1			1	1
Musculoskeletal chest pain	1	1	1	1		
Myalgia	2	8	1	6	1	2
Myasthenia gravis		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	1	2			1	2
Nausea		7		5		2
Nephrolithiasis	1	1			1	1
Nervous system disorder	1	1	1	1		
Neuralgic amyotrophy	1	1			1	1
Neutropenia	1	1			1	1
Oral herpes	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain in extremity		7		7		
Pain in jaw		1		1		
Palpitations		2		2		
Pancreatitis		1				1
Pancytopenia	1	1			1	1
Paraesthesia	2	6	1	5	1	1
Paraesthesia oral		2		2		
Pelvic fracture		1				1
Pericardial effusion	1	1			1	1
Pericarditis	4	4			4	4
Pleural effusion	1	1			1	1
Pneumonia		2				2
Pneumonia aspiration	1	1			1	1
Product preparation error		1		1		
Pseudomonas infection	1	1			1	1
Psoriatic arthropathy	1	1			1	1
Pulmonary embolism	1	1			1	1
Pulpitis dental		1		1		
Pyrexia	3	10	1	7	2	3
Rash		2		2		
Rash vesicular	1	1			1	1
Recall phenomenon	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder	1	1	1	1		
Respiratory rate increased		1				1
Rhinorrhoea		1		1		
Rib fracture		1				1
SARS-CoV-2 antibody test positive		1		1		
Seizure	3	3			3	3
Sensory loss	1	1			1	1
Skin burning sensation	1	2	1	2		
Skin exfoliation	1	1	1	1		
Skin reaction	1	1	1	1		
Speech disorder		1		1		
Sudden hearing loss	1	1			1	1
Swelling face		1		1		
Syncope	2	4			2	4
Tachycardia		1				1
Thrombosis		2				2
Tic		1		1		
Tonic convulsion	1	1			1	1
Toothache		1		1		
Tooth injury		1		1		
Transient ischaemic attack	1	1			1	1
Tremor		4		4		
Underdose		1		1		
Urosepsis	1	1			1	1
Urticaria		2		1		1
Vaccination site pain		4		4		
Vaccination site swelling		1		1		
Vertigo	2	4	1	2	1	2
Vomiting		4		4		
Wheezing		1		1		
	91	361	24	203	67	158

\* I=Interval, C=Cumulative  
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Agitation		1		1		
Angioedema	1	1			1	1
Aphasia	1	1	1	1		
Aspiration		1				1
Asthenia	3	7	3	4		3
Back pain		1				1
Blood pressure decreased		1				1
Bone pain		1		1		
Brain death		1				1
Brain injury		1				1
Brain oedema		1				1
Cardiac arrest		4				4
Cardiac disorder		1				1
Cardiac failure	2	4			2	4
Cardiac failure chronic	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chronic obstructive pulmonary disease		1				1
Circulatory collapse		1				1
Contusion		1				1
Cough	1	1	1	1		
COVID-19		3		1		2
C-reactive protein increased	1	1			1	1
Crying		1		1		
Death		6				6
Diarrhoea		1		1		
Dizziness		3		1		2
Drug hypersensitivity		1				1
Drug ineffective		2				2
Dyskinesia		3		2		1
Dyspepsia		1		1		
Dyspnoea	1	6	1	1		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Endocarditis		1					1
Eye irritation		2		1			1
Face injury		1					1
Facial paralysis	1	2			1		2
Fall		2					2
Fatigue		2		1			1
Feeling cold		1		1			
Gait disturbance		1		1			
Gastric haemorrhage		1					1
Gastrointestinal necrosis		1					1
General physical health deterioration	1	2			1		2
Haematemesis		1					1
Haemorrhage		1					1
Headache		2		2			
Herpes zoster	1	1	1	1			
Hypertension		1					1
Hypotension		1					1
Hypothermia		1					1
Inflammation		1					1
Ischaemic stroke		1					1
Lacrimation increased		2		1			1
Leukocytosis	1	2			1		2
Loss of consciousness	2	2			2		2
Lung infiltration	1	1			1		1
Malaise		1		1			
Movement disorder		1		1			
Myalgia		2		2			
Myocardial infarction	1	2			1		2
Oedema		1					1
Pain	1	3	1	3			
Pain in extremity	1	1			1		1
Peripheral artery occlusion	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral ischaemia	1	1			1	1
Personality change		1		1		
Pleural effusion		1				1
Pneumonia aspiration		1				1
Psychomotor hyperactivity		1		1		
Pulmonary embolism	1	1			1	1
Pulmonary oedema		2				2
Pyrexia	1	2			1	2
Respiratory disorder	1	1			1	1
Respiratory distress		1				1
Restlessness		1				1
Seizure	3	3			3	3
Sepsis		1				1
Septic shock		1				1
Slow speech		1				1
Speech disorder	1	1			1	1
Sudden hearing loss	1	1			1	1
Suffocation feeling		1				1
Syncope	1	2			1	2
Systemic inflammatory response syndrome	1	1			1	1
Therapeutic response unexpected	1	1	1	1		
Tinnitus	1	1			1	1
Transient ischaemic attack	4	4			4	4
Unresponsive to stimuli	1	1			1	1
Vomiting		1				1
	42	140	9	34	33	106

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abdominal pain upper		1		1		
Adverse event		2		2		
Ageusia		1		1		
Allergy to vaccine		1		1		
Alopecia		1		1		
Angina pectoris		1				1
Angioedema		1				1
Anosmia		2		2		
Anxiety	1	1	1	1		
Arrhythmia		1				1
Arthralgia	2	14	2	12		2
Arthropathy		1		1		
Asthenia	3	46	3	45		1
Asthenopia		1		1		
Asymptomatic COVID-19	3	3			3	3
Atrial fibrillation		1				1
Back pain	1	3	1	3		
Balance disorder		1		1		
Basedow's disease	1	1			1	1
Blood immunoglobulin M increased		1		1		
Blood pressure increased		2		1		1
Body temperature decreased		2		2		
Bone pain		1		1		
Cartilage injury		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	2	1	2		
Chest pain		5		4		1
Chills		27		27		
Choking		1				1
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cold sweat	1	1
Condition aggravated		3
Confusional state	1	2
Coronavirus infection	2	6
Cough		3
COVID-19	13	32
C-reactive protein increased		1
Death		1
Decreased appetite	1	3
Depressed mood		2
Diarrhoea		5
Discomfort	1	4
Disease recurrence		2
Dizziness		12
Drug exposure before pregnancy		1
Drug ineffective	13	31
Dry mouth		1
Dysaesthesia		1
Dyschromatopsia		1
Dysgeusia		2
Dysphagia		1
Dyspnoea		7
Dyspnoea exertional		1
Dysstasia	1	1
Ear pain		1
Epistaxis		1
Erythema	1	1
Exposure during pregnancy	1	2
Exposure via breast milk		2
Extensive swelling of vaccinated limb		1
Eye infection		2
Eyelid function disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	2		1
1	2		
		2	6
	3		
1	4	12	28
	1		
			1
1	3		
	2		
	5		
1	4		
	1		1
	12		
	1		
		13	31
	1		
	1		
	2		
	1		
	3		4
	1		
1	1		
	1		
			1
		1	1
1	2		
	2		
	1		
	2		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pain		5
Eye swelling		2
Facial paralysis		5
Fall		1
Fatigue	3	24
Feeling abnormal	1	5
Feeling cold		6
Foetal death		2
Foetal exposure during pregnancy		1
Foetal heart rate abnormal		1
Foetal movement disorder		1
Gastroenteritis viral		1
Gingivitis		1
Guillain-Barre syndrome		1
Hallucination		1
Hallucination, auditory		1
Headache	3	44
Head discomfort		2
Head injury		1
Heart rate increased		2
Hemiplegia		1
Hepatic enzyme increased	1	1
Hepatic failure	1	1
Hepatic function abnormal	1	1
Herpes simplex		1
Herpes zoster		6
Hormone level abnormal		1
Hyperhidrosis		2
Hypersensitivity	1	3
Hypertension		1
Hypoaesthesia	1	13
Hypoaesthesia oral		3

Spontaneous			
Nonserious		Serious	
I	C	I	C
	4		1
	1		1
			5
	1		
3	24		
	3	1	2
	6		
			2
			1
			1
			1
	1		
	1		
			1
			1
3	43		1
	2		
			1
	1		1
			1
		1	1
		1	1
		1	1
	1		
	6		
	1		
	2		
1	2		1
	1		
1	13		
	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inappropriate schedule of product administration		3
Incomplete course of vaccination		1
Incorrect dose administered	1	1
Inflammation	1	2
Influenza like illness		6
Initial insomnia		1
Injection site erythema		1
Insomnia		2
Intentional dose omission		1
International normalised ratio increased		1
Joint swelling		1
Leukocytosis		1
Limb discomfort		1
Lip pruritus		1
Liquid product physical issue		19
Liver function test increased		1
Loss of consciousness	1	2
Lymphadenopathy	1	6
Malaise	1	9
Maternal exposure during pregnancy		1
Mechanical urticaria		1
Menstrual disorder		1
Mental disorder		1
Migraine		1
Mobility decreased		2
Monoplegia		1
Mood altered		1
Motor dysfunction		1
Movement disorder		1
Multiple sclerosis relapse		1
Muscle contractions involuntary		2
Muscle disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		
	1		
1	1		
1	2		
	6		
	1		
	1		
	2		
	1		
	1		
	1		
	1		1
	1		
	1		
	19		
	1		
		1	2
1	6		
1	7		2
	1		
	1		
	1		
	1		
	1		1
			1
	1		
	1		1
			1
	2		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	2	2	2	2		
Muscular weakness		1				1
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort		1		1		
Myalgia	1	25	1	24		1
Myasthenia gravis		1				1
Myocarditis	3	4			3	4
Nasopharyngitis		1		1		
Nausea	2	19	2	19		
Neck pain	1	3	1	3		
Neuralgic amyotrophy		2		2		
Night sweats		1		1		
No adverse event	1	1	1	1		
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Oedema peripheral		1				1
Off label use		1		1		
Oral herpes	1	5	1	4		1
Oropharyngeal pain		2		2		
Overdose		2		2		
Pain	1	11	1	10		1
Pain in extremity	4	18	4	18		
Pain in jaw		1		1		
Palpitations		2		2		
Paraesthesia		11		10		1
Paraesthesia oral		6		5		1
Paralysis		1				1
Paraplegia		1				1
Pericardial effusion		1				1
Pericarditis	15	18			15	18
Peripheral coldness		2		2		
Peripheral swelling		3		3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	3
			1
3	36		
	1		
	1		
	1		
1	1		
	1		
	1		
	11		
	2		
1	2		
2	2		
	1		
1	3		
4	42		2
2	5		1
	1		
	1		1
	1		
	2		
1	1		
	1		1
	1		
1	9	1	9
	1		1
	1		
1	2		
	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence	1	2	1	2		
Stress		1		1		
Sudden cardiac death		1				1
Suspected COVID-19		1				1
Swelling		1		1		
Swelling face	1	1			1	1
Swollen tongue		1				1
Syncope		3				3
Syndactyly		1				1
Tachycardia		1		1		
Therapeutic response unexpected	2	5	2	5		
Thinking abnormal		1		1		
Tracheal oedema		1				1
Tremor		2		2		
Underdose		2		2		
Urinary tract infection		1		1		
Urticaria		1		1		
Vaccination failure	4	5			4	5
Vaccination site erythema		6		6		
Vaccination site hypersensitivity		2		2		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	1	3	1	3		
Vaccination site pain	2	45	2	45		
Vaccination site swelling		8		8		
Vaccination site vesicles	1	1	1	1		
Vaginal haemorrhage	1	2	1	2		
Vertigo		2		2		
Vision blurred		3		3		
Vomiting		5		5		
Weight decreased		1				1
Wrong technique in product usage process	1	2	1	2		
	129	885	65	691	64	194

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**ITALY**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Crying	1	1			1	1
Decreased appetite		1		1		
Exposure via breast milk	3	6		3	3	3
Fatigue		1		1		
Febrile convulsion	1	1			1	1
Infantile vomiting		1		1		
Insomnia	1	1			1	1
Nervousness	1	1			1	1
Product administered to patient of inappropriate age		1		1		
Pyrexia		1		1		
Vomiting		1		1		
	7	16		9	7	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal distension	1	1			1	1		
Abdominal pain	3	28			3	26		2
Abdominal pain lower		1				1		
Abdominal pain upper		11				10		1
Abscess		1						1
Acute respiratory distress syndrome	1	1					1	1
Administration site erythema		1				1		
Administration site pain		6				6		
Adrenomegaly		2				2		
Ageusia		3				3		
Agitation		1				1		
Amenorrhoea		1				1		
Amnesia	1	1			1	1		
Anaesthesia	1	2			1	2		
Anaesthesia oral		1				1		
Anal incontinence		1				1		
Anaphylactic reaction		9						9
Angioedema		2						2
Anosmia	1	3				2	1	1
Antinuclear antibody positive		1						1
Anuria		1						1
Anxiety		8				5		3
Aphasia		1						1
Aphonia	1	1					1	1
Aphthous ulcer		1				1		
Arrhythmia		3						3
Arthralgia	14	178			8	146	6	32
Arthritis reactive				1				
Asthenia	17	216			15	193	2	23
Asthenopia		2				2		
Asthma		3						3
Asthmatic crisis		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asymptomatic COVID-19	2	5
Atrial fibrillation		1
Axillary pain	2	12
Back pain	1	21
Binocular eye movement disorder	1	1
Blister		1
Blood pressure decreased		2
Blood pressure increased		4
Blood pressure systolic increased		3
Bone pain	1	20
Bradycardia		4
Breakthrough pain		1
Bronchospasm		3
Burning sensation	1	3
Chest discomfort		5
Chest pain	2	11
Chillblains	1	1
Chills	15	207
Choking		1
Choking sensation		2
Chromaturia	1	1
Clonus		1
Cluster headache		1
Cognitive disorder	1	1
Cold burn		1
Cold sweat		7
Colitis		1
Condition aggravated	1	1
Confusional state		11
Conjunctivitis		1
Contusion	1	2
Convulsions local		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	4
					1
1	1	2	12		
			13	1	8
				1	1
			1		
			1		1
			4		
			3		
		1	17		3
					4
					1
					3
		1	3		
			3		2
			4	2	7
		1	1		
		11	177	4	30
					1
			1		1
				1	1
			1		
			6		1
			1		
				1	1
			7		4
					1
			1	1	1
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coordination abnormal		1
Cough	3	12
COVID-19	9	31
C-reactive protein abnormal	1	1
Cyanosis	1	1
Deafness		1
Decreased appetite	1	5
Depressed level of consciousness		6
Dermal cyst		1
Dermatitis	1	3
Dermatitis bullous		1
Dermatitis herpetiformis		1
Diaphragmatic spasm		1
Diarrhoea	3	54
Diplegia		1
Diplopia	1	2
Discomfort	1	5
Disease recurrence		1
Disorientation		1
Dissociation		1
Disturbance in attention	1	2
Dizziness	9	70
Drug ineffective	2	7
Dry mouth		8
Dry skin		1
Dysentery		18
Dysgeusia	1	10
Dyslalia		1
Dysmetria		1
Dyspepsia	2	6
Dysphagia		12
Dysphonia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	5	2	7
		1	14	8	17
				1	1
				1	1
			3	1	2
					6
			1		
		1	3		
					1
					1
			1		
		3	44		10
					1
		1	2		
		1	3		2
	1				
					1
			1		
		1	2		
		7	45	2	25
				2	7
			7		1
			1		
1	1				18
		1	9		1
					1
					1
		1	4	1	2
			4		8
				1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea		30
Dysuria	1	1
Ear discomfort		1
Ear pain		3
Ectopic pregnancy		1
Electrocardiogram abnormal	1	1
Encephalopathy		1
Eruclation		1
Erythema	5	35
Erythema nodosum	1	1
Euphoric mood		1
Eye irritation		3
Eyelid oedema		2
Eye oedema		2
Eye pain	1	1
Eye pruritus	1	2
Eye swelling		1
Face injury		1
Face oedema		1
Facial nerve disorder		1
Facial paralysis	3	11
Facial paresis		2
Faeces soft		1
Fall	2	3
Fatigue	11	138
Febrile convulsion		4
Feeling abnormal		1
Feeling cold	4	21
Feeling hot		11
Feeling jittery		1
Feeling of body temperature change		3
Fibrin D dimer increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			16		14
			1	1	1
			1		2
				1	1
			1		1
		3	22	2	13
				1	1
			1		
			3		
			2		
			2		
		1	1		
			1	1	1
			1		
					1
					1
			1		1
					1
			1	3	10
					2
			1		
				2	3
		6	120	5	18
			3		1
					1
		3	19	1	2
			7		4
			1		
			2		1
				1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flank pain		1
Flushing	2	14
Frequent bowel movements		1
Furuncle		1
Gastritis		1
Gastroenteritis		1
Gastrointestinal disorder	2	6
Gastrointestinal pain		3
General physical health deterioration	1	1
Gingival oedema		1
Gingival swelling		1
Glossitis	1	1
Goitre		1
Haematuria		1
Headache	25	411
Head discomfort		4
Head injury	1	1
Heart rate decreased		2
Heart rate increased		1
Heat stroke		1
Hemianaesthesia	1	2
Hemiparaesthesia		1
Hemiparesis		1
Herpes ophthalmic		1
Herpes simplex		1
Herpes virus infection		1
Herpes zoster		4
Hidradenitis		1
Hot flush		9
Hyperaemia		2
Hyperaesthesia		1
Hyperglycaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	12		2
			1		
			1		
			1		
		2	6		
			3		
				1	1
			1		
					1
				1	1
					1
2	3	16	357	9	54
			4		
				1	1
			1		1
			1		
				1	2
					1
					1
			1		
			1		
1	1		2		2
					1
			8		1
			1		1
			1		
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperhidrosis	4	34
Hyperpyrexia	3	29
Hypersensitivity	2	7
Hypertension		2
Hypertensive crisis		3
Hyperthermia		5
Hypoacusis	1	1
Hypoaesthesia	1	20
Hypoaesthesia oral		5
Hypotension	2	30
Hypotensive crisis		1
Hypotonia		3
Illrd nerve paralysis		1
Illness		2
Immune system disorder		1
Incorrect dose administered		1
Incorrect route of product administration	1	3
Induration		4
Influenza		3
Influenza like illness	1	11
Initial insomnia		2
Injected limb mobility decreased	1	4
Injection site erythema	1	5
Injection site induration		2
Injection site lymphadenopathy		1
Injection site oedema		17
Injection site pain	1	174
Injection site paraesthesia		1
Injection site pruritus	1	2
Injection site swelling		2
Injection site urticaria		3
Injection site warmth		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	24	2	10
	1	1	1	2	28
		2	4		3
			2		
			4		3
			4		1
		1	1		
1	1	1	18		2
			4		1
			13	2	17
					1
			1		2
					1
			1		1
			1		
			1		
		1	3		
			4		
			2		1
1	1		9	1	2
			1		1
		1	4		
		1	5		
			2		
			1		
			17		
		1	174		
			1		
		1	2		
			2		
			3		
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Insomnia	1	21
Irritability		1
Jaw fracture		1
Joint range of motion decreased		1
Joint swelling	1	1
Laryngeal oedema		6
Laryngeal pain		1
Laryngospasm		1
Limb discomfort	1	7
Lip oedema	1	9
Lip pruritus		2
Lip swelling	1	6
Localised oedema		2
Loss of consciousness	3	25
Loss of personal independence in daily activities	1	2
Lymphadenitis	1	5
Lymphadenopathy	16	151
Lymph node pain	2	19
Lymphoedema		1
Macroglossia		1
Malaise	10	70
Maternal exposure during pregnancy	1	3
Mechanical urticaria		2
Menstrual disorder		1
Middle insomnia		3
Migraine	2	23
Migraine with aura		1
Mobility decreased	1	2
Motor dysfunction		1
Mouth swelling		1
Mouth ulceration		1
Muscle fatigue		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			18	1	3
			1		
					1
			1		
				1	1
					6
			1		
					1
		1	6		1
		1	5		4
					2
			4	1	2
			1		1
				3	25
		1	2		
			3	1	2
4	4	12	126	4	25
2	2	2	16		3
			1		
					1
		8	57	2	13
			2	1	1
			1		1
			1		
			3		
		2	21		2
			1		
		1	2		
			1		
			1		
			1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle oedema		1
Muscle rigidity		2
Muscle spasms		5
Muscular weakness		8
Musculoskeletal pain		26
Musculoskeletal stiffness	1	7
Myalgia	17	234
Myasthenia gravis		1
Mydriasis	1	1
Myocarditis	2	5
Myoclonus		1
Nasal congestion	2	4
Nasopharyngitis	4	8
Nausea	20	149
Neck pain	1	12
Nerve injury	1	1
Neuralgia		2
Neuritis		1
Neuropathy peripheral	1	2
Night sweats		2
Nuchal rigidity		1
Nystagmus		1
Obstructive airways disorder		2
Ocular hyperaemia	1	3
Oedema		1
Oedema peripheral		3
Ophthalmic herpes zoster	1	1
Oral discomfort		2
Oral dysaesthesia		2
Oral herpes		1
Oral pruritus		3
Oropharyngeal discomfort		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
			5		
			7		1
	1		22		4
		1	5		2
1	1	11	205	6	29
					1
				1	1
				2	5
			1		
		1	2	1	2
		3	7	1	1
1	1	11	122	9	27
		1	11		1
		1	1		
			1		1
				1	2
			2		
			1		
					1
			1		1
			2	1	1
			1		
			3		
				1	1
			2		
			2		
			1		
					3
			3		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oropharyngeal oedema		1
Oropharyngeal pain	1	10
Oropharyngeal plaque		1
Oropharyngeal swelling		1
Orthostatic hypotension		1
Overdose		6
Oxygen saturation decreased		2
Pain	3	50
Painful respiration	1	1
Pain in extremity	13	103
Palatal swelling	1	2
Pallor		5
Palpable purpura		1
Palpitations	1	4
Paraesthesia	8	61
Paraesthesia oral	1	23
Paralysis		1
Pericardial effusion		1
Pericarditis		1
Perineal pain	1	1
Peripheral coldness	2	2
Peripheral swelling	4	8
Pharyngeal erythema		1
Pharyngeal mass		1
Pharyngeal paraesthesia		2
Pharyngeal swelling		3
Pharyngitis		1
Photophobia		3
Pneumothorax	1	1
Presyncope	4	31
Product administered at inappropriate site		2
Product preparation issue		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	9		1
			1		1
			6		1
			40	3	10
		1	1		
1	1	9	88	4	15
				1	2
			4		1
			1		
		1	2		2
		5	44	3	17
		1	15		8
					1
					1
					1
		1	1		
		1	1	1	1
		2	5	2	3
			1		
					1
					2
					3
			1		
			3		
				1	1
		4	15		16
			2		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pruritus	5	46
Pruritus allergic		1
Psoriatic arthropathy	1	1
Puncture site induration		1
Pyrexia	35	477
Quality of life decreased		1
Rash	6	45
Rash erythematous		3
Rash macular		1
Rash maculo-papular	1	2
Rash pruritic	1	4
Rash vesicular		2
Renal pain		1
Respiratory arrest	1	1
Respiratory distress		1
Respiratory fatigue		2
Restlessness		1
Retching	1	1
Rhinitis	1	2
Rhinitis allergic		1
Rhinorrhoea		1
SARS-CoV-2 antibody test	1	1
SARS-CoV-2 antibody test positive	1	1
SARS-CoV-2 test positive	1	3
Sensation of foreign body	1	4
Sensitive skin		1
Sensory loss		2
Shock	1	1
Sinus tachycardia		3
Skin burning sensation		2
Skin discolouration		1
Skin laceration	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	36	2	10
			1		
			1	1	1
			1		
4	4	22	380	13	97
			1		
		3	30	3	15
	1		1		2
			1		
		1	2		
			1	1	3
					2
			1		
				1	1
					1
					2
			1		
		1	1		
		1	2		
			1		
			1		
				1	1
		1	1		
			2	1	1
			2	1	2
			1		
			1		
				1	1
			2		1
			1		1
			1		
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin reaction	1	3
Sleep disorder		1
Soft tissue infection		1
Somnolence	1	27
Sopor		1
Speech disorder		1
Spinal pain		1
Stupor		1
Sudden hearing loss		1
Suffocation feeling		2
Swelling	1	6
Swelling face	1	6
Swollen tongue	2	5
Syncope	5	33
Tachycardia	4	46
Tachycardia paroxysmal		1
Tachypnoea		1
Tendonitis		1
Tension headache		1
Terminal insomnia		1
Tetany	2	2
Thermal burns of eye		1
Thought blocking		1
Throat irritation	1	7
Throat tightness		9
Thrombocytopenia	1	1
Thrombophlebitis	1	1
Thyroid pain		1
Tinnitus	1	2
Tongue discomfort	1	1
Tongue oedema	1	3
Tongue pruritus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
			1		
					1
		1	23		4
			1		
			1		
			1		
					1
			1		1
		1	6		
		1	4		2
			1	2	4
				5	33
			31	4	15
	1				1
			1		
			1		
			1		
			1		
		1	1	1	1
					1
					1
				1	7
			5		4
				1	1
				1	1
					1
			1	1	1
				1	1
				1	3
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonic clonic movements		1
Tonsillitis		2
Toothache		1
Torticollis		1
Tracheal pain		1
Tremor	7	21
Troponin T increased	1	2
Type 1 diabetes mellitus	1	1
Type I hypersensitivity		1
Umbilical haematoma	1	1
Underdose		2
Urinary incontinence		1
Urinary tract infection		1
Urticaria	5	43
Urticaria thermal	1	1
Uveitis		1
Vaccination complication		8
Vaccination failure	9	13
Vaccination site dermatitis		1
Vaccination site discomfort		2
Vaccination site erythema	1	17
Vaccination site haematoma		1
Vaccination site hypoaesthesia		6
Vaccination site induration		4
Vaccination site joint movement impairment		1
Vaccination site joint pain		4
Vaccination site joint swelling		4
Vaccination site joint warmth		1
Vaccination site lymphadenopathy		5
Vaccination site mass		2
Vaccination site movement impairment		5
Vaccination site oedema		11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
			1		
			1		
					1
		5	13	2	8
				1	2
				1	1
					1
				1	1
			2		
					1
			1		
		4	33	1	10
		1	1		
					1
			8		
				9	13
					1
			2		
		1	10		7
			1		
			1		
			5		1
			3		1
			1		
			4		
			4		
			1		
			4		1
			2		
			5		
			9		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pain	35	266			32	243	3	23
Vaccination site paraesthesia		9				7		2
Vaccination site pruritus	1	11			1	9		2
Vaccination site rash		1						1
Vaccination site reaction		3				3		
Vaccination site swelling		28				23		5
Vaccination site urticaria		4				3		1
Vaccination site vesicles		1				1		
Vaccination site warmth		6				4		2
Vascular purpura		1				1		
Vasodilatation		1						1
Vertigo	4	31			2	23	2	8
Vestibular neuronitis	1	2				1	1	1
Viral corneal ulcer		1						1
Vision blurred	1	14			1	10		4
Visual impairment	1	3				2	1	1
Vitritis		1						1
Vomiting	7	41			5	31	2	10
Weight decreased	1	2					1	2
	484	4,819	20	27	280	3685	204	1134

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal discomfort		5				4			1
Abdominal distension	1	8				4		1	4
Abdominal pain	11	100			8	76		3	24
Abdominal pain lower	1	1						1	1
Abdominal pain upper	6	56	1	1	6	43			13
Abdominal rigidity		2				2			
Abortion	1	2						1	2
Abortion spontaneous	1	5						1	5
Accommodation disorder	1	1			1	1			
Acne		1				1			
Acquired macroglossia		1							1
Acute abdomen	1	1						1	1
Acute respiratory failure		1							1
Administration site oedema		4				4			
Administration site pain	1	18			1	18			
Administration site paraesthesia		1				1			
Adrenomegaly	1	1			1	1			
Ageusia	4	17			2	9		2	8
Agitation		16		1		12			4
Alanine aminotransferase increased		1				1			
Allergic cough		1							1
Allergy to vaccine		3				1			2
Allodynia		2				1			1
Alopecia		2							2
Amenorrhoea		1				1			
Amnesia		3				1			2
Amylase increased		2							2
Anaemia		1				1			
Anaesthesia		17				14			3
Anaesthesia oral		5				3			2
Anal sphincter atony		1							1
Anaphylactic reaction	1	32						1	32

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactic shock		7
Anaphylactoid reaction		2
Angina pectoris		3
Angioedema	3	30
Angiomyolipoma		1
Angular cheilitis		1
Anosmia	3	14
Anterograde amnesia		1
Anti-thyroid antibody positive		1
Anuria		2
Anxiety	1	8
Anxiety disorder due to a general medical condition		1
Apathy		2
Aphasia	2	4
Aphonia		3
Aphthous ulcer		4
Aptyalism		1
Arrhythmia	3	8
Arteriovenous fistula	1	1
Arthralgia	52	659
Arthritis		3
Arthropod sting		1
Asphyxia		1
Asthenia	55	653
Asthenopia		5
Asthma	1	11
Asthma exercise induced		1
Asthmatic crisis	2	7
Asymptomatic COVID-19	2	4
Ataxia		1
Atrial fibrillation		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					7
					2
					3
				3	30
					1
			1		
1	1	2	10	1	4
					1
			1		
					2
		1	3		5
			1		
					2
			1	2	3
			2		1
1	1		2		2
			1		
				3	8
				1	1
3	7	38	532	14	127
			2		1
					1
1	5	33	527	22	126
			4		1
			5	1	6
					1
	1			2	7
				2	4
					1
					2

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Atrial flutter		1				1		
Auditory disorder		1						1
Aura		2				2		
Autoimmune thyroiditis	1	3					1	3
Axillary pain	5	55	1	1	4	47	1	8
Azotaemia		1						1
Back pain	7	52		1	3	40	4	12
Balance disorder		12				7		5
Band sensation		6				4		2
Barotrauma		1				1		
Basedow's disease		1						1
Biliary colic	1	1					1	1
Blepharitis		1				1		
Blepharospasm		2				2		
Blindness		2						2
Blister		5				4		1
Blister infected		1				1		
Blood calcium decreased		1				1		
Blood glucose decreased		1				1		
Blood glucose increased		2				1		1
Blood potassium decreased		1				1		
Blood pressure decreased		10				5		5
Blood pressure diastolic increased		1				1		
Blood pressure fluctuation		1						1
Blood pressure increased	5	54			4	29	1	25
Blood pressure systolic increased	2	2					2	2
Body temperature decreased		2				2		
Body temperature increased	1	19	1	1	1	18		1
Bone marrow oedema	1	1					1	1
Bone pain	5	56			3	41	2	15
Bradycardia	1	5					1	5
Bradykinesia	1	1					1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brain neoplasm		1
Breast cyst		1
Breast oedema	1	3
Breast pain	1	7
Breast swelling	1	1
Breath sounds		1
Breath sounds abnormal		2
Bronchitis		1
Bronchospasm		17
Bronchostenosis		1
Brow ptosis		1
Burning mouth syndrome	1	2
Burning sensation	2	12
Burn oral cavity		1
Capillary fragility		1
Cardiac disorder	1	1
Cardiovascular disorder		1
Carotid artery dissection	1	2
Catarrh	1	1
Central cord syndrome		1
Cerebral haemorrhage	3	3
Cervical radiculopathy		1
Cervicobrachial syndrome		4
Chest discomfort	3	42
Chest expansion decreased		1
Chest pain	6	49
Chillblains	2	5
Chills	50	643
Choking		1
Choking sensation	1	1
Circulatory collapse		1
Circumoral oedema	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			2	1	1
			3	1	4
				1	1
					1
					2
					1
			7		10
					1
			1		
			1	1	1
		2	8		4
					1
					1
				1	1
			1		
				1	2
		1	1		
					1
				3	3
			1		
			3		1
	2		20	3	22
			1		
	1		24	6	25
		2	4		1
2	4	32	512	18	131
					1
				1	1
					1
		1	4		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Circumoral swelling		1
Clonus		2
Cluster headache		1
Cold sweat	1	12
Compulsions		1
Condition aggravated	1	4
Confusional state	5	44
Conjunctival haemorrhage	1	2
Conjunctival hyperaemia		2
Conjunctival irritation		1
Conjunctivitis		9
Connective tissue disorder		1
Constipation		4
Contusion	2	3
Corneal dystrophy	1	1
Corneal opacity		1
Cough	8	88
COVID-19	16	57
Cranial nerve disorder		3
Cranial nerve paralysis		1
C-reactive protein increased		3
Crying		1
Cyanosis		6
Cystitis		1
Cystitis haemorrhagic	1	3
Dactylitis	1	1
Deafness neurosensory		2
Death	1	1
Decreased appetite	3	35
Deep vein thrombosis	2	3
Dehydration		1
Delirium		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
			1		
			7	1	5
					1
			1	1	3
	1	3	25	2	19
				1	2
			1		1
			1		
			5		4
					1
			4		
		2	3		
				1	1
					1
		5	40	3	48
		2	11	14	46
			2		1
					1
			2		1
			1		
			2		4
			1		
				1	3
				1	1
					2
				1	1
		2	29	1	6
				2	3
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		2
Demyelination		1
Depressed level of consciousness	1	21
Depressed mood		2
Dermatitis		4
Dermatitis acneiform		1
Dermatitis allergic		5
Dermatitis atopic		1
Dermatitis bullous		2
Dermatitis exfoliative generalised		1
Diaphragmatic spasm		1
Diarrhoea	17	219
Diarrhoea haemorrhagic		1
Diastolic hypertension		1
Diastolic hypotension		1
Diplegia		2
Diplopia	5	10
Discomfort		9
Disease recurrence	1	6
Disorientation	1	10
Disturbance in attention	1	15
Dizziness	20	151
Drug abuse	1	1
Drug hypersensitivity	1	4
Drug ineffective	3	17
Dry eye	2	3
Dry mouth	5	39
Dry skin		3
Dry throat	2	5
Dysaesthesia	2	16
Dysaesthesia pharynx		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
					1
				1	21
			2		
			3		1
			1		
			4		1
			1		
1	1				2
					1
					1
1	2	12	169	5	50
					1
			1		
					1
					2
		4	7	1	3
			7		2
			2	1	4
		1	5		5
			7	1	8
	1	11	96	9	55
				1	1
				1	4
				3	17
		1	2	1	1
	1	2	21	3	18
					3
		1	3	1	2
		2	13		3
			2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysarthria		2
Dysentery	8	86
Dysgeusia	3	58
Dyskinesia		2
Dyspepsia	1	8
Dysphagia	2	41
Dysphemia	1	1
Dysphonia	3	23
Dyspnoea	19	162
Dyspnoea at rest	1	3
Dyspnoea exertional		5
Dysstasia	1	2
Dysuria		1
Ear discomfort	1	9
Ear disorder	1	2
Ear infection		5
Ear pain		17
Ear pruritus		3
Ear swelling	1	2
Ecchymosis	2	2
Eczema nummular		1
Electric shock		1
Electrocardiogram abnormal	1	2
Emotional disorder	1	1
Enanthema		1
Encephalopathy		1
Endometriosis	1	1
Enthesopathy	1	1
Eosinophil count decreased		1
Epilepsy		3
Epistaxis		5
Eructation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
1	2			8	86
1	1	2	47	1	11
			1		1
			7	1	1
	2	1	25	1	16
				1	1
	1	1	9	2	14
1	1	5	60	14	102
				1	3
			3		2
			1	1	1
			1		
		1	6		3
		1	2		
			4		1
			10		7
			3		
			1	1	1
		1	1	1	1
			1		
					1
		1	1		1
		1	1		
					1
				1	1
				1	1
					1
					3
			2		3
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema	8	155
Erythema multiforme		1
Erythema nodosum	1	2
Exposure during pregnancy		3
Exposure to SARS-CoV-2		1
Extensive swelling of vaccinated limb		2
Extraocular muscle paresis		1
Extrasystoles	3	7
Extremity contracture		1
Eye allergy		1
Eye colour change		1
Eye disorder	1	1
Eye irritation	2	20
Eyelid myoclonus		2
Eyelid oedema	2	12
Eyelid pain		1
Eyelid ptosis	1	5
Eyelids pruritus		1
Eye movement disorder		1
Eye oedema		4
Eye pain		22
Eye paraesthesia		3
Eye pruritus	1	9
Eye swelling	1	5
Face oedema	3	16
Facial nerve disorder		2
Facial neuralgia		1
Facial pain		6
Facial paralysis		25
Facial paresis	2	19
Facial spasm		1
Faeces soft		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	105	2	50
					1
		1	1		1
			3		
			1		
			2		
					1
		2	4	1	3
			1		
			1		
					1
				1	1
		2	17		3
					2
		1	4	1	8
					1
			3	1	2
			1		
					1
			2		2
			14		8
			3		
			3	1	6
		1	2		3
		1	6	2	10
			1		1
					1
			1		5
					25
		2	10		9
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fall	1	1
Fatigue	43	467
Febrile convulsion		7
Feeling abnormal	3	13
Feeling cold	3	63
Feeling hot	9	94
Feeling jittery	1	3
Feeling of body temperature change		3
Female sexual dysfunction	1	1
Fibromuscular dysplasia	1	1
Fibromyalgia		2
Flank pain		1
Flat affect		1
Flatulence		1
Fluid retention		2
Flushing	10	54
Folliculitis		1
Food aversion		1
Foreign body in throat		1
Foreign body sensation in eyes		1
Frequent bowel movements		2
Gait disturbance	2	17
Gastroenteritis		2
Gastroenteritis viral	1	1
Gastrointestinal disorder	4	11
Gastrointestinal hypermotility		1
Gastrointestinal motility disorder		1
Gastrointestinal pain	2	4
Gastroesophageal reflux disease		2
Generalised tonic-clonic seizure		1
Genital discomfort		1
Genital rash		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
2	2	24	363	19	104
			4		3
		2	9	1	4
		3	53		10
		5	66	4	28
			2	1	1
			2		1
		1	1		
				1	1
			1		1
			1		
			1		1
		7	40	3	14
			1		
			1		
					1
			1		
			2		
		1	12	1	5
			2		
				1	1
		3	9	1	2
					1
					1
		1	3	1	1
			2		
					1
					1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival discolouration	1	1
Gingival discomfort		
Gingival pain		1
Glomerulonephritis		1
Glossitis		2
Glossodynia	1	3
Glottal incompetence		1
Goitre		1
Grip strength decreased		1
Groin pain	1	4
Guillain-Barre syndrome		1
Haematochezia		1
Haematocrit decreased		1
Haematoma		4
Haematuria		2
Haemoglobin decreased		3
Haemorrhage	1	1
Hallucination		4
Hallucination, auditory		2
Hallucination, olfactory		2
Hallucination, visual		5
Hand deformity		1
Hand dermatitis		2
Haptoglobin increased		1
Headache	97	1,271
Head discomfort		2
Head injury		1
Heart rate abnormal		1
Heart rate decreased		2
Heart rate increased	3	8
Heart rate irregular		1
Hemianaesthesia		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
	1				
			1		
			2		1
				1	3
					1
			1		
			1		
1	1	1	4		
					1
					1
			1		
			3		1
			1		1
			2		1
				1	1
					4
					2
					2
					5
			1		
			2		
					1
4	10	68	1016	29	255
			2		
					1
					1
		2	4	1	4
					1
					4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemianopia heteronymous		1
Hemidysaesthesia		3
Hemihyperaesthesia		1
Hemiparaesthesia	2	17
Hemiparesis	2	9
Hemiplegia		2
Hepatic pain		2
Hepatitis A antibody positive		1
Hepatitis acute		1
Hepatitis B antibody positive		1
Herpes ophthalmic		2
Herpes simplex		3
Herpes virus infection		3
Herpes zoster	1	15
Herpes zoster infection neurological		1
Herpes zoster oticus		1
Herpes zoster reactivation		2
Hot flush	1	42
Hyperacusis		1
Hyperaemia	1	5
Hyperaesthesia		5
Hyperglycaemia		2
Hyperhidrosis	4	77
Hyperpyrexia	9	98
Hyperreflexia		1
Hypersensitivity	5	34
Hypersomnia	1	4
Hypertension	5	56
Hypertensive crisis	2	32
Hyperthermia	2	18
Hyperthyroidism		1
Hypertonia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
					1
				2	17
				2	9
					2
			2		
			1		
					1
			1		
					2
			2		1
			1		2
		1	11		4
					1
					1
			2		
		1	33		9
			1		
		1	4		1
			3		2
					2
	1	1	54	3	23
	1	1	1	8	97
					1
	2	2	11	3	23
		1	4		
		2	22	3	34
				2	32
		1	15	1	3
					1
			2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertrophy of tongue papillae		1
Hyperventilation	1	4
Hypoacusis	3	6
Hypoaesthesia	5	79
Hypoaesthesia oral	2	30
Hypogeusia		1
Hypoglycaemia		1
Hypokinesia		1
Hyporeflexia	1	1
Hyporesponsive to stimuli		1
Hyposmia		2
Hypotension	3	56
Hypotensive crisis		3
Hypothermia	1	10
Hypotonia		2
Hypoxia		1
Idiopathic urticaria		1
Illness		5
Immobile		1
Impaired quality of life		1
Impaired work ability		1
Inappropriate schedule of product administration	2	4
Incontinence		1
Incorrect dosage administered		1
Incorrect dose administered	1	3
Incorrect route of product administration	5	14
Increased upper airway secretion		1
Increased viscosity of bronchial secretion		1
Induration		4
Inflammation		2
Inflammatory pain		1
Influenza		11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	1	1	1		3
		1	1	2	5
	1	3	57	2	22
		1	23	1	7
			1		
					1
			1		
	1			1	1
			1		
			1		1
			1		
		2	33	1	23
					3
	1			1	10
			1		1
					1
			1		
			3		2
					1
			1		
					1
		2	4		
					1
			1		
		1	3		
		5	14		
			1		
					1
			4		
			2		
					1
			9		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	6	49
Infusion site pain		2
Initial insomnia	2	3
Injected limb mobility decreased	1	9
Injection site erythema		19
Injection site haematoma		2
Injection site haemorrhage		1
Injection site induration		2
Injection site infection		6
Injection site inflammation		1
Injection site joint pain		2
Injection site oedema		63
Injection site pain	4	435
Injection site paraesthesia		4
Injection site pruritus		11
Injection site reaction		4
Injection site swelling		13
Injection site urticaria		13
Injection site warmth		2
Injury		1
Insomnia	6	75
Intentional product misuse	1	1
Interstitial lung disease	1	3
Intestinal pseudo-obstruction		1
Intranasal hypoaesthesia		1
Intranasal paraesthesia		1
Iridocyclitis		1
Irritability		5
Joint contracture		1
Joint effusion	1	1
Joint hyperextension		1
Joint lock		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	42		7
			2		
		1	2	1	1
		1	9		
			19		
			2		
			1		
			2		
			6		
			1		
			2		
			63		
		4	434		1
			4		
			11		
			4		
			13		
			13		
			2		
			1		
		4	61	2	14
		1	1		
				1	3
					1
			1		
			1		
					1
			4		1
			1		
				1	1
			1		
			2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint range of motion decreased		3
Joint stabilisation		1
Joint stiffness		1
Joint warmth		1
Labyrinthitis		2
Lacrimation disorder	1	1
Lacrimation increased	2	9
Lagophthalmos	1	1
Laryngeal dyspnoea		2
Laryngeal obstruction		2
Laryngeal oedema	4	37
Laryngeal stenosis		1
Laryngospasm	2	6
Lethargy		1
Leukocytosis	1	1
Leukopenia	2	3
Limb discomfort	2	35
Limb immobilisation		1
Lipase increased		1
Lip erythema		3
Lip oedema	3	37
Lip pain		1
Lip pruritus		8
Lip swelling	2	12
Localised oedema	1	12
Local reaction		4
Loss of consciousness	5	37
Loss of control of legs		1
Loss of personal independence in daily activities		1
Lymphadenitis		21
Lymphadenopathy	43	471
Lymphangitis	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
			1		
			1		
					1
			2		
				1	1
		1	8	1	1
		1	1		
					2
					2
				4	37
					1
				2	6
			1		
		1	1		
				2	3
		2	30		5
			1		
					1
			2		1
1	1	2	19	1	18
			1		
			6		2
		1	5	1	7
			10	1	2
			4		
				5	37
					1
			1		
			11		10
5	8	35	378	8	93
				1	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphatic obstruction	1	1
Lymph node abscess		1
Lymph node pain	8	46
Lymphocyte count increased		1
Lymphocytosis		1
Lymphoedema		1
Lymphopenia		3
Madarosis	1	1
Malaise	12	245
Mastication disorder	1	1
Mastitis		3
Maternal exposure during pregnancy	3	10
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1
Mechanical urticaria		2
Memory impairment		4
Menorrhagia	3	6
Menstrual disorder		1
Menstruation irregular		1
Mental disorder		2
Mental impairment		1
Metrorrhagia		3
Micturition urgency		1
Middle insomnia		1
Migraine	5	85
Migraine with aura	1	3
Mobility decreased		5
Monocyte count decreased		1
Monoparesis		5
Monoplegia		2
Mood altered		2
Motor dysfunction	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
1	1	7	36	1	10
			1		1
			1		
					3
				1	1
	1	8	194	4	51
				1	1
					3
		3	10		
			1		
			1		
	1		2		
			1		3
			2	3	4
			1		
			1		
			1		1
					1
			1		2
					1
					1
		3	63	2	22
		1	2		1
			4		1
					1
			4		1
					2
			1		1
			1	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mouth haemorrhage		1
Mouth swelling		1
Mouth ulceration		1
Movement disorder	2	10
Mucosal dryness		1
Mucosal hyperaemia		1
Mucosal inflammation		1
Multiple sclerosis		2
Muscle contractions involuntary		6
Muscle contracture		6
Muscle discomfort		1
Muscle fatigue	1	3
Muscle oedema		2
Muscle rigidity	1	8
Muscle spasms	3	18
Muscle swelling		1
Muscle tightness		3
Muscle twitching		3
Muscular weakness	6	41
Musculoskeletal chest pain	1	10
Musculoskeletal discomfort		2
Musculoskeletal disorder	1	1
Musculoskeletal pain	4	121
Musculoskeletal stiffness	4	13
Myalgia	60	772
Myalgia intercostal		2
Myasthenia gravis		2
Myasthenia gravis crisis		1
Myoclonus		3
Myositis		1
Narcolepsy	1	2
Nasal congestion	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
			3	2	7
			1		
					1
			1		
					2
			5		1
			5		1
			1		
			2	1	1
					2
		1	5		3
1	1	2	13	1	5
					1
			2		1
			2		1
		5	28	1	13
		1	7		3
			1		1
		1	1		
		3	90	1	31
		3	6	1	7
3	5	45	632	15	140
			1		1
					2
					1
					3
					1
				1	2
			2	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal discomfort		1
Nasal herpes		1
Nasal obstruction		3
Nasal oedema		2
Nasopharyngitis	4	21
Nausea	44	524
Neck pain	9	56
Nerve compression	1	2
Nervousness		1
Nervous system disorder		1
Neuralgia	1	10
Neuralgic amyotrophy		1
Neuritis		4
Neurodermatitis		1
Neurological symptom		2
Neuropathy peripheral	3	7
Neurotoxicity		1
Neutrophil count increased		1
Neutrophil percentage increased		1
Nightmare		1
Night sweats		9
No adverse event		1
Noninfective gingivitis	1	1
Non-pitting oedema		2
Nuchal rigidity	2	10
Obstruction		1
Obstructive airways disorder		2
Occupational exposure to product		1
Ocular discomfort		3
Ocular hyperaemia	2	16
Odynophagia		2
Oedema	1	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			2		1
					2
		2	12	2	9
2	5	32	394	12	130
1	1	5	42	4	14
		1	2		
			1		
					1
	1	1	6		4
			1		
			2		2
			1		
			1		1
				3	7
					1
					1
			1		
			8		1
			1		
				1	1
			1		1
		1	3	1	7
			1		
					2
			1		
			3		
		1	10	1	6
			1		1
		1	13		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema mouth	2	2
Oedema mucosal		1
Oedema peripheral	2	15
Oesophageal pain		1
Oesophageal spasm		1
Off label use	2	13
Ophthalmic herpes simplex		2
Optic neuritis	1	4
Optic neuropathy		1
Oral discomfort	1	7
Oral dysaesthesia		1
Oral herpes	4	22
Oral pain		2
Oral pruritus		7
Orbital haematoma		1
Oropharyngeal discomfort		16
Oropharyngeal pain	6	57
Orthostatic hypotension	1	3
Osteoarthropathy	1	1
Overdose	1	10
Oxygen saturation decreased	1	15
Pain	15	205
Pain in extremity	51	398
Pain in jaw	1	11
Pain of skin	1	1
Palatal disorder		1
Palatal oedema		10
Palatal swelling		1
Pallor	2	8
Palpitations	2	22
Pancreatitis		1
Panic attack		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	1	1	1	1
					1
		2	10		5
					1
		2	12		1
					2
				1	4
					1
	1		5	1	2
			1		
		2	16	2	6
			2		
			4		3
					1
			9		7
		2	38	4	19
		1	3		
		1	1		
		1	10		
				1	15
1	1	9	162	6	43
		37	342	14	56
		1	6		5
				1	1
			1		
			5		5
			1		
	1		4	2	4
		1	14	1	8
					1
			3		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panic reaction		1
Papule		3
Paraesthesia	25	324
Paraesthesia ear	1	1
Paraesthesia oral	5	121
Paralysis		2
Paraparesis	1	3
Paresis	2	5
Paresis cranial nerve		1
Parosmia	1	4
Parvovirus B19 test positive		1
Pelvic pain		2
Pericardial effusion	1	3
Pericarditis		5
Periorbital discomfort		1
Periorbital oedema	1	5
Periorbital swelling		3
Peripheral coldness	1	6
Peripheral swelling	5	30
Petechiae	3	4
Petit mal epilepsy		1
Pharyngeal disorder		2
Pharyngeal erythema	1	5
Pharyngeal hypoaesthesia		2
Pharyngeal oedema		5
Pharyngeal paraesthesia	1	14
Pharyngeal swelling	1	8
Pharyngitis		4
Phlebitis	2	3
Phlebitis superficial	1	1
Photophobia	1	15
Photopsia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		1
	2	13	221	12	103
				1	1
	1	2	73	3	48
					2
				1	3
			2	2	3
					1
			3	1	1
			1		
			2		
				1	3
					5
					1
			3	1	2
			2		1
	1	1	5		1
		4	24	1	6
		2	3	1	1
					1
			1		1
			2	1	3
			1		1
					5
			7	1	7
			3	1	5
1	1		3		1
		2	2		1
		1	1		
			11	1	4
		1	2		1

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 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photosensitivity reaction		3
Piloerection		1
Pityriasis rosea	1	1
Pleural effusion		1
PO2 decreased	1	1
Pollakiuria		2
Polyarthrits		2
Polyneuropathy		1
Polyuria		3
Poor quality sleep		1
Premenstrual pain		2
Presyncope	5	72
Product administered at inappropriate site		1
Productive cough		1
Product preparation issue		1
Product use issue	1	9
Proteinuria		1
Pruritus	14	182
Pruritus genital		1
Psoriasis		1
Psoriatic arthropathy	2	2
Psychotic disorder	1	1
Pulmonary embolism	1	3
Puncture site induration		1
Puncture site pain		1
Pustule	1	4
Pyrexia	109	1,403
Q fever	1	5
Quality of life decreased		2
Radiculitis brachial		3
Radiculopathy		3
Rales		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					1
				1	1
					1
				1	1
			1		1
					2
					1
			2		1
			1		
			2		
	1	2	41	3	31
			1		
					1
			1		
		1	7		2
			1		
1	1	10	139	4	43
			1		
					1
	2			2	2
	1			1	1
	1			1	3
			1		
			1		
	1	1	2		2
10	21	77	1064	32	339
				1	5
			1		1
			3		
			2		1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash	14	143
Rash erythematous	2	12
Rash macular		4
Rash maculo-papular		2
Rash maculovesicular		1
Rash morbilliform		2
Rash papular		5
Rash pruritic	3	26
Rash pustular		1
Rash vesicular		3
Raynaud's phenomenon	1	1
Red blood cell count increased		1
Reduced facial expression		1
Renal pain		3
Respiration abnormal		1
Respiratory disorder		7
Respiratory distress	1	11
Respiratory failure		1
Respiratory fatigue		5
Respiratory rate increased		1
Respiratory tract oedema		1
Restless legs syndrome		2
Restlessness		1
Retching	3	17
Retrograde amnesia		1
Rheumatoid arthritis	1	1
Rhinitis		5
Rhinorrhoea	1	5
Rosacea		1
Sacroiliitis	1	1
Salivary hypersecretion	1	7
SARS-CoV-2 antibody test positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	6	91	8	52
		1	8	1	4
			3		1
			2		
			1		
			2		
			4		1
		2	16	1	10
			1		
			3		
		1	1		
			1		
					1
			3		
			1		
			2		5
				1	11
					1
			1		4
					1
					1
					2
			1		
		1	10	2	7
					1
				1	1
			3		2
			4	1	1
					1
		1	1		
		1	5		2
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test positive	2	8
Scarlet fever		
Scintillating scotoma		2
Scleral hyperaemia		1
Seasonal allergy		1
Seborrhoeic dermatitis		1
Sedation		2
Seizure	1	6
Sensation of foreign body	1	8
Sense of oppression	1	4
Sensory disturbance	1	4
Sensory loss		4
Severe acute respiratory syndrome	1	1
Shock		2
Sinus bradycardia		1
Sinus headache		1
Sinus tachycardia		6
Sjogren's syndrome		1
Skin burning sensation		4
Skin discolouration		1
Skin induration		1
Skin irritation		1
Skin laceration	1	1
Skin lesion		4
Skin mass		1
Skin reaction	4	11
Skin tightness		3
Skin warm		4
Sleep disorder	1	3
Somnolence	6	73
Sopor		2
Speech disorder	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	2	5
1	1				
			2		
			1		
					1
			1		
			1		1
				1	6
		1	5		3
		1	1		3
			1	1	3
			2		2
				1	1
					2
			1		
			1		
1	1		1		5
					1
			4		
					1
					1
					1
		1	1		
			4		
			1		
		1	6	3	5
			1		2
			2		2
		1	3		
		4	57	2	16
			2		
		1	4	2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Spider vein		1
Spinal pain	2	13
Splenomegaly		1
Stridor	1	1
Stupor	1	6
Subarachnoid haemorrhage	1	1
Submaxillary gland enlargement		1
Sudden death		1
Sudden onset of sleep		1
Suffocation feeling		3
Superinfection bacterial		1
Suspected COVID-19		1
Swelling	5	39
Swelling face		19
Swelling of eyelid		4
Swollen tongue	1	16
Syncope	6	45
Systemic lupus erythematosus		1
Tachyarrhythmia	1	2
Tachycardia	23	201
Tachycardia paroxysmal		2
Tachypnoea		10
Taste disorder	1	8
Temperature intolerance	1	1
Temporomandibular joint syndrome		1
Tenderness	1	5
Tenosynovitis	2	2
Tension headache	1	4
Terminal insomnia		2
Therapy change		1
Thirst	1	4
Throat irritation	2	30

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	12		1
					1
				1	1
			2	1	4
				1	1
			1		
					1
					1
			2		1
					1
					1
		3	31	2	8
			9		10
			4		
			7	1	9
	2			6	45
					1
		1	2		
	3	15	113	8	88
			2		
			5		5
			3	1	5
		1	1		
			1		
		1	4		1
		1	1	1	1
			2	1	2
			2		
			1		
		1	4		
		2	17		13

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Throat tightness	3	44
Thrombocytopenia	3	5
Thrombophlebitis superficial	1	1
Thrombosis	1	2
Thyroglobulin increased		1
Thyroglossal cyst	1	1
Thyroid disorder		1
Thyroid hormones increased		1
Thyroiditis subacute	2	3
Thyroid mass		1
Tinnitus	3	13
Tongue blistering		1
Tongue discolouration		1
Tongue discomfort		4
Tongue disorder		1
Tongue dry		4
Tongue eruption		1
Tongue erythema		1
Tongue geographic		1
Tongue movement disturbance	1	1
Tongue oedema	2	15
Tongue pruritus		3
Tongue ulceration	1	3
Tonic clonic movements		1
Tonic convulsion		1
Tonsillar erythema		1
Tonsillar hypertrophy		3
Toothache	1	1
Torticollis		4
Toxic skin eruption	1	2
Tracheitis		1
Tremor	6	62

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			14	3	30
				3	5
				1	1
				1	2
					1
			1	1	1
					1
		2	3		
					1
		1	5	2	8
			1		
					1
			3		1
			1		
			2		2
			1		
					1
			1		
				1	1
1	1	1	6	1	9
			2		1
			2	1	1
					1
					1
			1		
			3		
		1	1		
			4		
				1	2
					1
	2	3	30	3	32

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Trigeminal nerve disorder	1	6
Trigeminal neuralgia		3
Trismus		1
Type I hypersensitivity	1	5
Type IV hypersensitivity reaction	1	1
Underdose		6
Upper airway obstruction		1
Upper respiratory tract inflammation		1
Urinary incontinence		1
Urinary retention		1
Urine flow decreased		1
Urine output decreased		1
Urticaria	19	149
Urticaria papular	1	1
Use of accessory respiratory muscles		3
Uveitis		2
Vaccination complication		33
Vaccination error		1
Vaccination failure	14	29
Vaccination site anaesthesia		1
Vaccination site bruising		2
Vaccination site discomfort		1
Vaccination site erythema	8	56
Vaccination site haematoma		4
Vaccination site hyperaesthesia	1	1
Vaccination site hypoaesthesia	1	6
Vaccination site induration		9
Vaccination site inflammation		2
Vaccination site ischaemia		1
Vaccination site joint erythema		1
Vaccination site joint movement impairment		4
Vaccination site joint pain	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		3
			3		
			1		
				1	5
				1	1
			6		
					1
					1
			1		
			1		
					1
		11	94	8	55
		1	1		
					3
					2
	1		27		6
			1		
1	1			14	29
					1
			1		1
			1		
		5	40	3	16
			4		
				1	1
		1	5		1
			8		1
			1		1
					1
			1		
			3		1
		1	5		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site joint swelling	1	3
Vaccination site lymphadenopathy	1	13
Vaccination site mass		1
Vaccination site movement impairment		12
Vaccination site nodule		1
Vaccination site oedema	5	45
Vaccination site pain	91	694
Vaccination site paraesthesia		11
Vaccination site pruritus	2	21
Vaccination site rash		4
Vaccination site reaction		15
Vaccination site swelling	10	62
Vaccination site urticaria	2	16
Vaccination site vesicles		2
Vaccination site warmth		14
Vaginal infection	1	2
Vascular rupture		1
Vasculitic rash		1
Vasculitis	5	5
Vasoconstriction	1	8
Vasodilatation	1	1
Vasomotor rhinitis		1
Venous thrombosis	1	1
Ventricular extrasystoles	1	3
Vertigo	17	144
Vertigo positional		2
Vision blurred	2	17
Visual acuity reduced		1
Visual field defect		2
Visual impairment	2	9
Vocal cord dysfunction		1
Vocal cord paralysis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
		1	11		2
			1		
			12		
			1		
		4	36	1	9
	3	71	573	20	121
			8		3
		1	17	1	4
			4		
			13		2
	1	7	43	3	19
		2	11		5
			2		
			10		4
		1	2		
					1
					1
		4	4	1	1
		1	3		5
				1	1
			1		
				1	1
		1	1		2
		8	104	9	40
			1		1
		1	11	1	6
			1		
			1		1
	1		4	2	5
					1
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Volvulus		1							1
Vomiting	15	148	1	4	8	95	7	53	
Vomiting projectile		2							2
Vulvovaginal candidiasis		2				2			
Wheezing	1	9				4	1	5	
White blood cell count decreased		1				1			
White blood cell count increased		2							2
Withdrawal hypertension		1				1			
Wound		1							1
Wrong technique in product usage process		1				1			
Xerosis		1							1
Yellow skin		1				1			
	1,581	16,780	56	140	922	11807	659	4973	

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	3			1	3		
Abdominal distension		8				7		1
Abdominal pain	7	96			2	76	5	20
Abdominal pain lower		1				1		
Abdominal pain upper	3	40	1	1	2	29	1	11
Abdominal rigidity		1				1		
Accommodation disorder		1						1
Acute coronary syndrome		2						2
Acute kidney injury	1	1					1	1
Acute motor axonal neuropathy	1	1					1	1
Acute myocardial infarction		2						2
Acute polyneuropathy		1						1
Acute respiratory failure		2						2
Administration site erythema		1				1		
Administration site induration		1				1		
Administration site oedema		7				7		
Administration site pain		21				21		
Administration site pruritus		2				2		
Administration site reaction		1						1
Administration site swelling		2				2		
Ageusia	4	14	2	2	4	11		3
Agitation		8				5		3
Akathisia		1				1		
Akinesia	1	1					1	1
Alanine aminotransferase increased	1	2				1	1	1
Allergy to vaccine		4				1		3
Alopecia	1	2			1	1		1
Alpha globulin increased		1				1		
Amnesia		4				3		1
Anaesthesia	3	16			2	15	1	1
Anaesthesia oral		1				1		
Anaphylactic reaction	2	18		1			2	18

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactic shock		6
Anaphylactoid reaction		2
Angina pectoris		2
Angioedema	4	17
Anosmia	3	10
Anterograde amnesia		1
Anuria		1
Anxiety		13
Aphasia		3
Aphonia		5
Aphthous ulcer		7
Apnoea		1
Application site paraesthesia		1
Arrhythmia		11
Arthralgia	36	513
Asthenia	39	452
Asthenopia		3
Asthma		7
Asthmatic crisis	1	4
Asymptomatic COVID-19	2	7
Ataxia		1
Atrial fibrillation		4
Atrial flutter		1
Atrial tachycardia		2
Aura		1
Autoimmune thyroiditis		2
Axillary mass		1
Axillary pain	4	37
Back disorder		1
Back pain	2	53
Balance disorder	1	4
Bedridden	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				6
					2
					2
				4	17
1	1	2	6	1	4
					1
					1
			11		2
			1		2
			3		2
			7		
					1
			1		
					11
2	2	22	388	14	125
	2	30	354	9	98
			3		
			2		5
1	1			1	4
				2	7
					1
					4
					1
			2		
			1		
			1		
1	3	4	32		5
					1
	2	1	39	1	14
		1	4		
		1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder dysfunction	1	1
Blepharospasm		1
Blindness		2
Blindness unilateral	1	1
Blister		2
Blood alkaline phosphatase increased		1
Blood glucose increased		1
Blood lactate dehydrogenase increased	1	1
Blood pressure abnormal	1	1
Blood pressure decreased		1
Blood pressure fluctuation	1	2
Blood pressure increased	4	36
Blood pressure systolic increased		2
Blood thyroid stimulating hormone increased	1	1
Bloody discharge	1	1
Body temperature increased	1	12
Bone pain	2	45
Bradycardia		9
Bradykinesia		1
Breakthrough pain		1
Breast abscess		1
Breast discomfort		3
Breast enlargement		1
Breast oedema		2
Breast pain		6
Breast swelling		1
Breath sounds		1
Bronchial wall thickening		1
Bronchiectasis		1
Bronchospasm		11
Bundle branch block right		1
Burning sensation	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					2
				1	1
			1		1
					1
			1		
				1	1
		1	1		
	1		1		
				1	2
		1	20	3	16
					2
		1	1		
				1	1
		1	9		3
		2	30		15
					9
			1		
			1		
					1
			2		1
			2		
			4		2
					1
			1		
					1
					1
	1		2		9
					1
		1	3	1	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bursitis infective		1						1
Butterfly rash		1						1
Cardiac arrest	2	2					2	2
Cardio-respiratory arrest		1						1
Catarrh	1	3				1	1	2
Central pain syndrome		1				1		
Cerebral disorder		1						1
Cerebral venous sinus thrombosis		1						1
Cerebrovascular accident	1	1					1	1
Cervicobrachial syndrome		3				2		1
Chest discomfort	3	23			1	13	2	10
Chest pain	1	35			1	23		12
Chills	34	473	1	3	19	356	15	117
Chromaturia		1				1		
Chronic respiratory failure		1						1
Circulatory collapse	1	1					1	1
Circumoral oedema		2				2		
Circumoral swelling		1						1
Clonus		1						1
Cluster headache		1				1		
Coagulation factor increased	1	1					1	1
Coagulopathy		1						1
Cold sweat		9				4		5
Colitis		1				1		
Condition aggravated	1	5				1	1	4
Confusional state	4	30			3	22	1	8
Conjunctival haemorrhage		5						5
Conjunctival hyperaemia		3				1		2
Conjunctival irritation		2				1		1
Conjunctivitis	1	15			1	12		3
Conjunctivitis allergic		1				1		
Constipation		2				2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Corneal bleeding		1
Coronary artery dissection	1	1
Cough	8	73
COVID-19	13	43
COVID-19 pneumonia	2	4
Cramp-fasciculation syndrome	1	1
C-reactive protein abnormal		1
C-reactive protein increased	2	4
Crying		1
Cyanosis		1
Cystitis		2
Cystitis haemorrhagic		1
Deafness		2
Death	1	2
Decreased appetite	2	28
Deep vein thrombosis	2	3
Defaecation urgency		1
Delusion		1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness	1	14
Dermatitis		1
Dermatitis acneiform		1
Dermatitis allergic		2
Dermatitis bullous	1	6
Dermatitis exfoliative		1
Dermatitis herpetiformis		2
Diaphragmalgia		1
Diarrhoea	11	154
Diplopia	4	5
Discomfort		5
Disease recurrence		6
Disorientation	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
	1	2	40	6	33
	1	3	14	10	29
	1			2	4
				1	1
			1		
			1	2	3
			1		
					1
					1
					2
				1	2
1	1	2	23		5
				2	3
			1		
			1		
			1		
				1	14
			1		
			1		
					2
				1	6
					1
			1		1
			1		
		7	118	4	36
		3	3	1	2
			5		
			1		5
	1	1	6		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disturbance in attention		6
Dizziness	8	101
Droling		1
Drug eruption		1
Drug hypersensitivity		2
Drug ineffective	2	17
Drug interaction	1	1
Dry eye		3
Dry mouth	1	25
Dry skin		2
Dry throat	1	2
Dysaesthesia	1	6
Dysarthria	1	2
Dysentery	2	64
Dysgeusia	1	42
Dysgraphia		2
Dyskinesia		1
Dysmetria	1	1
Dyspepsia		9
Dysphagia	5	37
Dysphonia		17
Dyspnoea	13	77
Dyspnoea exertional		4
Dysstasia		2
Dysuria		2
Ear discomfort	1	3
Ear disorder		1
Ear infection	1	3
Ear pain		10
Ear pruritus		2
Ear swelling		1
Ecchymosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1		4		2
	2	4	73	4	28
			1		
			1		
			1		1
				2	17
				1	1
			2		1
		1	19		6
					2
		1	2		
			4	1	2
			1	1	1
3	3			2	64
2	2	1	36		6
			1		1
			1		
				1	1
			8		1
	1	2	21	3	16
			8		9
	3	2	16	11	61
			2		2
			1		1
			1		1
		1	2		1
					1
			2	1	1
			7		3
			2		
			1		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema asteatotic		1
Effusion		1
Electrocardiogram abnormal		1
Embolism	1	2
Emphysema		1
Enteritis		1
Eosinophil count increased		1
Epicondylitis		1
Epiglottic oedema		1
Epilepsy		4
Episcleritis		1
Epistaxis		9
Erectile dysfunction	1	2
Erythema	8	121
Erythema multiforme	1	4
Erythema nodosum	1	1
Erythema of eyelid		3
Erythematotelangiectatic rosacea		1
Euphoric mood		1
Extensive swelling of vaccinated limb		3
Extrasystoles		10
Eye disorder		1
Eye haematoma		1
Eye haemorrhage	1	2
Eye irritation		20
Eyelid function disorder		1
Eyelid oedema	1	10
Eyelid pain		1
Eyelid ptosis	1	4
Eyelids pruritus		1
Eye movement disorder		1
Eye oedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
				1	2
					1
			1		
					1
			1		
					1
					4
					1
			8		1
				1	2
	1	3	78	5	43
				1	4
		1	1		
			2		1
			1		
			1		
					2
			7		3
			1		
					1
				1	2
	1		15		5
					1
	1		6	1	4
			1		
			1	1	3
			1		
			1		
			1		1

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pain	1	16
Eye paraesthesia		1
Eye pruritus		7
Eye swelling	1	2
Face oedema	1	19
Facial bones fracture		1
Facial discomfort	1	3
Facial nerve disorder		2
Facial neuralgia		2
Facial pain		4
Facial paralysis	2	18
Facial paresis	1	9
Facial spasm		1
Fall		3
Fasciitis		1
Fatigue	27	348
Febrile convulsion		1
Feeling abnormal		9
Feeling cold	2	54
Feeling drunk		1
Feeling hot	6	58
Feeling jittery		1
Feeling of body temperature change		5
Fibrin D dimer increased	1	1
Flank pain		1
Flatulence		2
Fluid retention		1
Flushing	1	32
Food allergy		1
Frequent bowel movements		1
Gait disturbance	3	11
Gait inability	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	1	14		2
					1
			5		2
		1	2		
			10	1	9
					1
		1	3		
			1		1
			1		1
			4		
				2	18
		1	5		4
			1		
					3
			1		
2	3	17	256	10	92
					1
			8		1
	1	2	43		11
			1		
		5	40	1	18
					1
			3		2
				1	1
			1		
			2		
			1		
			27	1	5
					1
			1		
			4	3	7
				1	3

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gamma-glutamyltransferase increased		1
Gastric dilatation		1
Gastroenteritis		1
Gastrointestinal disorder	3	14
Gastrointestinal sounds abnormal	1	1
Generalised oedema		1
Generalised tonic-clonic seizure		2
Genital pain		1
Gingival bleeding		1
Gingival swelling		1
Gingivitis		2
Glossitis		2
Glossodynia		3
Grip strength decreased	1	1
Groin pain		1
Grunting		1
Guillain-Barre syndrome	1	2
Guttate psoriasis		1
Haematochezia		1
Haematoma	1	5
Haematuria		2
Haemochromatosis		1
Hallucination		1
Hallucinations, mixed		1
Headache	70	923
Head discomfort		12
Heart rate decreased		2
Heart rate increased	3	12
Heat stroke		2
Hemianaesthesia		3
Hemiparaesthesia		5
Hemiparesis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
1	1	3	11		3
		1	1		
			1		
					2
			1		
			1		
			1		
			2		
			2		
			3		
				1	1
1	1				
					1
				1	2
					1
					1
		1	4		1
			2		
			1		
					1
					1
1	6	42	710	28	213
			10		2
			2		
		2	6	1	6
			1		1
					3
					5
					4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiplegia		1
Herpes ophthalmic	1	3
Herpes simplex		2
Herpes simplex encephalitis		1
Herpes virus infection		3
Herpes zoster	1	13
HIV infection		1
Hot flush	1	20
Hydrocephalus	1	1
Hyperacusis	1	1
Hyperaemia		1
Hyperaesthesia		4
Hypercreatininaemia	1	1
Hyperglycaemia	1	3
Hyperhidrosis		49
Hyperkinesia		1
Hyperpyrexia	13	94
Hypersensitivity	2	20
Hypersensitivity vasculitis	1	1
Hypersomnia		1
Hypertension	7	50
Hypertensive crisis	6	35
Hyperthermia		11
Hypertonia		1
Hypertransaminasaemia		2
Hypertrophy of tongue papillae		2
Hyperventilation		3
Hypoacusis		3
Hypoaesthesia		24
Hypoaesthesia oral		9
Hypoglycaemia		2
Hypokinesia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	3
			2		
					1
			2		1
			7	1	6
					1
		1	13		7
				1	1
				1	1
			1		
			4		
				1	1
		1	2		1
			33		16
			1		
	1			13	94
	1		9	2	11
				1	1
			1		
		1	23	6	27
	2			6	35
			8		3
			1		
					2
			1		1
			1		2
					3
			19		5
			7		2
			2		
			1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyporeflexia		1
Hyporesponsive to stimuli		1
Hypotension	2	27
Hypotensive crisis		1
Hypothermia	2	7
Hypotonia	1	3
Hypoxia	1	2
Illness		1
Immunisation		2
Immunisation anxiety related reaction		1
Impaired gastric emptying		1
Inappropriate schedule of product administration	1	2
Incorrect route of product administration	1	8
Induration		1
Infected cyst		1
Infection	1	2
Inflammation		5
Influenza	2	15
Influenza like illness	4	30
Infusion site pain		1
Initial insomnia		1
Injected limb mobility decreased		4
Injection related reaction		1
Injection site discomfort		1
Injection site erythema		15
Injection site haematoma		1
Injection site hypersensitivity		1
Injection site induration		8
Injection site infection		3
Injection site inflammation		1
Injection site joint pain		1
Injection site muscle weakness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
	1		16	2	11
					1
				2	7
		1	3		
				1	2
			1		
			2		
			1		
					1
		1	2		
		1	8		
			1		
					1
		1	1		1
			3		2
		2	15		
		3	23	1	7
			1		
	1		3		1
			1		
			1		
			15		
			1		
			1		
			8		
			3		
			1		
			1		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site oedema		60
Injection site pain	3	355
Injection site paraesthesia		4
Injection site pruritus		6
Injection site rash		1
Injection site reaction		6
Injection site swelling		7
Injection site urticaria	1	6
Injection site warmth		1
Injury		1
Insomnia	4	58
Intranasal paraesthesia		1
Irritability		4
Ischaemic stroke		1
IVth nerve disorder	1	1
Jaundice	1	1
Joint dislocation		1
Joint effusion		1
Joint lock		1
Joint range of motion decreased	1	7
Joint stiffness		1
Joint swelling		3
Joint warmth		1
Labyrinthitis		3
Lacrimation increased	1	10
Laryngeal discomfort		1
Laryngeal dyspnoea		1
Laryngeal oedema	3	24
Laryngospasm	1	7
Larynx irritation		1
Lateropulsion	1	1
Lethargy		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			60		
		2	354	1	1
			4		
			6		
			1		
			6		
			7		
		1	5		1
			1		
					1
		2	52	2	6
			1		
			2		2
					1
				1	1
		1	1		
					1
			1		
			2		1
					1
		1	7		3
					1
					1
				3	24
			4	1	3
			1		
				1	1
			2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Leukocytosis		1
Leukopenia		1
Limb discomfort	2	14
Lipase increased		2
Lip disorder		1
Lip dry		1
Lipodystrophy acquired		1
Lip oedema	2	18
Lip pain		1
Lip pruritus	1	7
Lip swelling	1	13
Localised oedema	1	12
Local reaction		1
Loss of consciousness	1	13
Loss of libido	1	1
Loss of personal independence in daily activities		1
Lung neoplasm malignant		1
Lymphadenitis		6
Lymphadenopathy	21	267
Lymphangitis	1	2
Lymph node pain	4	26
Lymph node palpable		1
Lymphocytosis		1
Lymphoedema		6
Lymphoma	1	1
Macular rupture		1
Malaise	10	193
Mastitis	2	3
Maternal exposure during pregnancy	1	2
Mechanical urticaria		4
Medication error		1
Memory impairment		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		2	13		1
			1		1
					1
			1		
					1
			10	2	8
			1		
			3	1	4
	1	1	11		2
		1	10		2
			1		
				1	13
		1	1		
			1		
					1
			6		
1	2	14	208	7	59
				1	2
2	2	4	23		3
			1		
			1		
			4		2
				1	1
					1
	1	7	158	3	35
				2	3
		1	1		1
	1		2		2
			1		
					1

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mental impairment		1
Metrorrhagia	1	3
Micturition disorder		1
Middle insomnia		2
Migraine	2	46
Migraine with aura		2
Miosis		1
Mitral valve incompetence		1
Mobility decreased		1
Monoparesis		2
Monoplegia	1	5
Motor dysfunction	3	10
Mouth swelling		2
Movement disorder		6
Mucosal dryness		2
Mucous stools		1
Multiple organ dysfunction syndrome		1
Muscle contractions involuntary		1
Muscle contracture		3
Muscle rigidity		6
Muscle spasms	2	15
Muscle swelling		1
Muscle tightness		3
Muscle twitching		4
Muscular weakness	2	17
Musculoskeletal chest pain	2	9
Musculoskeletal pain	2	76
Musculoskeletal stiffness		9
Myalgia	46	593
Myocardial infarction	2	2
Myocardial necrosis marker increased		1
Myocarditis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		1
			1		
			2		
2	2	1	35	1	11
			2		
			1		
					1
					1
			2		
				1	5
		1	7	2	3
			1		1
			2		4
			2		
			1		
					1
			1		
1	1		2		1
			6		
		1	9	1	6
					1
			2		1
			3		1
		1	13	1	4
		1	5	1	4
			50	2	26
			5		4
2	5	26	468	20	125
				2	2
					1
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myoclonus		1
Myositis		3
Narcolepsy		1
Nasal congestion		4
Nasal discomfort		2
Nasal herpes	1	1
Nasal pruritus		1
Nasopharyngitis	1	10
Nausea	31	393
Neck pain	4	39
Nervous system disorder	1	1
Neuralgia	1	7
Neuralgic amyotrophy		
Neuritis	1	5
Neuropathy peripheral		5
Neurosensory hypoacusis	1	1
Neutropenia		1
Night sweats		3
Nodule		1
Non-cardiac chest pain	1	1
Noninfective gingivitis		1
Nuchal rigidity	1	5
Nystagmus	1	2
Occipital neuralgia		1
Ocular discomfort		2
Ocular hyperaemia		8
Oculogyric crisis		1
Odynophagia		5
Oedema		10
Oedema mouth		3
Oedema mucosal		1
Oedema peripheral	1	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1		1		2
					1
			4		
			2		
		1	1		
			1		
		1	8		2
1	5	23	289	8	104
1	1	1	27	3	12
				1	1
		1	4		3
	1				
		1	5		
					5
				1	1
					1
			3		
			1		
				1	1
			1		
		1	4		1
				1	2
					1
			2		
			6		2
					1
1	1		3		2
			8		2
			1		2
					1
		1	12		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedematous pancreatitis		1
Oesophageal spasm		1
Off label use	1	5
Ophthalmic herpes zoster		2
Optic ischaemic neuropathy	1	1
Oral candidiasis		1
Oral discomfort	1	12
Oral dysaesthesia		2
Oral herpes	3	18
Oral mucosal erythema		2
Oral pain		2
Oral pruritus		3
Orbital oedema		1
Oropharyngeal discomfort	1	4
Oropharyngeal oedema		1
Oropharyngeal pain	3	27
Oropharyngeal spasm		1
Oropharyngeal swelling		2
Orthopnoea		1
Otitis externa		1
Overdose	2	21
Oxygen saturation decreased	2	21
Pain	13	176
Pain in extremity	23	270
Pain in jaw		1
Pain of skin		2
Palatal oedema	2	10
Palatal swelling		2
Pallor		6
Palpitations	2	14
Pancreatitis	1	1
Panic attack		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	5		
					2
				1	1
			1		
		1	9		3
			2		
		2	11	1	7
			1		1
			1		1
			1		2
					1
		1	4		
					1
	1	3	22		5
					1
			1		1
					1
			1		
		1	19	1	2
			6	2	15
		4	139	9	37
	1	17	219	6	51
			1		
			2		
		2	8		2
			2		
			4		2
		1	7	1	7
				1	1
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panniculitis		1
Papule		2
Paraesthesia	21	205
Paraesthesia mucosal		2
Paraesthesia oral	4	78
Paralysis	1	2
Paraparesis	1	1
Paresis		1
Parosmia	2	5
Partial seizures	1	2
Pericardial effusion		1
Pericarditis	1	3
Perioral dermatitis		1
Periorbital oedema	1	6
Periorbital pain		3
Periorbital swelling		5
Peripheral artery thrombosis	1	1
Peripheral coldness		10
Peripheral embolism	1	1
Peripheral ischaemia	1	1
Peripheral sensorimotor neuropathy		1
Peripheral swelling	4	34
Peripheral venous disease		1
Petechiae		2
Pharyngeal erythema		2
Pharyngeal oedema	2	4
Pharyngeal paraesthesia	1	7
Pharyngeal swelling	1	3
Pharyngitis		3
Phlebitis	2	3
Phlebitis superficial	1	1
Photophobia		9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
1	1	13	144	8	61
			1		1
2	2	3	53	1	25
				1	2
				1	1
					1
		1	3	1	2
				1	2
					1
				1	3
			1		
		1	4		2
			3		
			4		1
				1	1
			8		2
				1	1
				1	1
					1
		3	25	1	9
			1		
			2		
			1		1
	1		1	2	3
			2	1	5
		1	2		1
			1		2
		2	2		1
				1	1
			7		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photopsia		4
Pityriasis rosea		1
Pleurisy		1
Pleuropericarditis	1	1
Plicated tongue		2
Pneumonia	1	5
Pneumonia bacterial		1
Pneumonitis		3
Pollakiuria	2	2
Polyarthritis	1	1
Polyuria		1
Presyncope	4	33
Product administered at inappropriate site	1	5
Productive cough	1	2
Product preparation issue		2
Product use issue		3
Pruritus	5	128
Pruritus genital		1
Psychomotor hyperactivity		1
Pulmonary embolism	2	2
Pulmonary hypoperfusion		1
Pulmonary microemboli	1	1
Pulmonary oedema	1	1
Pulmonary pain		3
Pulse abnormal		1
Puncture site pain		1
Pyrexia	85	1,058
Q fever		3
Quality of life decreased	1	2
Radiculopathy		1
Rash	4	76
Rash erythematous		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		3
			1		
				1	1
			1		1
				1	5
					1
					3
		1	1	1	1
				1	1
			1		
		2	18	2	15
		1	5		
				1	2
			2		
			3		
	1	3	93	2	35
			1		
			1		
	2			2	2
					1
	1			1	1
	1			1	1
			2		1
					1
			1		
2	8	47	775	38	283
					3
	1			1	2
			1		
	1	3	47	1	29
			7		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash macular		4
Rash maculo-papular		1
Rash papular		2
Rash pruritic	2	8
Rash vesicular		4
Raynaud's phenomenon		1
Reaction to excipient		1
Rectal haemorrhage		1
Red blood cell sedimentation rate increased	2	3
Renal pain		3
Respiratory depression		1
Respiratory disorder		4
Respiratory distress		8
Respiratory failure	2	3
Respiratory fatigue		1
Respiratory tract infection		1
Respiratory tract oedema		2
Restless legs syndrome		1
Restlessness		5
Retching	2	4
Retinal degeneration		1
Retinal detachment		2
Retinal disorder		1
Retinal vascular thrombosis		
Retinal vein thrombosis	1	1
Retrograde amnesia		1
Rhabdomyolysis	1	1
Rheumatic disorder		1
Rheumatoid arthritis		3
Rhinalgia	1	2
Rhinitis	2	14
Rhinorrhoea	2	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		1
			1		
			1		1
		1	5	1	3
			4		
			1		
					1
					1
			1	2	2
			3		
					1
			1		3
	1				8
				2	3
					1
					1
					2
					1
			2		3
		2	3		1
					1
					2
					1
	1				
				1	1
			1		
				1	1
					1
					3
		1	1		1
		1	10	1	4
			11	2	4

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhonchi		1
Salivary hypersecretion		1
Sarcoidosis		1
SARS-CoV-2 antibody test	1	1
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 antibody test positive		1
SARS-CoV-2 test positive	3	6
Scab		1
Sciatica		5
Secretion discharge	1	1
Sedation		3
Seizure	1	3
Seizure like phenomena		1
Sensation of foreign body		8
Sensorimotor disorder		1
Sensory loss		1
Septic shock		1
Severe acute respiratory syndrome	1	2
Sinusitis		1
Sinus pain		1
Sinus rhythm		1
Sinus tachycardia		4
Skin burning sensation	1	3
Skin discolouration		4
Skin exfoliation		1
Skin irritation		2
Skin laceration	1	2
Skin lesion	1	4
Skin mass	1	2
Skin oedema		1
Skin reaction		7
Skin striae	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
				1	1
				1	1
			1		
					1
			2	3	4
					1
			4		1
				1	1
			2		1
				1	3
					1
			4		4
					1
			1		
					1
				1	2
			1		
					1
					1
			3		1
		1	2		1
			2		2
			1		
			2		
			1	1	1
			2	1	2
		1	2		
			1		
			4		3
		1	1		

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin swelling		1
Skin warm		1
Sleep disorder	3	5
Sluggishness		1
Sneezing		4
Somnolence	3	61
Speech disorder		2
Spinal pain		5
Status epilepticus		1
Stoma site pain		1
Stomatitis		1
Stupor		3
Subarachnoid haemorrhage	2	2
Subcutaneous haematoma		1
Sudden death	1	1
Sudden onset of sleep		1
Suffocation feeling	1	2
Superinfection bacterial	1	1
Supraventricular extrasystoles		1
Supraventricular tachycardia		1
Suspected COVID-19	1	1
Swelling	1	26
Swelling face	3	14
Swelling of eyelid		3
Swollen tongue	2	14
Syncope	2	29
Systemic lupus erythematosus	1	1
Tachyarrhythmia		1
Tachycardia	8	89
Tachycardia paroxysmal		2
Tachypnoea		7
Taste disorder	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		2	4	1	1
					1
			3		1
		2	50	1	11
					2
			5		
					1
					1
					1
			1		2
				2	2
					1
				1	1
					1
			1	1	1
				1	1
			1		
		1	21		5
	1	3	9		5
			2		1
		1	7	1	7
				2	29
				1	1
			1		
	1	2	53	6	36
			1		1
			4		3
			3	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temporomandibular joint syndrome		2
Tenderness		2
Tendon pain		1
Tension		3
Tension headache		1
Thirst		1
Throat irritation	3	18
Throat tightness	2	38
Thrombocytopenia	1	3
Thrombophlebitis	2	2
Thrombophlebitis superficial	2	3
Thrombosis		1
Tinnitus		13
Tongue coated		2
Tongue discomfort		5
Tongue disorder		1
Tongue dry		1
Tongue oedema	1	15
Tongue pruritus		4
Tonsillar hypertrophy	1	2
Toothache		2
Torticollis		1
Transaminases increased	1	2
Traumatic fracture		1
Tremor	2	39
Trigeminal neuralgia		2
Trigger finger		1
Type I hypersensitivity		2
Underdose		2
Upper airway obstruction		1
Urinary retention		1
Urinary tract infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			2		
					1
			2		1
			1		
			1		
		2	10	1	8
	2	1	17	1	21
				1	3
		2	2		
		1	1	1	2
					1
			10		3
			2		
			5		
					1
			1		
			8	1	7
			2		2
		1	2		
			2		
			1		
		1	1		1
					1
			22	2	17
			1		1
			1		
					2
			2		
					1
					1
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urine odour abnormal		1
Urticaria	14	89
Urticaria vesiculosa	1	1
Use of accessory respiratory muscles		2
Uveitis		3
Vaccination complication		28
Vaccination failure	12	18
Vaccination site bruising		2
Vaccination site cellulitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort		1
Vaccination site eczema		1
Vaccination site erythema	7	52
Vaccination site extravasation		2
Vaccination site haematoma		2
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		2
Vaccination site induration	1	5
Vaccination site inflammation		3
Vaccination site irritation	1	1
Vaccination site joint erythema		1
Vaccination site joint movement impairment		2
Vaccination site joint pain		2
Vaccination site joint swelling	1	5
Vaccination site lymphadenopathy		6
Vaccination site movement impairment		7
Vaccination site nodule		1
Vaccination site oedema	3	37
Vaccination site pain	54	473
Vaccination site paraesthesia	1	8
Vaccination site phlebitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		10	62	4	27
		1	1		
			1		1
					3
	1		19		9
	1			12	18
			2		
					1
			1		
			1		
			1		
		6	38	1	14
			1		1
			2		
					1
			2		
		1	4		1
			2		1
		1	1		
			1		
			2		
		1	5		
			4		2
			6		1
			1		
		3	30		7
	1	49	406	5	67
			6	1	2
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site pruritus	1	16
Vaccination site rash	1	6
Vaccination site reaction	1	13
Vaccination site swelling	4	46
Vaccination site urticaria	1	7
Vaccination site vesicles		2
Vaccination site warmth		11
Vaginal haemorrhage		2
Vascular purpura	1	2
Vasculitis	2	2
Vasodilatation		1
Venous thrombosis	1	1
Venous thrombosis limb		
Ventricular extrasystoles		5
Ventricular fibrillation	1	1
Ventricular tachycardia		1
Vertigo	5	108
Vertigo positional		
Vestibular neuritis	1	1
Vision blurred	3	15
Visual acuity reduced		1
Visual field defect		2
Visual impairment	2	8
Vitreoretinal traction syndrome		1
Vitreous detachment		2
Vitreous disorder		3
Vitreous floaters		3
Vomiting	14	133
Vomiting projectile		1
Vulvovaginal burning sensation		1
Wandering pacemaker		1
Weight decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	11		5
		1	5		1
		1	9		4
		2	25	2	21
		1	4		3
			1		1
			8		3
			1		1
		1	1		1
		2	2		
			1		
				1	1
	1				
			5		
				1	1
					1
		3	80	2	28
	1				
				1	1
		2	11	1	4
					1
			2		
	1	1	4	1	4
					1
	1				2
			1		2
					3
	2	8	79	6	54
			1		
			1		
					1
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Wheezing		5				4			1
Xanthopsia		1							1
Xerophthalmia		1							1
Yellow skin	1	1			1	1			
	1,059	12,119	37	115	567	8478	492		3641

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1						1
Abdominal distension	2	2					2	2
Abdominal pain	2	5			1	3	1	2
Abdominal pain upper		5				4		1
Acute abdomen	1	1					1	1
Acute myocardial infarction	1	1					1	1
Acute respiratory failure	1	2					1	2
Administration site oedema		3				3		
Administration site pain		1				1		
Allergy to vaccine	1	1			1	1		
Altered state of consciousness	1	1					1	1
Amaurosis fugax	1	1					1	1
Anal incontinence		1						1
Angioedema	1	5					1	5
Aortic dissection	1	1					1	1
Aphasia	4	4					4	4
Aphonia	1	2				1	1	1
Application site coldness		1				1		
Arrhythmia	2	3					2	3
Arthralgia	3	35			1	24	2	11
Asthenia	8	52			4	40	4	12
Asymptomatic COVID-19	1	2					1	2
Atrial fibrillation	3	5					3	5
Atrial flutter		1						1
Back pain		2						2
Balance disorder		3				2		1
Bladder obstruction		1						1
Blood fibrinogen increased	1	1			1	1		
Blood pressure decreased		2				1		1
Blood pressure increased		3				2		1
Blood pressure systolic increased		1						1
Body temperature decreased	1	1					1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bone pain	1	4
Bradycardia		2
Breast pain		1
Burning sensation		1
Cardiac arrest	1	1
Cardiac failure		1
Cardio-respiratory arrest	2	2
Catarrh		1
Central nervous system lesion	1	1
Cerebellar ataxia	1	1
Cerebral haematoma		1
Cerebral ischaemia	2	2
Cerebral venous thrombosis	1	1
Cerebrovascular accident	3	3
Cervical radiculopathy		1
Chest discomfort		1
Chest pain		1
Chills	1	37
Choking sensation	1	1
Clonus		2
Cold sweat		1
Colitis ischaemic	1	1
Condition aggravated		3
Confusional state	2	5
Conjunctival irritation		1
Constipation		1
Coronary artery disease		1
Cough		7
COVID-19	5	10
COVID-19 pneumonia	1	1
Cystitis haemorrhagic		1
Death	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	2
	1				2
			1		
			1		
				1	1
					1
				2	2
					1
				1	1
				1	1
					1
				2	2
				1	1
				3	3
					1
			1		
			1		
			31	1	6
				1	1
			1		1
					1
				1	1
					3
			1	2	4
					1
					1
			6		1
			2	5	8
				1	1
					1
				2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased appetite	1	4
Deep vein thrombosis	1	3
Dehydration		1
Depressed level of consciousness		2
Diarrhoea	1	16
Diplegia		1
Diplopia	2	3
Discomfort		1
Disease recurrence		1
Disorientation		3
Diverticulitis		1
Dizziness	2	6
Drug hypersensitivity		1
Drug ineffective	3	6
Dry mouth		1
Dysaesthesia	1	1
Dysarthria	1	1
Dysbiosis		1
Dyschezia	1	1
Dysentery		3
Dysgeusia		2
Dysphagia		5
Dysphonia		3
Dyspnoea	2	12
Dysuria	2	2
Ear infection	1	1
Ear pain	1	2
Ear pruritus		1
Electrolyte imbalance		1
Embolism		1
Encephalitis		1
Enthesopathy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	2
				1	3
					1
	1				2
		1	14		2
					1
		2	2		1
			1		
					1
					3
					1
		2	6		
					1
			1	3	5
			1		
		1	1		
				1	1
					1
				1	1
					3
			2		
			2		3
			2		1
		1	4	1	8
				2	2
		1	1		
		1	2		
			1		
					1
					1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epilepsy	2	3
Erectile dysfunction		1
Erythema	6	15
Extrasystoles		3
Eye disorder		1
Eye irritation		2
Eyelid oedema		1
Eyelid retraction		1
Eye pain	1	2
Eye pruritus		1
Facial paralysis	2	8
Facial paresis		4
Fall		1
Fatigue	2	18
Feeling cold	1	4
Feeling hot		1
Feeling of body temperature change		1
Fibrin D dimer increased	3	3
Flatulence		2
Flushing		1
Focal dyscognitive seizures	1	1
Functional gastrointestinal disorder	1	1
Gait disturbance	3	5
Gait inability		1
Gastrointestinal disorder		2
Gastrointestinal pain		1
Gastrointestinal sounds abnormal		1
Gaze palsy	1	1
Genital herpes zoster		1
Gingival bleeding	1	1
Gingival oedema		1
Haematoma	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					1
		3	11	3	4
			2		1
			1		
			2		
			1		
					1
			1	1	1
			1		
				2	8
			2		2
					1
		1	15	1	3
		1	4		
			1		
					1
		2	2	1	1
			2		
			1		
				1	1
		1	1		
		1	2	2	3
					1
			2		
			1		
			1		
				1	1
					1
				1	1
					1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematuria		1
Hallucination		2
Headache	3	51
Head discomfort		1
Hemianopia	1	1
Hemiparaesthesia		1
Hemiparesis	1	1
Hemiplegia	2	3
Herpes virus infection	1	1
Herpes zoster	1	8
Herpes zoster oticus	1	1
Hot flush		2
Hyperaemia		1
Hyperaesthesia		1
Hypercapnia		1
Hyperhidrosis	2	7
Hyperpyrexia	1	5
Hypersensitivity	1	4
Hypertension	3	8
Hypertensive crisis	3	4
Hypoacusis		1
Hypoaesthesia	1	4
Hypoglossal nerve disorder		1
Hyponatraemia	1	1
Hyposmia		1
Hypotension	2	6
Hypotensive crisis	1	1
Hypothermia		1
Hypovolaemia		1
Hypoxia	1	2
Impaired quality of life	1	2
Incontinence	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
		1	38	2	13
					1
				1	1
					1
				1	1
				2	3
		1	1		
			3	1	5
				1	1
			2		
					1
			1		
					1
		1	4	1	3
				1	5
		1	2		2
		2	4	1	4
				3	4
					1
			2	1	2
					1
				1	1
			1		
			1	2	5
				1	1
					1
				1	2
		1	1		1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect route of product administration	1	2
Inflammation		1
Influenza		1
Influenza like illness		3
Injection site discomfort		1
Injection site erythema		3
Injection site oedema		7
Injection site pain		28
Injection site paraesthesia		1
Injection site reaction		2
Injection site swelling		2
Injection site urticaria	1	1
Injury	1	1
Insomnia		3
Inspiratory capacity abnormal		1
Interstitial lung disease		1
Intervertebral discitis		1
Intestinal ischaemia	4	4
Ischaemic stroke		1
Joint range of motion decreased		1
Lacrimation increased		3
Lagophthalmos	1	1
Laryngeal oedema	2	5
Laryngospasm		2
Leukopenia	1	1
Limb discomfort	1	1
Lip oedema		1
Listeriosis		1
Loss of consciousness	1	3
Loss of personal independence in daily activities		1
Lymphadenitis	1	1
Lymphadenopathy	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		
			1		
			3		
			1		
			3		
			7		
			28		
			1		
			2		
			2		
		1	1		
		1	1		
			3		
			1		
					1
					1
				4	4
					1
					1
			3		
				1	1
				2	5
					2
				1	1
				1	1
					1
				1	3
					1
				1	1
		1	4	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphangitis		1
Macroglossia		1
Malaise	5	19
Melaena		1
Metamorphopsia		1
Middle insomnia	1	2
Migraine		3
Motor dysfunction		3
Mouth swelling		1
Movement disorder		2
Muscle contracture		1
Muscle fatigue	1	1
Muscle rigidity		1
Muscle spasms		3
Muscular weakness		1
Musculoskeletal chest pain		1
Musculoskeletal pain	1	8
Musculoskeletal stiffness		2
Myalgia	5	39
Nasal congestion	1	1
Nasopharyngitis	1	3
Nausea	4	24
Neck pain	1	3
Neurogenic bladder		1
Night sweats		1
Ocular hyperaemia		1
Oedema		2
Oedema mouth		3
Oedema mucosal		1
Oedema peripheral		1
Oesophageal oedema		1
Oliguria	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		2	14	3	5
					1
					1
		1	2		
			3		
			2		1
					1
			2		
					1
				1	1
			1		
			3		
					1
					1
		1	7		1
			2		
		1	28	4	11
		1	1		
		1	2		1
		1	16	3	8
		1	3		
					1
			1		
			1		
			1		1
			3		
					1
					1
					1
				1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic neuritis		2
Oral discomfort		2
Oral herpes		1
Oral pain		1
Oropharyngeal pain		4
Otitis media		1
Overdose	1	5
Oxygen saturation decreased	2	4
Pain	3	13
Pain in extremity	3	22
Palatal oedema		3
Pallor	1	2
Panic attack		1
Papilloedema		2
Paraesthesia	5	13
Paraesthesia oral		4
Parosmia		1
Parotid gland enlargement		2
Paroxysmal arrhythmia		1
Pericardial effusion	2	2
Periorbital oedema	1	1
Periorbital swelling		1
Peripheral coldness		1
Peripheral swelling	1	1
Peritonsillar abscess		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngitis		3
Platelet count decreased	1	1
Platelet count increased	1	1
Pleural effusion	3	3
Pneumatoxis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			2		
					1
					1
			3		1
					1
		1	4		1
			1	2	3
		2	11	1	2
			15	3	7
			1		2
		1	1		1
			1		
					2
		1	6	4	7
			3		1
					1
			1		1
				2	2
				1	1
			1		
			1		
				1	1
					1
					1
			2		1
		1	1		
				1	1
				3	3
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia	2	4
Pneumonia legionella		1
Polyarthritis		1
Post herpetic neuralgia		1
Presyncope	4	7
Prurigo		1
Pruritus		8
Pulmonary embolism		3
Pulmonary mass	1	1
Pustular psoriasis	1	1
Pyrexia	11	119
Q fever	1	1
Quadripareisis		1
Rales	1	1
Rash	1	2
Rash erythematous	1	3
Rash papular		1
Rash pruritic	1	1
Respiratory disorder	1	1
Respiratory distress	1	1
Respiratory failure	1	4
Respiratory tract haemorrhage		1
Retching		1
Retinal vein occlusion	1	1
Rhinorrhoea		2
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 test positive		1
Scab		1
Sciatica		1
Seizure		2
Sensitisation		1
Sensory loss		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
					1
					1
					1
		1	3	3	4
			1		
			5		3
					3
				1	1
				1	1
		6	86	5	33
				1	1
					1
				1	1
		1	1		1
				1	3
			1		
				1	1
				1	1
				1	4
					1
			1		
				1	1
			2		
			1		
			1		
			1		
			1		
					2
			1		
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sepsis		1
Septic shock	1	1
Sinusitis		1
Sitting disability	1	1
Skin exfoliation		1
Sleep disorder		1
Somnolence	2	5
Sopor	1	1
Speech disorder		2
Stertor		1
Sudden death	2	4
Swelling	2	3
Swelling face	1	1
Swelling of eyelid		1
Swollen tongue		2
Syncope	2	6
Tachycardia	2	7
Tachypnoea		1
Taste disorder		3
Temperature regulation disorder		1
Throat irritation		2
Throat tightness		5
Thrombocytopenia	3	3
Thrombosis	2	3
Tinnitus		1
Tongue oedema		3
Torticollis		1
Tracheal pain		1
Transient ischaemic attack	1	1
Tremor		6
Trigeminal neuritis		1
Unresponsive to stimuli	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
		1	1		
			1		
					1
		1	4	1	1
				1	1
			1		1
					1
				2	4
			1	2	2
				1	1
					1
			1		1
1	1	1	1	1	5
		1	3	1	4
			1		
			1		2
			1		
			2		
			4		1
				3	3
				2	3
					1
			1		2
			1		
			1		
				1	1
			4		2
					1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Upper respiratory tract inflammation		1				1			
Urinary incontinence		1							1
Urticaria	1	4			1	1			3
Uveitis		1							1
Vaccination failure	3	5					3		5
Vaccination site erythema	1	3			1	2			1
Vaccination site induration	1	1					1		1
Vaccination site inflammation	1	2				1	1		1
Vaccination site joint swelling		1				1			
Vaccination site lymphadenopathy	1	1			1	1			
Vaccination site oedema		3				2			1
Vaccination site pain	5	53			2	49	3		4
Vaccination site pallor		1				1			
Vaccination site paraesthesia		1				1			
Vaccination site pruritus	1	2			1	2			
Vaccination site reaction	1	2				1	1		1
Vaccination site swelling		1				1			
Vaccination site warmth		1							1
Vasculitis	1	2					1		2
Ventricular extrasystoles		1							1
Vertigo	2	8		1	1	5	1		3
Vestibular neuronitis		1							1
Viral infection	1	1			1	1			
Virologic failure	1	1			1	1			
Vision blurred	1	1					1		1
Vlth nerve paralysis	1	2					1		2
Vlth nerve paresis	1	1			1	1			
Vitreous detachment		2							2
Vomiting	2	14			1	9	1		5
	270	1,248	1	4	75	711	195		537

\* I=Interval, C=Cumulative  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	4	6				1	4	5
Abdominal pain upper	2	2					2	2
Abnormal behaviour		1				1		
Acute coronary syndrome	3	5					3	5
Acute kidney injury	1	3		1			1	3
Acute myocardial infarction	2	6					2	6
Acute pulmonary oedema	1	2					1	2
Acute respiratory distress syndrome	1	1					1	1
Acute respiratory failure	1	5					1	5
Administration site movement impairment	1	1					1	1
Age-related macular degeneration	1	1					1	1
Agitation		3				2		1
Allergic reaction to excipient	1	1					1	1
Allergic respiratory symptom		1						1
Allergy to vaccine		1						1
Alpha tumour necrosis factor increased	1	1					1	1
Altered state of consciousness		1						1
Anaemia	2	3				1	2	2
Anaemia macrocytic	1	1					1	1
Anaesthesia		1						1
Anal erythema		1						1
Anal incontinence		1						1
Anaphylactic reaction		2	1	2				2
Aneurysm ruptured		1						1
Angioedema	1	1					1	1
Angiopathy	1	1					1	1
Anuria		1						1
Anxiety	1	2				1	1	1
Aortic dilatation	1	1			1	1		
Aphasia	8	10	1	1			8	10
Arrhythmia	2	4					2	4
Arteriosclerosis		1						1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arteriosclerotic retinopathy	1	1
Arteriospasm coronary		1
Arthralgia	7	11
Asthenia	18	28
Asthenopia	1	1
Asthma	1	1
Asthmatic crisis		
Asymptomatic COVID-19	4	6
Ataxia	1	1
Atrial fibrillation	8	12
Atrial flutter	2	2
Atrioventricular block complete		1
Atrioventricular block first degree	1	1
Back pain	1	1
Balance disorder	1	4
Blindness	1	1
Blister	1	2
Blood bilirubin increased	1	1
Blood creatinine increased	1	1
Blood glucose abnormal	1	1
Blood pressure increased	2	5
Blood pressure systolic increased		1
Body temperature abnormal	1	1
Body temperature increased		3
Bone pain	2	2
Bradycardia		1
Bradykinesia	1	2
Bradyphrenia	1	1
Brain compression	1	1
Brain stem haemorrhage		1
Brain stem stroke	1	1
Bronchitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	3	6	8
3	3	3	9	15	19
				1	1
				1	1
1	1				
				4	6
				1	1
				8	12
				2	2
					1
		1	1		
				1	1
2	2			1	4
				1	1
		1	2		
				1	1
		1	1		
				1	1
			1	2	4
			1		
		1	1		
			2		1
		1	1	1	1
					1
				1	2
				1	1
				1	1
					1
				1	1
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Bronchospasm	1	1
Cardiac arrest	9	16
Cardiac disorder		1
Cardiac failure	5	11
Cardiac failure congestive	2	3
Cardiac fibrillation	1	1
Cardiogenic shock		1
Cardiopulmonary failure	1	1
Cardio-respiratory arrest	3	5
Cerebellar haemorrhage		1
Cerebral artery occlusion	2	2
Cerebral artery thrombosis	1	1
Cerebral haemorrhage	5	8
Cerebral infarction	1	2
Cerebral ischaemia	10	10
Cerebral thrombosis	1	1
Cerebral ventricle collapse	1	1
Cerebrovascular accident	7	13
Chest discomfort	1	2
Chest pain	7	9
Chills	3	6
Cholangitis		1
Cholelithiasis	1	1
Chronic obstructive pulmonary disease	1	1
Circulatory collapse		2
Cognitive disorder		
Cold sweat		1
Coma	1	4
Coma scale abnormal		1
Condition aggravated	3	6
Confusional state	11	15
Conjunctival haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				9	16
					1
				5	11
				2	3
				1	1
					1
				1	1
				3	5
					1
				2	2
				1	1
				5	8
				1	2
				10	10
				1	1
				1	1
1	1			7	13
		1	2		
		1	1	6	8
			2	3	4
					1
				1	1
				1	1
					2
1	1				
					1
				1	4
					1
				3	6
4	5	1	3	10	12
	2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Constipation		1
Contraindicated product administered	1	1
Coordination abnormal		
Coronary artery disease	1	1
Coronary artery stenosis	1	2
Cough	3	4
COVID-19	13	22
COVID-19 pneumonia	5	5
C-reactive protein increased	1	1
Cyanosis	1	1
Deafness	2	2
Death	2	5
Decreased appetite	4	6
Deep vein thrombosis	6	8
Dehydration		3
Delusion	1	1
Depressed level of consciousness	1	3
Dermatitis allergic		1
Dermatitis bullous	2	3
Dermatitis exfoliative generalised		1
Diarrhoea	3	12
Dilatation atrial	1	1
Diplopia	1	1
Discomfort	1	1
Disease recurrence	5	9
Disorientation	2	4
Disseminated varicella zoster virus infection	1	1
Disturbance in attention	1	1
Dizziness	8	11
Droling	1	1
Drug ineffective	9	11
Dry mouth	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
1	1				
				1	1
				1	2
			1	3	3
1	1			13	22
1	1			5	5
		1	1		
				1	1
				2	2
				2	5
				4	6
1	1			6	8
					3
				1	1
				1	3
					1
				2	3
					1
1	1	1	4	2	8
				1	1
		1	1		
				1	1
				5	9
	1			2	4
				1	1
				1	1
		1	1	7	10
				1	1
1	1			9	11
		1	1	1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysarthria	4	6
Dysentery	4	5
Dyskinesia	1	1
Dyslexia	1	1
Dysphagia	3	5
Dyspnoea	17	38
Dyspnoea exertional	1	1
Dysstasia	1	1
Dysuria	1	2
Ear haemorrhage	1	1
Ear pain		1
Ecchymosis	3	3
Electrocardiogram T wave inversion		
Embolic stroke	1	1
Embolism venous		1
Encephalitis	1	1
Enteritis	1	1
Epilepsy	2	3
Epistaxis	1	3
Erectile dysfunction	1	1
Erysipelas	2	2
Erythema	3	15
Exposure to SARS-CoV-2	1	2
Eye infection	1	1
Eye irritation		1
Eyelid oedema		1
Eyelid ptosis	1	1
Eye pain	2	2
Face injury	1	1
Face oedema	4	6
Facial asymmetry	1	1
Facial pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			4	6
				4	5
				1	1
				1	1
				3	5
2	3	1	4	16	34
				1	1
				1	1
				1	2
		1	1		
					1
				3	3
	1				
				1	1
					1
				1	1
		1	1		
				2	3
		1	3		
				1	1
				2	2
1	1		9	3	6
		1	2		
				1	1
			1		
					1
		1	1		
		2	2		
				1	1
				4	6
				1	1
				1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Facial paralysis	5	8
Fall	3	6
Fatigue	4	13
Feeding disorder		1
Feeling abnormal	2	2
Feeling cold		1
Feeling hot	3	3
Fibrin D dimer increased	1	2
Fluid retention		1
Flushing	2	6
Foaming at mouth	2	2
Full blood count increased	1	1
Gait disturbance	4	4
Gait inability	1	1
Gastrointestinal disorder	1	1
Gastrointestinal haemorrhage		1
Gastrointestinal pain	1	1
Generalised tonic-clonic seizure		1
General physical health deterioration		4
Gingival bleeding	1	1
Glossitis	1	1
Guillain-Barre syndrome	1	1
Haematemesis	1	2
Haematoma	2	3
Haematuria	1	1
Haemoglobin decreased		1
Haemoperitoneum		1
Haemorrhage		1
Haemorrhage subcutaneous		1
Haemorrhagic cerebral infarction		1
Haemorrhagic stroke	1	1
Hallucination	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	2			5	8
				3	6
		3	11	1	2
					1
			1		
		2	2	1	1
		1	2		
					1
			4	2	2
				2	2
		1	1		
				4	4
				1	1
		1	1		
					1
			1		3
				1	1
				1	1
				1	1
				1	2
			1	2	2
				1	1
					1
					1
					1
				1	1
				1	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Hallucination, auditory	1	1
Hallucination, visual	1	1
Headache	15	17
Head discomfort	1	1
Heart rate decreased	1	1
Heart rate increased	2	2
Heart rate irregular		1
Hemianopia homonymous	1	1
Hemiparesis	4	11
Hemiplegia	3	4
Hepatic enzyme increased		
Hepatitis acute		1
Herpes ophthalmic		1
Herpes zoster	3	4
Herpes zoster reactivation	1	1
Hiccups	1	1
Hyperbilirubinaemia	1	1
Hyperglycaemia	1	1
Hyperhidrosis	3	5
Hyperpyrexia	1	9
Hypersensitivity	1	1
Hypertension	4	4
Hypertensive crisis	5	10
Hypertensive heart disease	3	3
Hyperthermia		3
Hypertrophic cardiomyopathy		1
Hyperventilation		1
Hypoaesthesia		1
Hypokalaemia	1	1
Hypokinesia	1	1
Hyporesponsive to stimuli		1
Hypotension	7	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
2	2	4	5	11	12
				1	1
				1	1
				2	2
					1
				1	1
				4	11
				3	4
	1				
					1
					1
			1	3	3
				1	1
		1	1		
				1	1
				1	1
			2	3	3
				1	9
				1	1
				4	4
				5	10
				3	3
			1		2
					1
					1
				1	1
				1	1
					1
1	2	2	4	5	12

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotensive crisis	1	1
Hypothermia	1	1
Hypotonia		1
Hypoxia	1	3
Illrd nerve paralysis	1	1
Immune thrombocytopenia		
Impaired quality of life	1	1
Inappropriate schedule of product administration	2	2
Incontinence		1
Incorrect route of product administration	3	4
Infarction		1
Inflammation	1	1
Influenza like illness		1
Injection site discomfort		1
Injection site erythema		1
Injection site pain		1
Injection site warmth		1
Insomnia	3	3
International normalised ratio increased	2	3
Interstitial lung disease	2	2
Intestinal obstruction		1
Intraventricular haemorrhage	1	2
Ischaemia	1	4
Ischaemic stroke	4	10
Jaundice		2
Jaundice cholestatic		1
Joint swelling	1	1
Laboratory test abnormal		1
Lacrimation increased		1
Lacunar stroke	1	1
Lagophthalmos		1
Laryngeal dyspnoea	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
					1
				1	3
				1	1
1	1				
		1	1		
		1	1	1	1
			1		
		3	4		
					1
				1	1
			1		
			1		
			1		
			1		
				3	3
			1	2	2
				2	2
					1
				1	2
				1	4
				4	10
					2
					1
				1	1
					1
				1	1
					1
				1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngeal oedema	2	3
Left ventricular dysfunction	1	1
Left ventricular failure		1
Left ventricular hypertrophy	1	1
Leukaemia	1	1
Leukocytosis		
Leukopenia		
Lip disorder	1	1
Lip pruritus		1
Lip swelling		1
Livedo reticularis		1
Localised oedema	1	1
Logorrhoea	1	1
Loss of consciousness	13	18
Lung disorder		1
Lymphadenopathy		2
Lymphangitis	1	1
Lymphocyte count decreased		1
Maculopathy	1	2
Malaise	10	26
Mean cell volume increased		1
Metabolic acidosis		1
Migraine	1	1
Mitral valve incompetence	3	3
Monocyte count increased		1
Motor dysfunction	2	2
Mouth haemorrhage	1	1
Movement disorder	1	1
Multiple organ dysfunction syndrome	1	2
Muscle contractions involuntary		1
Muscle rigidity	1	1
Muscle spasms	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
		1	1		
					1
				1	1
				1	1
	1				
	1				
				1	1
					1
					1
	1		1		
	1			1	1
				1	1
				13	18
					1
			1		1
				1	1
			1		
				1	2
		2	11	8	15
			1		
					1
				1	1
				3	3
			1		
				2	2
				1	1
		1	1		
	1			1	2
					1
				1	1
				1	1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscular weakness	3	3
Musculoskeletal pain	1	2
Musculoskeletal stiffness	1	1
Myalgia	7	12
Myasthenia gravis crisis	1	1
Myocardial infarction	2	3
Myocardial ischaemia	1	2
Myringitis	1	1
Nausea	7	10
Necrotising fasciitis		1
Nervous system disorder	1	1
Neurological symptom		
Neurologic neglect syndrome	1	1
Neutropenia		
Neutrophil count increased	1	1
Neutrophilia	2	2
Ocular discomfort	1	1
Oedema peripheral	4	5
Off label use	2	4
Oliguria		1
Oral herpes	1	1
Orchitis	1	1
Organic brain syndrome		1
Oropharyngeal pain		1
Overdose	5	6
Oxygen saturation abnormal		
Oxygen saturation decreased	9	16
Pain	3	3
Pain in extremity	7	9
Pallor		3
Palpable purpura	1	1
Pancreatitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
			1	1	1
				1	1
1	1	1	3	6	9
				1	1
				2	3
				1	2
				1	1
		3	5	4	5
					1
				1	1
	1				
				1	1
	1				
		1	1		
				2	2
		1	1		
2	2	1	2	3	3
		1	3	1	1
					1
				1	1
				1	1
					1
					1
		4	5	1	1
1	1				
	1	1	2	8	14
		2	2	1	1
		2	3	5	6
			2		1
				1	1
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Pancreatitis acute	1	1
Paraesthesia	4	5
Paraesthesia oral		1
Paraparesis	1	1
Pemphigoid		1
Pericardial effusion	3	3
Pericarditis	1	1
Periorbital oedema		1
Peripheral ischaemia	1	1
Peripheral swelling	2	4
Petechiae	1	1
Petit mal epilepsy	1	1
Pharyngeal mass	1	1
Pharyngeal paraesthesia		1
Phlebitis	1	1
Pleural effusion	4	4
Pneumonia	4	5
Pneumonia bacterial	1	1
Pneumonitis	2	2
Polymyalgia rheumatica	1	1
Polyuria		1
Presyncope	4	4
Procalcitonin increased	1	1
Productive cough		1
Product preparation issue		2
Product use issue	1	3
Pruritus	2	6
Psychomotor hyperactivity	1	2
Psychomotor skills impaired	1	1
Pulmonary congestion		1
Pulmonary embolism	10	15
Pulmonary hypertension	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				4	5
					1
				1	1
					1
				3	3
				1	1
					1
				1	1
			1	2	3
	1			1	1
				1	1
		1	1		
			1		
		1	1		
		1	1	3	3
				4	5
				1	1
				2	2
				1	1
					1
		1	1	3	3
		1	1		
					1
		1	3		
		1	5	1	1
			1	1	1
				1	1
					1
2	2			10	15
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Pulmonary infarction	1	1
Pulmonary oedema		1
Pulse volume decreased		1
Purpura		1
Pyrexia	34	115
Rales		1
Rash		4
Rash macular		1
Rash maculo-papular		1
Rash pruritic	1	2
Rectal haemorrhage	1	1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased	1	1
Red cell distribution width increased		1
Regurgitation		1
Renal failure	1	3
Renal impairment		1
Renal pain	1	1
Respiratory arrest		2
Respiratory disorder	1	3
Respiratory distress		1
Respiratory failure	9	11
Restlessness		1
Retching	1	3
Retinal artery occlusion	2	2
Retinal drusen	1	1
Retinal oedema	1	1
Retinal vein thrombosis	2	2
Rheumatoid arthritis	1	1
Right ventricular dilatation	1	1
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 test positive	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1		
	1				1
3	5	3	52	31	63
					1
			3		1
					1
			1		
			1	1	1
				1	1
					1
				1	1
			1		
					1
				1	3
					1
				1	1
					2
				1	3
					1
				9	11
					1
			1	1	2
				2	2
				1	1
				1	1
				2	2
				1	1
		1	1		
					1
				4	7

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scleral discolouration		1
Scrotal erythema	1	1
Sensation of foreign body		1
Sepsis	1	2
Septic shock	1	2
Serratia test positive		1
Skin discolouration	1	1
Skin exfoliation	1	1
Skin lesion		1
Sleep disorder	1	2
Slow speech	1	1
Soliloquy		1
Somnolence	5	9
Sopor	3	7
Speech disorder	6	6
Stenotrophomonas test positive		1
Stupor		1
Subdural haematoma	1	1
Sudden death	5	11
Suspected COVID-19	1	1
Swelling face	2	6
Syncope	11	16
Systolic hypertension		1
Tachycardia	2	4
Tachycardia paroxysmal	1	1
Tachypnoea		1
Testicular neoplasm	1	1
Throat tightness	1	2
Thromboangiitis obliterans	1	1
Thrombocytopenia	6	9
Thrombophlebitis	2	2
Thrombophlebitis superficial	5	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		
				1	2
				1	2
					1
				1	1
		1	1		
					1
		1	2		
				1	1
			1		
1	2	2	3	3	6
1	2		1	3	6
1	1			6	6
					1
					1
				1	1
				5	11
				1	1
			4	2	2
		1		11	16
					1
1	1		2	2	2
				1	1
			1		
				1	1
				1	2
				1	1
		1		6	9
		1	1	1	1
1	1			5	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombosis	3	3
Tinnitus	1	1
Tongue oedema	2	2
Tongue pruritus		1
Transient ischaemic attack	3	4
Tremor	3	4
Tricuspid valve incompetence	2	2
Trigeminal neuralgia	1	1
Troponin I increased	1	1
Troponin increased	1	1
Troponin T increased	1	1
Undersensing	1	1
Unresponsive to stimuli	1	2
Upper limb fracture	1	1
Upper respiratory tract infection	1	1
Urinary incontinence	1	2
Urinary retention	1	2
Urinary tract infection bacterial	1	1
Urine output decreased	1	1
Urosepsis	1	1
Urticaria	3	9
Vaccination failure	11	19
Vaccination site erythema		2
Vaccination site inflammation		4
Vaccination site oedema		
Vaccination site pain	2	7
Vaccination site reaction		2
Vaccination site swelling	1	2
Vaccination site warmth		
Vasculitis	1	1
Vasculitis necrotising	1	1
Venous thrombosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
				1	1
				2	2
					1
				3	4
				3	4
				2	2
				1	1
				1	1
				1	1
				1	1
				1	1
				1	2
				1	1
				1	1
				1	2
				1	1
				1	1
				1	1
		1	4	2	5
				11	19
			2		
			4		
1	1				
1	1		5	2	2
			2		
1	1		1	1	1
1	1				
		1	1		
				1	1
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Venous thrombosis limb	2	2			1	1	1	1
Ventricular arrhythmia		1						1
Ventricular fibrillation	1	1					1	1
Ventricular tachycardia	1	1					1	1
Vertigo	3	5	2	2	1	2	2	3
Vision blurred	3	3					3	3
Visual acuity reduced				1				
Visual impairment	5	5					5	5
Vitreous haemorrhage	1	1					1	1
Vomiting	11	30	1	1	5	15	6	15
Weight decreased		1						1
White blood cell count increased	1	1			1	1		
Xerophthalmia	1	1					1	1
	798	1,433	51	79	94	305	704	1128

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain		3		2		1
Abdominal pain upper		1		1		
Abortion spontaneous		1				1
Acute coronary syndrome		1				1
Agitation		1				1
Anaphylactic reaction		4				4
Anaphylactic shock		2				2
Antibody test abnormal		3		3		
Arthralgia	3	23	3	21		2
Asthenia		14		14		
Asthenopia		1		1		
Asthma		1				1
Asymptomatic COVID-19		1				1
Axillary pain	1	1	1	1		
Back pain	1	2	1	1		1
Blister	1	2	1	2		
Blood pressure fluctuation		1		1		
Blood pressure increased		1		1		
Bone pain	1	3	1	3		
Breast pain		1		1		
Breath sounds abnormal		1		1		
Burning sensation		1				1
Chest discomfort	1	3	1	3		
Chest pain	1	2	1	2		
Chills	2	10	2	10		
Circumstance or information capable of leading to medication error		1		1		
Cold urticaria	1	1	1	1		
Confusional state		1		1		
Conjunctivitis		1		1		
Cough		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	4	59		6	4	53
Deafness bilateral		1				1
Decreased appetite		1		1		
Dermal cyst	1	1	1	1		
Diarrhoea	1	7	1	7		
Diplopia		1		1		
Discomfort	1	1	1	1		
Dizziness	1	7	1	6		1
Drug ineffective	3	51			3	51
Dry mouth	1	4	1	4		
Dysaesthesia		1		1		
Dysentery		1				1
Dysgeusia	1	3	1	3		
Dyspnoea	1	3	1	2		1
Dysuria		1				1
Enterocolitis		1				1
Erythema	1	8		7	1	1
Exposure during pregnancy		1		1		
Eye pain		1		1		
Facial nerve disorder		1		1		
Facial pain	1	1	1	1		
Facial paralysis	1	3			1	3
Fall		1		1		
Fatigue	5	14	4	11	1	3
Feeling hot	1	3	1	3		
Flushing		1		1		
Foetal growth restriction		1				1
Gait inability		2		2		
Glossodynia		1		1		
Headache	6	36	5	32	1	4
Head discomfort		1		1		
Heart rate increased	1	1	1	1		

\* I=Interval, C=Cumulative  
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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			2
			1
	3		
			3
			1
			1
			2
	1		
	1		
	1		1
1	2		
1	1		
1		1	1
			1
1	5		
	1		
	1		
1	1		
	3		
	1		
	8		
	1		
	1		
	1		
	1		
1	2		
	1		
			1
	3	1	1
1	4		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	18		
	1		
1	7		
1	1		
2	4		
	1		
	5		
	1		
	1		1
	1		
	1		1
			1
	4		
3	18		
2	6		3
	1		1
			1
	2		
3	4		
2	8		
			1
2	5		
2	14		1
	1		
1	2		
		1	1
2	9		
	2		1
	1		
			1
	1		
	1		

Lymphadenopathy 1 18

Lymph node pain 1 1

Malaise 1 7

Maternal exposure before pregnancy 1 1

Maternal exposure during pregnancy 2 4

Meningeal disorder 1 1

Migraine 5 5

Muscle disorder 1 1

Muscle spasms 2 2

Muscle tightness 1 1

Muscular weakness 2 2

Musculoskeletal disorder 1 1

Musculoskeletal pain 4 4

Myalgia 3 18

Nausea 2 9

Neuralgia 2 2

Neuropathy peripheral 1 1

Night sweats 2 2

No adverse event 3 4

Off label use 2 8

Oxygen saturation decreased 1 1

Pain 2 5

Pain in extremity 2 15

Pallor 1 1

Palpitations 1 2

Pancreatitis 1 1

Paraesthesia 2 9

Paraesthesia oral 3 3

Paresis cranial nerve 1 1

Pericarditis 1 1

Peripheral coldness 1 1

Peripheral sensory neuropathy 1 1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Peripheral swelling		1		1			
Petechiae		1		1			
Pharyngeal paraesthesia		1					1
Pharyngeal swelling		1		1			
Photophobia		1		1			
Pityriasis rosea		1		1			
Pleural effusion	1	1			1		1
Pneumonia	1	1			1		1
Poor quality product administered		2		2			
Presyncope		1		1			
Product administration error		2		2			
Product label confusion		1		1			
Product preparation issue		1		1			
Product use issue	1	4	1	4			
Pruritus	2	5	1	2	1		3
Psoriasis	1	1	1	1			
Pyrexia	6	41	6	41			
Rash		5		4			1
Rash macular	1	1	1	1			
Root canal infection		1		1			
SARS-CoV-2 antibody test negative	1	5	1	5			
SARS-CoV-2 antibody test positive		4		4			
SARS-CoV-2 test false positive		1		1			
SARS-CoV-2 test positive		1					1
Sinus tachycardia	1	1	1	1			
Skin reaction		1		1			
Somnolence		3		3			
Stomatitis		1		1			
Subcutaneous abscess		1					1
Sudden death	1	1			1		1
Swelling face	1	2	1	2			
Syncope		5					5

\* I=Interval, C=Cumulative  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		5		4		1
Therapeutic response unexpected		1		1		
Throat tightness		1		1		
Tinnitus		1				1
Tongue discolouration	1	1	1	1		
Tongue dry	1	1	1	1		
Tongue oedema	1	1	1	1		
Tongue paralysis		1				1
Tooth infection		1		1		
Tremor		1		1		
Underdose		2		2		
Urticaria	2	8	2	8		
Vaccination failure	1	3			1	3
Vaccination site erythema		1		1		
Vaccination site haematoma		1		1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema		2		2		
Vaccination site pain	8	42	8	41		1
Vaccination site paraesthesia		1		1		
Vaccination site rash		2		1		1
Vaccination site swelling	1	4	1	4		
Vaccination site urticaria		2		2		
Vaccination site warmth		2		2		
Vertigo		5		3		2
Vestibular disorder		1				1
Vomiting		3		2		1
Wrong schedule		1		1		
Wrong technique in product usage process		1		1		
	106	697	87	503	19	194

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**JAPAN**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	7	11	5	6	2	5
Abdominal pain	13	16	8	9	5	7
Abdominal pain upper	1	1	1	1		
Accident	1	1			1	1
Acute coronary syndrome		2				2
Acute endocarditis	1	1			1	1
Allergy to vaccine	1	1	1	1		
Altered state of consciousness	2	4			2	4
Amnesia	1	1			1	1
Anaemia	1	1	1	1		
Anaphylactic reaction	93	143			93	143
Anaphylactic shock	3	6			3	6
Anaphylactoid reaction		2				2
Anxiety	2	2			2	2
Apnoea		2				2
Apnoeic attack		1				1
Arthralgia	18	21	12	13	6	8
Asthenia	5	9	3	3	2	6
Asthma	1	4		2	1	2
Autonomic nervous system imbalance	1	1			1	1
Autophony	1	1	1	1		
Back pain	2	2	2	2		
Blood glucose decreased		1				1
Blood pressure abnormal	1	2	1	1		1
Blood pressure decreased	14	17	7	9	7	8
Blood pressure diastolic increased	2	4	1	2	1	2
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased	8	13	5	7	3	6
Blood pressure systolic		1		1		
Blood pressure systolic abnormal	1	1			1	1
Blood pressure systolic increased		1		1		
Body temperature increased	3	3	3	3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia	3	3			3	3
Bradyphrenia	1	1			1	1
Brain compression		1				1
Brain neoplasm		1				1
Breast cancer	1	1			1	1
Breath sounds abnormal	1	1			1	1
Bronchospasm		1				1
Burning sensation	1	1	1	1		
Calculus urinary		1		1		
Cardio-respiratory arrest		1				1
Cerebral haemorrhage		1				1
Chest discomfort	3	5	2	3	1	2
Chest pain	2	3			2	3
Chills	20	24	13	15	7	9
Circulatory collapse	2	2			2	2
Cold sweat	13	17	8	10	5	7
Coma scale		1				1
Complex regional pain syndrome	1	2	1	1		1
Condition aggravated	3	3	1	1	2	2
Conjunctival hyperaemia	3	4	1	1	2	3
Cough	18	27	1	3	17	24
CSF protein increased	1	1			1	1
Cutaneous symptom		2		1		1
Daydreaming	1	1	1	1		
Decreased appetite	1	4		3	1	1
Dehydration	1	1			1	1
Depressed level of consciousness	2	5			2	5
Diarrhoea	12	17	11	14	1	3
Discomfort	4	5	1	2	3	3
Dizziness	25	37	16	20	9	17
Dizziness postural	1	2	1	2		
Drug hypersensitivity		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysaesthesia	1	1	1	1		
Dysphagia	1	2			1	2
Dysphoria	1	2	1	2		
Dyspnoea	27	46	17	24	10	22
Dysuria		1				1
Ear discomfort	1	1	1	1		
Eczema		1				1
Enteritis infectious	1	1			1	1
Enterocolitis	3	3			3	3
Epigastric discomfort	2	2	1	1	1	1
Erythema	37	58	27	34	10	24
Erythema multiforme	1	1			1	1
Erythema of eyelid	1	1	1	1		
Excessive eye blinking		1				1
Exposure during pregnancy	1	1	1	1		
Eye disorder	1	2	1	1		1
Eyelid oedema	1	2	1	1		1
Eye pruritus	2	2	1	1	1	1
Eye swelling	1	1	1	1		
Face oedema	1	3	1	2		1
Facial pain	1	2	1	1		1
Facial paralysis	2	3			2	3
Faeces soft	3	4	2	3	1	1
Fall	3	5	3	5		
Fatigue		1		1		
Feeding disorder	1	1	1	1		
Feeling abnormal	27	40	17	19	10	21
Feeling cold	7	7	4	4	3	3
Feeling hot	12	13	8	8	4	5
Flushing	4	7	3	4	1	3
Fracture	1	1	1	1		
Frequent bowel movements	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance	3	3			3	3
Gait inability		1				1
Gastroenteritis	1	1	1	1		
Gastrointestinal mucosal disorder	1	1			1	1
Gaze palsy		1				1
Glossodynia	1	1	1	1		
Grip strength decreased	1	3	1	2		1
Guillain-Barre syndrome	2	2			2	2
Haematochezia		1				1
Headache	50	69	33	42	17	27
Head discomfort	2	2	1	1	1	1
Heart rate decreased	2	2	1	1	1	1
Heart rate increased	4	6	1	2	3	4
Henoch-Schonlein purpura	1	1	1	1		
Hepatic function abnormal	1	1			1	1
Herpes virus infection	1	1			1	1
Herpes zoster	1	1			1	1
Hot flush	3	6	2	3	1	3
Hyperaesthesia	1	1			1	1
Hyperhidrosis	6	6	4	4	2	2
Hypersensitivity	10	13	8	8	2	5
Hypertension	1	1	1	1		
Hyperthermia	2	2	2	2		
Hyperventilation	6	8	2	2	4	6
Hypoacusis	1	1	1	1		
Hypoaesthesia	15	20	11	15	4	5
Hypoaesthesia oral	1	3			1	3
Hypophagia	2	2	1	1	1	1
Illusion		1				1
Incorrect route of product administration	2	2	2	2		
Injection site hypoaesthesia	1	1	1	1		
Injection site pain	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
1	1		
		2	2
		1	2
1	1		
		1	1
1	1	1	3
			1
			1
8	13	8	13
4	4		
43	63	31	23
			1
1	1	1	1
2	2	2	2
3	3	3	3
1	1	1	
1	1		1
2	3	1	2
			1
			1
7	9	4	5
9	12	6	5
1	1		1
4	6		6
1	1	1	1
47	75	26	37
1	2	1	1
6	10		10
1	1		1
1	1		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Opisthotonus	1	1			1	1
Oral discomfort	1	1			1	1
Oropharyngeal discomfort	14	33	5	11	9	22
Oropharyngeal pain	1	3		1	1	2
Orthostatic intolerance	1	1			1	1
Oxygen saturation decreased	2	2			2	2
Pain	6	7	6	7		
Pain in extremity	11	13	8	8	3	5
Pallor	9	11	5	7	4	4
Palpitations	22	27	17	18	5	9
Paraesthesia	3	6	1	3	2	3
Paraesthesia oral	1	1	1	1		
Paralysis		1				1
Pericarditis	1	1			1	1
Peripheral coldness	7	7	6	6	1	1
Peripheral nerve paresis	1	1			1	1
Pharyngitis bacterial	1	1			1	1
Photopsia	1	2	1	1		1
Physical deconditioning	2	2			2	2
Pneumothorax	2	2			2	2
Poor quality sleep	1	1	1	1		
Presyncope	19	27	18	25	1	2
Product administered at inappropriate site		1		1		
Productive cough	1	2		1	1	1
Pruritus	44	67	29	42	15	25
Pulse abnormal	2	2	1	1	1	1
Purpura	1	1	1	1		
Pyrexia	74	94	53	66	21	28
Radial pulse abnormal	1	2	1	1		1
Radial pulse increased		1				1
Rash	19	35	12	21	7	14
Rash erythematous	2	2	1	1	1	1

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic	1	1	1	1		
Rectal tenesmus	1	1			1	1
Respiratory alkalosis	1	1	1	1		
Respiratory disorder	3	4	1	1	2	3
Respiratory distress		3				3
Respiratory rate decreased	1	1	1	1		
Respiratory rate increased		1				1
Respiratory symptom		1				1
Rhinorrhoea	2	2	2	2		
Road traffic accident	1	1	1	1		
Seizure		1				1
Sensation of foreign body	1	1	1	1		
Sensory disturbance	2	2	2	2		
Shock	2	3			2	3
Shock symptom		1				1
Sinus bradycardia	1	1	1	1		
Sinus tachycardia	1	1	1	1		
Skin abrasion	1	1			1	1
Skin fissures	1	1	1	1		
Sleep disorder		1				1
Sleep disorder due to general medical condition, insomnia type	1	1			1	1
Slow response to stimuli	1	1			1	1
Sneezing	1	1			1	1
Somatic symptom disorder	1	1	1	1		
Somnolence		3		2		1
Speech disorder	1	1			1	1
Stenosis	1	1			1	1
Stomatitis	1	1	1	1		
Streptococcal infection	1	1			1	1
Stridor	1	1			1	1
Subarachnoid haemorrhage		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
2	2		1
1	1		2
1	3		3
		6	10
3	3	4	8
1	1	1	1
		1	1
			1
		1	1
2	4	1	3
1	1		1
2	2		
			1
1	1		
1	1		
		1	1
		1	2
2	2	2	2
1	1		
4	4	1	5
		2	3
1	1		
		1	2
19	24	8	13
		1	1
	2	2	2
1	1		
1	1		
10	13	4	6
2	4	1	2
2	2	1	2

Sudden hearing loss	1	1
Swelling	2	3
Swelling face	1	3
Swelling of eyelid	1	6
Syncope	6	10
Tachycardia	7	11
Tachypnoea	2	2
Temperature intolerance	1	1
Tension headache		1
Thirst	1	1
Throat irritation	3	7
Throat tightness	1	2
Tinnitus	2	2
Tongue disorder		1
Tongue oedema	1	1
Tonsillar disorder	1	1
Toxic skin eruption	1	1
Tracheal obstruction	1	2
Tracheal stenosis	2	2
Trance	1	1
Tremor	5	9
Type I hypersensitivity	2	3
Type IV hypersensitivity reaction	1	1
Unresponsive to stimuli	1	2
Urticaria	27	37
Vaccination complication	1	1
Vaccination site erythema	2	4
Vaccination site haemorrhage	1	1
Vaccination site joint discomfort	1	1
Vaccination site pain	14	19
Vaccination site pruritus	3	6
Vaccination site swelling	3	4

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria		1		1		
Vaccination site vesicles		1				1
Vertigo	2	3	1	1	1	2
Vision blurred	2	2	1	1	1	1
Visual impairment		1		1		
Vomiting	16	25	12	15	4	10
Wheezing	2	5		1	2	4
Yawning	1	1	1	1		
	1,123	1,649	613	789	510	860

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	5	9	3	5	2	4
Abdominal distension	1	1	1	1		
Abdominal pain	13	20	6	9	7	11
Abdominal pain lower		1				1
Abdominal pain upper	7	8	4	4	3	4
Abnormal sensation in eye	4	4	3	3	1	1
Acidosis		1				1
Acoustic neuroma	1	1			1	1
Acute febrile neutrophilic dermatosis		1				1
Affective disorder		1		1		
Agitation	1	1	1	1		
Allergy to vaccine	5	6	2	3	3	3
Altered state of consciousness		3				3
Amnesia	1	1			1	1
Anaemia	2	3	2	2		1
Anaesthesia dolorosa	1	1			1	1
Anaphylactic reaction	241	386	2	2	239	384
Anaphylactic shock	6	8			6	8
Anaphylactoid reaction	2	4			2	4
Angina pectoris		1				1
Angioedema	2	3			2	3
Anxiety	2	3	1	2	1	1
Aortic dissection	1	1			1	1
Aphonia	1	1	1	1		
Arrhythmia	3	5			3	5
Arthralgia	30	38	25	30	5	8
Arthritis	3	3	1	1	2	2
Asthenia	14	19	7	11	7	8
Asthenopia	2	2			2	2
Asthma	18	31	7	13	11	18
Atrial fibrillation		1				1
Atrial tachycardia	1	1			1	1

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	2	2	1	1	1	1
Back pain	9	10	6	6	3	4
Blepharospasm	3	3			3	3
Blood creatine phosphokinase increased		1		1		
Blood creatinine decreased		1		1		
Blood pressure decreased	8	11	4	6	4	5
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure fluctuation		1				1
Blood pressure immeasurable	1	1	1	1		
Blood pressure increased	53	73	28	34	25	39
Blood pressure systolic increased	2	4	1	2	1	2
Body temperature decreased	1	1	1	1		
Body temperature increased	5	7	5	7		
Bradycardia	3	3			3	3
Bronchial obstruction		1				1
Bronchiectasis	1	1			1	1
Bronchostenosis		1				1
Bundle branch block right		1		1		
Burning sensation	1	1			1	1
Cardiac tamponade	1	1			1	1
Cardio-respiratory arrest	3	3			3	3
Cardiovascular disorder	3	3	3	3		
Cellulitis	1	1			1	1
Cerebral congestion	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Chest discomfort	13	17	9	10	4	7
Chest pain	2	2	1	1	1	1
Chills	45	59	30	36	15	23
Choking	1	1			1	1
Choking sensation	1	1			1	1
Chromatopsia	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse	2	2			2	2
Cold sweat	11	17	5	7	6	10
Colitis ischaemic		1				1
Colitis ulcerative	1	1			1	1
Colour blindness		1		1		
Complex regional pain syndrome	1	1			1	1
Condition aggravated	2	2			2	2
Conjunctival haemorrhage	1	1			1	1
Conjunctival hyperaemia	8	11	5	7	3	4
Convulsions local	1	1			1	1
Cough	86	132	45	60	41	72
COVID-19		1		1		
C-reactive protein increased	1	1			1	1
Cutaneous symptom		2		1		1
Cyanosis	3	3	2	2	1	1
Daydreaming		1				1
Deafness	1	1			1	1
Deafness neurosensory	1	1			1	1
Death	1	1			1	1
Decreased appetite	5	8	1	2	4	6
Deep vein thrombosis	1	1			1	1
Dehydration		1				1
Delirium	1	1			1	1
Depressed level of consciousness	8	12			8	12
Dermatitis allergic	1	3	1	2		1
Dermatitis atopic	1	2	1	1		1
Diarrhoea	21	31	12	16	9	15
Diplopia	1	1			1	1
Discomfort	7	12	5	7	2	5
Disease recurrence	2	3	1	2	1	1
Dizziness	43	67	27	39	16	28
Dizziness postural	2	3	2	2		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug eruption	2	4	1	3	1	1
Drug hypersensitivity		1				1
Dry mouth	2	3	1	1	1	2
Dry skin	1	1	1	1		
Dry throat	1	1	1	1		
Dysgeusia	1	1	1	1		
Dyskinesia	1	1			1	1
Dyspepsia	1	1	1	1		
Dysphagia	2	2	1	1	1	1
Dysphonia	10	16	8	9	2	7
Dysphoria	4	5	2	2	2	3
Dyspnoea	61	98	24	30	37	68
Dysstasia		2		1		1
Ear discomfort	3	6	2	2	1	4
Ear pruritus	1	1			1	1
Eating disorder	2	2			2	2
Eczema	1	1	1	1		
Enteritis		1				1
Enterocolitis		1				1
Epilepsy	1	1			1	1
Epistaxis	1	2			1	2
Eructation		1		1		
Erythema	89	123	59	76	30	47
Extrasystoles	1	1	1	1		
Eye disorder	2	3			2	3
Eye haemorrhage	1	1			1	1
Eyelid function disorder	1	1			1	1
Eyelid irritation	1	1			1	1
Eyelid oedema	7	14	4	7	3	7
Eyelid ptosis	2	2			2	2
Eye movement disorder	1	1			1	1
Eye pain	2	3	1	1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pruritus	6	8	3	4	3	4
Eye swelling	1	2			1	2
Face oedema		2				2
Facial paralysis	8	9			8	9
Fall	1	3		1	1	2
Fatigue	7	9	7	8		1
Feeding disorder	2	3			2	3
Feeling abnormal	57	88	29	42	28	46
Feeling cold	5	9	3	5	2	4
Feeling hot	22	28	13	16	9	12
Feeling jittery	1	1			1	1
Fibrin degradation products increased	1	1			1	1
Flushing	9	15	3	5	6	10
Foreign body in throat		2				2
Gait disturbance	1	4		1	1	3
Gastrointestinal disorder	1	2			1	2
Gastrointestinal hypermotility		1				1
Gaze palsy	3	3			3	3
Generalised oedema	2	2	1	1	1	1
Grip strength decreased	3	3	2	2	1	1
Groin pain	1	1			1	1
Guillain-Barre syndrome	4	4			4	4
Haemarthrosis	1	1			1	1
Haematochezia	1	2			1	2
Haemoptysis		1				1
Haemorrhage subcutaneous	7	7			7	7
Hallucination, visual	1	1			1	1
Headache	106	147	75	102	31	45
Head discomfort	11	17	6	10	5	7
Head injury		1				1
Heart rate decreased	1	1	1	1		
Heart rate increased	10	17	7	11	3	6

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparesis	1	1			1	1
Hepatic function abnormal	3	3	1	1	2	2
Herpes zoster oticus	1	1			1	1
Hot flush	15	28	11	16	4	12
Hyperhidrosis	13	23	7	10	6	13
Hyperpyrexia	2	2			2	2
Hypersensitivity	17	24	10	13	7	11
Hypertension	9	14	3	3	6	11
Hypertensive emergency	1	1			1	1
Hyperventilation	7	10	3	4	4	6
Hypoacusis		1				1
Hypoaesthesia	49	61	27	35	22	26
Hypoaesthesia oral	4	10	4	9		1
Hypokalaemia	1	3			1	3
Hypokinesia	1	1	1	1		
Hypothermia	1	1			1	1
Hypotonia	1	1			1	1
Hypoxia		1				1
Iliad nerve paralysis	1	1			1	1
Ileus paralytic	1	1			1	1
Incorrect route of product administration	2	3	2	3		
Induration	1	1	1	1		
Infection	1	1	1	1		
Inflammation		1				1
Injected limb mobility decreased		1		1		
Injection site discomfort		1		1		
Injection site muscle weakness	1	1	1	1		
Injection site pain	1	1	1	1		
Injection site pruritus	1	1	1	1		
Injection site rash	1	1	1	1		
Injury		1				1
Insomnia	2	2	2	2		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Internal haemorrhage	11	11			11	11
Irregular breathing	1	1			1	1
Joint range of motion decreased	3	4	1	1	2	3
Joint swelling	2	2	2	2		
Kaposi's varicelliform eruption	1	1			1	1
Lacrimation increased	1	3	1	3		
Laryngeal discomfort	1	3	1	3		
Laryngeal obstruction		1				1
Laryngeal oedema	1	3			1	3
Larynx irritation	1	2	1	1		1
Lethargy	1	1			1	1
Leukopenia	1	1			1	1
Limb discomfort	3	7	3	7		
Lip oedema	2	2	1	1	1	1
Lip pruritus	1	2	1	1		1
Lip swelling	5	10	4	7	1	3
Listless	2	3	2	3		
Livedo reticularis	1	1	1	1		
Liver disorder	1	1			1	1
Local reaction	1	1	1	1		
Loss of consciousness	9	13			9	13
Loss of personal independence in daily activities		1				1
Lung infiltration		1				1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	6	7	4	5	2	2
Lymph node pain	2	2	1	1	1	1
Lymphocyte percentage decreased		1		1		
Lymphoedema	1	1			1	1
Malaise	101	129	75	89	26	40
Maternal exposure during pregnancy	1	1	1	1		
Memory impairment		1				1
Meningitis aseptic	1	3			1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	1	2		1	1	1
Mobility decreased	2	4	1	3	1	1
Monocyte percentage increased		1		1		
Motion sickness	1	1			1	1
Mouth swelling	1	2	1	2		
Movement disorder	2	3	1	2	1	1
Mucocutaneous disorder	1	1	1	1		
Mucosal disorder		1		1		
Muscle spasms	3	5		1	3	4
Muscle strain	1	1	1	1		
Muscle tightness	1	1	1	1		
Muscle twitching	1	1	1	1		
Muscular weakness	15	18	4	5	11	13
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort	2	2	1	1	1	1
Musculoskeletal stiffness	4	4	2	2	2	2
Myalgia	42	48	38	43	4	5
Mydriasis	1	1	1	1		
Myositis		2		1		1
Nasal congestion	1	3			1	3
Nasal mucosal disorder		1				1
Nasopharyngitis	2	2	2	2		
Nausea	97	130	55	63	42	67
Neck pain	4	4	2	2	2	2
Needle issue	1	1	1	1		
Nephrotic syndrome		1				1
Neurological symptom		1				1
Neuropathy peripheral	13	15	1	1	12	14
Neutrophilic dermatosis		1		1		
Night sweats		1		1		
Nystagmus		1				1
Ocular hyperaemia	9	13	6	8	3	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oculomucocutaneous syndrome	4	5			4	5
Odynophagia		1				1
Oedema	1	1			1	1
Oedema mouth		1				1
Oedema peripheral		1				1
Oral discomfort	6	7	6	6		1
Oral mucosa erosion	1	1	1	1		
Oral mucosal blistering	1	1	1	1		
Oral pain	1	1	1	1		
Oral pruritus	2	2	1	1	1	1
Organising pneumonia		1				1
Oropharyngeal discomfort	71	110	38	51	33	59
Oropharyngeal pain	12	16	10	12	2	4
Orthostatic hypotension		1				1
Oxygen saturation decreased	5	8	2	3	3	5
Oxygen saturation increased	1	1			1	1
Pain	14	17	10	13	4	4
Pain in extremity	23	29	19	25	4	4
Pallor	7	11	1	2	6	9
Palmar erythema		1		1		
Palpitations	56	82	33	45	23	37
Panic attack		1				1
Papule	1	1	1	1		
Paraesthesia	7	9	7	9		
Paraesthesia oral	4	4	3	3	1	1
Paralysis	1	1			1	1
Parosmia	1	2	1	2		
Parotitis	1	1	1	1		
Periorbital oedema	1	1			1	1
Periorbital swelling	1	1			1	1
Peripheral coldness	15	18	10	10	5	8
Peripheral swelling	4	4	4	4		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peritonitis	1	1			1	1
Petit mal epilepsy	1	2			1	2
Pharyngeal paraesthesia	1	1	1	1		
Pharyngeal stenosis	1	1			1	1
Pharyngeal swelling	4	6	2	3	2	3
Phlebitis	1	1	1	1		
Photopsia	2	2	2	2		
Physical deconditioning	2	6	2	5		1
Pigmentation disorder		1		1		
Piloerection	1	2			1	2
Platelet count decreased	2	2			2	2
Pneumonia	1	3			1	3
Pneumonia viral	1	1			1	1
Pollakiuria		1				1
Presyncope	19	28	12	17	7	11
Productive cough	1	3	1	1		2
Prolonged expiration		1		1		
Protein total decreased		1		1		
Pruritus	116	164	77	104	39	60
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism	1	1			1	1
Pyrexia	120	146	95	111	25	35
Radial pulse abnormal	2	2			2	2
Rash	74	98	47	59	27	39
Rash erythematous	4	6	3	4	1	2
Rash papular		1		1		
Raynaud's phenomenon	1	1	1	1		
Reaction to excipient		1				1
Reduced facial expression	1	1			1	1
Respiratory disorder	5	5	2	2	3	3
Respiratory distress		4		1		3
Respiratory rate increased	3	3			3	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory symptom	3	4	1	1	2	3
Retinal haemorrhage	1	1			1	1
Rhinorrhoea	6	11	5	7	1	4
Salivary hypersecretion	1	1			1	1
Scleritis	1	1			1	1
Seizure	12	14			12	14
Sensation of foreign body	3	3	2	2	1	1
Sensory disturbance	2	5	2	4		1
Serum sickness		1				1
Shoulder injury related to vaccine administration		1				1
Sialoadenitis	1	1			1	1
Sinus rhythm	1	1			1	1
Sinus tachycardia	1	2			1	2
Skin plaque	1	1			1	1
Sneezing		2		1		1
Somnolence	7	7	5	5	2	2
Spinal column injury	1	1	1	1		
Sputum discoloured	1	1	1	1		
Sputum purulent	2	2			2	2
Sputum retention	1	1	1	1		
Stenosis	1	1			1	1
Stress	2	2	2	2		
Stridor	2	4	1	2	1	2
Subarachnoid haemorrhage	3	3			3	3
Submaxillary gland enlargement	1	1	1	1		
Sudden hearing loss	2	4			2	4
Suffocation feeling	1	2		1	1	1
Sunburn	1	1	1	1		
Swelling	4	6	3	5	1	1
Swelling face	3	5	1	1	2	4
Swelling of eyelid	3	5	2	2	1	3
Sympathicotonia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	2	4			2	4
Tachycardia	11	20	4	6	7	14
Tachypnoea	1	5	1	3		2
Taste disorder	1	1	1	1		
Tension	1	1	1	1		
Tetany	1	1			1	1
Thirst	3	5	2	3	1	2
Throat irritation	14	21	12	16	2	5
Throat tightness	14	18	6	6	8	12
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis superficial	1	1	1	1		
Thrombosis	1	1			1	1
Tinnitus		2				2
Toxic skin eruption	3	3			3	3
Tremor	10	14	3	4	7	10
Trigeminal nerve disorder	2	3			2	3
Trigeminal neuralgia	1	1	1	1		
Type I hypersensitivity	3	4			3	4
Underdose	1	1	1	1		
Upper airway obstruction	1	1			1	1
Urinary retention		1				1
Urticaria	75	106	52	71	23	35
Vaccination complication	1	1	1	1		
Vaccination site bruising		1		1		
Vaccination site coldness	1	1	1	1		
Vaccination site erythema	13	17	11	13	2	4
Vaccination site haemorrhage	3	3	2	2	1	1
Vaccination site hypoaesthesia	3	5	2	4	1	1
Vaccination site induration	1	2	1	2		
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	4	4	2	2	2	2
Vaccination site pain	67	88	58	76	9	12

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	9	13	7	11	2	2
Vaccination site rash	2	3	2	3		
Vaccination site reaction	1	2	1	2		
Vaccination site swelling	9	10	7	7	2	3
Vaccination site urticaria	1	4	1	3		1
Vaccination site warmth	2	3			2	3
Vascular injury	1	1	1	1		
Vasculitis	1	1	1	1		
Vasodilatation	1	1	1	1		
Vasospasm	1	1			1	1
Ventricular extrasystoles	3	3	2	2	1	1
Vertebral artery dissection	1	1			1	1
Vertigo		3				3
Vestibular neuronitis		1				1
Viral infection	1	1			1	1
Vision blurred	2	2	2	2		
Visual impairment	3	6	2	3	1	3
Vlth nerve disorder		1				1
Vitreous floaters	1	1	1	1		
Vomiting	39	56	20	25	19	31
Wheezing	8	17	2	3	6	14
White blood cell count decreased	1	1			1	1
White blood cell count increased		1				1
Wrong technique in product usage process	1	1			1	1
Yawning	3	3	1	1	2	2
	2,734	3,916	1464	1913	1270	2003

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	5	1	2	3	3
Abdominal pain	5	6	2	2	3	4
Abdominal pain lower	1	2		1	1	1
Abdominal pain upper	2	2	1	1	1	1
Abdominal symptom	1	1			1	1
Abnormal sensation in eye		1				1
Acute lymphocytic leukaemia	1	1			1	1
Acute respiratory distress syndrome	2	2			2	2
Administration site movement impairment	1	1	1	1		
Allergy to vaccine	3	4	3	4		
Altered state of consciousness	2	2			2	2
Anaphylactic reaction	95	145			95	145
Anaphylactic shock	2	3			2	3
Anaphylactoid reaction	2	3			2	3
Aneurysm	1	1			1	1
Angina unstable		1				1
Anxiety	1	1	1	1		
Aphasia	1	1			1	1
Apnoea		1				1
Apraxia		1				1
Arrhythmia	2	2			2	2
Arthralgia	10	10	4	4	6	6
Ascites	1	1			1	1
Asthenia	2	3	2	2		1
Asthma	6	12	1	3	5	9
Autonomic neuropathy	1	1			1	1
Back pain	2	2	2	2		
Blister	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure decreased	4	4	3	3	1	1
Blood pressure increased	21	33	10	15	11	18
Blood pressure systolic increased	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature abnormal		1				
Bradycardia		1				1
Breath sounds abnormal		1				1
Bronchostenosis	1	1			1	1
Burning sensation		1		1		
Cardiac discomfort		1		1		
Cardiac failure	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cellulitis	3	3			3	3
Cerebral haemorrhage	2	2			2	2
Cerebral infarction	2	3			2	3
Cheilitis	1	1	1	1		
Chest discomfort	2	5	1	1	1	4
Chest pain	1	2	1	1		1
Chills	13	15	9	10	4	5
Cholinergic syndrome	1	1			1	1
Cold sweat	5	7	3	3	2	4
Colitis	1	1			1	1
Confusional state	1	1	1	1		
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia	2	3	2	2		1
Cough	20	35	6	9	14	26
Decreased appetite	3	3	1	1	2	2
Decreased vibratory sense	2	2			2	2
Deep vein thrombosis	1	1			1	1
Dehydration	2	2	1	1	1	1
Depressed level of consciousness	2	4			2	4
Dermatitis	1	1	1	1		
Dermatitis allergic	1	1	1	1		
Dermatitis atopic	1	1	1	1		
Diarrhoea	10	11	6	6	4	5
Diplopia	1	1	1	1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
			1
		1	1
	1		
	1		
		1	1
		1	1
		3	3
		2	2
		2	3
1	1		
1	1	1	4
1	1		1
9	10	4	5
		1	1
3	3	2	4
		1	1
1	1		
			1
2	2		1
6	9	14	26
1	1	2	2
		2	2
		1	1
1	1	1	1
		2	4
1	1		
1	1		
1	1		
6	6	4	5
1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2	1	1
		1	1
		2	2
		1	1
12	12	3	4
1	2	1	1
		1	1
2	2		1
		1	1
1	1		
1	1		
		2	2
1	1		
		1	1
1	1	5	7
			1
11	12	16	22
1	1		
		1	1
1	1		1
		1	1
1	1		
		1	2
1	1	1	1
		3	3
	1		
		2	2

Discomfort	3	3
Disseminated intravascular coagulation	1	1
Diverticulitis	2	2
Diverticulum	1	1
Dizziness	15	16
Dizziness postural	2	3
Drowning	1	1
Drug eruption	2	3
Drug hypersensitivity	1	1
Dry skin	1	1
Dry throat	1	1
Dysaesthesia	2	2
Dyslalia	1	1
Dyspepsia	1	1
Dysphonia	6	8
Dysphoria		1
Dyspnoea	27	34
Ear discomfort	1	1
Ear swelling	1	1
Eczema	1	2
Embolism venous	1	1
Epigastric discomfort	1	1
Erythema	37	49
Eye disorder		1
Eyelid oedema	2	2
Eye oedema		1
Eye pruritus	1	1
Face oedema	1	2
Facial pain	2	2
Facial paralysis	3	3
Faeces soft		1
Fall	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	1	2	1	1		1
Feeling abnormal	23	28	14	15	9	13
Feeling cold	2	5			2	5
Feeling hot	9	12	6	9	3	3
Flushing	4	8	4	7		1
Gait disturbance	3	3	1	1	2	2
Gastroenteritis bacterial	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal hypermotility		1				1
Gastrointestinal motility disorder	1	1	1	1		
Gastrointestinal oedema	1	1			1	1
Grunting	1	1			1	1
Haematochezia	2	2			2	2
Haemorrhage	1	1			1	1
Headache	34	45	22	27	12	18
Head discomfort	5	7	3	4	2	3
Heart rate decreased	1	1	1	1		
Heart rate increased	4	7	3	6	1	1
Hemiplegia	1	1			1	1
Hepatic function abnormal	2	2			2	2
Herpes zoster	1	1			1	1
Herpes zoster oticus	1	1			1	1
Hot flush	7	8	5	6	2	2
Hyperaemia	1	1			1	1
Hyperaesthesia	1	1			1	1
Hyperhidrosis	7	10	3	5	4	5
Hyperreflexia		1		1		
Hypersensitivity	5	10	3	3	2	7
Hypertension	8	11	2	2	6	9
Hypertensive emergency	1	1			1	1
Hypertensive urgency		1				1
Hyperthermia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertonia	1	1	1	1		
Hypoaesthesia	18	22	12	16	6	6
Hypoaesthesia oral	6	7	4	5	2	2
Hypothermia	1	1			1	1
Hypoventilation		1				1
Hypoxia	1	1			1	1
Induration	1	1	1	1		
Inflammation		1		1		
Injected limb mobility decreased	1	2		1	1	1
Injection site swelling		1		1		
Intracranial aneurysm	1	1			1	1
Joint range of motion decreased	1	1			1	1
Lacrimation increased	3	3	1	1	2	2
Lacunar infarction	1	1			1	1
Laryngeal discomfort	1	1			1	1
Laryngeal oedema	3	3			3	3
Larynx irritation	1	1			1	1
Lid margin discharge	1	1	1	1		
Lip erythema	1	1			1	1
Lip swelling	2	3	1	2	1	1
Loss of consciousness	4	4			4	4
Malaise	29	38	21	28	8	10
Melaena	1	1			1	1
Meningitis aseptic		1				1
Mobility decreased	1	1			1	1
Mouth swelling	2	2	1	1	1	1
Muscle spasms	2	2	2	2		
Muscular weakness	2	4	1	2	1	2
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness	2	2	2	2		
Myalgia	6	11	5	10	1	1
Myocardial infarction	1	1			1	1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal congestion	1	1			1	1
Nasal obstruction	1	3	1	1		2
Nasal pruritus		1				1
Nausea	20	31	13	19	7	12
Neck pain	2	2			2	2
Neuritis	1	1	1	1		
Neuropathy peripheral	3	3			3	3
Obstructive airways disorder	1	1			1	1
Ocular hyperaemia	4	5	3	4	1	1
Oculomucocutaneous syndrome	3	3			3	3
Oedema	2	2			2	2
Oedema peripheral	1	2		1	1	1
Oral discomfort	1	1	1	1		
Oral mucosa haematoma	1	1	1	1		
Oral pruritus	3	3	1	1	2	2
Oropharyngeal discomfort	19	27	10	11	9	16
Oropharyngeal pain	6	10	5	8	1	2
Oxygen saturation decreased	4	6	3	3	1	3
Pain	8	9	5	6	3	3
Pain in extremity	3	5	3	5		
Pallor	1	1			1	1
Palpitations	25	33	15	18	10	15
Paraesthesia	3	4	1	2	2	2
Paraesthesia oral	1	3	1	2		1
Periorbital swelling	1	1			1	1
Peripheral circulatory failure	1	1			1	1
Peripheral coldness	3	3	2	2	1	1
Peripheral swelling	2	3	2	3		
Pharyngeal disorder	1	1			1	1
Pharyngeal erythema	1	1	1	1		
Pharyngeal paraesthesia	1	1	1	1		
Pharyngeal swelling	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pollakiuria	1	1			1	1
Post thrombotic syndrome	1	1			1	1
Postural tremor		1		1		
Presyncope	3	3	2	2	1	1
Prostatitis	1	1			1	1
Prostatomegaly	1	1			1	1
Pruritus	34	55	23	32	11	23
Pulse abnormal	1	1			1	1
Puncture site pain	1	1	1	1		
Pyrexia	35	43	24	30	11	13
Rash	26	38	16	22	10	16
Rash erythematous	2	2	1	1	1	1
Reaction to excipient		1				1
Respiratory disorder	1	1			1	1
Respiratory distress	1	2			1	2
Respiratory symptom		1				1
Rhinorrhoea	6	8	3	4	3	4
Seizure	2	3			2	3
Sensation of foreign body	2	2	2	2		
Sensory disturbance	1	1			1	1
Sinus rhythm	1	1			1	1
Sinus tachycardia	1	1	1	1		
Sitting disability	1	1	1	1		
Sneezing	2	2	1	1	1	1
Soft tissue atrophy	1	1			1	1
Somatic symptom disorder		1		1		
Somnolence	1	2	1	1		1
Speech disorder	1	1	1	1		
Speech sound disorder	1	1	1	1		
Stress	1	1			1	1
Subarachnoid haemorrhage	2	3			2	3
Sudden hearing loss	2	3			2	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	4	4	1	1	3	3
Swelling face	4	6	3	5	1	1
Swelling of eyelid	2	4	2	3		1
Tachycardia	2	4	1	2	1	2
Tachypnoea	2	2	1	1	1	1
Tenderness	1	1			1	1
Thirst		1				1
Throat irritation	2	7	1	1	1	6
Throat tightness	2	5	2	4		1
Thrombosis	1	1			1	1
Tinnitus	1	1	1	1		
Toothache	1	1	1	1		
Tremor		1		1		
Type I hypersensitivity	1	1			1	1
Underdose		1		1		
Urinary retention		1				1
Urticaria	32	53	23	33	9	20
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema		1				1
Vaccination site movement impairment	2	3	1	2	1	1
Vaccination site necrosis	2	2			2	2
Vaccination site pain	29	35	26	32	3	3
Vaccination site pruritus	2	3	2	3		
Vaccination site rash	2	2	2	2		
Vaccination site swelling	5	5	3	3	2	2
Vaccination site warmth	1	1	1	1		
Vagus nerve disorder		1				1
Ventricular fibrillation	1	1			1	1
Ventricular hypokinesia	1	1			1	1
Vertebral artery dissection	1	1			1	1
Vertigo	1	1			1	1
Vocal cord disorder	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	14	18	7	10	7	8
Wheezing	7	7	1	1	6	6
White blood cell count increased	1	1	1	1		
	985	1,354	483	626	502	728

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anaphylactic reaction	12	16			12	16
Asthma	1	1			1	1
Back pain	1	1	1	1		
Bilirubinuria	1	1			1	1
Blood pressure decreased	2	3		1	2	2
Blood pressure increased	1	1			1	1
Brain stem haemorrhage	1	1			1	1
Brain stem infarction	1	1			1	1
Bronchostenosis	1	1			1	1
Cerebral haemorrhage	2	2			2	2
Cerebral infarction	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	2	2	1	1	1	1
Chills	1	1	1	1		
Cold sweat	1	1			1	1
Cough	4	4			4	4
Dermatitis allergic	1	1	1	1		
Disturbance in attention	1	1			1	1
Dizziness	2	2	1	1	1	1
Dysphonia	1	1			1	1
Dyspnoea	3	4			3	4
Erythema	4	5	2	3	2	2
Feeding disorder	1	1			1	1
Feeling abnormal	3	4	2	2	1	2
Flushing	1	1			1	1
Gait disturbance	1	1			1	1
Guillain-Barre syndrome	1	1			1	1
Headache	1	1			1	1
Head discomfort	1	1	1	1		
Hot flush	2	2	1	1	1	1
Hypoaesthesia		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Infective spondylitis	1	1			1	1
Interstitial lung disease	1	1			1	1
Malaise	1	1			1	1
Musculoskeletal discomfort	1	1	1	1		
Myalgia	3	4	2	3	1	1
Myocardial infarction	1	1			1	1
Nasal obstruction	1	1			1	1
Nausea	3	4		1	3	3
Nephrotic syndrome	1	1			1	1
Off label use	1	1	1	1		
Oropharyngeal discomfort	4	4	3	3	1	1
Oropharyngeal pain		1				1
Oxygen saturation decreased	1	1			1	1
Palpitations	1	1	1	1		
Pericarditis	1	1			1	1
Periorbital swelling	1	1	1	1		
Pharyngeal stenosis	1	1			1	1
Productive cough	1	1	1	1		
Product leakage	1	1	1	1		
Protein urine present	1	1	1	1		
Pruritus	4	5	2	3	2	2
Pyrexia	4	4	1	1	3	3
Sensation of blood flow	1	1			1	1
Sepsis	1	1			1	1
Somnolence		1				1
Swelling face	1	1	1	1		
Syncope		1				1
Tachycardia	1	1	1	1		
Tachypnoea	1	1	1	1		
Throat tightness	2	2			2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper gastrointestinal haemorrhage		1				1
Urine abnormality	1	1			1	1
Urticaria	3	3	1	1	2	2
Vaccination site induration	1	1	1	1		
Vaccination site pain	5	6	5	6		
Vertigo	4	4	1	1	3	3
Vision blurred		1		1		
Vomiting	1	1			1	1
Wheezing	1	1			1	1
Yawning		1		1		
	115	135	39	48	76	87

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Anal incontinence	1	1	1	1		
Anaphylactic reaction	5	5			5	5
Asthma	1	1			1	1
Axillary pain	1	1	1	1		
Balance disorder	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood pressure increased	1	1			1	1
Cardiac death	1	1			1	1
Cardiac failure	2	2			2	2
Cardiac failure acute	1	1			1	1
Cardio-respiratory arrest	2	2			2	2
Cerebral haemorrhage	1	1			1	1
Cold sweat	1	1			1	1
Depressed level of consciousness	1	1	1	1		
Dyspnoea	1	1			1	1
Eczema	1	1	1	1		
Flushing	1	1			1	1
Hemiplegia	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	1	1	1	1		
Marasmus	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pruritus	1	1	1	1		
Pupils unequal	1	1	1	1		
Pyrexia	1	1	1	1		
Rash	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wheezing	1	1			1	1
	39	39	14	14	25	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	3	3	2	2	1	1
Acute respiratory distress syndrome	1	1			1	1
Anaemia	1	1	1	1		
Anaphylactic reaction	20	33			20	33
Anaphylactic shock	4	4			4	4
Anaphylactoid reaction		1				1
Anxiety	2	2			2	2
Aortic dissection	1	1			1	1
Arrhythmia	2	2			2	2
Arthralgia	2	2	2	2		
Arthritis reactive	1	1			1	1
Asthenia	2	2	1	1	1	1
Asthma	5	6	2	3	3	3
Asymptomatic COVID-19	2	2			2	2
Back pain	1	1	1	1		
Blood pressure decreased		1		1		
Blood pressure increased	6	7	4	4	2	3
Bronchostenosis	1	1			1	1
Capillaritis	1	1	1	1		
Cardiac failure		1				1
Cellulitis	1	1			1	1
Cerebral infarction	1	1			1	1
Chest discomfort	1	1	1	1		
Chills	7	7	6	6	1	1
Cold sweat	1	1			1	1
Condition aggravated	1	1			1	1
Cough	8	9	4	4	4	5
COVID-19	6	7	1	1	5	6
Deafness	1	1			1	1
Death	1	1			1	1
Decreased appetite	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	3	2	2
2	2	1	2
	1		
	1		
		6	7
			1
		1	1
		1	1
2	2	3	4
1	4		
8	11	2	4
1	1		
		1	1
1	1		
		1	1
6	12		
		1	1
		1	6
2	2	1	2
		1	1
		1	1
		1	1
		1	1
15	18	5	5
1	1		
1	2		
1	1	1	1
3	3	1	2
		2	2
1	3	1	2

Dermatitis allergic		1
Diarrhoea	2	5
Dizziness	3	4
Drug eruption		1
Drug hypersensitivity		1
Drug ineffective	6	7
Dysgeusia		1
Dyspepsia	1	1
Dysphagia	1	1
Dyspnoea	5	6
Eczema	1	4
Erythema	10	15
Erythema ab igne	1	1
Erythema multiforme	1	1
Eyelid oedema	1	1
Face oedema	1	1
Fatigue	1	1
Feeling abnormal	6	12
Feeling cold	1	1
Feeling hot	3	7
Flushing	3	4
Gastrointestinal disorder	1	1
Gastrointestinal hypermotility	1	1
General physical health deterioration	1	1
Haemorrhage subcutaneous	1	1
Headache	20	23
Hepatic function abnormal	1	1
HIV antibody positive	1	2
Hot flush	2	2
Hyperhidrosis	4	5
Hyperpyrexia	2	2
Hypersensitivity	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthermia	1	1			1	1
Hyperventilation	1	1			1	1
Hypoaesthesia	3	4	2	3	1	1
Hypoaesthesia oral	1	2	1	1		1
Hypothyroidism	1	1			1	1
Incorrect dose administered	2	2	2	2		
Incorrect route of product administration	1	1	1	1		
Injected limb mobility decreased	1	2	1	2		
Internal haemorrhage	1	1			1	1
Joint range of motion decreased	2	2	2	2		
Laryngeal discomfort	1	1	1	1		
Limb discomfort	1	2	1	2		
Lymphadenitis bacterial		1				1
Lymphadenopathy	1	1	1	1		
Lymphoma	1	1			1	1
Malaise	24	27	23	26	1	1
Meningitis	2	2			2	2
Meningitis aseptic		1				1
Mobility decreased		1		1		
Motion sickness	1	1	1	1		
Muscle tightness	1	1	1	1		
Muscular weakness		1		1		
Myalgia	16	23	16	23		
Myocarditis	1	1			1	1
Nausea	10	13	4	7	6	6
Needle issue	1	1	1	1		
Ocular hyperaemia	1	1	1	1		
Oedema mucosal	1	1			1	1
Optic atrophy	1	1			1	1
Oral discomfort		1				1
Oropharyngeal discomfort	6	7	4	4	2	3
Oropharyngeal pain	1	4	1	4		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
4	6	1	1
	2		
			1
2	2	2	2
1	1		
	1		
	2		1
		1	1
		1	1
		1	1
		1	1
2	2		
	1		
	2		
4	7	7	7
1	1		
25	42	3	4
6	12	1	4
1	1		
			1
		1	1
1	1		
1	1		
		3	3
			1
	1		
1	1	1	1
	1		
		1	2
		1	1
1	3		

Overdose

Pain 5 7

Pain in extremity 2

Pallor 1

Palpitations 4 4

Paraesthesia oral 1 1

Parotitis 1 1

Periorbital swelling 3

Pharyngeal paraesthesia 1 1

Pharyngeal swelling 1 1

Physical deconditioning 1 1

Platelet count decreased 1 1

Presyncope 2 2

Product leakage 1

Product preparation issue 2

Pruritus 11 14

Purpura 1 1

Pyrexia 28 46

Rash 7 16

Rash erythematous 1 1

Respiratory distress 1

Retinal haemorrhage 1 1

Rhinorrhoea 1 1

Seasonal allergy 1 1

Seizure 3 3

Shock 1

Skin disorder 1

Somnolence 2 2

Stomatitis 1

Sudden hearing loss 1 2

Suspected COVID-19 1 1

Swelling 1 3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling face	1	4			1	4
Tachycardia	4	4	4	4		
Thirst	1	1	1	1		
Throat irritation	3	3	1	1	2	2
Thrombosis	1	1			1	1
Tremor	1	2			1	2
Type I hypersensitivity	1	1			1	1
Underdose		3		3		
Urticaria	12	19	10	16	2	3
Vaccination failure	1	1			1	1
Vaccination site erythema	1	3	1	1		2
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	17	29	16	28	1	1
Vaccination site paraesthesia	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	2	5	2	5		
Vaccination site urticaria		1		1		
Vasodilatation	1	1	1	1		
Vertigo	1	1	1	1		
Visual field defect	1	1	1	1		
Vomiting	7	7	4	4	3	3
	385	551	230	344	155	207

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**JORDAN**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough		1		1
Dysgeusia		1		1
Fatigue		2		2
Headache		1		1
Influenza like illness		1		1
Injection site pain		1		1
Muscle spasms		1		1
Myalgia		1		1
Pain in extremity		1		1
Swelling face		1		1
Vaccination site pain		1		1
		12		12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia		1		1		
Asthenia	1	1			1	1
Blood pressure increased		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Confusional state	1	1			1	1
Erythema		1				1
Influenza		1		1		
Myalgia		1		1		
Obstructive airways disorder		1				1
Swelling		1				1
Syncope		1				1
	4	12		3	4	9

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gangrene		1				1
Haematemesis		1				1
Mesenteric vein thrombosis		1				1
Pain		2		2		
Pain in extremity		2		2		
Weight decreased		1		1		
		8		5		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal pain		1		1
Condition aggravated		1		1
COVID-19		1		1
COVID-19 pneumonia		1		1
Hypoxia		1		1
Increased bronchial secretion		1		1
Increased viscosity of upper respiratory secretion		1		1
Lung disorder		1		1
Respiratory failure		1		1
Sputum retention		1		1
Tachypnoea		1		1
Vaccination failure		1		1
		12		12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1		1		
Chills		1		1		
COVID-19		2		1		1
Dizziness		1		1		
Dyspnoea		1				1
Fatigue		1		1		
Loss of consciousness		1				1
Myalgia		1		1		
Pneumonia		1				1
Pyrexia		1		1		
Syncope		1				1
Tongue disorder		1		1		
Vaccination site pain		1		1		
		14		9		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**KOREA, REPUBLIC OF (SOUTH KOREA)**

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Joint swelling	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**KUWAIT**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
Lymphocyte percentage increased		1		1
Mean cell haemoglobin concentration increased		1		1
Polyp		1		1
Pyrexia		1		1
Splenomegaly		1		1
		6		6

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Pain	1	1	1	1
Pain in extremity		1		1
Peripheral swelling		1		1
Tenderness		1		1
	3	6	3	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Lymphadenopathy		1		1
Myalgia		1		1
Neck pain		1		1
Pyrexia		1		1
Swelling		1		1
Tenderness		1		1
Vaccination site pain		1		1
Vaccination site swelling		1		1
		9		9

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma		1		1
COVID-19	1	2	1	2
Fatigue		1		1
	1	4	1	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**LATVIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abortion missed	1	1			1	1
Anosmia	1	1			1	1
Arrhythmia		1				1
Arthralgia		18		15		3
Asthenia		10		9		1
Asthma		1		1		
Bacille Calmette-Guerin scar reactivation		1		1		
Back pain		2		2		
Blood pressure increased		1				1
Body temperature increased	1	12	1	12		
Bone pain		1		1		
Burning sensation		2				2
Chest pain		1		1		
Chills		22		22		
Condition aggravated		1		1		
Confusional state		1		1		
Conjunctival haemorrhage		1				1
Cough		2		2		
COVID-19	1	3			1	3
C-reactive protein increased		2		2		
Deafness		1				1
Decreased appetite		1		1		
Depressed mood		1		1		
Disturbance in attention		3		1		2
Dizziness	1	7		5	1	2
Drug ineffective		2				2
Dyspnoea		3		1		2
Dyspnoea exertional		1		1		
Erythema		2		1		1
Exposure during pregnancy		1		1		
Eye pain		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	1	25		20	1	5
Headache		32		29		3
Hot flush		1		1		
Hyperaesthesia		2		1		1
Hyperhidrosis		2		2		
Hypertension		1		1		
Hypoaesthesia		1				1
Increased appetite		1		1		
Influenza like illness		1		1		
Lymphadenitis		1				1
Lymphadenopathy		10		8		2
Lymph node pain		1				1
Mental impairment		1				1
Muscle spasms		1		1		
Muscular weakness		3		1		2
Musculoskeletal stiffness		1		1		
Myalgia	1	20	1	18		2
Nasal congestion		1		1		
Nausea		8		8		
Neck pain		3		2		1
Neuralgia		1				1
Pain		2		1		1
Pain in extremity		2		1		1
Palpitations		1				1
Paraesthesia		2		1		1
Peripheral sensory neuropathy		1				1
Photophobia		1				1
Pruritus		1				1
Pyrexia		29		25		4
Rash		1		1		
Rash pruritic		2		2		
Rhinorrhoea	1	2		1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder		1		1		
Somnolence		2		2		
Tachycardia		4				4
Throat irritation		2		2		
Vaccination failure	1	1			1	1
Vaccination site erythema		3		2		1
Vaccination site haematoma		1				1
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation	1	1	1	1		
Vaccination site mass		1				1
Vaccination site oedema		3		2		1
Vaccination site pain	1	34	1	32		2
Vaccination site pruritus		1				1
Vaccination site rash		1				1
Vaccination site warmth		1				1
Vomiting		2		2		
	11	330	4	258	7	72

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Abdominal pain upper		1				1
Abnormal sensation in eye		1		1		
Anaphylactic reaction		1				1
Angina pectoris		1				1
Anxiety		1				1
Arthralgia		23		23		
Asthenia		11		9		2
Asthma		1				1
Blepharitis		1		1		
Blood pressure increased		1				1
Body temperature increased	1	24	1	23		1
Bone pain		1		1		
Bradycardia		1				1
Bundle branch block left		1				1
Chest pain		1		1		
Chills		26		26		
Cold sweat		2		1		1
Cough		4		4		
COVID-19	2	3			2	3
C-reactive protein increased		1		1		
Decreased appetite		4		4		
Diarrhoea		5		5		
Disease recurrence		1				1
Disturbance in attention		3		2		1
Dizziness		8		6		2
Drug ineffective		1				1
Dry mouth		2		1		1
Dry skin		1		1		
Dysgeusia		4		2		2
Dysphonia		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea		3
Ear pain		2
Exposure during pregnancy		1
Eye pain		7
Fatigue		33
Feeling hot		2
Generalised tonic-clonic seizure		1
Headache		36
Head discomfort		1
Heart rate increased		1
Hot flush		2
Hyperaesthesia		5
Hyperhidrosis		2
Inappropriate schedule of product administration		1
Initial insomnia		2
Joint stiffness		1
Lacrimation increased	1	1
Loss of proprioception		1
Lymphadenopathy		8
Lymph node pain		3
Migraine		1
Muscle spasms		1
Muscular weakness		1
Musculoskeletal discomfort		2
Musculoskeletal stiffness		1
Myalgia		26
Nasal congestion		1
Nasal oedema		1
Nausea		10
Neuralgia		2
Neutrophil count increased		1
Off label use		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		1
	1		1
			1
	7		
	31		2
	2		
			1
	32		4
	1		
	1		
	1		1
	3		2
	2		
	1		
	2		
			1
1	1		
			1
	7		1
	1		2
			1
			1
	2		
			1
	24		2
	1		
	1		
	9		1
			2
	1		
	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		1
	1		
	2		1
	1		
			2
			3
			2
	1		1
	1		
	2		
	1		
	1		1
	1		
	1		
	1		
	1		2
	29		8
	1		
	1		
	1		
	1		1
	1		
	3		2
	1		1
	2		
	1		1
	1		
	1		1
	2		
	1		
	1		1
	2		2

Oropharyngeal pain

3

Pain

1

Pain in extremity

3

Palatal swelling

1

Palpitations

2

Paraesthesia

3

Paraesthesia oral

2

Peripheral coldness

2

Pharyngeal oedema

1

Photophobia

2

Polymenorrhoea

1

Presyncope

1

Product use issue

1

Pruritus

1

Pulse volume decreased

1

Purpura

2

Pyrexia

37

Rash

1

Rash macular

1

Rash pruritic

1

Respiratory distress

1

Restless legs syndrome

1

Sleep disorder

1

Somnolence

5

Syncope

1

Tachycardia

3

Thirst

1

Throat irritation

2

Tongue spasm

1

Toothache

1

Tunnel vision

1

Vaccination failure

2

2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema		7		6		1
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		1				1
Vaccination site oedema		4		3		1
Vaccination site pain		30		28		2
Vaccination site pruritus		2		2		
Vaccination site rash		1				1
Vaccination site reaction		2		2		
Vaccination site swelling		1		1		
Vaccination site warmth		3		3		
Vertigo		2		2		
Vision blurred		1				1
Vomiting		5		4		1
	6	450	2	360	4	90

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1				1
Arthralgia		7		6		1
Asthenia		3		3		
Atrial fibrillation		1				1
Blood pressure increased		1		1		
Body temperature decreased		1		1		
Body temperature increased		12		12		
Burning sensation		1				1
Chest discomfort	1	1			1	1
Chills		6		6		
Coordination abnormal		1		1		
Costovertebral angle tenderness		1		1		
Cough	1	2	1	2		
COVID-19		3		3		
Decreased appetite		2		2		
Diplopia		1				1
Disease recurrence		1				1
Disturbance in attention		2		2		
Dizziness		3		3		
Dyspnoea exertional		1		1		
Epistaxis		1				1
Extrasystoles		1				1
Eye pain		2		2		
Face oedema		1				1
Facial paralysis		1				1
Facial paresis		2				2
Fatigue		8		8		
Gait disturbance		1		1		
Generalised oedema		1				1
Headache		7		6		1
Heart rate increased		1				1
Herpes zoster		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis		2		2		
Hypertension		1				1
Hypertensive crisis		2				2
Hypoacusis		1		1		
Illness		2		2		
Initial insomnia		1		1		
Insomnia		1		1		
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Lacrimation increased		1				1
Lymphadenitis		1		1		
Lymphadenopathy		3		2		1
Lymph node pain		1		1		
Malaise		2		2		
Muscular weakness		1		1		
Myalgia		8		8		
Nausea		5		5		
Night sweats		1		1		
Oedema mucosal	1	1			1	1
Oedema peripheral		1				1
Oropharyngeal pain		1		1		
Pain	1	1	1	1		
Paraesthesia		2				2
Peripheral swelling	1	1	1	1		
Pruritus		1				1
Pyrexia		10		9		1
Rash	1	2	1	1		1
Skin tightness		1				1
Sleep disorder due to general medical condition, insomnia type		1		1		
Somatic dysfunction		1				1
Somnolence		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Stomatitis		1				1	
Syncope		1				1	
Thirst		1		1			
Transient ischaemic attack	1	1			1	1	
Urticaria	1	1	1	1			
Vaccination site discolouration		1		1			
Vaccination site erythema		1		1			
Vaccination site oedema		1		1			
Vaccination site pain		7		7			
Vaccination site pruritus		1		1			
Vaccination site warmth		1		1			
Vasculitic rash	1	1	1	1			
Vertebrobasilar stroke	1	1			1	1	
Vertigo	1	2	1	2			
	11	159	7	124	4	35	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Arrhythmia		1				1
Arthralgia		2		2		
Asthenia		1				1
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased		1		1		
Condition aggravated		1				1
Diarrhoea		1		1		
Dizziness		2		2		
Ear discomfort		1				1
Fatigue		3		2		1
Gait disturbance		1		1		
Glomerular filtration rate decreased		1		1		
Headache		1		1		
Hyperhidrosis		1		1		
Hypertension		1		1		
Hypotension		1		1		
Hypothyroidism		1				1
Insomnia		1				1
Myalgia		3		3		
Nausea		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Pyrexia		3		2		1
Rhabdomyolysis		1				1
Skin burning sensation		1				1
Vaccination site erythema		1		1		
Vaccination site pain		2		2		
		37		26		11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Body temperature increased		1		1		
Bradyphrenia		1		1		
Burning sensation		1		1		
Depression		1		1		
Dizziness		1		1		
Eye pain		1		1		
Fatigue		1		1		
Headache		3		2		1
Lymphadenopathy		1		1		
Lymph node pain		1		1		
Malaise		1		1		
Migraine		1		1		
Myalgia		1		1		
Nasopharyngitis		1		1		
Nausea		1		1		
Oral discomfort		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		2		2		
Pyrexia		2		1		1
SARS-CoV-2 test positive		1				1
Upper respiratory tract congestion		1		1		
		26		23		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LEBANON**

Age Range

**18 - 30 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Erythema	1	1	1	1
Pruritus	1	1	1	1
Throat tightness	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Chills		1		1		
Dermatitis allergic		1		1		
Dyspnoea	1	1	1	1		
Flushing	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity		1				1
Hypertension	1	1			1	1
Hypoaesthesia	1	1	1	1		
Incorrect route of product administration		1		1		
Malaise		1		1		
Oropharyngeal pain		1		1		
Panic attack	1	1	1	1		
Paraesthesia		2		2		
Pyrexia		2		2		
Rash		1				1
Tachycardia	1	1	1	1		
Urticaria		1		1		
Vaccination site pain		1		1		
Vision blurred	1	1	1	1		
	9	22	8	19	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Back pain		1		1		
Chills		1				1
Headache		1		1		
Hypertension		1				1
Influenza		1		1		
Limb discomfort		1		1		
Muscle twitching		1		1		
Myalgia		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Paraesthesia		1		1		
Pyrexia		1				1
		13		9		4

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident		1				1
Chills		1		1		
Decreased appetite		1		1		
Dizziness		1		1		
Headache		1		1		
Hypertension		1		1		
Pain		1		1		
Pain in extremity		1		1		
		8		7		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Death		1				1
Facial paresis		1				1
Fatigue		1		1		
Pyrexia		1		1		
Speech disorder		1		1		
		6		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Allergic reaction to excipient	1	1	1	1		
Back pain		1		1		
Chest discomfort		1		1		
Chills	3	3	3	3		
COVID-19	7	13	1	4	6	9
Death	10	10			10	10
Dehydration	1	1	1	1		
Diarrhoea	1	1	1	1		
Drug ineffective	2	4			2	4
Dysphonia		1				1
Dyspnoea		1		1		
Extrasystoles		1				1
Facial paralysis	1	1			1	1
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Headache		1		1		
Hyperhidrosis	1	1	1	1		
Hypertension	2	2	2	2		
Hypotension	1	1	1	1		
Incorrect route of product administration		1		1		
Insomnia	1	1	1	1		
Irritable bowel syndrome		1		1		
Loss of consciousness	1	1			1	1
Lung disorder	1	1			1	1
Mood altered	1	1	1	1		
Myalgia		1		1		
Paraesthesia		1		1		
Pyelonephritis	1	1			1	1
Pyrexia	2	2	2	2		
Rash		1				1
Respiratory tract oedema		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea	2	2	2	2		
Sciatica		1		1		
Tachycardia	1	1	1	1		
Throat irritation	2	2	2	2		
Vaccination failure	4	4			4	4
	48	70	22	35	26	35

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**LIECHTENSTEIN**

Age Range

**65 - 79 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LITHUANIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		2		1		1
Anaphylactic reaction		1				1
Angina pectoris		1				1
Anxiety	1	1			1	1
Apathy		1		1		
Arthralgia	1	3	1	3		
Asthenia	4	10	3	8	1	2
Axillary pain		1		1		
Blood pressure decreased		1				1
Blood pressure increased		1				1
Body temperature increased		1				1
Bone pain	1	1	1	1		
Chills		6		6		
Cold sweat		1		1		
Coordination abnormal		1				1
Cough	1	2	1	2		
Decreased appetite		1		1		
Depressed level of consciousness	1	1			1	1
Diarrhoea		1		1		
Disorientation		1				1
Dizziness	1	5		3	1	2
Dry eye	1	1	1	1		
Dyspepsia		1		1		
Dyspnoea		1		1		
Ear pain	1	1	1	1		
Exposure during pregnancy		1		1		
Eye irritation		1		1		
Eye pain	1	2	1	2		
Fatigue		1		1		
Feeling abnormal		1		1		
Feeling of body temperature change	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	3	7	2	5	1	2
Heart rate increased		3		2		1
Herpes simplex		1		1		
Hypoaesthesia		2		2		
Lacrimation increased	1	2	1	2		
Loss of consciousness		1				1
Lymphadenopathy		2		2		
Lymph node abscess	2	2			2	2
Lymph node pain		1				1
Lymph node palpable		1				1
Mucosal disorder	1	1	1	1		
Myalgia	3	8	3	7		1
Nasopharyngitis	2	2	2	2		
Nausea	2	4	1	3	1	1
Pain in extremity		2		2		
Pallor	1	1			1	1
Peripheral swelling		1		1		
Peritonitis		1				1
Peritonsillar abscess	1	1			1	1
Pyrexia	3	8	3	8		
Seizure		4				4
Slow response to stimuli	1	1	1	1		
Sneezing		1		1		
Somnolence	1	4	1	4		
Syncope		2				2
Tachycardia		1		1		
Tendon pain		1		1		
Tinnitus		1		1		
Tonsillar hypertrophy	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain	3	9	3	9		
Vaccination site swelling		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	39	134	29	100	10	34

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Angina pectoris	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	1	5	1	4		1
Asthenia	3	10	3	8		2
Axillary pain	1	2	1	1		1
Back pain		1		1		
Blood pressure decreased		1				1
Blood pressure fluctuation		1				1
Blood pressure increased		1		1		
Body temperature increased	2	3	2	3		
Bone pain	1	3	1	3		
Chills	2	9	2	7		2
Cognitive disorder		1				1
Condition aggravated		1				1
Confusional state		1		1		
Convulsions local		1				1
Cough	1	1	1	1		
COVID-19	1	1	1	1		
Diarrhoea		2		2		
Disorientation		1				1
Dizziness	1	7	1	5		2
Erythema	1	1	1	1		
Eye pain	1	1	1	1		
Facial nerve disorder	1	1	1	1		
Fatigue		3		2		1
Feeling drunk		1		1		
Feeling hot		1		1		
Headache	1	12	1	9		3
Heart rate increased		1		1		
Hot flush	1	1	1	1		
Hyperhidrosis		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		1		1		
Hypoaesthesia		2		2		
Injected limb mobility decreased	1	1	1	1		
Loss of consciousness		2				2
Lymphadenopathy		2		1		1
Lymph node abscess	4	4			4	4
Memory impairment		1		1		
Muscle spasms		1		1		
Muscular weakness		1		1		
Myalgia	1	8	1	7		1
Myositis		1		1		
Nasopharyngitis	1	1	1	1		
Nausea	2	7	2	5		2
Neck pain		1		1		
Neuralgia		1				1
Overdose		1		1		
Pain		1		1		
Pain in extremity	3	7	3	7		
Paraesthesia		1				1
Paresis		1				1
Peripheral coldness		1		1		
Peripheral swelling		3		2		1
Pneumonia	1	1			1	1
Polymyositis		1				1
Pruritus		1		1		
Pyrexia	4	14	4	13		1
Rash	1	1	1	1		
Rash maculo-papular	1	1	1	1		
Seizure		1				1
Sensitive skin		1		1		
Skin mass		1				1
Syncope		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		1				1
Tinnitus		1				1
Tremor		4		3		1
Underdose		1		1		
Urinary incontinence		1		1		
Vaccination complication		1		1		
Vaccination site erythema	2	5	2	5		
Vaccination site induration	1	1	1	1		
Vaccination site inflammation		1		1		
Vaccination site pain	1	4	1	4		
Vaccination site reaction		1		1		
Vaccination site swelling	3	5	3	5		
Vaccination site warmth		2		2		
Vomiting		2		2		
	46	181	39	137	7	44

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Accidental overdose		1				1	
Angina pectoris	1	2			1	2	
Arthralgia	2	6	2	6			
Asthenia	2	5	2	3		2	
Axillary pain	2	2	2	2			
Balance disorder		1		1			
Blood pressure abnormal	1	1	1	1			
Blood pressure ambulatory increased	1	1	1	1			
Blood pressure fluctuation		1		1			
Blood pressure increased		5				5	
Chest discomfort		1				1	
Chest pain		1		1			
Chills	2	2	2	2			
Chronic gastritis		1		1			
Chronic sinusitis	1	1	1	1			
Cough	1	1	1	1			
Diarrhoea		1				1	
Diverticulum		1		1			
Dizziness		1		1			
Dysgeusia		1		1			
Dysphagia		1				1	
Dyspnoea		3		1		2	
Ear pain		1		1			
Epilepsy		1				1	
Erythema	1	2	1	1		1	
Eyelid function disorder		1				1	
Eye pain	1	2	1	2			
Facial asymmetry		1				1	
Facial paralysis	1	5			1	5	
Fatigue	1	2	1	2			
Feeling hot		1				1	
Flatulence		1		1			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	2		2
1	1		
1	2		2
			1
1	1		
			1
			1
	1		
1	4		1
			1
1	1		
			1
	1		
			1
1	2		
2	2	2	2
1	1		
1	1		
	1		
	1		
1	1		
			1
1	2		
1	1		
	1		
1	1		
	1		
1	1		
			1
1	2		
1	1		
3	6		
1	2		
			1
	1		
	1		
1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		1				1
Stress		1		1		
Swelling face		1		1		
Syncope		2				2
Taste disorder		1				1
Tremor		1				1
Vaccination site erythema	1	4	1	3		1
Vaccination site pain	1	5	1	4		1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	3	1	2		1
Vaccination site warmth		1				1
Vomiting		2				2
	40	131	36	79	4	52

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
Death		2				2
Deep vein thrombosis	1	1			1	1
Diarrhoea		1				1
Gait disturbance	1	1			1	1
Hypersensitivity		1				1
Hypotension		1				1
Off label use		1		1		
Pain in extremity	1	1			1	1
Product use issue		1		1		
Pulmonary oedema		1				1
Rash papular		1				1
Vomiting		1				1
	3	14		2	3	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction		1		1
Cardiogenic shock		1		1
Condition aggravated		1		1
COVID-19 pneumonia		1		1
Death		1		1
Dyspnoea		1		1
Irritability		1		1
Loss of consciousness		1		1
Malaise		2		2
Pain		1		1
Vaccination failure		1		1
		12		12

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone pain	1	1	1	1		
Decreased appetite	1	1	1	1		
Diarrhoea		1		1		
Eye disorder	1	1	1	1		
Headache	2	3	2	3		
Lymph node abscess	1	1			1	1
Myalgia		2		2		
Nausea	1	1	1	1		
Pain of skin	1	1	1	1		
Pyrexia	1	3	1	3		
Thrombosis	1	1			1	1
Vaccination site pain		1		1		
Visual impairment	1	1	1	1		
	11	18	9	16	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LUXEMBOURG**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	2	1	1		1
Chills	1	2	1	1		1
Diarrhoea		2				2
Dizziness	1	1			1	1
Fatigue	1	2			1	2
Headache	2	4	1	1	1	3
Hypotension	1	1			1	1
Lymphadenopathy		1		1		
Malaise	1	1	1	1		
Myalgia	2	4	2	3		1
Pyrexia	1	1			1	1
Tachycardia	1	1			1	1
Tetany	1	1	1	1		
Tinnitus	1	1			1	1
Vaccination site reaction		1				1
	14	25	7	9	7	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	1	8	1	1		7
Asthenia		2				2
Chest discomfort	1	2			1	2
Chest pain		2		1		1
Chillblains	1	1	1	1		
Chills	2	12	2	2		10
Cough		1				1
COVID-19		1				1
Decreased appetite		1				1
Dermatitis allergic		1				1
Dermatitis bullous		1				1
Diarrhoea		2				2
Dizziness	1	4			1	4
Drug ineffective		1				1
Dry mouth		2				2
Dry skin		1				1
Dysgeusia		1				1
Dysphonia	1	2			1	2
Dyspnoea		2				2
Erythema nodosum		1				1
Eyelid oedema	1	1			1	1
Eye pain	1	1			1	1
Face oedema	1	1			1	1
Fall		1				1
Fatigue	1	20		1	1	19
General physical health deterioration		1				1
Headache	6	24	4	4	2	20
Herpes zoster		1		1		
Hot flush	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypersensitivity		1					1
Hypertension	1	2			1		2
Influenza	1	4		1	1		3
Injected limb mobility decreased		1					1
Injection site reaction	1	1	1	1			
Insomnia		1					1
Laryngeal discomfort		1					1
Lymphadenopathy	3	4	3	3			1
Malaise	2	6			2		6
Migraine		1					1
Musculoskeletal stiffness	1	2			1		2
Myalgia	2	17	2	2			15
Nausea	3	5	1	1	2		4
Neck pain	1	2		1	1		1
Oral herpes		1		1			
Pain		1					1
Pain in extremity	2	5	1	1	1		4
Palpitations		2					2
Paraesthesia		1					1
Peripheral coldness	1	1			1		1
Peripheral swelling	2	3	1	2	1		1
Productive cough		1					1
Pruritus	1	5	1	1			4
Pulmonary pain		1					1
Pyrexia	3	12	2	2	1		10
Rash		3					3
SARS-CoV-2 antibody test negative		1					1
Skin haemorrhage		1					1
Somnolence		1					1
Swelling face		1		1			
Tachycardia		2					2
Therapeutic response unexpected	1	1	1	1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	1	1			1	1
Tongue ulceration		1				1
Tremor	1	2			1	2
Urticaria	1	1	1	1		
Vaccination complication		2				2
Vaccination site pain		2				2
Vaccination site reaction	12	16	12	12		4
Vertigo	1	1	1	1		
Vomiting		1				1
	61	220	35	43	26	177

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	2	5	1	1	1	4
Asthenia		1		1		
Asthmatic crisis		1				1
Back pain		1		1		
Bradypnea		1				1
Chills		1				1
Diarrhoea	1	3	1	1		2
Diplopia		1				1
Dizziness		1				1
Dysaesthesia		1				1
Dyspnoea		1				1
Dyspnoea exertional		1				1
Epilepsy	2	3			2	3
Epistaxis		1				1
Eyelid oedema	1	1	1	1		
Eye movement disorder		1				1
Face oedema		1				1
Fatigue	2	4	2	2		2
Feeding disorder		1				1
Feeling abnormal		1				1
Feeling hot		1				1
Haemoglobin decreased		1				1
Headache	1	6	1	1		5
Heart rate increased		1				1
Hemiparaesthesia		1				1
Hyperhidrosis		2				2
Hypersensitivity		1				1
Hypersomnia		1		1		
Hypertension	1	4			1	4
Hypoaesthesia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension		3				3
Influenza		2		1		1
Loss of consciousness		2				2
Malaise		3				3
Myalgia	1	5		1	1	4
Nasopharyngitis		1		1		
Nausea		5				5
Oropharyngeal discomfort		1				1
Pallor		1				1
Paraesthesia		1				1
Paraesthesia oral	1	1	1	1		
Paresis	1	1			1	1
Pneumonia	1	1			1	1
Presyncope		1				1
Pruritus		1				1
Pulmonary embolism	1	1			1	1
Pulse abnormal		1				1
Pyrexia		3				3
Rectal haemorrhage		1				1
Swelling		1				1
Swelling face		1				1
Tachycardia		1				1
Urinary incontinence		1				1
Vaccination complication		1				1
Vaccination site pain		1				1
Vaccination site reaction	4	6	4	4		2
Vitamin B12 deficiency		1				1
Vomiting		2				2
Wheezing		1				1
	22	103	13	19	9	84

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute kidney injury		1				1
Altered state of consciousness		1				1
Arrhythmia		1				1
Arthralgia	1	1	1	1		
Conjunctivitis		1				1
Deep vein thrombosis	1	1			1	1
Formication		1				1
Haematoma	1	1	1	1		
Hypernatraemia		1				1
Hyperthermia		1				1
Lung disorder		1				1
Muscular weakness		1				1
Pain in extremity	1	1	1	1		
Palpitations		1				1
Paraesthesia		1				1
Pulmonary embolism	1	1			1	1
Sepsis		1				1
	6	18	3	3	3	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Anxiety		1				1
Blood pressure increased		1				1
Cerebral haemorrhage	1	1			1	1
Chest discomfort		1				1
Chills		1				1
COVID-19	1	1			1	1
Dyspnoea		2				2
Fall	1	1			1	1
Fatigue		2				2
Headache		2				2
Hypersensitivity		1				1
Hypertension	1	1	1	1		
Hyperthermia	1	1	1	1		
Hypotension		1		1		
Hypoxia		1				1
Malaise		2		2		
Nausea		1				1
Oxygen saturation decreased		1				1
Pulmonary embolism	1	1			1	1
Pyrexia		2				2
Respiratory failure		1				1
Tremor	1	1	1	1		
Urinary tract infection	1	1	1	1		
Vaccination complication		1				1
Vlth nerve paralysis	1	1			1	1
Vomiting		1				1
Wheezing		1				1
	9	33	4	7	5	26

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**MACAO**

Age Range

**65 - 79 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**MACEDONIA, THE FORMER YUGOSLAV**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Administration site pain		1		1
Asthenia		1		1
Body temperature increased		1		1
Headache		2		2
Incorrect route of product administration		1		1
Malaise		1		1
Nasopharyngitis		1		1
Pyrexia		1		1
Rash maculo-papular		1		1
Rhinorrhoea		1		1
		11		11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Body temperature increased		1		1		
Eye oedema		1		1		
Headache	2	2	2	2		
Hypersensitivity		1		1		
Lip oedema		1		1		
Loss of consciousness	1	1			1	1
Malaise		2		2		
Myalgia	1	3	1	3		
Pyrexia		2		2		
Vaccination site pain	1	1	1	1		
	6	16	5	15	1	1

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Body temperature increased		1		1
Malaise		1		1
Pyrexia		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MALAYSIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
	1	1	1	1

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Dizziness		1		1		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Pyrexia	1	1	1	1		
Seizure		1				1
Vaccination site pain	1	2	1	2		
	6	9	6	8		1

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous	1	1	1	1		
Rash papular	1	1	1	1		
Skin necrosis	1	1			1	1
	3	3	2	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Constipation	1	1	1	1		
COVID-19		1		1		
Death		1				1
Hair texture abnormal	1	1	1	1		
Headache	1	1	1	1		
Malaise		1		1		
Musculoskeletal stiffness	1	1	1	1		
Neuropathy peripheral		2				2
No adverse event		1		1		
Urticaria		1		1		
	4	11	4	8		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MALTA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Chills		2		2		
Cough		1		1		
Deep vein thrombosis		1				1
Diarrhoea		1		1		
Facial paralysis	1	1			1	1
Fatigue		1		1		
Fear of injection		1		1		
Headache	1	1	1	1		
Hot flush		1		1		
Hyperhidrosis		1		1		
Hypersensitivity	1	1	1	1		
Hypoaesthesia		1				1
Influenza like illness		1		1		
Injection		1		1		
Lethargy	1	3	1	3		
Malaise		2		2		
Myalgia		1		1		
Oropharyngeal pain		1		1		
Pain	2	4	2	4		
Pain in extremity	1	3	1	2		1
Parosmia		1		1		
Pyrexia	1	5	1	5		
Somnolence		1		1		
Swelling		1				1
Syncope		1				1
Taste disorder	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site pain		3		3		
	9	44	8	38	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Anaphylactic reaction	3	7			3	7
Arthralgia		2		2		
Arthritis infective	1	1			1	1
Asthenia		1		1		
Asthma		2				2
Bone pain	1	2	1	2		
Bronchospasm		1				1
Burning sensation	1	1	1	1		
Chest discomfort	2	2			2	2
Chills	1	7	1	7		
Cough		1				1
COVID-19	1	1			1	1
Decreased appetite		1		1		
Defaecation urgency		1		1		
Diarrhoea		2		1		1
Discomfort		1		1		
Dizziness		4		4		
Dysgeusia		2		1		1
Dysphonia	2	3			2	3
Dyspnoea	1	3			1	3
Erythema	1	3		1	1	2
Eye swelling	1	1			1	1
Facial paralysis		3				3
Fatigue	1	8	1	8		
Feeling abnormal		1		1		
Gait disturbance		1		1		
Gait inability		1		1		
Headache	2	3	1	2	1	1
Hot flush	1	2	1	2		
Hyperhidrosis		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	3	4			3	4
Hypertension		1				1
Hypoaesthesia		2		2		
Injection site pain		1		1		
Insomnia		1		1		
Lethargy	2	6	2	6		
Limb discomfort		2		1		1
Lip swelling	1	1			1	1
Lymphadenopathy		1		1		
Lymph node pain		1		1		
Malaise		2		2		
Migraine		1		1		
Mobility decreased		1		1		
Muscle spasms	1	1	1	1		
Muscle twitching		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	3	8	3	8		
Nausea		3		2		1
Neck pain	1	2		1	1	1
Night sweats		1		1		
Off label use	1	2	1	2		
Overdose		1		1		
Pain		5		5		
Pain in extremity		5		4		1
Palpitations	2	4		1	2	3
Paraesthesia		3		3		
Peripheral swelling	1	1	1	1		
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Pruritus	3	5	1	2	2	3
Pyrexia	2	11	2	11		
Rash		3		1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous		3		1		2
Rash pruritic	1	2			1	2
Respiratory depression		1				1
Respiratory distress		1				1
Restlessness		1		1		
Retinal vein occlusion	1	1			1	1
Sinus tachycardia		1				1
Somnolence		2		2		
Swelling face	2	2			2	2
Swollen tongue	1	1			1	1
Syncope	1	2			1	2
Tachycardia		2				2
Tachypnoea		1				1
Throat tightness		1				1
Toothache	1	1	1	1		
Urticaria		1				1
Vaccination failure	1	1			1	1
Vaccination site pain	2	7	2	7		
Vaccination site pruritus	1	1	1	1		
Vaccination site urticaria		2		1		1
Vision blurred	2	2			2	2
Vomiting		3		2		1
Wheezing		2				2
	52	197	21	124	31	73

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Dehydration		1		1		
Dysphagia		1				1
Erythema		1		1		
Fatigue	1	3	1	1		2
Goitre		1		1		
Headache	1	1	1	1		
Lethargy		1		1		
Panic reaction		1		1		
Paraesthesia		2		2		
Pyrexia		3		1		2
Swelling face		1		1		
Vaccination site pain		1		1		
	4	19	3	13	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
Cough		1		1		
COVID-19		2		1		1
Drug ineffective		1				1
Ear swelling		1		1		
Erythema	2	3	2	3		
Facial paralysis	1	1			1	1
Fatigue	1	3	1	3		
Flushing	1	1	1	1		
Headache		1		1		
Hypersensitivity		1		1		
Lethargy	1	1	1	1		
Lip swelling		1		1		
Lymphadenopathy	1	1	1	1		
Malaise		2		2		
Ocular hyperaemia		1		1		
Periorbital swelling		1		1		
Pruritus		2		2		
Pyrexia	2	4	2	4		
Rash	1	2	1	2		
Swelling face	1	1	1	1		
Urticaria	1	2	1	2		
Vaccination site erythema	1	1	1	1		
Vaccination site movement impairment		1		1		
Vaccination site pain		1		1		
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	1	1	1		
	16	39	15	36	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged		1		1		
Activated partial thromboplastin time ratio increased		1		1		
Acute kidney injury		1				1
Alanine aminotransferase increased		1		1		
Altered state of consciousness		1				1
Arthralgia	1	1	1	1		
Atrial fibrillation		1				1
Basophil count increased		1		1		
Blood alkaline phosphatase increased		1		1		
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood magnesium decreased		1		1		
Blood osmolarity increased		1		1		
Blood phosphorus decreased		1		1		
Blood urea increased		2		2		
Cerebellar atrophy		1				1
Cerebral atrophy		2				2
Chest pain	1	1	1	1		
COVID-19		5				5
COVID-19 pneumonia		2				2
C-reactive protein increased		2		2		
Drug ineffective		4				4
Dyspnoea		1				1
Eosinophil count decreased		1		1		
Erythema		1				1
Generalised tonic-clonic seizure		1				1
Haematocrit decreased		2		2		
Haemoglobin decreased		2		2		
Hypertension		1				1
Hypoaesthesia		1		1		
Hypothermia		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoxia		2				2
Immature granulocyte count increased		1		1		
Lymphocyte count decreased		2		2		
Mean cell haemoglobin concentration increased		1		1		
Monocyte count decreased		1		1		
Monocyte count increased		1		1		
Nausea		1		1		
Neck pain	1	1	1	1		
Neutrophil count increased		2		2		
Normochromic normocytic anaemia		1		1		
Nucleated red cells		1		1		
Oxygen saturation decreased		1		1		
Peripheral coldness		1		1		
Platelet count decreased		1		1		
Platelet count increased		1		1		
Poor peripheral circulation		1		1		
Pruritus		1				1
Pulmonary embolism	1	1			1	1
Red blood cell count decreased		2		2		
Red cell distribution width increased		1		1		
Reticulocyte count increased		1		1		
Sepsis		1				1
Septic shock		1				1
Swelling face		1				1
Tachypnoea		1				1
Thrombocytopenia		1				1
Vaccination failure		1				1
Vaccination site induration		1		1		
White blood cell count increased		1		1		
	4	77	3	45	1	32

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1			1	1
Chest pain	1	1			1	1
COVID-19		1				1
Drug ineffective		1				1
Fatigue	1	1	1	1		
Feeling of body temperature change	1	1			1	1
Heart rate increased	1	1	1	1		
Hypersensitivity		1		1		
Hypertension	1	1	1	1		
Pain in extremity	1	1	1	1		
Palpitations	1	1			1	1
Tremor	1	1			1	1
	9	12	4	5	5	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**MEXICO**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
Lymphadenopathy		1		1
		2		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	10	43	8	36	2	7
Abnormal faeces		1		1		
Abscess	1	1	1	1		
Ageusia		1		1		
Allergy to vaccine		1		1		
Allodynia		1		1		
Anaphylactic reaction	3	9			3	9
Anaphylactic shock	3	11			3	11
Angioedema		1				1
Anosmia	3	8	3	8		
Anxiety	3	10	1	5	2	5
Aphonia	1	1	1	1		
Arthralgia	38	170	32	153	6	17
Asthenia	70	221	58	193	12	28
Asthmatic crisis		1				1
Atrial fibrillation		2				2
Axillary mass		1		1		
Axillary pain		1		1		
Back pain	2	6	2	6		
Balance disorder	1	2		1	1	1
Blood pressure increased	1	4	1	4		
Body temperature increased	18	55	14	45	4	10
Bone pain		1				1
Bowel movement irregularity		1		1		
Bradycardia		4				4
Bronchospasm	6	16	3	8	3	8
Cellulitis	1	9			1	9
Chest discomfort	1	2		1	1	1
Chest pain	6	26	5	20	1	6
Chills	37	145	26	120	11	25
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctivitis	1	2	1	2		
Cough	18	83	13	67	5	16
COVID-19	4	11	4	7		4
Crying	5	8	5	7		1
Cyanosis		1		1		
Deafness unilateral		1				1
Decreased appetite	4	21	4	19		2
Delirium	1	1			1	1
Dermatosis		1		1		
Diarrhoea	12	66	7	54	5	12
Diffuse large B-cell lymphoma	1	1			1	1
Discomfort	2	9	2	9		
Disorientation		1				1
Disseminated Bacillus Calmette-Guerin infection	1	3			1	3
Disturbance in attention		1		1		
Dizziness	55	185	39	142	16	43
Drug ineffective		4				4
Dry mouth	1	4		1	1	3
Dysarthria		1		1		
Dysgeusia	2	7	2	6		1
Dysphagia		3		2		1
Dysphonia	1	1	1	1		
Dyspnoea	20	155	15	109	5	46
Dyspnoea exertional	1	4	1	4		
Dysstasia		1				1
Dystonia	1	1			1	1
Ear discomfort		2		2		
Ear disorder		1		1		
Ear pain	1	3	1	3		
Epistaxis		2		2		
Erythema	15	50	11	42	4	8
Erythema multiforme		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2	1	3
1	5		
	2	1	1
	1		
	3		
	1		
	4	1	4
	1		
	1		
	1		
1	1		
38	149	7	23
4	11	1	2
1	1		1
1	2		3
	1		
	2		
	1		
	1	1	1
1	1		
	1		1
	1		
	4		
	1		1
	5	2	5
	1	1	1
	2	1	2
71	281	16	40
	2		
1	4		
	1		1

Eye disorder		1
Eye injury	1	5
Eye irritation	1	5
Eyelid oedema	1	3
Eyelid ptosis		1
Eye pain		3
Face oedema		1
Facial paralysis	1	4
Facial paresis		1
Faeces discoloured		1
Fall		1
Fasting	1	1
Fatigue	45	172
Febrile convulsion	5	13
Feeling abnormal	1	2
Feeling hot	1	5
Feeling of body temperature change		1
Flushing		2
Frequent bowel movements		1
Gastroenteritis	1	1
Gastrointestinal hypomotility	1	1
Generalised tonic-clonic seizure		1
General physical condition abnormal		1
General physical health deterioration	1	4
Guillain-Barre syndrome		1
Haematochezia	2	5
Haemorrhage	1	1
Haemorrhagic disorder	1	2
Headache	87	321
Head discomfort		2
Heart rate increased	1	4
Hemiparaesthesia		1

\* I=Interval, C=Cumulative  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hemiparesis		1					1
Hemiplegia		1					1
Hot flush		1		1			
Hyperaemia		1					1
Hyperaesthesia	1	1	1	1			
Hyperhidrosis	3	12		8	3		4
Hyperpyrexia		1					1
Hypersensitivity	1	10	1	7			3
Hypertension	3	18		11	3		7
Hypertensive crisis		6					6
Hypertensive emergency		1					1
Hyperthermia	2	2	2	2			
Hypoaesthesia	3	16	2	10	1		6
Hypoaesthesia oral	1	4	1	4			
Hypokinesia		5		4			1
Hyposmia	1	2	1	2			
Hypotension	3	11		4	3		7
Hypothermia	1	3			1		3
Hypotonia	1	1	1	1			
Hypoventilation	1	2			1		2
Hypovolaemic shock	2	3			2		3
Hypoxia	1	1			1		1
Induration	13	43	11	39	2		4
Inflammation	14	51	10	42	4		9
Influenza	1	2	1	2			
Injection site haemorrhage		1		1			
Insomnia		1		1			
Intussusception	2	2			2		2
Irritability	11	30	9	25	2		5
Irritability postvaccinal		1		1			
Joint injury		1		1			
Lacrimation increased	1	4	1	4			

\* I=Interval, C=Cumulative  
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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1	1	1
			1
	1		
4	16		2
			7
4	21		1
7	27	1	4
	1		
	3		
			1
	1		
	5		
		1	2
	3	1	4
39	186	6	16
	1		
	5		
1	1		
	3		
32	128	12	25
2	4		
1	2		
11	42	2	5
	1		
	1		
7	17	3	7
12	52	6	16
1	5	1	1
	3		
			3
16	86	3	9

Laryngospasm	1	1
Lethargy	1	2
Leukopenia		1
Lip discolouration		1
Local reaction	4	18
Loss of consciousness		7
Lymphadenopathy	4	22
Malaise	8	31
Mass		1
Maternal exposure during pregnancy		3
Meningitis		1
Metrorrhagia		1
Mobility decreased		5
Muscle contractions involuntary	1	2
Muscular weakness	1	7
Myalgia	45	202
Nail discolouration		1
Nasal congestion		5
Nasal obstruction	1	1
Nasopharyngitis		3
Nausea	44	153
Neck pain	2	4
Neuritis	1	2
Nodule	13	47
Ocular discomfort		1
Ocular hyperaemia		1
Odynophagia	10	24
Oedema	18	68
Oedema peripheral	2	6
Off label use		3
Oropharyngeal discomfort		3
Oropharyngeal pain	19	95

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Otitis media acute		1		1			
Oxygen saturation decreased	2	11	1	4	1	7	
Pain	50	189	41	166	9	23	
Painful respiration		1		1			
Pain in extremity	2	11	2	9		2	
Pallor		3		3			
Palpitations		1				1	
Paraesthesia	9	30	5	18	4	12	
Paraesthesia oral	3	6	2	3	1	3	
Paralysis		11				11	
Pelvic discomfort	1	1			1	1	
Pelvic pain		1		1			
Peripheral coldness	1	3		2	1	1	
Petechiae		1				1	
Pharyngeal disorder	1	1	1	1			
Pharyngeal hypoaesthesia		1				1	
Pharyngeal oedema		1				1	
Pharyngeal paraesthesia	1	3		1	1	2	
Photophobia		1		1			
Photopsia	1	5	1	4		1	
Pneumonia	1	2			1	2	
Pneumonitis		1		1			
Product use issue		3		3			
Prurigo		2		2			
Pruritus	18	54	10	35	8	19	
Pyrexia	33	155	28	140	5	15	
Radiculitis brachial	1	1	1	1			
Rash	10	41	6	26	4	15	
Rash macular		1				1	
Respiratory distress	18	151			18	151	
Rhinitis	1	1	1	1			
Rhinorrhoea	19	73	19	70		3	

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	6	18			6	18
Sensation of foreign body	3	3			3	3
Sensitive skin	52	160	43	142	9	18
Sensory loss		1		1		
Sepsis	1	1			1	1
Shock		2				2
Sinus tachycardia		1		1		
Skin burning sensation	1	1	1	1		
Skin lesion		1		1		
Sneezing	1	1	1	1		
Somnolence	1	3	1	3		
Suffocation feeling		1		1		
Suspected COVID-19	1	2		1	1	1
Swelling		3		1		2
Syncope	4	20			4	20
Tachyarrhythmia		1		1		
Tachycardia	25	122	13	92	12	30
Tachypnoea	1	3		1	1	2
Temperature intolerance		1		1		
Tenderness		2		2		
Thermal burns of eye		1				1
Thirst		2		1		1
Throat irritation		3		3		
Tinnitus	1	5	1	4		1
Tremor	2	8		6	2	2
Urticaria	1	3		2	1	1
Vaccination site abscess		1		1		
Vaccination site cellulitis		6		4		2
Vaccination site discomfort	2	3	2	3		
Vaccination site erythema	1	4	1	4		
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity	2	9	2	9		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia		1		1		
Vaccination site induration	1	8	1	8		
Vaccination site inflammation		5		5		
Vaccination site movement impairment		2		2		
Vaccination site nodule	1	5	1	5		
Vaccination site oedema		1		1		
Vaccination site pain	25	97	23	91	2	6
Vaccination site paraesthesia		2		2		
Vaccination site pruritus		1		1		
Vaccination site reaction	2	6	2	6		
Vaccination site swelling	2	3	2	3		
Vaccination site warmth		2		2		
Vertigo	4	12	4	9		3
Vision blurred		3		2		1
Visual impairment		1		1		
Vomiting	23	69	17	54	6	15
Wheezing		1		1		
	1,080	4,300	794	3336	286	964

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1		1		
Abdominal pain	23	105	17	94	6	11
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	6	1	5		1
Abnormal faeces	1	3	1	2		1
Abscess	2	3	2	3		
Affect lability		1		1		
Ageusia		6		5		1
Agitation		1		1		
Akathisia		1		1		
Alanine aminotransferase increased	1	1	1	1		
Allergy to vaccine		3		2		1
Allodynia		1		1		
Anaphylactic reaction	6	13			6	13
Anaphylactic shock	9	24			9	24
Angina pectoris		1				1
Angioedema	2	7			2	7
Anosmia	5	16	4	13	1	3
Anxiety	8	24	5	20	3	4
Aphasia		1		1		
Aphonia	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Arrhythmia	1	4			1	4
Arthralgia	91	365	73	324	18	41
Aspartate aminotransferase increased	1	1			1	1
Asterixis	1	1			1	1
Asthenia	130	484	104	428	26	56
Asthma		1		1		
Asthmatic crisis		1				1
Ataxia		1		1		
Atrophy	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Atypical pneumonia		1					1
Auricular swelling		1		1			
Axillary pain	2	3	2	3			
Axonal neuropathy		1					1
Back pain	7	23	5	20	2		3
Balance disorder	1	2	1	1			1
Blepharitis	1	1	1	1			
Blepharospasm		1		1			
Blindness		1					1
Blindness transient		1					1
Blister		2		1			1
Blood glucose decreased		1					1
Blood glucose increased	2	3	2	3			
Blood pressure abnormal	1	3	1	3			
Blood pressure diastolic increased		1		1			
Blood pressure increased	12	31	7	19	5		12
Body temperature decreased		1		1			
Body temperature fluctuation		1					1
Body temperature increased	24	84	21	77	3		7
Bradycardia	2	12			2		12
Brain stem ischaemia	1	2			1		2
Bronchial disorder		2		2			
Bronchospasm	17	44	10	25	7		19
Burning sensation	2	5	1	1	1		4
Catarrh	1	1	1	1			
Cellulitis	6	20			6		20
Chest discomfort	2	13	1	10	1		3
Chest pain	10	56	5	45	5		11
Chills	78	339	61	300	17		39
Choluria		1					1
Clonic convulsion		1					1
Coagulation time prolonged		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Colitis		1		1		
Condition aggravated	1	3	1	2		1
Confusional state		3		2		1
Conjunctival haemorrhage	3	4			3	4
Conjunctival hyperaemia	1	3		2	1	1
Conjunctivitis	2	9	2	9		
Contusion		1		1		
Conversion disorder	1	2	1	2		
Cough	42	189	31	165	11	24
Counterfeit product administered	2	2	2	2		
COVID-19	7	28	6	19	1	9
COVID-19 pneumonia		2				2
C-reactive protein increased		1		1		
Crying	5	21	4	19	1	2
Cyanosis	1	3		2	1	1
Deafness		1				1
Deafness unilateral		1				1
Death		1				1
Decreased appetite	16	49	15	44	1	5
Deficiency of bile secretion		1				1
Dehydration	1	4	1	2		2
Demyelination		3				3
Depressed level of consciousness	2	6			2	6
Diabetic ketoacidosis		1				1
Diarrhoea	32	128	23	111	9	17
Diarrhoea haemorrhagic		1				1
Diplopia		1		1		
Discharge		1		1		
Discomfort	6	25	6	24		1
Disease recurrence		4		3		1
Disorientation	1	6		5	1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disseminated Bacillus Calmette-Guerin infection	2	5			2	5
Dizziness	103	407	71	341	32	66
Dizziness postural		1		1		
Drug hypersensitivity	1	2			1	2
Drug ineffective	1	11			1	11
Dry mouth	5	15	4	12	1	3
Dry throat	1	1	1	1		
Dysaesthesia		2		2		
Dysarthria	1	2	1	2		
Dysgeusia	8	19	7	16	1	3
Dyskinesia	1	1	1	1		
Dyslipidaemia	1	1	1	1		
Dysmenorrhoea		1		1		
Dysphagia		11		8		3
Dysphonia		3		3		
Dyspnoea	53	353	36	276	17	77
Dyspnoea at rest		1				1
Dyspnoea exertional		2		2		
Ear discomfort		2		2		
Ear infection	1	3	1	3		
Ear pain	1	4	1	4		
Ecchymosis	2	2	1	1	1	1
Electrolyte imbalance		1				1
Encephalitis post immunisation		1				1
Epigastric discomfort		1		1		
Epiglottic oedema		2				2
Epilepsy	1	1			1	1
Epistaxis		3		2		1
Erythema	26	109	19	93	7	16
Expired product administered	1	2	1	2		
Exposure during pregnancy		2		2		
Exposure to SARS-CoV-2		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
External ear inflammation		1		1			
Eye disorder	1	2	1	2			
Eye inflammation		1		1			
Eye injury	2	13	1	12	1	1	
Eye irritation	1	6	1	6			
Eyelid oedema	2	4	1	3	1	1	
Eyelid pain		1		1			
Eyelid ptosis		1		1			
Eyelid rash		1		1			
Eyelid sensory disorder		1		1			
Eyelids pruritus		1		1			
Eye pain	5	17	4	16	1	1	
Eye pruritus		3		3			
Eye swelling		2		1		1	
Face oedema	1	5	1	5			
Facial nerve disorder		1		1			
Facial paralysis	3	15			3	15	
Facial paresis	1	1	1	1			
Fall	1	1	1	1			
Fatigue	93	363	73	324	20	39	
Febrile convulsion	5	17	3	10	2	7	
Feeling abnormal		2		2			
Feeling cold		4		4			
Feeling drunk	1	1	1	1			
Feeling hot		9		7		2	
Feeling of despair		2		2			
Fibrosis	1	1	1	1			
Flushing	1	8		6	1	2	
Foreign body in throat		1				1	
Foreign body sensation in eyes		1		1			
Gait disturbance		3		3			
Gastritis		1		1			

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gastroenteritis		1		1			
Gastrointestinal disorder		1					1
Gastrointestinal hypermotility	1	1	1	1			
Gastrointestinal motility disorder	2	3	2	3			
Generalised oedema	1	1	1	1			
Generalised tonic-clonic seizure	2	4			2		4
General physical health deterioration	1	6	1	6			
Genital paraesthesia	1	1	1	1			
Glabellar reflex abnormal		1		1			
Groin pain	1	1	1	1			
Guillain-Barre syndrome	1	1			1		1
Haematochezia	1	7			1		7
Haematoma	1	1	1	1			
Haemoptysis		1		1			
Haemorrhage	7	9			7		9
Haemorrhagic disorder	3	3			3		3
Hallucination, visual	1	2			1		2
Headache	187	695	146	605	41		90
Heart rate abnormal		2		2			
Heart rate increased	1	6	1	5			1
Heart rate irregular		1					1
Hemiparaesthesia	2	5			2		5
Hemiparesis	2	7			2		7
Hemiplegia		1					1
Hepatic function abnormal	1	1	1	1			
Hepatic pain		1		1			
Hot flush	1	2	1	2			
Hunger		1		1			
Hyperaemia	1	4	1	4			
Hyperaesthesia	1	6	1	6			
Hyperbilirubinaemia		1					1
Hyperglycaemia		1					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	9	26	5	19	4	7
Hypernatraemia		1				1
Hyperreflexia	1	1	1	1		
Hypersensitivity	2	21		17	2	4
Hypersomnia		1		1		
Hypertension	19	67	12	41	7	26
Hypertensive crisis	3	32			3	32
Hypertensive emergency	1	1			1	1
Hyperthermia	3	10	2	9	1	1
Hypoacusis		2		2		
Hypoaesthesia	3	17	3	14		3
Hypoaesthesia oral	1	7	1	6		1
Hypokinesia	1	3	1	3		
Hypotension	3	11	3	8		3
Hypothermia	3	11			3	11
Hypotonia	1	2	1	2		
Hypovolaemic shock	8	17			8	17
Inappropriate schedule of product administration	1	4	1	4		
Incorrect route of product administration	1	1	1	1		
Induration	30	95	28	89	2	6
Inflammation	22	78	20	72	2	6
Influenza	1	3	1	3		
Influenza like illness		2		2		
Injection site pain	1	1	1	1		
Insomnia		1		1		
Intracranial aneurysm	1	1			1	1
Intussusception	2	6			2	6
Irritability	22	69	14	57	8	12
Irritability postvaccinal		2		2		
Jaundice		1				1
Joint stiffness		1		1		
Lacrimation increased	1	8	1	8		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal inflammation		1				1
Laryngeal obstruction		1				1
Laryngeal oedema	2	4			2	4
Laryngospasm		1				1
Leukopenia		1				1
Limb discomfort	1	2	1	1		1
Lip disorder		1		1		
Lip oedema	2	5	2	5		
Lip pain	1	1	1	1		
Livedo reticularis	2	3	2	3		
Localised oedema	2	3	2	3		
Local reaction	4	30	4	29		1
Loss of consciousness	3	8			3	8
Loss of personal independence in daily activities		2		1		1
Lymphadenitis		1		1		
Lymphadenopathy	17	48	16	43	1	5
Lymphangitis		1				1
Lymphopenia		2		1		1
Malaise	18	55	14	51	4	4
Maternal exposure during pregnancy	1	3	1	3		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Mean cell haemoglobin decreased	1	1	1	1		
Mean cell volume decreased	1	1	1	1		
Mean platelet volume decreased	1	1	1	1		
Mechanical urticaria		1		1		
Meningitis		1				1
Menstrual disorder		1		1		
Mobility decreased	1	7	1	7		
Monocyte count increased	1	1	1	1		
Mononeuropathy		2				2
Monoparesis	1	1	1	1		
Motor dysfunction		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Mouth haemorrhage		1					1
Movement disorder	1	5		3	1		2
Mucosal dryness	2	2	2	2			
Mucous stools		1		1			
Muscle atrophy		1		1			
Muscle contractions involuntary		3		3			
Muscle contracture		2		2			
Muscle fatigue	2	3	2	3			
Muscle rigidity		1		1			
Muscle spasms	3	8	3	7			1
Muscle spasticity		1					1
Muscle strength abnormal	1	1	1	1			
Muscle tightness		1		1			
Muscular weakness	5	11	2	8	3		3
Musculoskeletal chest pain	1	1	1	1			
Musculoskeletal stiffness		1		1			
Myalgia	105	427	84	379	21		48
Myelitis		1					1
Myelitis transverse		1					1
Myoclonus		1		1			
Myopathy	1	1	1	1			
Narcolepsy	1	1			1		1
Nasal abscess	1	1			1		1
Nasal congestion		9		9			
Nasal obstruction		1		1			
Nasopharyngitis	1	3		1	1		2
Nausea	101	326	78	279	23		47
Near death experience		1					1
Neck pain	5	16	5	16			
Nerve degeneration		1					1
Nervousness	1	5	1	4			1
Nervous system disorder		1					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuritis	1	3	1	1		2
Neuropathy peripheral		1				1
Night sweats		1		1		
Nodule	35	108	33	100	2	8
Nystagmus		1		1		
Ocular hyperaemia	1	6		5	1	1
Odynophagia	9	32	7	29	2	3
Oedema	29	125	23	106	6	19
Oedema peripheral	3	7	3	7		
Off label use	2	3	2	3		
Oral candidiasis	1	1	1	1		
Oral discomfort	1	1			1	1
Oral disorder	2	2	1	1	1	1
Oral dysaesthesia		1		1		
Oral herpes	1	1	1	1		
Oropharyngeal discomfort	1	6		4	1	2
Oropharyngeal pain	46	204	37	183	9	21
Otitis externa		1		1		
Otitis media	1	1	1	1		
Oxygen saturation abnormal	1	7		4	1	3
Oxygen saturation decreased	4	21	3	15	1	6
Pain	109	414	85	363	24	51
Painful respiration		1		1		
Pain in extremity	14	44	13	42	1	2
Pain in jaw		1		1		
Pain of skin	1	2	1	2		
Pallor	1	5	1	3		2
Palmar erythema		1		1		
Palpitations	3	18	2	15	1	3
Papule	1	2	1	2		
Paraesthesia	25	79	20	66	5	13
Paraesthesia oral	7	22	5	18	2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis	2	11			2	11
Paraparesis	1	1			1	1
Paresis	2	2	2	2		
Parosmia		1		1		
Patient elopement		1		1		
Pelvic pain		1		1		
Pericardial disease	1	1	1	1		
Periorbital oedema		1		1		
Peripheral coldness	2	5	2	5		
Peripheral motor neuropathy		1				1
Peripheral swelling	2	3	1	1	1	2
Peroneal nerve injury		1				1
Persistent depressive disorder		1		1		
Petechiae	2	4	1	2	1	2
Pharyngeal disorder		2		2		
Pharyngeal erythema	1	1	1	1		
Pharyngeal inflammation		2				2
Pharyngeal oedema		2				2
Pharyngeal paraesthesia		1				1
Pharyngitis		1				1
Photophobia		3		3		
Photopsia	1	1			1	1
Photosensitivity reaction		1		1		
Pigmentation disorder		1		1		
Platelet count increased	1	1	1	1		
Pleural effusion		1		1		
Pneumonia	1	11			1	11
Presyncope		3		1		2
Productive cough	1	2		1	1	1
Product supply issue		1		1		
Product use issue	1	1	1	1		
Pruritus	28	97	23	85	5	12

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pulmonary oedema		1					1
Purpura		3		2			1
Pyrexia	73	304	61	270	12		34
Radiculopathy		2					2
Rales		1		1			
Rash	25	97	20	78	5		19
Rash erythematous		1		1			
Rash maculo-papular	1	4		3	1		1
Raynaud's phenomenon	1	2	1	2			
Reflexes abnormal	1	1	1	1			
Respiratory disorder	1	1	1	1			
Respiratory distress	48	346			48		346
Respiratory rate increased		1		1			
Respiratory tract infection viral		1		1			
Restlessness		1		1			
Rhinitis		1		1			
Rhinorrhoea	31	169	28	156	3		13
Ruptured cerebral aneurysm		1					1
Sacroiliitis		1					1
Salivary hypersecretion	1	1	1	1			
SARS-CoV-2 antibody test negative		2		2			
SARS-CoV-2 test positive	1	3	1	1			2
Scab		1					1
Sciatica		1					1
Sciatic nerve neuropathy		1					1
Secretion discharge		1		1			
Seizure	8	39			8		39
Sensation of foreign body	4	12	1	6	3		6
Sensitisation		1		1			
Sensitive skin	104	324	85	283	19		41
Sensory disturbance		1		1			
Sensory loss	1	2	1	1			1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock	1	2			1	2
Sinus tachycardia	2	3	1	1	1	2
Skeletal injury	1	1	1	1		
Skin discolouration		1		1		
Skin exfoliation		1		1		
Skin haemorrhage		1		1		
Skin injury	1	1	1	1		
Skin lesion		1		1		
Skin sensitisation		2		2		
Skin swelling		1		1		
Sleep disorder	1	1			1	1
Slow response to stimuli		2		2		
Sneezing		1		1		
Somnolence	1	11		9	1	2
Speech disorder	1	2	1	2		
Sputum discoloured		1		1		
Sputum purulent		1				1
Stevens-Johnson syndrome	2	3			2	3
Stridor	1	2			1	2
Subarachnoid haemorrhage	1	2			1	2
Sudden infant death syndrome	1	1			1	1
Suffocation feeling		1				1
Suspected counterfeit product	2	2	2	2		
Suspected COVID-19		2		2		
Sweating fever		1				1
Swelling		2		2		
Swelling face	1	2		1	1	1
Swollen tongue	1	1	1	1		
Syncope	6	48			6	48
Synovial cyst	1	1	1	1		
Systemic lupus erythematosus		1				1
Tachycardia	61	261	40	205	21	56

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	2	6		3	2	3
Temperature intolerance		1		1		
Temperature regulation disorder	1	1	1	1		
Tenderness		2		2		
Thirst		1		1		
Throat irritation	1	10	1	9		1
Throat tightness	1	2	1	2		
Thrombocytopenia	1	2			1	2
Thrombocytopenic purpura	2	3	1	2	1	1
Tinnitus	2	6	1	5	1	1
Tongue oedema		2		1		1
Tongue paralysis	1	1			1	1
Toothache		1		1		
Transaminases increased		1				1
Traumatic lung injury		2		2		
Tremor	6	13	6	13		
Tympanic membrane disorder		1		1		
Type I hypersensitivity		1				1
Upper-airway cough syndrome		1		1		
Urinary incontinence		2		2		
Urinary tract infection		1		1		
Urticaria	3	5	3	5		
Vaccination complication	2	2	1	1	1	1
Vaccination site cellulitis	4	13	3	6	1	7
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	3	12	2	11	1	1
Vaccination site haemorrhage		1				1
Vaccination site hyperaesthesia		2		2		
Vaccination site hypersensitivity	8	25	8	25		
Vaccination site hypoaesthesia	1	2	1	2		
Vaccination site induration	7	20	6	16	1	4
Vaccination site inflammation	2	11	1	9	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site joint pain		1		1		
Vaccination site movement impairment	2	4	2	4		
Vaccination site nodule	1	7		5	1	2
Vaccination site oedema	3	12	2	10	1	2
Vaccination site pain	50	181	47	171	3	10
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus		2		1		1
Vaccination site rash	1	2	1	1		1
Vaccination site reaction	1	9	1	9		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	13	1	13		
Vaginal haemorrhage		1		1		
Vasodilatation		1		1		
Vertigo	6	17	5	15	1	2
Vestibular neuronitis		1				1
Vision blurred	8	25	7	22	1	3
Vomiting	39	128	25	103	14	25
Wheezing	1	1			1	1
White blood cell count increased		1				1
Wrong technique in product usage process	1	1	1	1		
Xerophthalmia	1	1			1	1
	2,452	9,564	1798	7573	654	1991

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	6	19	6	17		2
Abdominal pain upper		2		2		
Abscess	2	2	1	1	1	1
Acne	1	1	1	1		
Acute myocardial infarction		1				1
Anaphylactic reaction	1	4			1	4
Anaphylactic shock	2	10			2	10
Angioedema		1				1
Anosmia		1		1		
Antibody test negative	1	1	1	1		
Anxiety	3	7	1	3	2	4
Application site pain		1		1		
Arrhythmia	1	2			1	2
Arthralgia	24	64	22	56	2	8
Asthenia	37	85	33	76	4	9
Asthma	1	1	1	1		
Aura		1				1
Axillary pain	1	3	1	3		
Back pain	2	3	2	3		
Balance disorder	1	1	1	1		
Blister	1	1	1	1		
Blood pressure increased	2	8	2	5		3
Body temperature increased	9	16	8	15	1	1
Bradycardia		2				2
Brain oedema		1				1
Breast pain		1		1		
Bronchospasm	4	10	1	5	3	5
Burning sensation	1	1	1	1		
Cellulitis	8	11			8	11
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	6		5	1	1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	6	10	5	9	1	1
Chills	18	54	18	45		9
Condition aggravated		1				1
Confusional state		1		1		
Conjunctivitis	1	1	1	1		
Contusion	1	1	1	1		
Cough	14	34	13	30	1	4
COVID-19	3	10	3	3		7
COVID-19 pneumonia		2				2
Crying	1	1	1	1		
Death	1	1			1	1
Decreased activity		1		1		
Decreased appetite	4	18	4	15		3
Dehydration		1		1		
Demyelinating polyneuropathy	1	1			1	1
Dermatitis allergic	1	1	1	1		
Dermatosis		1		1		
Diarrhoea	12	21	8	15	4	6
Diplegia		1				1
Diplopia	1	1	1	1		
Discomfort	2	5	1	3	1	2
Disease recurrence	1	1			1	1
Disorientation		1		1		
Disturbance in attention	1	1	1	1		
Dizziness	23	96	19	78	4	18
Drug ineffective		5				5
Dry mouth		2		1		1
Dry throat		1				1
Dysaesthesia		3		2		1
Dysgeusia	1	2	1	2		
Dyslalia	1	1			1	1
Dyspepsia	1	2	1	2		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	1	3	1	3		
Dysphonia	2	3	1	2	1	1
Dyspnoea	27	88	19	67	8	21
Dystonia	1	1			1	1
Ear discomfort		1		1		
Ear pain	1	2	1	1		1
Ecchymosis		1		1		
Embolism	1	1			1	1
Epistaxis		1		1		
Erythema	9	20	9	20		
Eye injury		1				1
Eyelid oedema		1		1		
Eyelid ptosis	2	2	2	2		
Eye movement disorder		1				1
Eye pain	1	1	1	1		
Eye pruritus	1	1	1	1		
Face oedema	1	1	1	1		
Facial nerve disorder		1		1		
Facial paralysis	2	7			2	7
Facial paresis		1		1		
Facial spasm	1	1	1	1		
Fall	2	2	1	1	1	1
Fatigue	27	70	24	62	3	8
Febrile convulsion	1	1	1	1		
Feeling abnormal		2		1		1
Feeling cold	2	2	1	1	1	1
Feeling hot	2	3	2	3		
Flank pain		1		1		
Gastrointestinal haemorrhage	1	1			1	1
Gastrooesophageal reflux disease	1	1	1	1		
Generalised tonic-clonic seizure		2				2
General physical health deterioration		2		2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General symptom	1	1			1	1
Guillain-Barre syndrome	2	3			2	3
Haematochezia	2	3			2	3
Haematoma	1	1	1	1		
Haemorrhage	6	8			6	8
Haemorrhagic disorder	3	3			3	3
Hallucination, visual		1				1
Headache	47	132	38	110	9	22
Heart rate increased	1	3	1	3		
Hemiparaesthesia	1	1			1	1
Hemiparesis		1				1
Hot flush		1		1		
Hyperaemia	2	2	2	2		
Hyperglycaemia	1	1			1	1
Hyperhidrosis		6		3		3
Hypersensitivity	2	6	2	4		2
Hypertension	4	16		8	4	8
Hypertensive crisis	5	24			5	24
Hyperthermia	1	3	1	3		
Hypoacusis		1		1		
Hypoaesthesia	2	3	1	1	1	2
Hypoaesthesia oral	1	3	1	2		1
Hypoglycaemia		1				1
Hypokinesia	1	1	1	1		
Hypotension	2	2			2	2
Hypothermia		3				3
Hypovolaemic shock	4	5			4	5
Induration	10	19	8	17	2	2
Inflammation	3	15	3	15		
Influenza like illness	1	1	1	1		
Insomnia	1	2	1	2		
Intussusception	2	2			2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Irritability	3	9	1	6	2	3
Ischaemic stroke	1	1			1	1
Joint swelling		1		1		
Laryngeal oedema	1	3			1	3
Laryngospasm		1				1
Larynx irritation		1				1
Lateropulsion		1				1
Lethargy		1				1
Leukopenia		1				1
Limb discomfort	2	2	2	2		
Lip disorder		1		1		
Lip oedema		1		1		
Local reaction	4	5	4	5		
Loss of consciousness		2				2
Lymphadenopathy	3	6	2	4	1	2
Malaise	3	11	2	7	1	4
Masticatory pain		1		1		
Metamorphopsia		1		1		
Mobility decreased	1	3	1	3		
Monoparesis	1	1			1	1
Monoplegia		1				1
Movement disorder	1	1	1	1		
Muscle spasms		2		2		
Muscular weakness	1	4		2	1	2
Myalgia	25	71	23	61	2	10
Nasal congestion	2	2	2	2		
Nasal pruritus	1	2	1	2		
Nausea	24	68	17	56	7	12
Neck pain		2		2		
Nervous system disorder	1	1			1	1
Neuralgia	1	1	1	1		
Neuropathy peripheral		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nodule	10	21	8	18	2	3
Obstructive airways disorder		1				1
Ocular hyperaemia	1	1	1	1		
Odynophagia	1	5	1	5		
Oedema	7	26	5	24	2	2
Oedema peripheral	1	2	1	2		
Off label use		1		1		
Oral administration complication		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	8	36	6	32	2	4
Oxygen saturation abnormal	1	2	1	1		1
Oxygen saturation decreased	1	7	1	6		1
Pain	37	99	32	86	5	13
Pain in extremity	10	14	10	14		
Pain in jaw		1				1
Pain of skin		1		1		
Pallor		1		1		
Palpitations	3	4	3	4		
Paraesthesia	4	15	1	9	3	6
Paraesthesia mucosal	1	1			1	1
Paraesthesia oral	2	3	1	1	1	2
Paralysis		1				1
Parotid gland enlargement		1		1		
Parotitis		1		1		
Petit mal epilepsy		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	1	1	1	1		
Photophobia	1	1	1	1		
Pneumonia	1	4			1	4
Productive cough	1	1	1	1		
Product use issue		1		1		
Pruritus	13	25	10	21	3	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary pain	1	1	1	1		
Pyrexia	22	55	21	49	1	6
Rash	5	20	4	15	1	5
Rash erythematous		1				1
Respiratory disorder	1	2		1	1	1
Respiratory distress	24	84			24	84
Respiratory failure	2	3			2	3
Rhinalgia		1		1		
Rhinorrhoea	9	26	8	23	1	3
Salivary hypersecretion		1				1
Seizure	2	8			2	8
Sensation of foreign body	2	3			2	3
Sensitisation		1		1		
Sensitive skin	34	73	29	66	5	7
Skin burning sensation		1		1		
Skin disorder		1		1		
Sleep inertia		1				1
Somnolence	1	4	1	4		
Stevens-Johnson syndrome	1	2			1	2
Swelling	2	2	2	2		
Syncope	3	10			3	10
Tachycardia	18	61	14	47	4	14
Tachypnoea	2	3	1	1	1	2
Taste disorder	1	1	1	1		
Tension headache		1		1		
Thirst		1		1		
Throat irritation		1				1
Tinnitus		2		2		
Tongue oedema		1		1		
Toothache		1		1		
Tremor	2	3	2	3		
Upper airway obstruction		1				1

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	2	3	2	3		
Vaccination site abscess	1	1	1	1		
Vaccination site cellulitis	3	3	3	3		
Vaccination site discomfort	2	3	2	3		
Vaccination site erythema	3	6	3	5		1
Vaccination site haematoma	1	1	1	1		
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity		2		2		
Vaccination site induration	1	5	1	4		1
Vaccination site inflammation	2	3	2	3		
Vaccination site movement impairment	1	1	1	1		
Vaccination site nodule	1	3	1	3		
Vaccination site oedema	1	4	1	3		1
Vaccination site pain	16	39	16	39		
Vaccination site pruritus	1	2	1	2		
Vaccination site reaction		3		2		1
Vaccination site swelling	1	1	1	1		
Vascular test abnormal		1		1		
Vertigo		3		2		1
Vision blurred		3		2		1
Vomiting	12	25	8	17	4	8
Wheezing	2	4		1	2	3
Wrong technique in product usage process	2	2	2	2		
	760	2,036	562	1491	198	545

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2	1	1	1	1
Abdominal pain	6	7	3	4	3	3
Abdominal pain upper	1	1	1	1		
Abdominal symptom	1	1	1	1		
Abnormal faeces	1	1			1	1
Abscess	2	2	2	2		
Aggression	2	2	2	2		
Amnesia	1	1			1	1
Angioedema		1				1
Anosmia	1	1	1	1		
Anxiety	1	1	1	1		
Aphasia		1		1		
Aphthous ulcer	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	5	9	3	6	2	3
Arthritis	1	1	1	1		
Asthenia	25	31	20	26	5	5
Asymptomatic COVID-19		1				1
Back pain		1		1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	5	5	2	2	3	3
Body temperature increased	4	6	4	6		
Bronchospasm	1	2			1	2
Cardio-respiratory arrest	1	1			1	1
Cardiovascular disorder	1	1	1	1		
Cellulitis	4	4			4	4
Cerebral haematoma		1				1
Chills	8	12	6	10	2	2
Choluria	1	1			1	1
Colitis	1	1	1	1		
Condition aggravated	1	1			1	1
Cough	3	6	2	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Crying	1	1
Cystitis	1	1
Death		1
Decreased appetite	3	4
Depressed level of consciousness		1
Diabetes mellitus	1	1
Diarrhoea	7	9
Discomfort	2	4
Disseminated Bacillus Calmette-Guerin infection	2	2
Diverticulum intestinal	1	1
Dizziness	13	18
Drug ineffective		1
Dry mouth	1	1
Dysgeusia	1	1
Dyspnoea	10	17
Dysstasia		1
Eating disorder	1	1
Embolism	1	1
End stage renal disease	1	1
Erythema	5	8
Eye discharge	1	1
Eye irritation	1	1
Eyelid ptosis	1	1
Facial paralysis	2	2
Fall		1
Fatigue	21	26
Feeling cold		1
Gait disturbance		1
Gastritis	1	1
Generalised tonic-clonic seizure	1	1
Gingival pain	1	1
Gingival swelling	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
			1
3	4		
			1
		1	1
5	7	2	2
1	3	1	1
		2	2
		1	1
11	16	2	2
			1
1	1		
1	1		
6	11	4	6
	1		
1	1		
		1	1
		1	1
3	6	2	2
1	1		
1	1		
1	1		
		2	2
			1
18	23	3	3
	1		
	1		
1	1		
		1	1
1	1		
1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glossodynia	1	1	1	1		
Guillain-Barre syndrome	2	2			2	2
Haematochezia	3	3			3	3
Haemolytic anaemia	1	1			1	1
Haemorrhage	7	7			7	7
Haemorrhagic disorder	2	2			2	2
Headache	23	30	20	27	3	3
Heart rate increased	1	1	1	1		
Hemiparesis	1	1			1	1
Herpes zoster		1		1		
Hip fracture		1				1
Hyperhidrosis		2		2		
Hypersensitivity	1	1	1	1		
Hypersomnia	1	1	1	1		
Hypertension		2				2
Hypertensive crisis	3	7			3	7
Hyperthermia		1		1		
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1			1	1
Hypotension	1	1	1	1		
Hypovolaemic shock	5	5			5	5
Induration	7	7	7	7		
Inflammation	3	5	3	5		
Intussusception	2	2			2	2
Irritability	2	3	2	3		
Jaundice	1	1			1	1
Joint range of motion decreased	1	1	1	1		
Lip oedema	1	1	1	1		
Local reaction	2	2	2	2		
Loss of consciousness	1	2			1	2
Lung disorder	1	1	1	1		
Lymphadenopathy	6	7	6	7		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	3	4	3	4		
Migraine	1	1	1	1		
Mobility decreased		1		1		
Movement disorder	1	1			1	1
Muscle tightness	1	1	1	1		
Muscular weakness	1	2		1	1	1
Myalgia	10	15	6	10	4	5
Myalgia intercostal	1	1	1	1		
Myocardial infarction		1				1
Myoclonic epilepsy	1	1			1	1
Nasopharyngitis	1	1	1	1		
Nausea	11	14	8	11	3	3
Neck pain	1	1	1	1		
Nodule	7	7	7	7		
Ocular hyperaemia	1	1	1	1		
Odynophagia		1		1		
Oedema	1	4	1	4		
Oedema peripheral	2	2	2	2		
Off label use	1	1	1	1		
Oropharyngeal pain	2	3	2	2		1
Oxygen saturation decreased		1				1
Pain	18	22	16	20	2	2
Pain in extremity	7	8	7	8		
Panic attack	1	1	1	1		
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1			1	1
Paralysis	3	3			3	3
Peripheral swelling	1	1	1	1		
Peripheral vascular disorder	1	1			1	1
Platelet count decreased	1	1			1	1
Pneumonia	1	2			1	2
Poor quality product administered	1	1	1	1		

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 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	5	8	4	6	1	2
Pyrexia	10	14	9	12	1	2
Rash	4	8	4	7		1
Respiratory arrest	2	2			2	2
Respiratory distress	13	20			13	20
Rhinorrhoea	4	6	4	5		1
Screaming	1	1	1	1		
Seizure	1	2			1	2
Sensitive skin	12	15	10	13	2	2
Septic shock	1	1			1	1
Skin lesion	1	1	1	1		
Slow speech	1	1	1	1		
Somnolence		2		2		
Splenomegaly	1	1	1	1		
Stomatitis	1	1	1	1		
Swelling face	1	1	1	1		
Swollen tongue	1	1	1	1		
Syncope	2	2			2	2
Tachycardia	7	9	6	8	1	1
Tachypnoea	1	1			1	1
Thermal burns of eye	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus	1	1			1	1
Urinary tract infection	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site cellulitis	1	2	1	1		1
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	1	1	1	1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hyperaesthesia		1		1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site induration	1	2	1	2		
Vaccination site inflammation	1	1	1	1		
Vaccination site nodule	1	2	1	2		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	14	16	14	16		
Vaccination site pruritus	2	2	2	2		
Vaccination site reaction	3	3	3	3		
Vaccination site recall reaction	1	1	1	1		
Vertigo		1		1		
Vomiting	6	7	4	5	2	2
Wrong product administered	1	1	1	1		
Wrong technique in product usage process	3	3	3	3		
	443	584	310	412	133	172

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Acute myocardial infarction	1	1			1	1
Arthralgia	2	2	2	2		
Asthenia	9	9	5	5	4	4
Body temperature increased	1	1	1	1		
Cardio-respiratory arrest	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills	4	4	2	2	2	2
Contusion	1	1	1	1		
Cough	2	2	1	1	1	1
COVID-19	1	1	1	1		
COVID-19 pneumonia	1	1			1	1
Diarrhoea	2	2	2	2		
Disseminated Bacillus Calmette-Guerin infection	2	2			2	2
Dizziness	2	2	1	1	1	1
Dyspnoea	2	2	2	2		
Epistaxis	1	1			1	1
Erythema	2	2	1	1	1	1
Eye irritation	1	1	1	1		
Fall	1	1			1	1
Fatigue	5	5	3	3	2	2
Gait disturbance	1	1	1	1		
Guillain-Barre syndrome	2	2			2	2
Haematochezia	1	1			1	1
Haemorrhage	1	1			1	1
Headache	5	5	3	3	2	2
Hemiparaesthesia	1	1			1	1
Hypertension	1	1			1	1
Hypovolaemic shock	1	1			1	1
Induration	1	1			1	1
Insomnia	1	1			1	1
Intussusception	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Irritability	1	1			1	1
Lacrimation increased	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Muscular weakness	2	2	1	1	1	1
Myalgia	3	3	2	2	1	1
Myocardial infarction	1	1			1	1
Nausea	3	3	2	2	1	1
Nodule	1	1			1	1
Ocular hyperaemia	1	1	1	1		
Oropharyngeal pain	1	1			1	1
Pain	4	4	2	2	2	2
Pain in extremity	1	1			1	1
Palpitations	1	1	1	1		
Paraesthesia	2	2	1	1	1	1
Paraparesis	1	1			1	1
Pneumonia	1	1			1	1
Pruritus	2	2	2	2		
Pyrexia	4	4	2	2	2	2
Rash	3	3	3	3		
Rash macular	1	1	1	1		
Rash maculo-papular	1	1	1	1		
Respiratory distress	2	2			2	2
Rhinorrhoea	1	1	1	1		
Sensitive skin	3	3	1	1	2	2
Skin mass	1	1	1	1		
Skin reaction	1	1			1	1
Somnolence	1	1	1	1		
Swelling	1	1	1	1		
Urticaria	2	2	1	1	1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	3	2	2	1	1
Vomiting	3	3	1	1	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	114	114	59	59	55	55

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Acne	1	1	1	1		
Allergy to vaccine		3		3		
Anaphylactic reaction		1				1
Anaphylactoid reaction		1				1
Anosmia		1		1		
Antibody test abnormal	1	2	1	2		
Antibody test negative	1	2	1	2		
Anxiety	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	3	6	3	6		
Asthenia	3	5	2	4	1	1
Back pain	1	1	1	1		
Blister	1	1			1	1
Blood pressure decreased		1				1
Blood pressure increased	2	2	1	1	1	1
Body temperature increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Bronchospasm		1				1
Burning sensation	1	1	1	1		
Burn oral cavity	1	1			1	1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	1	1			1	1
Chest pain		2		1		1
Chills		1		1		
Choking	1	1			1	1
Choking sensation		1				1
Cough	2	2	1	1	1	1
Counterfeit product administered	2	2	2	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3	4	10
			1
1	1		
1	1		
1	1		
1	1		
2	4	1	1
1	3	1	1
2	4		
		1	1
		4	9
		1	1
	1		1
			1
1	1	1	1
3	3		
1	1		
		1	
1	1		
			1
1	5		
1	1		
1	1		
1	1		
1	2		
	1		
1	1		
6	10	2	2
	1		
	1		1
1	1		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemia	2	2	2	2		
Hyperhidrosis	1	1			1	1
Hypersensitivity	1	3	1	3		
Hypoaesthesia		3		3		
Immunology test abnormal	1	1	1	1		
Inappropriate schedule of product administration	3	6	3	6		
Laryngospasm		1		1		
Laziness	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	5	6	4	5	1	1
Lymph node pain		1		1		
Malaise	3	5	2	4	1	1
Maternal exposure during pregnancy	4	8	4	8		
Measles	1	1			1	1
Melaena	1	1			1	1
Monoparesis		1				1
Mouth swelling	1	1			1	1
Muscle spasms		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia		2		2		
Nasal congestion	1	1	1	1		
Nausea		4		4		
Neck pain	1	1	1	1		
Nervousness		1		1		
Neutrophil count increased	2	2	2	2		
Night sweats	1	1			1	1
Noninfective gingivitis	1	1	1	1		
Ocular discomfort	1	1	1	1		
Off label use	1	4	1	4		
Oral candidiasis		1		1		
Oropharyngeal pain		1		1		
Overdose	1	1	1	1		

\* I=Interval, C=Cumulative  
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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
6	8		
5	5		
	1		
	5	1	1
	1		
			1
1	1		
2	2		
			3
1	1		
1	1		
1	1		
	2		
1	1		
			1
4	10	3	9
2	4		2
1	1	1	2
			2
	1		
	1		
	2		2
1	1		
2	2		
1	1		
1	1		
	1		
2	2		
1	2	1	2
2	2		
1	1		

Oxygen saturation decreased 1

Pain 6 8

Pain in extremity 5 5

Palate injury 1 1

Paraesthesia 1 6

Parotitis 1 1

Pharyngeal oedema 1 1

Pharyngeal ulceration 1 1

Platelet count increased 2 2

Pneumonia 3

Poor quality product administered 1 1

Product colour issue 1 1

Product complaint 1 1

Product use issue 2

Pruritus 1 1

Pyelonephritis 1 1

Pyrexia 4 10

Rash 2 4

Rash macular 1 1

Respiratory distress 2

Rhinitis 1 1

Rhinorrhoea 1 1

Seizure 2 2

Skin discolouration 1 1

Somnolence 2 2

Stasis dermatitis 1 1

Stress 1 1

Suffocation feeling 1 1

Suspected counterfeit product 2 2

Suspected COVID-19 1 2

Swelling 2 2

Synovial cyst 1 1

\* I=Interval, C=Cumulative  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tachycardia		3		2		1	
Thermal burn	1	1			1	1	
Throat tightness	1	1			1	1	
Thrombosis	2	2			2	2	
Toxic epidermal necrolysis	1	1			1	1	
Toxicity to various agents	1	1			1	1	
Transaminases increased		1				1	
Urticaria		1		1			
Vaccination site pain	3	9	3	9			
Vaccination site rash		1		1			
Vaccination site swelling	1	1	1	1			
Vertigo	1	1	1	1			
Vomiting	1	2	1	2			
Wrong product administered	1	1	1	1			
	150	291	109	211	41	80	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred  
**MONACO**

Age Range

**65 - 79 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
Drug ineffective		1		1
Speech disorder		1		1
		3		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**NETHERLANDS**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain	3	4	3	4		
Abdominal pain upper	1	3	1	3		
Abnormal loss of weight	1	1	1	1		
Abortion missed	1	1			1	1
Abortion spontaneous	3	4			3	4
Affect lability	1	1	1	1		
Ageusia		1		1		
Allergy to vaccine	1	2	1	1		1
Anal sphincter hypertonia		1		1		
Anaphylactic reaction		3				3
Angioedema		1				1
Anosmia		1		1		
Anxiety	1	1	1	1		
Aphasia		1		1		
Arthralgia	27	81	27	81		
Asthenia		2		2		
Axillary pain	1	3	1	3		
Back pain	1	2	1	2		
Balance disorder		1		1		
Blindness	1	1			1	1
Blindness unilateral		1				1
Blister		1		1		
Blood pressure increased	2	2	2	2		
Blood pressure systolic increased		1		1		
Body temperature increased	3	12	3	12		
Cerebral venous sinus thrombosis	1	1			1	1
Chest discomfort	2	4	1	2	1	2
Chest pain	2	5	2	5		
Chillblains	1	1	1	1		
Chills	44	116	44	114		2
Constipation		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	1	1	1		
Cough		1		1		
COVID-19	2	4			2	4
Cyanosis		1				1
Dacryocystitis	1	1			1	1
Dark circles under eyes		1		1		
Decreased appetite	1	2	1	2		
Delirium febrile		1				1
Depressed level of consciousness		1				1
Dermatitis bullous		1				1
Diarrhoea	1	6	1	6		
Diplopia		1		1		
Discomfort	1	1	1	1		
Disturbance in attention		1		1		
Dizziness	4	26	3	22	1	4
Drug ineffective	2	4			2	4
Dysarthria		1		1		
Dysgeusia		2		2		
Dyspepsia	1	1	1	1		
Dysphagia	1	3	1	2		1
Dyspnoea	3	9	2	7	1	2
Dyspnoea at rest	2	2			2	2
Dyspnoea exertional	1	1	1	1		
Emotional distress	1	1	1	1		
Encephalitis autoimmune	1	1			1	1
Endocrine ophthalmopathy	1	1			1	1
Epilepsy	3	6			3	6
Epistaxis	1	1	1	1		
Erythema		5		5		
Exposure during pregnancy		1		1		
Extensive swelling of vaccinated limb	23	66	23	66		
Extrasystoles		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Eye pruritus		1		1			
Eye swelling	1	1	1	1			
Eye symptom	1	1	1	1			
Facial paralysis	1	2			1	2	
Facial paresis		1		1			
Faeces discoloured	1	2	1	2			
Fatigue	89	187	89	186		1	
Feeling abnormal	1	1	1	1			
Feeling hot		3		3			
Feeling jittery	1	1	1	1			
Feeling of body temperature change	1	1	1	1			
Flushing		2		2			
Gait disturbance		2		2			
Gastrointestinal pain		1		1			
Generalised tonic-clonic seizure	1	4			1	4	
Genital paraesthesia		1		1			
Haematocrit decreased	1	1	1	1			
Haemoglobin decreased	1	1	1	1			
Haemorrhage	1	1			1	1	
Headache	99	217	98	214	1	3	
Head discomfort		2		1		1	
Heart rate increased	1	1	1	1			
Hemianaesthesia		1					1
Hepatic failure	1	1			1	1	
Hepatitis acute	1	1			1	1	
Herpes zoster		1		1			
Hot flush		1		1			
Hyperaesthesia teeth		1		1			
Hyperhidrosis		8		7		1	
Hyperpyrexia	8	18			8	18	
Hypersensitivity	1	7	1	2		5	
Hypertension	1	6	1	5		1	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperventilation		3
Hypoacusis		1
Hypoaesthesia oral		1
Hyponatraemia		1
Hypotension		1
Hypoxia	1	1
Injected limb mobility decreased		1
Injection site discomfort		1
Injection site erythema		1
Injection site haematoma		1
Injection site inflammation		1
Injection site pain	1	3
Injection site pruritus		1
Injection site swelling	1	2
Injection site warmth		1
Insomnia	2	2
Laryngitis		1
Lip swelling	1	1
Listless	1	1
Loss of consciousness	1	6
Lung disorder		1
Lymphadenopathy	5	18
Malaise	78	185
Migraine		2
Muscle spasms		1
Muscle strain		1
Muscle twitching	1	2
Muscular weakness	1	2
Musculoskeletal pain	8	8
Myalgia	106	236
Myoclonus	1	1
Nasopharyngitis	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		2
	1		
			1
	1		
			1
		1	1
	1		
	1		
	1		
	1		
1	3		
	1		
1	2		
	1		
2	2		
	1		
1	1		
1	1		
		1	6
	1		
5	18		
77	180	1	5
	1		1
	1		
	1		
1	2		
	1	1	1
8	8		
106	236		
1	1		
1	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
51	113		3
		2	3
	1		
	1		
	1		
1	1		
1	4		
1	1		
5	7		
1	1		
4	7		
1	3		
	1		1
1	2		3
2	6		
	1		
1	1		
	1		
1	1		
			1
	1		2
1	1		
		2	2
1	1		
1	2	1	1
2	8		
	1		
39	84	4	5
1	4		1
	1		
	1		
		1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract irritation	1	1	1	1		
Restless legs syndrome		1		1		
Restlessness		1		1		
Seizure	1	2			1	2
Skin discolouration	1	1	1	1		
Skin induration	1	1	1	1		
Speech disorder		1		1		
Status epilepticus	1	2			1	2
Swelling	2	4	2	4		
Swelling face		2		1		1
Swelling of eyelid	1	2	1	2		
Swollen tongue		1		1		
Syncope	7	19			7	19
Tachycardia		1				1
Tachypnoea	1	1	1	1		
Thirst	1	1	1	1		
Throat tightness		1				1
Thrombocytopenia	1	1			1	1
Tinnitus	1	1	1	1		
Tonsillitis		1		1		
Torticollis		1		1		
Tremor		1		1		
Urinary retention		2				2
Urinary tract infection		1		1		
Urticaria	2	9	2	5		4
Uvulitis		1		1		
Vaccination site bruising	8	17	8	17		
Vaccination site erythema	29	77	29	77		
Vaccination site haematoma	5	20	5	20		
Vaccination site induration		3		3		
Vaccination site inflammation	28	56	28	56		
Vaccination site pain	73	161	73	161		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	14	35	14	35		
Vaccination site rash		1		1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	39	90	39	90		
Vaccination site warmth	39	91	39	91		
Vasculitis	1	1	1	1		
Vertigo	1	5	1	5		
Vision blurred	1	2	1	2		
Visual impairment	2	3	2	2		1
Vomiting	1	4	1	4		
Wound		1		1		
	953	2,289	894	2127	59	162

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal discomfort		3				3			
Abdominal pain	4	4			4	4			
Abdominal pain upper		5				5			
Abnormal dreams		1				1			
Abortion missed	1	1					1	1	
Abortion spontaneous	4	5					4	5	
Accommodation disorder		1				1			
Acute myocardial infarction	1	1					1	1	
Ageusia	1	3			1	3			
Allergy to vaccine				1					
Anaphylactic reaction	1	7					1	7	
Anaphylactic shock	1	2					1	2	
Anembryonic gestation	1	1					1	1	
Angina pectoris		1							1
Angina unstable		1							1
Angioedema	2	6					2	6	
Anosmia	1	2			1	2			
Anxiety	1	1			1	1			
Aphonia		1							1
Appendicitis	1	1					1	1	
Arrhythmia	5	7					5	7	
Arthralgia	63	145			62	144	1	1	
Asthma		1							1
Ataxia	1	1					1	1	
Autonomic nervous system imbalance		1							1
Axillary pain	1	7			1	7			
Back pain	1	2			1	2			
Balance disorder	1	2				1	1	1	
Blood glucose decreased		2				2			
Blood pressure decreased		2				1			1
Blood pressure increased		1				1			
Body temperature increased	3	25			3	24			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bradycardia		1
Bronchospasm		1
Bundle branch block right		1
Catatonia		1
Cerebellar infarction	1	1
Cerebellar ischaemia	1	1
Chest discomfort	2	4
Chest pain	4	11
Chillblains	1	1
Chills	76	190
Choking sensation		1
Cholecystitis		1
Cold sweat	3	4
Condition aggravated		1
Confusional state	1	2
Conjunctival haemorrhage		1
Conversion disorder		1
Coordination abnormal	1	1
Cough	1	5
COVID-19		1
Cystitis	1	1
Deafness neurosensory		1
Deafness unilateral		1
Death		1
Decreased appetite		1
Delirium		1
Depressed level of consciousness		1
Depressed mood		1
Depression		2
Derealisation		1
Dermatitis bullous	1	1
Diaphragmalgia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
					1
				1	1
				1	1
		2	4		
		3	9	1	2
		1	1		
		75	189	1	1
					1
					1
		3	4		
					1
		1	1		1
					1
					1
		1	1		
		1	3		2
			1		
		1	1		
					1
			1		
					1
					1
			1		
			2		
			1		
				1	1
			1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diarrhoea	4	14
Diplopia	1	1
Discomfort	1	1
Disease recurrence	1	1
Disturbance in attention		3
Dizziness	9	35
Dry eye		1
Dysarthria		2
Dysgeusia	1	3
Dysphagia		3
Dyspnoea	8	24
Dyspnoea exertional	1	3
Ear pain		2
Eczema	1	1
Epilepsy	2	7
Epistaxis		1
Eructation		1
Erysipelas		2
Erythema	4	14
Exposure during pregnancy		1
Extensive swelling of vaccinated limb	41	118
Extrasystoles	1	1
Eye disorder		1
Eye pain		1
Eye pruritus	1	2
Eye swelling	1	2
Facial neuralgia	1	1
Facial paralysis	2	2
Facial paresis	1	1
Fall		1
Fatigue	126	271
Feeling abnormal	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	14		
		1	1		
				1	1
				1	1
			3		
		9	35		
			1		
			1		1
		1	3		
			2		1
	1	6	18	2	6
			1	1	2
			2		
		1	1		
				2	7
			1		
			1		
					2
		4	13		1
			1		
		40	117	1	1
		1	1		
			1		
			1		
		1	2		
		1	2		
		1	1		
				2	2
		1	1		
					1
		125	269	1	2
		1	3	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling cold	1	6
Feeling drunk		2
Feeling hot	1	6
Fluid retention		1
Flushing		1
Food allergy		1
Gait disturbance		2
Gait inability	1	1
Generalised tonic-clonic seizure		2
Haemoptysis	1	1
Hallucination		1
Headache	148	310
Head discomfort		1
Heart rate increased		2
Hemiplegia	1	1
Hepatitis	1	1
Hepatitis cholestatic		1
Herpes zoster		2
Hot flush	1	2
Hyperhidrosis		3
Hyperpyrexia	12	29
Hypersensitivity	1	4
Hypersomnia		1
Hypertension		5
Hyperventilation	2	2
Hypoaesthesia		3
Hypoaesthesia oral		1
Hypoglycaemia		1
Hypotension		3
Ill-defined disorder	1	1
Inappropriate schedule of product administration	3	3
Incorrect route of product administration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		1
			2		
		1	6		
			1		
			1		
			1		
			1		1
		1	1		
					2
		1	1		
					1
		146	306	2	4
			1		
			1		1
				1	1
				1	1
			2		
		1	2		
			3		
				12	29
		1	3		1
			1		
			4		1
		2	2		
			2		1
			1		
			1		
			2		1
				1	1
		3	3		
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased tendency to bruise		1
Increased upper airway secretion		1
Injected limb mobility decreased	2	3
Injection site erythema	1	4
Injection site induration		1
Injection site inflammation	4	7
Injection site pain	6	11
Injection site pruritus	1	2
Injection site swelling	2	4
Injection site warmth	3	5
Intracranial pressure increased	1	1
Jaundice		1
Lacrimation increased		1
Limb discomfort	1	2
Loss of consciousness	2	6
Loss of control of legs	1	1
Loss of personal independence in daily activities		1
Lung disorder	1	1
Lymphadenopathy	21	41
Lymphangitis		2
Lymph node pain	3	4
Malaise	114	266
Maternal exposure during pregnancy	2	2
Memory impairment		1
Meniere's disease		1
Mental impairment	1	1
Migraine	2	2
Multiple sclerosis	1	2
Muscle contractions involuntary	1	1
Muscle disorder	1	1
Muscle rigidity	1	1
Muscle strain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		2	3		
		1	4		
			1		
		4	7		
		6	11		
		1	2		
		2	4		
		3	5		
				1	1
					1
			1		
			1	1	1
				2	6
				1	1
			1		
		1	1		
		21	41		
					2
		3	4		
		112	259	2	7
		1	1	1	1
			1		
					1
				1	1
		2	2		
				1	2
		1	1		
		1	1		
		1	1		
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle tightness		1
Muscular weakness	1	1
Musculoskeletal discomfort		1
Musculoskeletal pain	6	6
Musculoskeletal stiffness	2	3
Myalgia	137	299
Nasal congestion		1
Nasopharyngitis	2	2
Nausea	50	123
Neck pain		1
Neuralgia		1
Neuropathy peripheral	1	1
Ocular hyperaemia		1
Oedema		1
Oedema peripheral		1
Off label use	3	3
Optic neuritis		1
Oral mucosal blistering		2
Oropharyngeal discomfort		2
Oropharyngeal pain	4	10
Oxygen saturation decreased	1	1
Pain	7	13
Painful respiration		1
Pain in extremity	9	27
Pain in jaw	2	2
Pain of skin		1
Pallor	1	3
Palpitations	2	8
Paraesthesia	3	15
Paraesthesia oral	2	6
Parosmia		1
Pericarditis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			1		
		6	6		
		2	3		
		135	296	2	3
			1		
		2	2		
		49	121	1	2
			1		
			1		
				1	1
			1		
			1		
			1		
		3	3		
					1
			2		
			2		
		4	10		
		1	1		
		7	13		
			1		
		8	26	1	1
		2	2		
			1		
		1	2		1
		2	6		2
		2	14	1	1
		1	5	1	1
			1		
				1	1

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Periorbital swelling		1
Peripheral coldness		1
Peripheral swelling	1	3
Petechiae	1	1
Pharyngeal oedema		1
Pharyngeal paraesthesia	1	1
Pharyngeal swelling	2	4
Pituitary apoplexy		1
Pneumonia	1	2
Pneumonia aspiration	1	1
Polyuria		1
Presyncope		5
Pruritus	1	7
Psychotic symptom		2
Pulmonary embolism	4	5
Pulmonary pain		1
Pyrexia	63	126
Rash	2	6
Rash erythematous	1	4
Rash papular		2
Raynaud's phenomenon		1
Renal disorder		1
Respiratory disorder		1
Respiratory rate increased		1
Respiratory tract oedema		1
Restlessness		1
Retching		1
Rheumatoid arthritis		1
Rhinorrhoea	1	2
Salivary gland pain		1
Sciatica		1
Sensation of foreign body	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	3		
		1	1		
					1
				1	1
		2	2		2
					1
				1	2
				1	1
			1		
			4		1
	1	1	7		
					2
				4	5
			1		
		61	121	2	5
	1	2	4		2
		1	4		
			2		
			1		
			1		
					1
					1
			1		
			1		
					1
		1	2		
			1		
					1
				1	2

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus tachycardia	1	2
Skin burning sensation		1
Skin discolouration		1
Sneezing		2
Somnolence		1
Speech disorder		1
Stridor		1
Sudden hearing loss	1	3
Swelling	3	4
Swelling face		3
Swelling of eyelid	1	2
Swollen tongue		5
Syncope	10	20
Tachycardia		2
Taste disorder		1
Throat tightness	1	1
Thrombophlebitis		1
Thrombosis	2	3
Tinnitus	1	4
Tongue disorder		3
Tongue oedema		1
Tonsillitis		1
Transient ischaemic attack	2	4
Tremor	2	8
Urticaria	1	6
Vaccination site bruising	6	12
Vaccination site discomfort	2	6
Vaccination site erythema	41	116
Vaccination site haematoma	8	21
Vaccination site haemorrhage		1
Vaccination site induration	3	10
Vaccination site inflammation	27	76

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		
			1		
			2		
			1		
					1
					1
				1	3
		3	4		
			2		1
		1	2		
			2		3
				10	20
			1		1
			1		
		1	1		
			1		
				2	3
1	1		3	1	1
			2		1
			1		
				2	4
		2	8		
		1	6		
		6	12		
		2	6		
		40	115	1	1
		8	21		
			1		
		3	10		
		27	76		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site movement impairment	1	1			1	1		
Vaccination site pain	112	266			111	265	1	1
Vaccination site pruritus	18	44			18	44		
Vaccination site rash		1				1		
Vaccination site reaction	1	3			1	3		
Vaccination site swelling	58	154			57	153	1	1
Vaccination site urticaria		1				1		
Vaccination site warmth	45	125			45	125		
Vertigo	1	7				5	1	2
Vestibular neuronitis		1						1
Vision blurred	1	4			1	4		
Visual impairment	1	1			1	1		
Vomiting	4	11			2	9	2	2
Wound infection		1						1
	1,410	3,463	1	5	1306	3208	104	255

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	5	3	5		
Abdominal pain	2	3	2	3		
Abdominal pain lower	1	1	1	1		
Agitation	1	1	1	1		
Alanine aminotransferase increased	1	1	1	1		
Allodynia		1		1		
Anaphylactic reaction	1	3			1	3
Anaphylactic shock		1				1
Angina pectoris	1	2			1	2
Angioedema	2	3			2	3
Anosmia		1		1		
Anxiety	2	3	2	2		1
Apathy		1		1		
Aphasia		2				2
Aphonia		1		1		
Arrhythmia		1				1
Arthralgia	51	108	51	108		
Aspartate aminotransferase increased	1	1	1	1		
Asthenia		2		2		
Asthma		1				1
Ataxia		1				1
Atrial fibrillation		4				4
Auricular swelling		1		1		
Autonomic nervous system imbalance		1				1
Axillary pain	1	4	1	4		
Back pain	1	1	1	1		
Balance disorder	1	2	1	2		
Blindness	1	1			1	1
Blindness unilateral	1	1			1	1
Blood alkaline phosphatase increased	1	1	1	1		
Blood bilirubin increased	1	1	1	1		
Blood creatine phosphokinase increased	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose fluctuation		1		1		
Blood glucose increased		1		1		
Blood pressure increased		1				1
Body temperature increased	2	11	2	11		
Bradyphrenia	1	2	1	1		1
Breast disorder female		1		1		
Burning sensation	1	2	1	2		
Catatonia		1		1		
Cerebral infarction		1				1
Cerebrovascular accident		2				2
Cervical radiculopathy	1	1	1	1		
Chest discomfort	1	3	1	2		1
Chest pain	2	3	2	3		
Chills	66	162	66	161		1
Choking sensation		1				1
Cold sweat		1		1		
Condition aggravated		1		1		
Conjunctival haemorrhage		1				1
Contusion	1	1	1	1		
Coordination abnormal	1	2	1	1		1
Cough	1	8	1	8		
COVID-19		3		3		
C-reactive protein increased	2	2	2	2		
Cystitis	1	1	1	1		
Dandruff		1		1		
Deafness unilateral		1				1
Decreased appetite	1	4	1	4		
Decreased immune responsiveness		1				1
Deep vein thrombosis	2	3			2	3
Delirium	1	1			1	1
Depressed level of consciousness		2				2
Depressed mood	2	3	2	3		

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis	1	1	1	1		
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea	3	9	3	9		
Diplopia	1	1	1	1		
Discomfort		1		1		
Disease recurrence	1	1			1	1
Disorganised speech		1		1		
Dizziness	5	30	5	29		1
Dry eye	1	1	1	1		
Dry mouth		1		1		
Dysgeusia	1	4	1	4		
Dysphagia		2				2
Dysphonia	1	1			1	1
Dyspnoea	3	16	3	13		3
Ear discomfort	1	1	1	1		
Ear pain	1	3	1	3		
Electrocardiogram ST segment abnormal		1				1
Epilepsy	4	7			4	7
Erectile dysfunction		1				1
Erysipelas		1				1
Erythema	2	6	1	4	1	2
Extensive swelling of vaccinated limb	29	70	29	70		
Eye pain	1	1			1	1
Eye swelling	1	2	1	1		1
Facial pain		1		1		
Facial paralysis		1				1
Fall		2		2		
Fatigue	84	201	83	198	1	3
Fear		1		1		
Febrile convulsion	1	1	1	1		
Feeling abnormal	2	4	2	4		
Feeling hot	1	2	1	2		

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling jittery		2		2		
Flushing		1		1		
Gamma-glutamyltransferase increased	1	1	1	1		
General physical health deterioration		1				1
Gingival discomfort	1	1	1	1		
Glomerulonephritis minimal lesion		1				1
Glossodynia		1		1		
Haematochezia	1	1			1	1
Haematoma	1	1	1	1		
Headache	97	236	97	233		3
Heart rate increased	1	2	1	2		
Herpes ophthalmic	1	2			1	2
Herpes zoster		3		2		1
Hyperacusis		1		1		
Hyperaesthesia		1		1		
Hyperhidrosis	1	5	1	5		
Hyperpyrexia	11	20			11	20
Hypersensitivity	2	6	2	4		2
Hypersomnia		1		1		
Hypertension	2	3	2	2		1
Hypoaesthesia	1	4	1	4		
Hypoaesthesia oral		1		1		
Hypoglycaemia		1				1
Hypotension		1		1		
Hypothermia	1	3			1	3
Hypotony of eye	1	1			1	1
Hypoxia	2	2			2	2
Immune system disorder		1				1
Inappropriate schedule of product administration	1	2	1	2		
Inflammation	1	1	1	1		
Influenza like illness	1	4	1	4		
Ingrowing nail		1		1		

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
	5		
	1		
1	3		
	2		
	1		1
1	1		
1	1		
	1	1	1
	1		
2	3		
	1		
1	2	1	1
1	1		
2	8	2	7
7	12		
2	2		
83	197		3
	1		
1	1		
	1		
1	1		
3	7	1	1
2	3		
1	3		1
	1		
1	1		
2	3		
80	188		
1	6		1
43	113		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	2	3	2	3		
Nephrotic syndrome		2				2
Neuralgia	2	2	2	2		
Neuropathy peripheral	2	2			2	2
Neutrophil count increased	1	1	1	1		
Night blindness		1		1		
Oedema	1	2	1	2		
Off label use	1	2	1	2		
Oliguria		1		1		
Oophoritis	1	1			1	1
Ophthalmic herpes zoster	1	1			1	1
Oral herpes	2	2	2	2		
Oral pain	1	1	1	1		
Oral pruritus		1				1
Oropharyngeal pain	1	3	1	3		
Oxygen saturation decreased		1				1
Pain	13	13	13	13		
Pain in extremity	5	17	5	16		1
Pain of skin	1	1	1	1		
Pallor		2		2		
Palpitations	6	16	6	15		1
Paraesthesia	3	9	3	8		1
Paraesthesia ear		1		1		
Paraesthesia oral	2	9	2	8		1
Pelvic pain	1	1	1	1		
Pemphigoid		1				1
Periorbital oedema	1	1	1	1		
Peripheral coldness		2		2		
Peripheral swelling		2		2		
Peroneal nerve palsy		1		1		
Pharyngeal swelling	1	3			1	3
Piloerection	1	1	1	1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count increased	1	1	1	1		
Pneumonia	1	3			1	3
Pneumonia aspiration		1				1
Postmenopausal haemorrhage	1	2			1	2
Presyncope	1	2	1	2		
Productive cough		1		1		
Pruritus	1	4		2	1	2
Pulmonary embolism	3	4			3	4
Pulmonary infarction	1	1			1	1
Pulmonary pain	1	2	1	2		
Puncture site pain		1		1		
Pyrexia	59	121	54	115	5	6
Rash	2	3	1	2	1	1
Rash erythematous		2		2		
Rash macular		1		1		
Rash maculo-papular		1		1		
Rash papular		1		1		
Rash pruritic		1		1		
Rash vesicular		1		1		
Rectal haemorrhage		1				1
Renal failure		1				1
Respiratory failure	1	1			1	1
Respiratory rate increased	1	1			1	1
Respiratory tract infection viral	1	1			1	1
Respiratory tract irritation	1	1	1	1		
Resting tremor		1		1		
Retinal detachment	1	1			1	1
Rhinitis		2		2		
Rhinorrhoea	2	2	2	2		
Right ventricular failure	1	1			1	1
SARS-CoV-2 antibody test positive		1		1		
Seizure	1	2			1	2

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensitive skin	1	2	1	2		
Sialoadenitis		2				2
Sinus bradycardia	1	1			1	1
Skin burning sensation	1	2	1	2		
Skin discolouration	1	2	1	2		
Sneezing	1	1	1	1		
Somnolence		2		2		
Sputum increased		1		1		
Stiff person syndrome	1	1			1	1
Stomatitis	1	1	1	1		
Stridor	1	1			1	1
Sudden hearing loss		2				2
Supraventricular tachycardia		1				1
Swelling		2		2		
Swelling face		5		4		1
Swollen tongue		1				1
Syncope	11	18			11	18
Tachycardia	1	4	1	3		1
Taste disorder	1	2	1	2		
Throat tightness		2		1		1
Thrombosis		1				1
Thunderclap headache		1				1
Tinnitus	1	2	1	2		
Transient ischaemic attack	2	3			2	3
Trichodynia		1		1		
Underweight		1		1		
Unresponsive to stimuli		2				2
Urinary tract infection		1				1
Urine output decreased		1		1		
Vaccination site bruising	1	3	1	3		
Vaccination site discomfort		1		1		
Vaccination site erythema	30	83	30	83		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haematoma	3	8	3	8		
Vaccination site induration	6	8	6	8		
Vaccination site inflammation	20	61	20	61		
Vaccination site pain	73	176	73	176		
Vaccination site papule		1		1		
Vaccination site pruritus	13	30	13	30		
Vaccination site rash		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling	36	95	35	94	1	1
Vaccination site warmth	31	90	31	90		
Vertigo		2		2		
Vision blurred	1	2	1	2		
Visual impairment	1	2			1	2
Vomiting	6	12	6	12		
Vulvovaginal pain	1	1	1	1		
Weight decreased		1		1		
Weight increased		1		1		
Wheezing		1		1		
White blood cell count increased	1	1	1	1		
Wound haemorrhage	1	1	1	1		
	1,046	2,577	963	2368	83	209

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour	1	1					1	1
Acute coronary syndrome		1						1
Acute myocardial infarction	1	1					1	1
Amnesia	1	1					1	1
Amylase increased	1	1			1	1		
Anaphylactic reaction	1	1					1	1
Aneurysm		1						1
Angina pectoris	1	1					1	1
Anxiety	1	2			1	2		
Aortic dissection	1	1					1	1
Apathy		1						1
Aphasia		1						1
Arrhythmia		1						1
Arthralgia	3	5			3	5		
Asthenia		2						2
Asthma		1						1
Atrial fibrillation	2	4	1	1			2	4
Axillary pain		1				1		
Azotaemia		1						1
Bacterial infection	1	1					1	1
Balance disorder		2				1		1
Blood alkaline phosphatase increased	1	1			1	1		
Blood bilirubin increased	1	2			1	2		
Blood potassium decreased	1	1			1	1		
Blood pressure decreased	1	1					1	1
Blood pressure increased	1	2			1	1		1
Body temperature increased	1	1			1	1		
Bradykinesia	1	1			1	1		
Bradyphrenia	1	1			1	1		
Burning sensation	1	1			1	1		
Cardiac arrest		2						2
Cardiac failure		3						3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac failure acute	1	1
Cardiopulmonary failure		1
Cerebral haemorrhage	2	3
Cerebral infarction	3	3
Cerebral thrombosis	1	1
Cerebrovascular accident	1	3
Chest discomfort	1	1
Chest pain	2	3
Chillblains	1	1
Chills	9	13
Chorea		1
Circulatory collapse		2
Cold sweat	1	1
Concussion		1
Condition aggravated	2	2
Confusional state	2	3
Conjunctival oedema		1
Contusion	1	1
COVID-19	1	3
C-reactive protein increased	3	3
Death	4	10
Decreased appetite		1
Deep vein thrombosis	4	4
Delirium	2	5
Depressed level of consciousness	2	4
Depression		3
Diarrhoea	1	1
Diplopia	1	1
Disorientation	1	1
Dizziness	2	2
Drug ineffective	1	1
Dysphagia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				2	3
				3	3
				1	1
				1	3
		1	1		
		1	2	1	1
		1	1		
		7	8	2	5
					1
					2
				1	1
					1
		1	1		
			1		
			1	1	1
			1	2	2
					1
		1	1		
			1	1	2
		2	2	1	1
				4	10
					1
				4	4
				2	5
				2	4
			2		1
		1	1		
		1	1		
				1	1
		1	1	1	1
				1	1
					2

\* I=Interval, C=Cumulative  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea	4	9
Epilepsy	4	6
Erythema	1	1
Extensive swelling of vaccinated limb	3	5
Eye haematoma	1	1
Face oedema	1	1
Facial paralysis	2	2
Fall		3
Fatigue	8	16
Feeding disorder	1	1
Fibrin D dimer increased	1	1
Fluid intake reduced	1	2
Fluid retention	1	1
Gamma-glutamyltransferase increased	1	1
General physical health deterioration		2
Glomerular filtration rate decreased	1	1
Haemarthrosis	1	1
Haematocrit decreased	2	2
Haemoglobin decreased	2	2
Headache	7	13
Heart rate decreased		1
Heart rate increased	2	5
Hemiparesis	2	4
Hyperaesthesia		1
Hyperglycaemia		1
Hypernatraemia		1
Hyperpyrexia		1
Hypertension	3	4
Hypertensive urgency	1	1
Hypoglycaemia		1
Hypokinesia	1	1
Hypophagia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	4	8
				4	6
		1	1		
		3	5		
				1	1
				1	1
				2	2
					3
		7	12	1	4
				1	1
				1	1
			1	1	1
				1	1
		1	1		
					2
		1	1		
				1	1
		2	2		
		2	2		
		6	12	1	1
			1		
		1	1	1	4
				2	4
			1		
					1
					1
		1	1	2	3
				1	1
					1
		1	1		
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotension	1	4
Hypoxia	1	1
Infection	1	2
Injection site inflammation	1	1
Injection site pain	1	1
Injection site pruritus	1	1
Injection site warmth	1	1
Intestinal haemorrhage	1	1
Ischaemic cerebral infarction	5	6
Joint abscess	1	1
Lip swelling		1
Loss of consciousness		1
Lymphadenopathy	1	1
Malaise	18	32
Memory impairment		1
Meniere's disease		2
Mobility decreased		1
Mouth swelling		1
Movement disorder	2	2
Myalgia	11	18
Myocardial infarction	3	5
Nausea	9	16
Neck pain	1	1
Neuropathy peripheral	1	1
Oedema	1	1
Oropharyngeal pain		2
Oscillopsia	1	1
Oxygen saturation decreased	1	7
Pain	2	2
Pain in extremity	2	2
Pallor		1
Palpitations	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1		1	1	3
				1	1
				1	2
		1	1		
		1	1		
		1	1		
				1	1
				5	6
				1	1
					1
					1
		1	1		
		8	16	10	16
			1		
					2
					1
					1
		2	2		
		9	15	2	3
				3	5
		6	12	3	4
		1	1		
				1	1
				1	1
			2		
		1	1		
				1	7
		2	2		
		2	2		
					1
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paralysis	2	2
Peripheral coldness		1
Peripheral swelling		1
Pharyngeal swelling	1	1
Platelet count decreased	1	1
Pneumonia	2	3
Poor quality sleep		1
Post concussion syndrome		1
Postictal state		1
Presyncope		1
Pulmonary embolism	6	7
Pulmonary infarction	1	1
Pyrexia	10	21
Red blood cell count decreased	2	2
Respiratory failure		2
Respiratory rate decreased		1
Restlessness		1
Retching		1
Retinal vein occlusion	1	1
Seizure		1
Sensory disturbance	1	1
Sepsis	1	1
Shock		1
Skin discolouration	1	1
Slow speech	1	1
Somnambulism		2
Speech disorder	2	2
Stridor	1	1
Sudden death	1	4
Suicidal ideation		1
Swelling face	1	2
Swollen tongue	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
			1		
					1
				1	1
		1	1		
				2	3
			1		
			1		
			1		
					1
				6	7
				1	1
		7	11	3	10
		2	2		
					2
			1		
			1		
					1
				1	1
					1
		1	1		
				1	1
					1
				1	1
		1	1		
			2		
				2	2
				1	1
				1	4
					1
		1	1		1
		1	1		1

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 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Syncope	5	8	1	1			5	8
Thrombophlebitis	1	1			1	1		
Thrombosis	4	4					4	4
Toothache		1				1		
Transient ischaemic attack	9	9	1	1			9	9
Unresponsive to stimuli		1						1
Urinary tract infection		1				1		
Urticaria		1				1		
Vaccination site erythema	4	6			4	6		
Vaccination site haematoma		1				1		
Vaccination site inflammation		1				1		
Vaccination site movement impairment	1	1			1	1		
Vaccination site pain	4	8			4	8		
Vaccination site pallor	1	1					1	1
Vaccination site pruritus		2				2		
Vaccination site swelling	2	3			2	3		
Vaccination site warmth	2	4			2	4		
Vascular stent thrombosis	1	1					1	1
Ventricular fibrillation	1	2					1	2
Vision blurred	1	1			1	1		
Vomiting	1	4				1	1	3
Weight decreased		1						1
White blood cell count increased	1	1			1	1		
	265	476	4	4	122	204	143	272

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		2						2
Abdominal pain	3	3			1	1	2	2
Abdominal pain upper		1				1		
Abnormal faeces		1						1
Abscess	1	1					1	1
Acne	1	1			1	1		
Activated partial thromboplastin time shortened		1				1		
Acute abdomen		1						1
Acute cardiac event	1	1					1	1
Acute kidney injury	1	1					1	1
Acute myocardial infarction	3	5					3	5
Acute respiratory failure		1						1
Adrenal disorder		1						1
Ageusia	1	2			1	2		
Alanine aminotransferase decreased		1				1		
Altered state of consciousness		1						1
Amaurosis fugax	1	1			1	1		
Amnesia	1	1					1	1
Anaemia	1	1			1	1		
Anamnestic reaction	1	1					1	1
Anaphylactic reaction		1						1
Angina pectoris	3	4					3	4
Angioedema	3	4					3	4
Anosmia		1				1		
Anxiety	1	2			1	2		
Aortic valve stenosis	1	3					1	3
Apallic syndrome	1	2					1	2
Aphasia	6	10			1	2	5	8
Aphonia		1						1
Aphthous ulcer		1				1		
Apraxia	1	1					1	1
Arrhythmia	5	8					5	8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arterial thrombosis		1						1
Arthralgia	15	28			10	16	5	12
Arthritis	2	3			1	1	1	2
Aspartate aminotransferase increased	1	1			1	1		
Aspiration		1						1
Asthenia	5	8			4	5	1	3
Atrial fibrillation	4	16					4	16
Atrial flutter	1	2				1	1	1
Atrioventricular block complete	1	1					1	1
Azotaemia		1						1
Back pain	1	4				3	1	1
Bacterial test positive	1	1					1	1
Balance disorder		2				1		1
Basilar artery thrombosis	1	1					1	1
Basophil count decreased	1	1			1	1		
Bedridden		2				1		1
Blindness	2	5	1	1			2	5
Blindness unilateral	1	1					1	1
Blister	1	1					1	1
Blood alcohol decreased	1	1			1	1		
Blood bicarbonate decreased	1	2			1	2		
Blood bilirubin increased		1				1		
Blood calcium decreased	1	1			1	1		
Blood cholesterol abnormal	1	1			1	1		
Blood cholesterol increased	1	2			1	2		
Blood creatinine increased	1	2			1	2		
Blood glucose decreased	1	1			1	1		
Blood glucose increased	2	5			2	4		1
Blood lactate dehydrogenase increased	1	1			1	1		
Blood lactic acid increased		1				1		
Blood potassium decreased	1	1			1	1		
Blood pressure abnormal	1	1			1	1		

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous					
			Non Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood pressure decreased		3						3
Blood pressure increased	2	4			1	3	1	1
Blood pressure systolic increased	1	1					1	1
Blood sodium decreased	2	2			2	2		
Blood urea abnormal	1	1			1	1		
Blood urea increased	2	3			2	3		
Blood uric acid increased		1				1		
Body temperature decreased		3				1		2
Body temperature increased	2	8				4	2	4
Bradycardia		1						1
Brain death	1	1					1	1
Bronchitis		1						1
Burning sensation		1				1		
Cachexia	1	3					1	3
Candida infection		1						1
Cardiac arrest	6	14					6	14
Cardiac asthma	5	6					5	6
Cardiac death	1	3					1	3
Cardiac disorder	3	5			1	1	2	4
Cardiac failure	8	26					8	26
Cardiac failure acute	1	3					1	3
Cardiac failure congestive		1						1
Cardiac ventricular thrombosis		1						1
Cardiogenic shock	1	3					1	3
Carotid arteriosclerosis	1	1					1	1
Carotid artery thrombosis	1	1					1	1
Cerebellar haematoma	1	1					1	1
Cerebral amyloid angiopathy	1	1					1	1
Cerebral haemorrhage	5	8					5	8
Cerebral infarction	12	19					12	19
Cerebral ischaemia	1	2					1	2
Cerebral thrombosis	3	3					3	3

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrovascular accident	7	23
Cerebrovascular disorder		1
Chest discomfort	2	3
Chest injury	2	2
Chest pain	7	12
Chills	16	32
Choking		1
Chronic obstructive pulmonary disease	1	4
Circulatory collapse	1	3
Coagulopathy	1	1
Cognitive disorder		1
Cold sweat		2
Coma hepatic		1
Condition aggravated	3	8
Confusional state	11	17
Consciousness fluctuating		1
Constipation		2
Contusion	2	2
Coombs negative haemolytic anaemia	1	1
Coordination abnormal	1	2
Coronary artery disease	1	1
Cough		4
COVID-19	4	14
COVID-19 pneumonia	1	2
C-reactive protein increased	2	6
Cyanosis		1
Cystitis	2	6
Cystitis noninfective	1	1
Deafness	1	1
Deafness transitory	1	1
Deafness unilateral	2	2
Death	3	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			7	23
					1
		1	2	1	1
				2	2
		2	3	5	9
		13	19	3	13
					1
		1	1		3
				1	3
		1	1		
					1
					2
					1
			1	3	7
		3	7	8	10
					1
			1		1
				2	2
				1	1
			1	1	1
				1	1
			3		1
		1	2	3	12
				1	2
		2	4		2
					1
			2	2	4
				1	1
				1	1
				1	1
				2	2
				3	23

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased appetite	3	13
Deep vein thrombosis	15	20
Dehydration	2	5
Delirium	9	16
Delusion		1
Dementia		1
Dementia Alzheimer's type		1
Depressed level of consciousness	3	7
Depression	1	1
Dermatitis allergic	1	1
Diabetes mellitus inadequate control		1
Diarrhoea	7	10
Dilatation atrial		1
Diplopia	5	6
Discomfort	1	1
Disease recurrence	3	5
Disorientation	1	1
Dissociation		1
Dizziness	14	21
Drug hypersensitivity		1
Drug ineffective	3	5
Dry mouth		1
Dysarthria	4	7
Dysgraphia	2	2
Dysphagia	3	9
Dysphonia	1	3
Dyspnoea	19	52
Dyspnoea exertional	1	1
Dysstasia	1	2
Ecchymosis	1	2
Electrolyte imbalance		1
Embolism	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8	2	5
				15	20
			1	2	4
				9	16
			1		
					1
					1
				3	7
				1	1
		1	1		
					1
		5	7	2	3
					1
		4	4	1	2
		1	1		
				3	5
		1	1		
			1		
		8	13	6	8
					1
				3	5
			1		
			1	4	6
		1	1	1	1
			1	3	8
				1	3
		3	10	16	42
				1	1
			1	1	1
				1	2
					1
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Emotional disorder	1	1
Emotional poverty	1	1
Encephalitis enteroviral		1
Endocarditis		1
Enterocolitis		1
Eosinophil count decreased	1	2
Epilepsy	4	8
Epistaxis	8	9
Erysipelas		1
Erythema	3	6
Erythema nodosum	1	1
Escherichia urinary tract infection	1	1
Extensive swelling of vaccinated limb	13	17
Eye disorder	1	1
Eye haemorrhage	3	3
Eyelid ptosis	1	1
Eye movement disorder	1	1
Facial bones fracture	1	1
Facial pain	1	1
Facial paralysis	5	7
Facial paresis	2	2
Fall	12	20
Fatigue	45	98
Fear	1	1
Febrile convulsion	1	1
Feeding disorder	1	2
Feeling abnormal	2	5
Feeling cold		2
Feeling hot	1	3
Fibrin D dimer increased	1	1
Fluid intake reduced		1
Fluid retention		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
					1
					1
					1
		1	2		
				4	8
		2	2	6	7
					1
		2	2	1	4
				1	1
				1	1
		13	17		
		1	1		
				3	3
		1	1		
		1	1		
				1	1
				1	1
				5	7
				2	2
1	1	4	8	8	12
		26	53	19	45
				1	1
		1	1		
		1	2		
		1	4	1	1
			2		
				1	3
		1	1		
					1
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fracture		1
Gait disturbance	4	6
Gait inability	3	3
Gamma-glutamyltransferase increased		1
Gastric haemorrhage	1	1
Gastroenteritis		1
Gastrointestinal disorder		1
Gastrointestinal haemorrhage	1	6
Gastrointestinal obstruction		1
Gaze palsy		1
General physical health deterioration	7	12
Giant cell arteritis	1	2
Glomerular filtration rate decreased		3
Glucose tolerance impaired		1
Guillain-Barre syndrome	1	1
Haematemesis		1
Haematocrit decreased	1	1
Haematocrit increased		1
Haematoma	1	1
Haemodynamic instability	1	1
Haemoglobin abnormal	1	1
Haemoglobin decreased	5	6
Haemophagocytic lymphohistiocytosis	1	1
Haemophilia		1
Haemoptysis	1	1
Haemorrhage		1
Haemorrhoids		1
Hallucination	2	3
Hallucination, visual	1	1
Hand deformity		1
Hand fracture		1
Headache	23	43

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	4	2	2
		1	1	2	2
			1		
				1	1
					1
			1		
				1	6
					1
					1
		1	4	6	8
				1	2
			3		
			1		
				1	1
					1
		1	1		
			1		
				1	1
				1	1
		1	1		
		2	3	3	3
				1	1
					1
				1	1
			1		
				2	3
				1	1
					1
					1
					1
		16	29	7	14

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head injury	2	2
Heart rate decreased	2	3
Heart rate increased	1	4
Heart rate irregular		1
Hemiparesis	2	6
Hemiplegia	1	3
Hepatic failure		1
Hepatitis C		1
Hernia pain		1
Herpes ophthalmic		1
Herpes virus infection		1
Herpes zoster	2	2
Herpes zoster reactivation		1
Hiatus hernia		1
Hip fracture	1	2
Hot flush	1	1
Hyperaesthesia	1	1
Hyperhidrosis	4	7
Hyperkalaemia	1	1
Hypernatraemia		1
Hyperpyrexia	2	3
Hypersensitivity	2	2
Hypersensitivity vasculitis	2	2
Hypersomnia		1
Hypertension	9	13
Hypertensive crisis		1
Hypertriglyceridaemia	1	1
Hyperventilation	1	1
Hypokalaemia		1
Hypophagia		4
Hypotension	7	10
Hypothermia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		2	2		1
		1	2		2
			1		
				2	6
				1	3
					1
					1
			1		
			1		1
				2	2
					1
					1
				1	2
				1	1
				1	1
		3	4	1	3
				1	1
					1
				2	3
				2	2
				2	2
			1		
		3	3	6	10
					1
				1	1
				1	1
					1
			1		3
		3	3	4	7
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hypovolaemic shock		1						1
Hypoxia	2	10					2	10
Illness		1						1
Immune thrombocytopenia		1						1
Imperception	1	1					1	1
Inappropriate schedule of product administration	2	4			2	4		
Incontinence	1	3					1	3
Infarction	1	1					1	1
Infection		2						2
Infection susceptibility increased		1						1
Inflammation	3	4			1	2	2	2
Inflammatory marker increased		1						1
Influenza like illness		2				1		1
Injection site pruritus	1	1			1	1		
Intentional product use issue	1	1			1	1		
Intention tremor	1	1					1	1
International normalised ratio fluctuation	1	1					1	1
International normalised ratio increased	2	2					2	2
Interstitial lung disease		1						1
Intestinal haemorrhage		1						1
Intestinal ischaemia	1	2					1	2
Intestinal obstruction	1	1					1	1
Iridocyclitis	1	1					1	1
Ischaemic cerebral infarction	9	17					9	17
Ischaemic stroke	1	1					1	1
IVth nerve paralysis	1	1					1	1
Jaundice	1	2					1	2
Kidney infection	1	1					1	1
Lacrimation increased	1	1			1	1		
Lacunar infarction	1	1					1	1
Left ventricular dysfunction		1						1
Left ventricular failure	1	1					1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	10
					1
					1
				1	1
		2	4		
				1	3
				1	1
					2
					1
		1	2	2	2
					1
			1		1
		1	1		
		1	1		
				1	1
				1	1
				2	2
					1
					1
				1	2
				1	1
				1	1
				1	2
				1	1
		1	1		
				1	1
					1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Leukopenia		1
Limb discomfort	1	2
Limb injury	1	2
Listless	1	2
Livedo reticularis		1
Localised infection	1	1
Loss of consciousness	7	9
Loss of personal independence in daily activities		2
Lung disorder		4
Lymphadenopathy	1	1
Lymphocyte count decreased	2	2
Macular degeneration		1
Malaise	65	132
Mean cell volume increased	1	1
Melaena		1
Meniere's disease	1	2
Mental impairment	2	3
Mesenteric artery thrombosis		1
Metabolic acidosis		1
Mobility decreased	1	2
Monoparesis	2	2
Monoplegia	1	1
Mood altered	1	1
Mouth swelling	1	1
Movement disorder	2	2
Multiple organ dysfunction syndrome	1	2
Muscle spasms		1
Muscle strain	1	1
Muscle twitching		1
Muscular weakness	3	6
Musculoskeletal chest pain	1	1
Musculoskeletal disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
			1	1	1
		1	2		
					1
				1	1
				7	9
			1		1
					4
				1	1
		1	1	1	1
					1
		37	60	28	72
		1	1		
					1
				1	2
				2	3
					1
			1		
		1	2		
				2	2
				1	1
		1	1		
				1	1
				2	2
				1	2
			1		
				1	1
					1
		1	3	2	3
				1	1
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Musculoskeletal stiffness	1	1
Mutism	1	2
Myalgia	22	43
Myelodysplastic syndrome		1
Myelopathy	1	1
Myocardial infarction	7	15
Nasal congestion	2	2
Nasopharyngitis		2
Nausea	25	55
Neck pain	2	2
Neuritis		1
Neurologic neglect syndrome	1	1
Neutrophil count decreased	1	1
Neutrophil count increased	1	1
Night sweats	1	1
Ocular hyperaemia		1
Ocular myasthenia	1	1
Oedema		1
Oedema peripheral	4	4
Off label use	2	3
Optic nerve infarction	1	1
Oral bacterial infection		1
Oral discomfort	1	1
Oral mucosal blistering	1	1
Oral mucosal erythema	1	1
Oropharyngeal blistering	1	1
Oropharyngeal pain		4
Oxygen saturation abnormal	1	2
Oxygen saturation decreased	2	11
Pain	2	7
Pain in extremity	4	7
Pain in jaw	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	2
		16	27	6	16
					1
				1	1
				7	15
		1	1	1	1
			2		
		16	25	9	30
				2	2
					1
				1	1
				1	1
		1	1		
		1	1		
					1
				1	1
					1
		1	1	3	3
		2	3		
				1	1
					1
		1	1		
				1	1
				1	1
				1	1
			3		1
				1	2
				2	11
			2	2	5
		3	4	1	3
		1	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Pallor	1	6
Palpitations	1	1
Pancytopenia	1	1
Panic attack	1	1
Panniculitis	1	1
Paraesthesia	1	1
Paralysis	1	2
Parkinson's disease	2	2
Pelvic fracture	1	1
Pericarditis		2
Peripheral coldness		3
Peripheral swelling	1	3
Peroneal nerve palsy		1
Personality disorder		1
Petechiae	2	2
Pharyngeal erythema	1	1
Pharyngeal swelling	1	1
Platelet count decreased	3	4
Pleural effusion	2	3
Pneumonia	9	18
Pneumonia aspiration	1	8
Pneumonia bacterial	1	1
Posterior reversible encephalopathy syndrome	1	1
Presyncope	1	1
Productive cough	1	1
Prolapse		1
Prothrombin time ratio increased	1	1
Pruritus	1	2
Pulmonary arterial pressure increased	1	1
Pulmonary embolism	17	19
Pulmonary haemorrhage		1
Pulmonary hypertension	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	4
				1	1
				1	1
		1	1		
				1	1
		1	1		
				1	2
				2	2
				1	1
					2
			1		2
			1	1	2
					1
			1		
		2	2		
				1	1
				1	1
		2	3	1	1
				2	3
				9	18
				1	8
				1	1
				1	1
		1	1		
				1	1
		1	1		
				1	1
				17	19
					1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary infarction	1	1
Pulmonary mass	1	1
Pulmonary oedema	1	2
Pyelonephritis	1	1
Pyrexia	25	67
Quadriplegia	1	1
Rash	1	3
Rash erythematous	1	1
Rash pruritic	1	1
Rectal haemorrhage	2	2
Rectal prolapse		1
Red blood cell count decreased	1	1
Reduced facial expression	1	1
Renal disorder	1	1
Renal failure	1	2
Renal impairment		2
Renal infarct	1	1
Respiration abnormal		1
Respiratory disorder		1
Respiratory failure	3	6
Respiratory rate decreased		1
Respiratory rate increased		3
Respiratory tract infection		2
Restlessness	1	2
Retching		1
Retinal artery occlusion	1	1
Retinal vein occlusion	1	1
Rheumatoid arthritis	1	1
Right ventricular failure		1
Salivary hypersecretion		1
SARS-CoV-2 test positive	1	3
Scrotal injury		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	2
				1	1
		15	23	10	44
				1	1
		1	2		1
		1	1		
				1	1
				2	2
					1
		1	1		
				1	1
				2	2
					2
				1	1
					1
					1
				3	6
			1		
			2		1
					2
			1	1	1
					1
				1	1
				1	1
					1
				1	3
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Secondary adrenocortical insufficiency	1	1
Seizure	4	5
Sepsis		1
Serum ferritin abnormal	1	1
Shock		1
Sinus tachycardia		1
Skin discolouration	1	1
Skin swelling	1	1
Sleep disorder	1	1
Small intestinal obstruction		1
Snoring		1
Soft tissue infection		1
Soft tissue swelling	1	1
Somnolence	2	10
Speech disorder	4	4
Spinal cord compression	1	1
Spinal epidural haemorrhage	1	1
Spinal meningeal cyst	1	1
Spinal osteoarthritis	1	1
Splenic infarction	1	1
Status epilepticus		1
Stiff tongue	1	1
Subdural haematoma	2	2
Sudden cardiac death	1	4
Sudden death	4	10
Sudden hearing loss	2	2
Supraventricular tachycardia		1
Suspected COVID-19		2
Suspiciousness		1
Swelling	1	1
Swelling face	2	2
Swelling of eyelid		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				4	5
					1
				1	1
					1
			1		
				1	1
		1	1		
		1	1		
					1
			1		
					1
				1	1
			2	2	8
		1	1	3	3
				1	1
				1	1
		1	1		
				1	1
					1
		1	1		
				2	2
				1	4
				4	10
				2	2
			1		
			1		1
			1		
		1	1		
				2	2
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Swollen tongue		1
Symptom recurrence	1	1
Syncope	15	20
Tachycardia		1
Tachypnoea	1	3
Thinking abnormal		1
Thirst decreased		1
Throat tightness	1	1
Thrombocytopenia	3	3
Thrombophlebitis	3	4
Thrombophlebitis superficial	1	1
Thrombosis	10	13
Thrombosis mesenteric vessel		1
Thrombotic cerebral infarction	1	1
Tinnitus	1	1
Tongue disorder		1
Toxic skin eruption	1	1
Transient aphasia	1	1
Transient ischaemic attack	25	32
Traumatic haematoma	1	1
Tremor	3	4
Troponin increased	1	2
Unresponsive to stimuli	2	5
Upper limb fracture		1
Urinary incontinence	2	3
Urinary retention	1	3
Urinary tract infection	3	4
Urosepsis	1	4
Urticaria	2	2
Vaccination failure		1
Vaccination site bruising	2	3
Vaccination site discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				15	20
					1
		1	2		1
			1		
					1
				1	1
				3	3
		2	2	1	2
				1	1
				10	13
					1
				1	1
		1	1		
					1
				1	1
				1	1
				25	32
				1	1
		1	2	2	2
			1	1	1
				2	5
					1
		1	2	1	1
				1	3
		1	1	2	3
				1	4
		1	1	1	1
					1
		2	3		
		1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site erythema	11	19			11	19		
Vaccination site haematoma	5	5			5	5		
Vaccination site inflammation	4	8			4	8		
Vaccination site pain	16	29			16	27		2
Vaccination site pruritus	7	9			7	9		
Vaccination site swelling	12	16			12	16		
Vaccination site warmth	10	16			10	16		
Vasculitis	2	2			2	2		
Ventricular fibrillation	1	1					1	1
Viral infection	1	2					1	2
Visual impairment	4	6			1	1	3	5
Vomiting	5	22			3	7	2	15
Weight decreased		4				3		1
White blood cell count decreased	1	1			1	1		
Wrist fracture		1						1
	1,051	2,044	3	3	393	700	658	1344

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	2	1	2		
Abortion spontaneous	2	2			2	2
Anaphylactic shock		1				1
Anembryonic gestation	1	1			1	1
Arthralgia	2	8	2	8		
Basilar artery thrombosis		1				1
Blood pressure increased	1	1			1	1
Body temperature increased		2		2		
Bradycardia		2				2
Chest pain	1	3	1	3		
Chills	5	13	5	13		
Circumstance or information capable of leading to medication error		1		1		
COVID-19	2	3	1	1	1	2
Crohn's disease	1	1			1	1
Diarrhoea	2	2	2	2		
Discomfort		1		1		
Dizziness	2	4	2	4		
Drug ineffective		1				1
Dyspnoea		2		2		
Erythema		2		2		
Exposure to SARS-CoV-2		1		1		
Exposure via breast milk		1		1		
Extensive swelling of vaccinated limb	1	10	1	10		
Eye pain	1	1	1	1		
Fatigue	8	18	8	18		
Feeling cold		1		1		
Feeling hot	1	1	1	1		
Flank pain	1	1	1	1		
Gait disturbance	1	1	1	1		
Headache	15	31	15	31		
Heart rate abnormal	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	1		
1	1		
	1		
	6		
8	20		
		1	1
1	1		
1	2		
	1		
19	32		
1	1		
5	14		
		1	1
	1		
	1		
1	2		
2	3		
1	3		
2	3		
1	1		
1	1		
1	1		
1	2		
	1		
	1		
1	2		
1	1		
	1		
9	15		
	1		

Hot flush

Hyperhidrosis

Hypersensitivity

Hypoaesthesia 1

Incorrect dose administered 1

Lymphadenopathy 6

Malaise 8 20

Maternal exposure during pregnancy 1 1

Mouth swelling 1 1

Musculoskeletal pain 1 2

Musculoskeletal stiffness 1 1

Myalgia 19 32

Nasopharyngitis 1 1

Nausea 5 14

Neuropathy peripheral 1 1

Occupational exposure to product 1 1

Oropharyngeal pain 1 1

Pain 1 2

Pain in extremity 2 3

Palpitations 1 3

Paraesthesia 2 3

Paraesthesia oral 1 1

Pharyngeal swelling 1 1

Poor quality product administered 1 1

Presyncope 1 2

Product label confusion 1 1

Product packaging quantity issue 1 1

Product preparation error 1 2

Product storage error 1 1

Pruritus 1 1

Pyrexia 9 15

Rash 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Rash erythematous		1		1			
Respiratory disorder		1		1			
Restlessness		1		1			
Skin warm		1		1			
Swelling		1		1			
Syncope		1					1
Tachycardia		3		3			
Tinea versicolour		1		1			
Tinnitus		2		2			
Type 1 diabetes mellitus	1	1			1		1
Urticaria		2		2			
Vaccination failure	1	1			1		1
Vaccination site discomfort	1	1	1	1			
Vaccination site erythema	1	4	1	4			
Vaccination site haematoma	2	4	2	4			
Vaccination site inflammation	3	5	3	5			
Vaccination site pain	14	28	14	28			
Vaccination site pruritus	2	5	2	5			
Vaccination site reaction	1	1	1	1			
Vaccination site swelling	2	10	2	10			
Vaccination site warmth	4	12	4	12			
Visual impairment		1		1			
	140	332	130	315	10		17

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**NEW ZEALAND**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia		1		1
		1		1

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia	1	1	1	1
Nausea	1	1	1	1
	2	2	2	2

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1			1	
Drug ineffective		1			1	
Exposure to SARS-CoV-2		1			1	
Hypersensitivity	5	5			5	5
Hypoglycaemia		1		1		
Influenza like illness	1	1			1	1
Reactogenicity event	1	1			1	1
	7	11		1	7	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Chest discomfort		1		1
Chills		1		1
Disorientation		1		1
Dizziness		1		1
Fatigue		1		1
Headache		1		1
Pain in extremity		1		1
Poor quality sleep		1		1
		9		9

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**NORWAY**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper	1	1			1	1
Abnormal dreams		1		1		
Allergy to vaccine		1				1
Anaphylactic reaction	1	1			1	1
Angioedema		1				1
Arrhythmia	1	1			1	1
Arthralgia		3		3		
Asthenia		1				1
Asthma		1				1
Axillary mass		1				1
Axillary pain		1				1
Back pain		1		1		
Blood glucose fluctuation		2		2		
Blood pressure decreased		1				1
Blood pressure systolic decreased	1	1			1	1
Bradycardia		1				1
Chest pain		2		1		1
Chills		6		3		3
Cough		4		3		1
Depressed level of consciousness	1	1			1	1
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea		2		2		
Diplopia		1		1		
Discomfort	1	2		1	1	1
Disturbance in attention		2		2		
Dizziness	5	8	2	3	3	5
Dyspnoea	1	4	1	2		2
Ear discomfort		1		1		
Eczema		1				1
Erythema		1				1
Extrasystoles	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis		1
Facial paresis		3
Fatigue	1	13
Feeling abnormal	1	2
Feeling drunk		1
Feeling hot		1
General physical health deterioration	1	3
Grip strength decreased	1	1
Haematoma		1
Hallucination, auditory		2
Hallucinations, mixed	1	1
Hallucination, visual		1
Headache	5	23
Heart rate increased	1	1
Hemiparesis	1	2
Hot flush		1
Hyperaesthesia		1
Hyperglycaemia	1	1
Hyperhidrosis		2
Hypersensitivity		1
Hypoaesthesia		3
Hypoaesthesia oral	1	3
Hypogeusia		1
Hypothermia		1
Immune thrombocytopenia	1	1
Increased tendency to bruise	1	1
Influenza like illness		2
Limb discomfort	1	1
Lymphadenopathy		2
Malaise		8
Memory impairment	1	2
Mouth swelling		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	2		1
1	11		2
1	2		
	1		
	1		
	2	1	1
		1	1
		1	1
			1
2	17	3	6
		1	1
		1	2
	1		
			1
1	1		
	2		
			1
	2		1
	1		
			1
		1	1
		1	1
	2		
		1	1
	1		1
	7		1
1	2		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	1	1			1	1
Myalgia		11		9		2
Myopia	1	1			1	1
Nasal congestion		1		1		
Nasopharyngitis		1		1		
Nausea	5	14	2	10	3	4
Neck pain		1		1		
Neuroborreliosis		1				1
Neuropathy peripheral		1				1
Obstructive airways disorder		1				1
Oral pruritus		1				1
Oropharyngeal pain	1	3		2	1	1
Pain		2		2		
Pain in extremity	1	1			1	1
Palpitations		1		1		
Paraesthesia		1				1
Parosmia	1	1	1	1		
Peripheral swelling		1				1
Petechiae	1	1			1	1
Pharyngeal swelling		1				1
Photophobia		2		2		
Presyncope	1	1			1	1
Pruritus	1	5		1	1	4
Pyrexia	2	16	1	14	1	2
Rash		1				1
Rash erythematous		1		1		
Rash pruritic		1				1
Respiratory rate increased		1				1
Restlessness		1				1
Retching		1		1		
Rhinorrhoea		1		1		
Sneezing		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence		2		2		
Swelling face		1				1
Syncope		1				1
Tachycardia	1	1	1	1		
Tenderness		2		2		
Thrombocytopenia	1	1			1	1
Time perception altered	1	1	1	1		
Urticaria		3				3
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	2	6	1	3	1	3
Vaccination site reaction		1		1		
Vaccination site swelling		1				1
Vaccination site warmth		1				1
Vision blurred		1				1
Visual impairment		1		1		
Vomiting		1		1		
	53	248	17	145	36	103

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	7		4	1	3
Abdominal pain upper	1	6		1	1	5
Abortion spontaneous		1				1
Acute kidney injury	1	1			1	1
Allergy to vaccine		1				1
Amnesia		1				1
Anaphylactic reaction	2	6			2	6
Angioedema		1				1
Apallic syndrome		1				1
Apathy		1				1
Apnoea		1				1
Appendicitis	2	2			2	2
Arthralgia	6	13	6	11		2
Arthritis		1				1
Arthritis reactive		1				1
Asthenia		3		1		2
Autonomic nervous system imbalance		1				1
Axillary pain		1		1		
Back pain		2		1		1
Balance disorder		2				2
Basedow's disease		1				1
Bedridden	1	3	1	2		1
Blepharospasm		1		1		
Blood glucose decreased		1		1		
Blood glucose fluctuation		1		1		
Blood pressure decreased		2		1		1
Blood pressure increased		1				1
Blood pressure systolic increased	1	1			1	1
Bone pain	1	2	1	1		1
Bradycardia		1				1
Breast enlargement		1		1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Breast pain		1		1			
Burning sensation		1					1
Cerebral haemorrhage		1					1
Cerebral thrombosis		1					1
Chest discomfort	1	3	1	2			1
Chest pain	2	7	2	3			4
Chills	2	15	2	10			5
Cold sweat		6		4			2
Concussion		1					1
Confusional state	1	2	1	1			1
Constipation		1					1
Cough		3		2			1
COVID-19	2	2	1	1	1		1
Cyanosis		1					1
Decreased activity		1		1			
Decreased appetite		2		2			
Diarrhoea		6		3			3
Discomfort		1		1			
Disease recurrence	1	2		1	1		1
Diverticulitis		1					1
Dizziness	5	21	3	10	2		11
Drug ineffective	1	1			1		1
Dry mouth		3		3			
Dysarthria	1	2	1	1			1
Dysgeusia		2		1			1
Dyskinesia		1					1
Dysphagia		2		1			1
Dyspnoea	3	12	1	3	2		9
Ear discomfort		1		1			
Ear pain		1		1			
Ear swelling		1		1			
Epilepsy		1					1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	2	6	1	3	1	3
Eye pain		1		1		
Facial paresis	1	2			1	2
Faeces discoloured		1		1		
Fall		2				2
Fatigue	6	29	5	23	1	6
Feeling cold		2		2		
Feeling hot	1	4	1	3		1
Feeling of body temperature change		1		1		
Flatulence		1		1		
Flushing	1	1	1	1		
Frostbite		1				1
Gastric disorder		1				1
General physical health deterioration	1	2			1	2
Glomerulonephritis minimal lesion		1				1
Grip strength decreased		1				1
Haematoma		1				1
Haemorrhage		1				1
Hallucination		2				2
Headache	7	33	6	27	1	6
Heart rate increased		5		2		3
Herpes simplex reactivation	1	1	1	1		
Hyperhidrosis		2		2		
Hypersensitivity	1	5		1	1	4
Hypersomnia		1		1		
Hypertension		1				1
Hyperthyroidism		1				1
Hyperventilation		3		1		2
Hypoaesthesia	1	5	1	4		1
Hypoaesthesia oral	1	2		1	1	1
Hypokinesia		1		1		
Hypotension		4				4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Increased viscosity of upper respiratory secretion	1	1	1	1		
Influenza		1		1		
Influenza like illness		3		2		1
Injection site pain		1		1		
Intranasal hypoaesthesia		1		1		
Intranasal paraesthesia		1		1		
Iridocyclitis	1	1			1	1
Joint swelling		1		1		
Limb discomfort		2		2		
Lip pruritus		1				1
Loss of consciousness		1				1
Lymphadenitis	2	2	1	1	1	1
Lymphadenopathy		2		2		
Lymphangitis	1	1			1	1
Malaise	2	11	2	9		2
Memory impairment	1	1	1	1		
Middle insomnia		1		1		
Migraine	1	2	1	2		
Mobility decreased		1		1		
Mouth haemorrhage	1	1	1	1		
Muscle contractions involuntary	1	1	1	1		
Muscle spasms		2		1		1
Muscular weakness	1	2			1	2
Musculoskeletal stiffness		5		3		2
Myalgia	4	16	4	13		3
Nasal pruritus		1				1
Nausea	5	22	5	17		5
Neck pain		3		2		1
Neuropathy peripheral		1				1
Night sweats		1		1		
Ocular hyperaemia		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oral pruritus		1					1
Oropharyngeal pain	1	1	1	1			
Oropharyngeal swelling	1	1			1		1
Orthostatic hypotension		1		1			
Oxygen saturation decreased		2					2
Pain	3	6	3	5			1
Pain in extremity	3	8	3	8			
Pain of skin		1					1
Pallor		5		3			2
Palpitations		1					1
Paraesthesia	1	5	1	3			2
Paraesthesia oral	1	2		1	1		1
Paranasal sinus discomfort		1		1			
Pericarditis	2	2			2		2
Peripheral coldness		1		1			
Peripheral swelling	1	3	1	2			1
Petechiae		1					1
Pharyngeal swelling	1	2		1	1		1
Photophobia		1					1
Postictal state		1		1			
Presyncope	1	2	1	1			1
Pruritus		5		2			3
Pulmonary embolism		2					2
Pulmonary necrosis		1					1
Pyrexia	4	23	4	19			4
Rash		5		3			2
Rash erythematous		1		1			
Rash pruritic	1	2		1	1		1
Respiratory alkalosis		1					1
Respiratory arrest		1					1
Respiratory rate decreased		1		1			
Respiratory tract congestion		1					1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restlessness		4
Retching		4
Secretion discharge		1
Seizure		1
Shock		1
Skin haemorrhage	1	1
Skin laceration		1
Sleep disorder		1
Somnolence		1
Speech disorder		2
Stridor	1	1
Swelling	1	1
Swelling face	1	3
Swelling of eyelid	1	2
Syncope	2	12
Tendon pain		1
Thirst		1
Throat clearing		1
Throat irritation		2
Throat tightness		2
Thrombocytopenia		1
Thrombophlebitis	1	1
Thrombophlebitis superficial	1	1
Tooth avulsion		1
Tremor	1	3
Urticaria	1	4
Vaccination site erythema		3
Vaccination site hypoaesthesia		1
Vaccination site pain		16
Vaccination site paraesthesia		2
Vaccination site pruritus		3
Vaccination site reaction		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		2
	1		3
			1
			1
			1
1	1		
			1
	1		
			1
			2
		1	1
		1	1
	1	1	2
1	1		1
		2	12
	1		
	1		
	1		
			2
			2
			1
		1	1
1	1		
			1
1	2		1
	1	1	3
	3		
	1		
	14		2
	2		
	2		1
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		1		1		
Vaccination site warmth		2		2		
Ventricular tachycardia		1				1
Vertigo		1		1		
Vertigo positional		1				1
Vomiting		5		3		2
Wheezing	1	1			1	1
	111	573	71	325	40	248

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain		1		1			
Abdominal pain upper	1	2		1	1	1	
Abdominal wall haemorrhage		1				1	
Anaphylactic reaction	1	2			1	2	
Angioedema		1				1	
Antinuclear antibody increased	1	1	1	1			
Anti-thyroid antibody	1	1	1	1			
Arthralgia	4	5	3	4	1	1	
Arthritis		1		1			
Asthenia	1	1	1	1			
Atrial fibrillation		1					1
Back pain	2	3	1	2	1	1	
Blood glucose increased		1		1			
Blood pressure decreased		1		1			
Cardiac arrest		1					1
Cerebral infarction		1					1
Chest pain	2	3	1	1	1	2	
Chills	2	6	1	5	1	1	
Circulatory collapse		1					1
Coma		1					1
Coordination abnormal	1	1	1	1			
Cough	2	3	1	2	1	1	
COVID-19	2	2			2	2	
C-reactive protein increased	1	3	1	2		1	
Deep vein thrombosis	1	1			1	1	
Delirium	1	1			1	1	
Diarrhoea		2		2			
Dizziness	1	4		3	1	1	
Drug ineffective	1	1			1	1	
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1	
Dysgeusia	1	2	1	2			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	3	7	1	3	2	4
Ear pain		1		1		
Eosinophilia	1	1			1	1
Erysipelas	2	2			2	2
Facial paresis	1	1			1	1
Fatigue	6	14	5	12	1	2
Fear of death	1	1	1	1		
Feeling cold		1		1		
Flushing		1		1		
Gastritis		1		1		
General physical health deterioration	1	1			1	1
Headache	5	13	3	9	2	4
Heart rate increased	2	2			2	2
Hyperaesthesia	1	1			1	1
Hyperhidrosis	1	1	1	1		
Hyperpyrexia		1				1
Hypersensitivity		1		1		
Hypertension	1	1			1	1
Hyposmia	1	1	1	1		
Hypotension		1				1
Incorrect route of product administration		1		1		
Influenza		1		1		
Influenza like illness		1		1		
Injection site muscle weakness		1		1		
Insomnia	1	1	1	1		
International normalised ratio increased		1				1
Lethargy		1		1		
Listless		1		1		
Livedo reticularis		1		1		
Loss of consciousness		1				1
Malaise	1	3	1	3		
Migraine		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms		1				1
Musculoskeletal stiffness		1		1		
Myalgia	3	10	2	8	1	2
Nausea	1	4		3	1	1
Neck pain		1		1		
Nephrolithiasis	1	1			1	1
Neutropenia		1				1
Nightmare	1	1	1	1		
Oropharyngeal pain		2		1		1
Pain	1	1	1	1		
Pain in extremity	1	2	1	1		1
Pain of skin	1	1	1	1		
Palpitations	2	2	1	1	1	1
Panic attack	1	1	1	1		
Pericarditis	1	1			1	1
Peripheral coldness		1		1		
Peripheral swelling	1	1	1	1		
Pharyngeal paraesthesia	1	1			1	1
Pneumonia	1	1			1	1
Presyncope		1				1
Pruritus		1		1		
Psychomotor hyperactivity		1		1		
Pyrexia	9	15	6	10	3	5
Rash	1	1			1	1
Renal failure	1	1			1	1
Rhinorrhoea		1		1		
Somnolence		2		1		1
Status migrainosus		1				1
Swelling face	1	1	1	1		
Syncope	1	2			1	2
Tachycardia		1		1		
Tachypnoea		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	1	1			1	1
Thrombocytopenia	2	2			2	2
Thrombophlebitis	1	1	1	1		
Urosepsis	1	1			1	1
Vaccination failure	1	1			1	1
Vaccination site erythema		2		2		
Vaccination site pain		4		4		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccine breakthrough infection	1	1			1	1
Vomiting	1	2			1	2
White blood cell count increased	1	2	1	1		1
	93	205	45	123	48	82

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2			1	2
Abnormal behaviour		1				1
Adverse event		1		1		
Adverse reaction		1		1		
Altered state of consciousness		3				3
Amnesia		1		1		
Anaphylactic reaction	1	2			1	2
Angina pectoris		2				2
Aphasia	1	1			1	1
Apnoeic attack		1				1
Arteriovenous fistula thrombosis	1	1			1	1
Arthralgia		1		1		
Aspiration		1				1
Asthenia	1	1			1	1
Atelectasis		1				1
Atrial fibrillation	1	1			1	1
Auditory disorder	1	1	1	1		
Bacterial test positive		1		1		
Balance disorder	1	2		1	1	1
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	4			1	4
Body temperature increased		1		1		
Bradycardia		1				1
Cardiac arrest	1	1			1	1
Cardiovascular disorder		1				1
Carotid artery occlusion	1	1			1	1
Cerebellar infarction	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	2	2			2	2
Cerebral infarction	3	3			3	3
Cerebral thrombosis	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	1	3			1	3
Chest pain	2	2	1	1	1	1
Chills	1	1			1	1
Chronic obstructive pulmonary disease	1	2			1	2
Circulatory collapse	1	1			1	1
Cold sweat		2				2
Concomitant disease aggravated		1				1
Concussion	1	1			1	1
Condition aggravated	1	1	1	1		
Confusional state	2	8		2	2	6
Contusion	1	1			1	1
Cough	1	3			1	3
COVID-19	1	1			1	1
C-reactive protein increased	3	6	1	2	2	4
Death	2	4			2	4
Deep vein thrombosis	3	4			3	4
Dehydration	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dermatitis allergic		1				1
Diarrhoea	2	6		2	2	4
Discomfort	1	1	1	1		
Disease recurrence		1				1
Dizziness	3	7		3	3	4
Drug interaction	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	5	10	1	2	4	8
Electrolyte imbalance	1	1			1	1
Epilepsy		4				4
Erysipelas		1				1
Erythema		1		1		
Face oedema		1				1
Fall	3	5	1	1	2	4

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	2	7	1	5	1	2
Feeling abnormal		1		1		
Feeling hot		2		2		
Flushing	1	2		1	1	1
Foaming at mouth		1		1		
Gastroenteritis		1				1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	2	8		1	2	7
General symptom		1				1
Haemorrhage subcutaneous		1				1
Hallucination		1				1
Headache	2	5		3	2	2
Head injury		1				1
Heart rate irregular		1		1		
Hemianopia	1	1			1	1
Hemiplegia	1	2			1	2
Hepatic cyst	1	1			1	1
Hypercapnia	1	1			1	1
Hypoaesthesia		1		1		
Hypotension		3				3
Hypoxia		2				2
Illness	1	1	1	1		
Incorrect route of product administration		1		1		
Increased bronchial secretion	1	1			1	1
Infective exacerbation of chronic obstructive airways disease		1				1
Inferior vena caval occlusion	1	1			1	1
Influenza like illness	2	2	1	1	1	1
Irritability postvaccinal		1				1
Lethargy	1	1			1	1
Loss of consciousness		3				3
Loss of personal independence in daily activities	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Malaise		6		5		1	
Malignant hypertension		1					1
Mania		1					1
Moaning	1	1			1		1
Muscle spasms	1	1			1		1
Muscular weakness	1	1			1		1
Myalgia	3	3			3		3
Myocardial infarction		1					1
Nausea	4	13	1	7	3		6
Neck pain		1		1			
N-terminal prohormone brain natriuretic peptide increased	1	1			1		1
Nystagmus	1	1			1		1
Obstructive airways disorder		1					1
Oedema peripheral		1					1
Ophthalmic herpes zoster		1					1
Orbital oedema		1					1
Oxygen saturation decreased	3	6	1	1	2		5
Pain		2		2			
Pallor		2					2
Palpitations	1	1	1	1			
Peripheral coldness		1					1
Personality change		1					1
Pneumonia	3	7			3		7
Pneumonia aspiration		1					1
Presyncope		1					1
Pruritus	1	1			1		1
Pulmonary congestion	1	1			1		1
Pulmonary embolism	5	5			5		5
Pulmonary thrombosis	1	1			1		1
Pyrexia	6	14	1	6	5		8
Rales		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash		1		1		
Renal failure	1	1			1	1
Respiratory acidosis	1	1			1	1
Respiratory failure	2	4			2	4
Respiratory rate increased	1	3	1	1		2
Retching	1	2		1	1	1
Rhinorrhoea		1		1		
Salmonella test positive	1	1			1	1
Sepsis		1				1
Somnolence		4		1		3
Sputum increased		1		1		
Status epilepticus		1				1
Sudden death		1				1
Syncope	2	6			2	6
Tachycardia	1	2	1	1		1
Thrombocytopenia	1	1			1	1
Transient ischaemic attack	2	2			2	2
Unresponsive to stimuli	1	1			1	1
Urinary incontinence		1		1		
Urinary tract infection		1		1		
Urticaria	1	1			1	1
Vaccination failure	1	1			1	1
Vaccination site pain	1	3	1	3		
Vertigo	2	2			2	2
Vision blurred	1	1			1	1
Visual impairment	1	2			1	2
Vomiting	1	7		2	1	5
White blood cell count increased	1	1	1	1		
	134	319	20	84	114	235

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		2		1
Abdominal pain upper	1	5		2	1	3
Acute coronary syndrome		1				1
Acute kidney injury		1				1
Acute myocardial infarction		5				5
Aggression	1	1	1	1		
Agitation		1				1
Altered state of consciousness		4				4
Anal incontinence		1				1
Anaphylactic reaction		2				2
Anxiety		3		1		2
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Apathy		1				1
Aphasia	2	4			2	4
Apnoea		2				2
Arrhythmia		1				1
Arterial haemorrhage		1				1
Arteriosclerosis coronary artery		1				1
Arteriovenous fistula thrombosis	1	1			1	1
Arthralgia	1	2		1	1	1
Arthritis bacterial		1				1
Asthenia	3	9	1	4	2	5
Atrial fibrillation		1				1
Atrial flutter		1				1
Atrioventricular block first degree		1				1
Back pain	1	8	1	4		4
Bacterial sepsis		1				1
Balance disorder		3		1		2
Bedridden		4				4
Blindness	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	4			1	4
Blood pressure diastolic decreased		1		1		
Blood pressure increased		1		1		
Blood pressure systolic increased	1	1			1	1
Body temperature decreased		1		1		
Body temperature fluctuation	1	1			1	1
Body temperature increased	1	1			1	1
Bradycardia		2				2
Brain stem stroke		1				1
Breath sounds abnormal		1				1
Bronchitis		1		1		
Cardiac arrest		1				1
Cardiac failure		4				4
Cardiac fibrillation	1	1			1	1
Cardio-respiratory arrest		1				1
Carotid arteriosclerosis		1		1		
Cerebral haemorrhage	3	7			3	7
Cerebral infarction	2	5			2	5
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	3	19			3	19
Cerebrovascular disorder		1				1
Chest pain	2	6			2	6
Chills	1	5		2	1	3
Cholecystitis		1				1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease		4				4
Circulatory collapse	1	2			1	2
Cognitive disorder		3		1		2
Cold sweat		5				5
Communication disorder		1		1		
Concomitant disease aggravated		1				1
Condition aggravated	2	6		1	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	2	21		7	2	14
Conjunctivitis		1		1		
Constipation		1		1		
Coordination abnormal	1	2			1	2
Coronary artery occlusion		1				1
Cough	1	7		4	1	3
C-reactive protein increased	6	21	1	4	5	17
Cyanosis		1				1
Cystic lung disease		1		1		
Death		25				25
Decreased appetite	1	13	1	5		8
Decubitus ulcer		1		1		
Deep vein thrombosis	1	1			1	1
Defaecation disorder		1				1
Dehydration		2		1		1
Delirium	1	4			1	4
Dementia		2				2
Dementia Alzheimer's type		1				1
Demyelinating polyneuropathy	1	1			1	1
Depressed level of consciousness		5				5
Depressed mood		1		1		
Diarrhoea	2	15	1	9	1	6
Diplopia	1	2			1	2
Discomfort		2		1		1
Disease recurrence		3				3
Disorientation	1	1			1	1
Dizziness	5	13	1	6	4	7
Drooling		1		1		
Drug interaction	2	3	2	2		1
Dry mouth		1				1
Dry skin		1		1		
Duodenitis		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysarthria	2	5	1	1	1	4
Dysphagia	1	5	1	1		4
Dysphonia		3		3		
Dyspnoea	6	33	2	7	4	26
Dyspnoea at rest		1				1
Ear discomfort	1	1	1	1		
Embolic cerebral infarction		1				1
Emphysema		1		1		
Epistaxis		1		1		
Erythema		3		3		
Exfoliative rash	1	1			1	1
Eye haemorrhage		2				2
Facial paralysis		3				3
Facial paresis	1	3	1	1		2
Faeces discoloured		1				1
Fall	2	16		4	2	12
Fatigue	7	46	3	28	4	18
Feeling abnormal		2		1		1
Feeling hot	1	2			1	2
Femoral neck fracture		2				2
Femur fracture		1				1
Food refusal		1				1
Fracture		1				1
Gait disturbance	1	2	1	1		1
Gastric haemorrhage	1	1			1	1
Gastrointestinal haemorrhage		2				2
Gastrointestinal necrosis		1				1
General physical health deterioration	10	53	5	13	5	40
Giant cell arteritis	1	1			1	1
Glomerulonephritis chronic		1				1
Guillain-Barre syndrome	1	1			1	1
Haematemesis	1	2			1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased	1	3			1	3
Haemorrhage		2				2
Haemorrhage subcutaneous	1	1			1	1
Haemothorax		1				1
Hallucination		3				3
Headache	5	17	1	11	4	6
Head injury		1				1
Heart rate decreased		1				1
Heart rate increased		6		2		4
Heart rate irregular		1				1
Hemiparesis	1	3			1	3
Hemiplegia	1	2			1	2
Hyperglycaemia		1				1
Hyperkalaemia		1				1
Hypernatraemia		1				1
Hypertension		4		4		
Hyperventilation		4		3		1
Hypokinesia		1				1
Hyponatraemia	2	2			2	2
Hypophagia	1	4			1	4
Hypotension	2	9	1	1	1	8
Hypoxia		2				2
Immobile		1				1
Immune-mediated adverse reaction	1	1			1	1
Inappropriate schedule of product administration	2	3	2	3		
Incontinence	1	1			1	1
Incorrect route of product administration		1		1		
Increased bronchial secretion		2		1		1
Infection		8		1		7
Inflammation		1				1
Inflammatory marker increased	1	1			1	1
Influenza like illness		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
International normalised ratio increased		1					1
Interstitial lung disease		1					1
Intestinal ischaemia		1					1
Intracardiac thrombus		1					1
Iridocyclitis	1	1			1		1
Ischaemic stroke	2	3			2		3
Kidney fibrosis		1					1
Left ventricular failure		1					1
Lethargy	1	5		2	1		3
Leukocytosis		2		1			1
Local reaction		1					1
Loss of consciousness	3	8			3		8
Loss of personal independence in daily activities	1	1			1		1
Lower respiratory tract infection		1					1
Lung consolidation	1	1			1		1
Lung opacity	1	3			1		3
Malaise	2	12	1	5	1		7
Malignant hypertension		1					1
Marasmus		1					1
Mediastinal haemorrhage		1					1
Melaena		1					1
Mental impairment	1	1			1		1
Mesenteric artery embolism		1					1
Metastases to peritoneum		1					1
Monoparesis		1					1
Monoplegia	1	1			1		1
Motor dysfunction		1		1			
Multiple fractures		1					1
Muscle rigidity		1					1
Muscle spasms		1					1
Muscle spasticity	1	1			1		1
Muscle twitching		1		1			

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness	2	3	1	1	1	2
Musculoskeletal stiffness		1		1		
Myalgia		3		2		1
Myocardial infarction	1	1			1	1
Nasal congestion		3		3		
Nasopharyngitis		1				1
Nausea	1	26	1	15		11
Neck pain		1				1
N-terminal prohormone brain natriuretic peptide increased		1				1
Ocular hyperaemia		1		1		
Oedema peripheral		4		2		2
Off label use	2	2	2	2		
Ophthalmic herpes zoster	1	1			1	1
Oropharyngeal pain		5		3		2
Orthostatic hypotension	1	1			1	1
Oxygen saturation decreased		11		1		10
Pain	2	8		3	2	5
Pain in extremity		3		2		1
Pallor		4				4
Palpitations		1				1
Pancytopenia	1	1			1	1
Paraesthesia		1				1
Paralysis		1				1
Paresis	1	1	1	1		
Pericardial effusion		2				2
Pericardial haemorrhage		1				1
Pericarditis	1	3			1	3
Peripheral swelling	1	1			1	1
Petechiae	2	3	1	1	1	2
Pleural effusion		2				2
Pleurisy		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	1	17			1	17
Pneumonia aspiration	1	2			1	2
Pneumonia bacterial	1	1			1	1
Pneumonitis	1	2			1	2
Presyncope	1	3			1	3
Productive cough		5				5
Pruritus	1	3			1	3
Psychomotor hyperactivity		1				1
Pulmonary embolism	1	6			1	6
Pulmonary oedema		1				1
Pupil fixed		2				2
Pyelonephritis		1				1
Pyrexia	1	39		12	1	27
Rales		3		2		1
Rash		3		3		
Rash erythematous	1	1			1	1
Rash pruritic	1	2		1	1	1
Rectal haemorrhage	1	2			1	2
Red blood cell sedimentation rate increased	1	1	1	1		
Renal impairment		1				1
Respiration abnormal		1				1
Respiratory arrest		3				3
Respiratory disorder		1				1
Respiratory failure	2	6			2	6
Respiratory rate increased		7		4		3
Respiratory tract infection		1				1
Restlessness	1	8		3	1	5
Rhinorrhoea		3		3		
Secretion discharge		1				1
Sepsis		3				3
Skin haemorrhage		1		1		
Sleep disorder	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Snoring	1	1			1	1
Somnolence	1	8		5	1	3
Speech disorder		3		2		1
Staphylococcal sepsis	1	1			1	1
Stridor		1				1
Subdural haematoma	1	1			1	1
Subdural haemorrhage	1	1			1	1
Sudden cardiac death		1				1
Sudden death		7				7
Supraventricular extrasystoles		1				1
Syncope	4	12			4	12
Tachycardia		4		1		3
Tachypnoea		2		1		1
Terminal state		1				1
Therapeutic product effect decreased	1	1	1	1		
Thirst		1				1
Thrombophlebitis	1	1	1	1		
Thrombophlebitis superficial	2	2			2	2
Thrombosis		1				1
Thrombotic stroke		1				1
Transfusion reaction	1	1	1	1		
Transient ischaemic attack	1	3			1	3
Tremor	1	5		1	1	4
Troponin increased		1				1
Tubulointerstitial nephritis		1				1
Unresponsive to stimuli		3				3
Urinary incontinence		1				1
Urinary retention		2				2
Urinary tract infection		5		4		1
Urticaria		1				1
Vaccination site erythema		4		3		1
Vaccination site pain		6		4		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site reaction		1				1	
Vaccination site swelling		4		2		2	
Vision blurred	1	1			1	1	
Visual impairment	1	1	1	1			
Vlith nerve paralysis	1	1			1	1	
Vomiting	1	28	1	10		18	
Weight decreased		1		1			
Wheezing	1	2			1	2	
	180	1,022	41	283	139	739	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial fibrillation		1				1
Dizziness		2		2		
Dry mouth		2		2		
Dyspnoea		1		1		
Exposure during pregnancy		2		2		
Fatigue		3		3		
General physical health deterioration		1		1		
Hyperhidrosis		1		1		
Incorrect dose administered		5		5		
Incorrect route of product administration		1		1		
Intentional product use issue	1	1	1	1		
Intercepted product preparation error		1		1		
Maternal exposure during pregnancy		1		1		
Myalgia		1		1		
Pain in extremity		1		1		
Poor quality product administered		6		6		
Presyncope		1		1		
Product administered at inappropriate site		1		1		
Product preparation error		2		2		
Product preparation issue		8		8		
Product temperature excursion issue	1	7	1	7		
Tachycardia		1		1		
Wrong technique in product usage process		1		1		
	2	51	2	50		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**OMAN**

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Fatigue		1		1
Gastritis		1		1
Headache		1		1
Inappropriate schedule of product administration		1		1
Pain		1		1
Product supply issue		1		1
Pyrexia		1		1
Therapeutic response unexpected		1		1
		9		9

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PANAMA**

Age Range

**18 - 30 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Erythema		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia		1		1		
Chills		1		1		
Dyspnoea	1	1			1	1
Gait disturbance	1	1			1	1
Hemiparesis	1	1			1	1
Hypersensitivity		1		1		
Hypoaesthesia oral	1	1			1	1
Hypotonia		1		1		
Hypotonic-hyporesponsive episode		2		1		1
Incorrect route of product administration		1		1		
Irritability		1		1		
Local reaction	1	2	1	2		
Overdose		1		1		
Pallor		1		1		
Palpitations		1		1		
Paraesthesia	1	1			1	1
Pulmonary pain	1	1			1	1
Pyrexia	1	1			1	1
Rash erythematous		1				1
Rash pruritic		1				1
Syncope		2				2
Vaccination site pain	1	1			1	1
Vaccination site reaction		1		1		
	10	27	2	14	8	13

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Asthenia		2		2		
Headache	1	1	1	1		
Lip dry	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Vaccination site pain	1	1	1	1		
	4	7	4	6		1

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain		1		1
		1		1

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state	1	1	1	1
Fatigue	1	1	1	1
Vaccination site pain	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2	2	2		
Asthenia		1		1		
Dry throat	1	1	1	1		
Dysphagia	1	1	1	1		
Flatulence		1		1		
Hypersensitivity	1	1	1	1		
Rash pruritic		6				6
Syncope		1				1
	5	14	5	7		7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PERU**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	1	1	1
Pyrexia	1	1	1	1
	2	2	2	2

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Headache	1	2	1	2
Pain in extremity	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain		1		1
	4	6	4	6

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
Heart rate increased	1	1	1	1
Pyrexia	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	1	1	1	1
Chest pain	1	1	1	1
Discomfort	1	1	1	1
Headache	2	2	2	2
Hyperhidrosis	1	1	1	1
Nasal dryness	1	1	1	1
Oropharyngeal pain	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	10	10	10	10

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Arthralgia	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	1			1	1
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Pyrexia	2	2	2	2		
	10	10	8	8	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1	1	1		
Discomfort	1	1	1	1		
Epistaxis	1	1			1	1
Exposure via breast milk	1	1	1	1		
Off label use	2	2	2	2		
Product use issue	2	2	2	2		
Pyrexia	1	1	1	1		
	9	9	8	8	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**POLAND**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety		1		1
Diarrhoea		1		1
Exposure via breast milk	1	3	1	3
Pyrexia		1		1
	1	6	1	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		1				1
Ageusia		1		1		
Agitation		1				1
Alanine aminotransferase increased		1				1
Anaphylactic reaction		2				2
Angioedema		1				1
Anosmia	1	1	1	1		
Anxiety		2		1		1
Apnoea		1				1
Arrhythmia	1	1			1	1
Arthralgia	1	8	1	2		6
Asthenia	2	16	2	9		7
Asthma		1				1
Asthmatic crisis		1				1
Axillary pain		2		2		
Balance disorder		1		1		
Blood pressure decreased		2		1		1
Blood pressure increased	1	2			1	2
Body temperature fluctuation		1		1		
Body temperature increased		1				1
Bone pain		3				3
Bradycardia		2				2
Chest pain		2				2
Chills	1	9	1	4		5
Contusion		1				1
Cough		1				1
COVID-19		1				1
C-reactive protein increased	1	1	1	1		
Decreased appetite		2		1		1
Delirium		1				1
Diarrhoea	1	2	1	1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Disturbance in attention		1					1
Dizziness	1	8	1	3			5
Drug ineffective		1					1
Dysgeusia		1		1			
Dyspnoea	1	3	1	1			2
Dyspnoea exertional	1	1			1		1
Epistaxis		1		1			
Erythema		1					1
Exposure during pregnancy	1	1	1	1			
Eye pain		5					5
Fatigue	3	6	3	6			
Feeling cold		3					3
Feeling hot		1					1
Formication		1					1
Headache	4	19	3	10	1		9
Head discomfort		1		1			
Hyperaesthesia	1	1	1	1			
Hyperhidrosis		3		2			1
Hypersensitivity		1					1
Hypoaesthesia		3					3
Hypoaesthesia oral		1					1
Hypotension		1		1			
Hypotonic-hyporesponsive episode		2		2			
Infection		1					1
Injection site pain		1		1			
Irregular breathing		1					1
Lacrimation increased		1					1
Laryngospasm		1					1
Lymphadenopathy	2	9		2	2		7
Lymph node pain	2	8		1	2		7
Malaise		2					2
Movement disorder	1	1	1	1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle spasms		1
Musculoskeletal stiffness		1
Myalgia	3	14
Myocarditis		1
Nausea	1	6
Neck pain		5
Optic neuritis		1
Pain		1
Pain in extremity	1	13
Pallor		1
Palpitations		2
Pancreatitis acute		1
Paraesthesia		1
Peripheral coldness		1
Pharyngeal hypoaesthesia		1
Presyncope		1
Pyrexia	5	28
Rash	1	3
Rash morbilliform		1
Respiratory disorder		1
Restlessness		1
Rhinitis		1
Seizure		2
Sensory disturbance		1
Skin lesion		1
Somnolence		1
Spinal pain		1
Syncope		3
Tachycardia		4
Tachypnoea		1
Taste disorder		1
Thrombosis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
3	6		8
1	4		2
	2		3
	1		1
	6	1	7
			1
	1		1
			1
			1
3	10	2	18
		1	3
			1
			1
			1
			2
			1
			1
			1
	1		3
			1
	1		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus		1		1		
Tremor		1				1
Vaccination site erythema		3		2		1
Vaccination site pain		14		12		2
Vaccination site pruritus	1	2	1	2		
Vaccination site reaction		5				5
Vaccination site swelling		2		2		
Vertigo		2				2
Visual field defect		1		1		
Visual impairment		1		1		
Vomiting		2				2
Walking disability		1		1		
	38	301	26	118	12	183

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	6		2	1	4
Abdominal pain upper		1		1		
Ageusia		3		3		
Allergic respiratory symptom		2				2
Allergy to vaccine		2				2
Anaphylactic reaction		6				6
Anaphylactic shock		7				7
Angioedema		5				5
Anosmia		3		3		
Anuria		1				1
Anxiety		1				1
Aphasia	1	1			1	1
Arrhythmia	1	4			1	4
Arthralgia	2	30		15	2	15
Arthritis		1		1		
Aspartate aminotransferase increased		1				1
Asphyxia		1				1
Asthenia	7	46	3	20	4	26
Asthma		5				5
Asymptomatic COVID-19		1		1		
Back pain	2	6	2	6		
Balance disorder	1	1			1	1
Basophil count decreased		1		1		
Blister		1				1
Blood creatine phosphokinase increased		3		1		2
Blood pressure abnormal		1				1
Blood pressure decreased	2	9	2	2		7
Blood pressure increased		9				9
Blood smear test abnormal		1		1		
Body temperature increased		3		1		2
Bone pain	1	2			1	2
Brachial plexus injury		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Breath sounds abnormal		1					1
Bronchial oedema		1					1
Cardiac arrest		1					1
Cardiovascular disorder		1					1
Chest discomfort		1		1			
Chest pain		4					4
Chills	3	33	1	16	2		17
Choking		1					1
Chromaturia	1	1			1		1
Coagulopathy		1					1
Cold sweat		1					1
Confusional state	1	2			1		2
Conjunctival hyperaemia		1					1
Conjunctival pallor		1					1
Contusion	1	2	1	1			1
Cough	1	4		2	1		2
COVID-19	4	14		2	4		12
Decreased appetite		2		1			1
Dermatitis allergic		1					1
Diarrhoea		4		1			3
Disease recurrence		1					1
Disorientation	1	1			1		1
Disturbance in attention	1	3	1	2			1
Dizziness	2	17	1	5	1		12
Drug hypersensitivity		1					1
Drug ineffective		7					7
Dry mouth	1	2	1	1			1
Dysarthria		1					1
Dysgeusia		2					2
Dysphagia		3					3
Dyspnoea	2	16		2	2		14
Dyspnoea at rest		1					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysstasia		1		1		
Ear pain		1		1		
Ecchymosis		1				1
Encephalopathy		1				1
Eosinophil count decreased		1		1		
Erythema		4		2		2
Exercise tolerance decreased	1	1	1	1		
Extrasystoles		1				1
Eyelid oedema		1				1
Eye pain	1	3		1	1	2
Eye pruritus		1				1
Face oedema		1				1
Facial paralysis	1	5			1	5
Fatigue	3	6	2	4	1	2
Febrile convulsion		4				4
Feeling abnormal		2		2		
Feeling cold		3		1		2
Feeling hot		3		2		1
Feeling of relaxation		1				1
Flushing		1				1
Generalised tonic-clonic seizure		1				1
Guillain-Barre syndrome		1				1
Haematoma		1		1		
Haematuria		1		1		
Headache	5	44	2	24	3	20
Heart rate increased		5		2		3
Hemiparesis		1				1
Hot flush		1				1
Hydronephrosis		1				1
Hyperhidrosis	2	7		2	2	5
Hypersensitivity		17		2		15
Hypertension	2	4		1	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	3	15	2	4	1	11
Hypoaesthesia oral	1	6	1	2		4
Hypopnoea	1	2			1	2
Hypotension		1				1
Hypothermia		1				1
Hypotonia		1				1
Hypotonic-hyporesponsive episode		16		2		14
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration	1	1	1	1		
Influenza		1		1		
Initial insomnia		1		1		
Injection site pain	1	2	1	2		
Injection site swelling		1		1		
Insomnia		1		1		
Joint range of motion decreased		1		1		
Joint swelling		1				1
Labyrinthitis	1	1			1	1
Lacrimation increased		3				3
Laryngospasm		6				6
Lip blister		1				1
Lip swelling		2				2
Lividity		2				2
Localised oedema		1				1
Loss of consciousness		10				10
Lymphadenopathy	2	27	1	9	1	18
Lymph node pain		19		4		15
Lymphocyte count decreased		1		1		
Malaise	2	12		7	2	5
Maternal exposure during pregnancy		2		2		
Memory impairment	2	2	1	1	1	1
Middle insomnia		1		1		
Monocyte count decreased		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monoparesis		1				1
Multiple sclerosis relapse		1				1
Muscle injury		1				1
Muscular weakness		2				2
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	6	42	2	17	4	25
Myocardial hypoxia		1				1
Myoglobinuria	1	1			1	1
Nasal congestion		2		1		1
Nausea	2	23		13	2	10
Neck pain		1		1		
Nervousness		1		1		
Neuropathy peripheral	1	1			1	1
Neutrophil count increased		1		1		
Oedema		1				1
Oedema peripheral		2				2
Off label use	1	2	1	2		
Oliguria		1		1		
Oropharyngeal pain	1	4	1	3		1
Oxygen saturation decreased	1	6	1	2		4
Pain		3		2		1
Painful respiration		1		1		
Pain in extremity	4	20	4	16		4
Pain of skin	1	2		1	1	1
Pallor	1	7			1	7
Palpitations	1	5			1	5
Paraesthesia	4	6	3	3	1	3
Paraparesis		2				2
Parosmia		2				2
Peripheral swelling	2	3	1	2	1	1
Petechiae		3		1		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pharyngeal swelling		1					1
Phlebitis	1	1	1	1			
Photophobia		1					1
Poor quality product administered		1		1			
Presyncope		5		1			4
Product administered at inappropriate site		1		1			
Product use issue		1		1			
Protein urine present		1		1			
Pruritus	1	5		1	1		4
Pulpitis dental		1		1			
Pyrexia	7	67	3	27	4		40
Radicular pain		1		1			
Rash	2	9	1	1	1		8
Rash erythematous		1					1
Rash macular		1		1			
Rash papular		2					2
Rash rubelliform		1					1
Rash vesicular	1	1			1		1
Renal pain		1		1			
Respiratory arrest		2					2
Respiratory tract oedema		1					1
Rhabdomyolysis		1					1
Rhinitis		1					1
Rhinorrhoea		3		2			1
SARS-CoV-2 test positive		1					1
Sciatica	1	2		1	1		1
Seizure	1	11			1		11
Shock symptom		1					1
Skin exfoliation		1					1
Skin hypertrophy		1		1			
Skin mass		1		1			
Sluggishness	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somnolence		4
Speech disorder	2	4
Spinal pain		1
Stress		1
Subclavian vein thrombosis		1
Sudden cardiac death	1	1
Suspected COVID-19		1
Swelling		1
Swelling face	1	1
Swollen tongue		2
Syncope	1	11
Systemic lupus erythematosus		1
Tachyarrhythmia		1
Tachycardia	3	15
Tachypnoea		1
Taste disorder		2
Therapeutic response unexpected		1
Thirst		1
Throat irritation		1
Thrombophlebitis	1	1
Tongue oedema		1
Toothache		2
Tracheal oedema		1
Tremor		1
Trigeminal neuralgia		1
Trigeminal neuritis		1
Urticaria	1	7
Vaccination complication		1
Vaccination failure	3	4
Vaccination site discomfort		1
Vaccination site erythema	2	8
Vaccination site extravasation		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		2
	1	2	3
			1
			1
			1
		1	1
	1		
	1		
		1	1
			2
		1	11
			1
			1
1	1	2	14
			1
	1		1
	1		
	1		
1	1		
			1
	1		1
			1
1	2		5
	1		
		3	4
			1
2	6		2
	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration		2		2		
Vaccination site movement impairment		2		2		
Vaccination site oedema	1	2	1	1		1
Vaccination site pain	3	37	2	31	1	6
Vaccination site pruritus	1	5	1	5		
Vaccination site reaction		29		4		25
Vaccination site swelling	1	7	1	5		2
Vaccination site warmth		3		2		1
Venous thrombosis	1	1			1	1
Ventricular extrasystoles		1				1
Vertigo		2		1		1
Vestibular neuronitis	1	1	1	1		
Visual field defect		1		1		
Visual impairment	1	2	1	1		1
Vomiting		6		3		3
	131	1,029	55	380	76	649

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	4		1	1	3
Abdominal pain upper		2		1		1
Ageusia		4		2		2
Allergic reaction to excipient		1		1		
Altered state of consciousness		1				1
Anaemia		1				1
Anal incontinence		2		1		1
Anaphylactic reaction		4				4
Anaphylactic shock	1	2			1	2
Angioedema	1	4			1	4
Anosmia		4		2		2
Anuria		1				1
Anxiety		1		1		
Arrhythmia		2				2
Arthralgia	2	12	1	3	1	9
Arthropathy		1		1		
Asthenia	4	35	2	18	2	17
Back pain		3		2		1
Blood pressure decreased	2	7		1	2	6
Blood pressure fluctuation		1				1
Blood pressure increased	3	9		2	3	7
Blood thyroid stimulating hormone decreased		1				1
Body temperature decreased		1		1		
Body temperature increased		5		4		1
Bone pain	1	5		3	1	2
Brain stem syndrome		1				1
Breast pain		1				1
Burning sensation		1		1		
Cardiovascular disorder	1	2	1	1		1
Cerebrovascular accident		1				1
Chest discomfort		4		3		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Chest pain		1					1
Chills	2	18	1	10	1		8
Choking sensation		1					1
Confusional state		4		2			2
Conjunctival hyperaemia		2		1			1
Contusion		1					1
Cough	1	9		3	1		6
COVID-19		7		2			5
C-reactive protein increased		2					2
Death	1	1			1		1
Decreased activity		1		1			
Decreased appetite		3		1			2
Defaecation urgency		1		1			
Diarrhoea	2	5	1	2	1		3
Discomfort		1		1			
Disease progression		1					1
Disorientation		1					1
Dizziness	1	10		5	1		5
Drug hypersensitivity	1	1			1		1
Drug ineffective		3					3
Dry mouth		1		1			
Dysgeusia		1					1
Dyspnoea	1	8		1	1		7
Encephalopathy		1					1
Epigastric discomfort	1	1			1		1
Erythema	1	5		1	1		4
Erythema multiforme		2					2
Eyelids pruritus		1					1
Eye pain		1					1
Face oedema		1					1
Facial paralysis		3					3
Faeces soft	1	1			1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	1	8	1	7		1
Febrile convulsion		1				1
Feeling abnormal		3		3		
Feeling cold		2		1		1
Feeling hot	1	3	1	2		1
Fibrin D dimer increased		1				1
Flatulence	1	1			1	1
Gait disturbance		1		1		
Gastrointestinal disorder	1	1	1	1		
Goitre		1				1
Haemorrhagic diathesis	1	1			1	1
Hallucination, olfactory	1	1			1	1
Headache	3	38	2	20	1	18
Head discomfort		1		1		
Heart rate increased	2	4			2	4
Herpes virus infection		1		1		
Hot flush		1		1		
Hyperaesthesia	1	4	1	1		3
Hyperhidrosis		4		3		1
Hyperpyrexia	1	1			1	1
Hypersensitivity		5		1		4
Hypertension	1	1	1	1		
Hypoaesthesia		4		1		3
Hypoaesthesia eye		2				2
Hypotension		2				2
Hypotonia		1				1
Hypotonic-hyporesponsive episode	1	3			1	3
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration		1		1		
Influenza like illness		4		3		1
Joint swelling		2		1		1
Labyrinthitis		1				1

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
			1
	1		
			1
			1
	2	2	7
1	5	1	8
1	2	1	7
	5		3
	1		
	1		
	1		
	1		
	1		
	1		
			2
		1	1
	2		
1	8	1	12
	1		
	5	2	10
	1		1
		1	1
			1
			1
	2		
	1		1
	9	1	5
	1		
	1		3
			1

Lacrimation increased

2

Laryngospasm

1

Lethargy

1

Lip pruritus

1

Lividity

1

Loss of consciousness

2

7

Lymphadenopathy

2

13

Lymph node pain

2

9

Malaise

8

Memory impairment

1

Migraine

1

Mood altered

1

Movement disorder

1

Muscle spasms

1

Muscle tightness

1

Muscular weakness

2

Musculoskeletal pain

1

1

Musculoskeletal stiffness

2

Myalgia

2

20

Nasopharyngitis

1

Nausea

2

15

Neck pain

2

Nervousness

1

1

Neuritis cranial

1

Oedema

1

Oedema peripheral

1

Off label use

2

Oropharyngeal pain

2

Pain in extremity

1

14

Pallor

1

Paraesthesia

4

Paraesthesia oral

1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paresis		1
Parosmia		1
Peripheral coldness		1
Peripheral swelling	1	1
Petechiae		1
Photophobia		1
Pneumonia		2
Product use issue		1
Prostatitis		1
Pruritus	1	2
Pyrexia	3	47
Rash erythematous	1	1
Rash papular		1
Rash pruritic		1
Rash rubelliform		1
Rhinitis		1
Rhinorrhoea		1
Seizure		4
Sensation of foreign body		1
Sensory disturbance		1
Somnolence		1
Speech disorder		2
Spinal pain		1
Sudden death	1	1
Supraventricular extrasystoles	1	1
Suspected COVID-19		1
Swelling		1
Swelling face		1
Syncope		4
Tachycardia	1	5
Tachypnoea		1
Taste disorder		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
	1		
		1	1
			1
	1		
			2
	1		
	1	1	1
2	17	1	30
		1	1
	1		
	1		
			1
			1
	1		
			4
			1
			1
	1		
			2
	1		
		1	1
		1	1
			1
	1		
			1
			4
	1	1	5
			1
	2		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness		2		1		1
Thyroiditis		1				1
Thyroid pain		1				1
Tinnitus	1	1			1	1
Transaminases increased		1				1
Tremor		3		3		
Trigeminal nerve disorder		1		1		
Trigeminal neuralgia		1		1		
Urinary incontinence		1				1
Urinary tract inflammation		1				1
Urticaria	1	3		1	1	2
Vaccination complication		1		1		
Vaccination failure		1				1
Vaccination site abscess sterile		2				2
Vaccination site erythema		5		3		2
Vaccination site extravasation		1		1		
Vaccination site hypersensitivity		1				1
Vaccination site inflammation		1		1		
Vaccination site oedema		2		2		
Vaccination site pain	1	16		12	1	4
Vaccination site pruritus		2		2		
Vaccination site rash		1				1
Vaccination site reaction	2	18		3	2	15
Vaccination site swelling		3		2		1
Vaccination site warmth		1		1		
Vertigo		2				2
Vision blurred		1		1		
Visual acuity reduced		1				1
Visual impairment		1				1
Vomiting	1	8	1	2		6
White blood cell count increased		1				1
	72	626	19	252	53	374

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\* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	2		
Abdominal pain lower		1				1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	2			1	2
Alanine aminotransferase increased		1				1
Allergic reaction to excipient		1		1		
Anal incontinence	1	1			1	1
Angioedema		1				1
Angiopathy		1				1
Anuria		1				1
Apnoea	1	1			1	1
Arrhythmia		1				1
Arteriosclerosis		1				1
Arthralgia		3		2		1
Aspartate aminotransferase increased		1				1
Asthenia	4	8	2	4	2	4
Asthma		1				1
Asymptomatic COVID-19		1				1
Atrial fibrillation	1	2			1	2
Atrial flutter	1	1			1	1
Bladder disorder		1		1		
Bleeding varicose vein	1	1			1	1
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure fluctuation		1				1
Blood pressure increased	1	1			1	1
Body temperature increased	1	1			1	1
Bone pain		1		1		
Brain oedema		1				1
Bursitis		1		1		
Cardiac arrest		1				1
Cardiogenic shock		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	4			1	4
Cervical spinal stenosis		1				1
Chest pain		1				1
Chills	1	5	1	2		3
Coma		1				1
Condition aggravated	1	1	1	1		
Contusion		1				1
Coronary artery thrombosis		1				1
Cough	2	2	1	1	1	1
COVID-19	7	11		1	7	10
Cyanosis		1				1
Deafness unilateral		1				1
Death	2	2			2	2
Decreased appetite	1	1			1	1
Decreased nasolabial fold		1		1		
Depressed level of consciousness		1				1
Diarrhoea	1	3	1	2		1
Discomfort		1		1		
Drug ineffective	4	7			4	7
Dysphonia		1		1		
Dyspnoea	1	1			1	1
Erysipelas	1	1			1	1
Erythema		1				1
Erythema multiforme		1				1
Fall	1	1			1	1
Febrile convulsion		1				1
Feeling cold		2		1		1
Gait disturbance		1				1
Gait inability	1	1			1	1
General physical health deterioration		1				1
Grip strength decreased		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage subcutaneous		1				1
Headache		4		3		1
Heart rate abnormal	1	1	1	1		
Helplessness		1				1
Herpes virus infection		1		1		
Hyperaesthesia		2		1		1
Hyperhidrosis	1	1	1	1		
Hypersensitivity		1				1
Hypotonia		1				1
Hypotonic-hyporesponsive episode	1	1			1	1
Incorrect route of product administration	1	3	1	3		
Inflammation		1				1
International normalised ratio increased	1	1	1	1		
Intervertebral disc protrusion		1				1
Ischaemic stroke	1	1			1	1
Joint effusion		1		1		
Joint injury		1				1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling		1				1
Loss of consciousness	1	2			1	2
Malaise		4		3		1
Metabolic acidosis		1				1
Muscle tightness		1		1		
Myalgia		4		2		2
Nausea	1	2	1	1		1
Oral herpes	1	1	1	1		
Oxygen saturation decreased	2	2			2	2
Pain		2		1		1
Pain in extremity	1	4	1	3		1
Pain in jaw		1		1		
Pancreatitis acute	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis		1				1
Paraparesis		1				1
PCO2 abnormal	1	1			1	1
Pleural effusion		1		1		
Pneumonia viral	1	1			1	1
Presyncope	1	1			1	1
Prostatic specific antigen increased		1				1
Protein urine present		1		1		
Pyrexia	7	19	3	10	4	9
Reaction to excipient		1		1		
Renal failure	1	1			1	1
Respiration abnormal		1		1		
Respiratory failure	1	3			1	3
Seizure		2				2
Speech disorder		1		1		
Spinal cord compression		1				1
Swelling		2				2
Synovial disorder		1		1		
Temperature intolerance		1		1		
Thrombocytopenia	1	1			1	1
Thrombosis	2	4			2	4
Tinnitus	1	1	1	1		
Urinary incontinence	1	1			1	1
Urticaria		1				1
Vaccination failure	1	2			1	2
Vaccination site erythema	1	2	1	2		
Vaccination site infection		1		1		
Vaccination site pain	1	5	1	5		
Vaccination site reaction		2		1		1
Vaccination site scab		1		1		
Vaccination site swelling		1		1		
Vaccination site vesicles		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	72	221	20	81	52	140

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2			1	2
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Altered state of consciousness		1				1
Anal incontinence	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angioedema		1				1
Anuria		1				1
Aortic aneurysm rupture		1				1
Aphasia		2		1		1
Arrhythmia	1	1			1	1
Arteriosclerosis	1	1	1	1		
Arthralgia		1		1		
Asthenia	4	16	2	6	2	10
Atrial fibrillation		1				1
Atrial flutter		1				1
Back pain		1				1
Balance disorder		1		1		
Bladder cancer		1				1
Blood glucose increased		1				1
Blood pressure abnormal		2		1		1
Blood pressure decreased		1				1
Blood pressure increased		1				1
Bone density decreased	1	1	1	1		
Bone pain		1		1		
Bradycardia		1				1
Brain stem stroke	1	1			1	1
Burning sensation		1		1		
Cardiac arrest	4	8			4	8
Cardiac death		1				1
Cardiogenic shock		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cerebral haematoma		2					2
Chills	1	1			1		1
Cognitive disorder		1		1			
Condition aggravated	1	1			1		1
Contusion		2					2
Cough	2	2	1	1	1		1
COVID-19	2	5			2		5
COVID-19 pneumonia		1					1
C-reactive protein increased		1		1			
Cyanosis		2					2
Death	1	8			1		8
Decreased appetite	1	3		1	1		2
Depressed level of consciousness		1					1
Diarrhoea	4	10	2	3	2		7
Distractibility		1		1			
Dizziness		2		1			1
Drug ineffective		2					2
Dysarthria	1	1			1		1
Dysgeusia		1					1
Dyspnoea	4	7	1	2	3		5
Ear swelling		1					1
Electrolyte imbalance		1		1			
Emphysema	1	1	1	1			
Erythema	1	1			1		1
Essential hypertension	1	1			1		1
Eye disorder		1		1			
Eye pain		1					1
Facial paralysis		2					2
Fall	1	3			1		3
Fatigue		2		2			
Feeling abnormal	1	1			1		1
Feeling cold	1	1			1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot		2		2		
Gait disturbance		2		2		
Gastrointestinal disorder		1				1
Gastrointestinal haemorrhage		1				1
Haematemesis		2				2
Haematuria		1				1
Haemoptysis	1	1	1	1		
Haemorrhagic stroke		1				1
Headache		1				1
Head injury	1	1			1	1
Heart rate increased	1	1	1	1		
Hot flush		1		1		
Hyperhidrosis		3		1		2
Hypersensitivity		1				1
Hypoaesthesia		3		1		2
Hypotension		1				1
Hypotonic-hyporesponsive episode		3				3
Illiteracy		1				1
Inflammation		1		1		
Injection site pain		1		1		
Insomnia		2		2		
Lacrimation increased		1				1
Lethargy	1	1			1	1
Lividity		1				1
Loss of consciousness		5				5
Lung disorder	1	1	1	1		
Lung opacity	1	1	1	1		
Lymphadenopathy	1	1			1	1
Lymph node pain	1	1			1	1
Malaise	1	6	1	4		2
Melaena		1				1
Mobility decreased	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Movement disorder		1				1
Muscular weakness		1		1		
Musculoskeletal pain		1				1
Mutism		1		1		
Myalgia	1	4		3	1	1
Myocardial infarction		1				1
Nasopharyngitis	1	1	1	1		
Nausea		3		2		1
Ocular hyperaemia		1				1
Oedema		1		1		
Oedema peripheral	1	1	1	1		
Oxygen saturation decreased		3				3
Pain		2		1		1
Pain in extremity	1	3	1	3		
Pain of skin		1		1		
Pallor		1				1
Peripheral swelling		1				1
Pneumonia	2	5			2	5
Pneumonia viral	1	1			1	1
Product use issue		1		1		
Pruritus		1		1		
Pulmonary calcification	1	1	1	1		
Pulmonary congestion	1	1			1	1
Pulmonary mass	1	1	1	1		
Pulmonary oedema		2				2
Pyrexia	6	14	3	6	3	8
Rash erythematous		1		1		
Renal failure		1				1
Rhinorrhoea		1				1
Seizure	1	4			1	4
Sensory disturbance		1				1
Sleep disorder	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder		2		1		1
Stupor	1	1			1	1
Sudden death		1				1
Swelling face		1				1
Swollen tongue		1				1
Syncope	2	5			2	5
Thrombosis		1				1
Transient ischaemic attack		1				1
Tremor	1	2	1	1		1
Type 2 diabetes mellitus	1	1			1	1
Urinary incontinence		1				1
Urticaria		1				1
Vaccination failure	1	1			1	1
Vaccination site pain	1	3	1	3		
Visual impairment		1				1
Vomiting	2	8		1	2	7
Walking disability		1				1
Yellow skin		1				1
	74	274	24	81	50	193

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Adnexa uteri pain		1		1		
Adverse reaction	1	1	1	1		
Ageusia		1		1		
Altered state of consciousness	1	1			1	1
Anaphylactic shock		2				2
Anosmia		3		3		
Antibody test abnormal		10		10		
Anuria		1				1
Anxiety		1		1		
Aphthous ulcer		1		1		
Arthralgia	2	27	2	26		1
Arthropathy		1		1		
Asthenia	3	31	2	28	1	3
Asthma		1				1
Asymptomatic COVID-19	5	6			5	6
Axillary mass		1		1		
Axillary pain	1	4	1	4		
Back pain		5		5		
Blood glucose increased	1	1			1	1
Blood pressure decreased		3		1		2
Blood pressure increased	3	4	2	2	1	2
Blood urine present		1		1		
Bone pain		5		5		
Breast enlargement		1		1		
Breast pain		1		1		
Burning sensation		1		1		
Cardiac arrest	1	1			1	1
Chest discomfort		1		1		
Chest pain		1		1		
Chills	3	29	2	27	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Chorea		1		1			
Circulatory collapse	1	1		1	1	1	
Circumstance or information capable of leading to medication error		1		1			
Coagulopathy		1		1			
Confusional state		1		1			
COVID-19	14	40	1	4	13	36	
Crying		1		1			
Cyanosis		1				1	
Cystitis		1		1			
Deafness		2				2	
Death		6				6	
Decreased appetite		2		2			
Delirium	1	1			1	1	
Diarrhoea	3	10	3	10			
Disease recurrence		1				1	
Disturbance in attention		3		3			
Dizziness	1	10		9	1	1	
Drug ineffective	14	34			14	34	
Dysgeusia		2		1		1	
Dysphonia		2		2			
Dyspnoea	1	7	1	4		3	
Eating disorder		1		1			
Epistaxis		1		1			
Exercise tolerance decreased		1		1			
Exposure during pregnancy		3		3			
Exposure via breast milk		5		5			
Extensive swelling of vaccinated limb		1		1			
Eye pain		1		1			
Facial paralysis	2	2			2	2	
Fall	1	1			1	1	
Fatigue	2	13	1	11	1	2	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Febrile convulsion		2
Feeling abnormal		5
Feeling cold	2	8
Feeling hot	1	4
Flatulence		1
Flushing		2
Gingival swelling	1	1
Headache	2	34
Heart rate increased		2
Herpes virus infection		1
Herpes zoster		1
Hot flush		1
Hyperacusis		1
Hyperaesthesia teeth		1
Hyperhidrosis		5
Hyperpyrexia	1	1
Hypertension		2
Hypoaesthesia		8
Hypoaesthesia oral		2
Hypoxia		1
Illness		1
Inappropriate schedule of product administration		2
Incorrect dose administered		1
Incorrect route of product administration		1
Increased upper airway secretion		1
Infection		2
Inflammation		2
Influenza like illness	1	6
Injection site erythema		1
Injection site pain		2
Injection site swelling		1
Insomnia		7

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
	5		
1	7	1	1
1	4		
	1		
	2		
1	1		
2	34		
	2		
	1		
	1		
	1		
	1		
	5		
		1	1
			2
	8		
	1		1
	1		
	2		
	2		
	2		
1	6		
	1		
	2		
	1		
	7		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Iritis		1		1			
Lagophthalmos	1	1	1	1			
Laryngeal oedema		1					1
Limb discomfort		1		1			
Lip swelling		1		1			
Loss of consciousness	1	4			1		4
Lung disorder		1		1			
Lymphadenopathy	2	11	1	9	1		2
Lymph node pain		3		3			
Macule	1	1			1		1
Malaise	2	30		28	2		2
Memory impairment		1		1			
Mental disorder		1		1			
Migraine		1		1			
Muscular weakness		1		1			
Musculoskeletal pain		1		1			
Myalgia	6	43	6	42			1
Myocardial hypoxia		1					1
Myocardial infarction		1					1
Nasopharyngitis		1		1			
Nausea		12		12			
Neck pain		2		2			
Needle issue		1		1			
Nightmare		1		1			
Night sweats		1		1			
Oedema	1	2		1	1		1
Off label use	1	11	1	10			1
Oral candidiasis		1		1			
Oral herpes		1		1			
Oxygen saturation decreased		3		1			2
Pain		4		4			
Pain in extremity	3	24	3	23			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations		1
Paraesthesia		4
Paralysis		1
Paresis		1
Parosmia	1	1
Parotitis		1
Peripheral coldness		1
Pharyngeal hypoaesthesia		1
Pharyngeal swelling		1
Photophobia		1
Pneumonia		1
Poor quality product administered		3
Poor quality sleep		1
Presyncope		1
Product contamination physical		1
Product label confusion		2
Product preparation error		1
Product temperature excursion issue		1
Product use issue	1	8
Pruritus		1
Psoriatic arthropathy	1	1
Pulmonary oedema		1
Pulmonary pain	1	1
Pyrexia	7	54
Radiculitis brachial		1
Rash		3
Rash vesicular	1	1
Respiratory disorder	1	1
Respiratory failure	1	2
Respiratory tract infection		1
Retching		1
Rhinorrhoea		5

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	4		
			1
			1
1	1		
	1		
	1		
			1
	1		
	1		
			1
	3		
	1		
	1		
	1		
	2		
	1		
	1		
1	7		1
	1		
		1	1
5	47	2	7
	1		
	3		
		1	1
		1	1
		1	2
			1
	1		
	5		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 antibody test positive	1	1
SARS-CoV-2 test positive		1
Seizure	1	1
Sepsis		1
Shock	1	1
Sinus headache		1
Sinusitis		1
Somnolence	1	6
Spinal pain		1
Suppressed lactation		2
Swelling	1	2
Swollen tongue		1
Syncope	1	5
Tachycardia		5
Tension headache		1
Therapeutic response unexpected	1	2
Thirst		1
Thrombosis	1	2
Tinnitus		3
Tonsillar hypertrophy		1
Ulnar nerve palsy		1
Vaccination failure	2	5
Vaccination site erythema		3
Vaccination site hypersensitivity		1
Vaccination site induration		1
Vaccination site macule		1
Vaccination site movement impairment		1
Vaccination site oedema	1	2
Vaccination site pain	3	41
Vaccination site paraesthesia		1
Vaccination site pruritus		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
	1		
		1	1
			1
		1	1
			1
	1		
	5	1	1
	1		
	1		1
1	2		
	1		
		1	5
	2		3
	1		
1	2		
	1		
		1	2
	3		
	1		
	1		
	1		
	1		
		1	2
3	40		1
	1		
	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction		5		5		
Vaccination site swelling		6		6		
Vaccination site warmth		2		2		
Vein disorder		1		1		
Viral infection		1		1		
Vomiting	2	10	2	9		1
		1		1		
	117	817	49	629	68	188

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PORTUGAL**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Eructation		1		1
Exposure via breast milk	3	7	3	7
Infant irritability		1		1
	3	9	3	9

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		4		1		3
Abdominal pain upper	1	1			1	1
Aborted pregnancy		1				1
Adenopathy syphilitic		1				1
Ageusia		2		1		1
Anaphylactic reaction		2				2
Angioedema		1				1
Anosmia		3		2		1
Anxiety	2	2	2	2		
Aphthous ulcer	1	2	1	1		1
Arrhythmia		1				1
Arthralgia	12	28			12	28
Asthenia		8		1		7
Asymptomatic COVID-19	1	3			1	3
Axillary pain		7		1		6
Back pain		4				4
Balance disorder		1				1
Body temperature increased		1		1		
Bradycardia		1				1
Breast pain		1				1
Bronchospasm		3				3
Chest discomfort		2				2
Chest pain	1	4	1	1		3
Chills	15	49	3	7	12	42
Cold sweat		2				2
Condition aggravated		2		1		1
Constipation	1	1			1	1
Cough	1	2	1	1		1
COVID-19	1	21	1	7		14
Decreased appetite		4		1		3
Depressed mood		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dermatitis allergic		1					1
Diarrhoea	3	12		2	3		10
Diastolic hypertension		1					1
Discomfort		1					1
Dizziness	4	20	1	2	3		18
Dizziness postural		1					1
Drug ineffective		10					10
Dry mouth		2					2
Dysphagia		1					1
Dysphonia		1					1
Dyspnoea	2	8		1	2		7
Ear pain		2					2
Eczema		1					1
Episcleritis		1					1
Erythema	1	5	1	2			3
Exposure during pregnancy		1		1			
Face oedema	1	3		1	1		2
Facial asymmetry		1					1
Facial spasm		1					1
Fatigue	10	33	1	4	9		29
Febrile convulsion		1					1
Feeling cold	1	1			1		1
Feeling hot		3		1			2
Flatulence		1		1			
Flushing	1	2	1	1			1
Generalised tonic-clonic seizure		1					1
Granulomatous lymphadenitis		1					1
Haematoma		2		1			1
Headache	23	113	9	24	14		89
Hemiparaesthesia		1					1
Hot flush		1					1
Hyperaesthesia		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperhidrosis	1	5
Hypersensitivity		3
Hypertension	1	3
Hyperthermia	1	2
Hypoaesthesia	3	4
Hypoaesthesia oral		1
Hypoglycaemia		1
Hyposmia		1
Hypotension		5
Hypothermia	1	1
Illness		1
Inappropriate schedule of product administration		2
Incorrect route of product administration	1	4
Influenza		1
Injected limb mobility decreased		2
Injection site warmth		1
Insomnia		2
Joint range of motion decreased		1
Laryngeal oedema		2
Lip oedema		1
Localised oedema		1
Loss of personal independence in daily activities		1
Lymphadenitis	1	3
Lymphadenopathy	14	53
Lymph node palpable		1
Malaise	2	14
Mobility decreased	1	2
Mood altered		1
Motor dysfunction		2
Movement disorder		1
Muscle twitching		1
Muscular weakness	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	5
			3
		1	3
	1	1	1
2	2	1	2
			1
			1
			1
			5
		1	1
	1		
	1		1
1	4		
			1
	1		1
			2
			1
			2
			1
			1
			1
1	1		2
4	9	10	44
			1
1	4	1	10
		1	2
			1
			2
			1
			1
		1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	18	17	103
			1
		1	4
5	8	6	37
		1	2
			1
1	1		3
		1	2
			2
1	1		
			1
	1	1	1
	2		
	2	1	12
			1
	2	1	10
			3
		1	2
2	5	3	11
			2
1	1		
			1
			1
			1
	1	1	3
1	1		
1	1		1
			1
			1
3	12	12	85
1	2		5
			2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular		1				1
Rash pruritic		1		1		
Rhinitis		1		1		
Rhinorrhoea		4		1		3
SARS-CoV-2 test positive		2		1		1
Seizure		1				1
Sensation of foreign body	1	1	1	1		
Sensitive skin		2		1		1
Sinusitis		1		1		
Skin burning sensation		1				1
Skin warm	1	4			1	4
Sneezing	1	1			1	1
Somnolence	2	5	1	3	1	2
Spinal pain	1	1			1	1
Swelling	1	3	1	1		2
Syncope	2	7			2	7
Synovial cyst		1				1
Tachycardia	2	5	1	1	1	4
Throat irritation		3		1		2
Throat tightness		3				3
Thrombocytopenia		1				1
Tinnitus		1				1
Tongue oedema		2				2
Tonic clonic movements		1				1
Tremor	1	8		2	1	6
Urinary tract infection		3				3
Urticaria		3		1		2
Vaccination failure	1	4			1	4
Vaccination site abscess		1		1		
Vaccination site eczema		2		1		1
Vaccination site erythema	5	15	2	4	3	11
Vaccination site haematoma	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration		2				2
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema	8	21	1	7	7	14
Vaccination site pain	28	96	11	36	17	60
Vaccination site paraesthesia		1				1
Vaccination site reaction		1		1		
Vaccination site swelling	2	8	1	2	1	6
Vaccination site warmth		2		1		1
Vaginal haemorrhage		1				1
Vision blurred		1				1
Vomiting	2	19		1	2	18
Wheezing		1				1
	236	1,128	72	224	164	904

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2				2
Abdominal distension		1				1
Abdominal pain	5	15	2	2	3	13
Abdominal pain lower		1				1
Abdominal pain upper	2	12	1	4	1	8
Abnormal faeces		1				1
Abortion spontaneous	1	1			1	1
Acne		1				1
Adenopathy syphilitic	1	1			1	1
Administration site bruise		1		1		
Ageusia		1				1
Agitation		1				1
Allergy to vaccine		3				3
Anaphylactic reaction	2	11			2	11
Anaphylactic shock		2				2
Anaphylactoid reaction		1				1
Angioedema		7				7
Anosmia		1		1		
Anxiety		4		2		2
Aphonia	1	1			1	1
Aphthous ulcer		1				1
Apnoea	1	1			1	1
Arrhythmia		3				3
Arthralgia	26	121	5	12	21	109
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	7	79	4	13	3	66
Asthenopia		1				1
Asymptomatic COVID-19	1	4			1	4
Atelectasis		1		1		
Autonomic nervous system imbalance		1				1
Autophony		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary lymphadenectomy	1	1			1	1
Axillary pain	5	21	3	7	2	14
Back pain	2	9	1	1	1	8
Balance disorder		1				1
Bedridden		1				1
Bladder disorder	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	1	4			1	4
Blood thyroid stimulating hormone increased		1				1
Body temperature increased		4				4
Bradycardia		4				4
Bradyphrenia		2				2
Breast pain		2		1		1
Breast swelling	1	2		1	1	1
Bronchospasm		2				2
Burning sensation		2				2
Cerebral venous sinus thrombosis		1				1
Chest discomfort		7		3		4
Chest pain	5	17	1	1	4	16
Chillblains		1		1		
Chills	27	116	7	21	20	95
Cholinergic syndrome		1				1
Cold sweat		2				2
Computerised tomogram thorax abnormal		1		1		
Condition aggravated		4		1		3
Confusional state		1				1
Conjunctival haemorrhage		1				1
Contraindicated product administered	1	1	1	1		
Conus medullaris syndrome	1	1			1	1
Corneal degeneration		1				1
Corneal opacity		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #	Spontaneous			
	Spontaneous AE	Spontaneous AE	Nonserious		Serious	
			I	C	I	C
Cough	7	27	1	7	6	20
COVID-19	5	31	3	6	2	25
Crying		1		1		
Cutaneous vasculitis		1				1
Cyanosis		1				1
Deafness		1				1
Deafness transitory		1				1
Deafness unilateral		1				1
Decreased appetite		4				4
Depressed level of consciousness		1				1
Dermatitis exfoliative	1	1			1	1
Diarrhoea	11	41	5	7	6	34
Discomfort	1	3			1	3
Disease recurrence		1				1
Disturbance in attention	1	1			1	1
Dizziness	20	83	11	20	9	63
Dizziness postural		1				1
Droling		1		1		
Drug hypersensitivity		1				1
Drug ineffective	1	18			1	18
Drug interaction		1				1
Dry eye		1		1		
Dry mouth	1	7	1	3		4
Dysarthria		3				3
Dysgeusia	11	20	10	13	1	7
Dyskinesia		1				1
Dyspepsia	1	1	1	1		
Dysphagia	2	9	1	1	1	8
Dysphonia	3	7		1	3	6
Dyspnoea	5	23		5	5	18
Dyspnoea at rest		1				1
Dyspnoea exertional	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysuria	1	1
Ear pain	1	1
Eczema		1
Epistaxis		3
Eructation		1
Erythema		14
Erythema nodosum	1	1
Exophthalmos		1
Exposure during pregnancy	1	3
Extrasystoles		2
Eye disorder		2
Eye irritation		2
Eyelid myokymia		1
Eyelid oedema		3
Eyelid sensory disorder		1
Eye movement disorder		1
Eye pain		2
Eye paraesthesia		1
Eye swelling		1
Face oedema	2	9
Facial nerve disorder		1
Facial paralysis	1	5
Facial paresis		2
Facial spasm		1
Faeces soft		1
Fatigue	38	130
Feeling abnormal		1
Feeling cold	1	7
Feeling hot	4	20
Flatulence		1
Flushing	3	12
Functional gastrointestinal disorder		3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
			1
	2		1
	1		
	4		10
		1	1
			1
	2	1	1
	1		1
	1		1
	2		
			1
			3
	1		
			1
	2		
			1
2	2		7
			1
		1	5
			2
	1		
			1
9	24	29	106
	1		
1	1		6
3	4	1	16
			1
1	2	2	10
			3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gait disturbance		1		1			
Gait inability		1		1			
Gastrointestinal pain		1					1
Generalised tonic-clonic seizure		2					2
Glossodynia	1	2	1	2			
Gonorrhoea		1					1
Groin pain		1					1
Haematoma		1					1
Headache	76	351	30	71	46		280
Head discomfort	1	2	1	1			1
Heart rate increased		4					4
Hemianaesthesia		1					1
Hemidysaesthesia		1					1
Hemiparaesthesia	1	1			1		1
Hemiparesis	1	1			1		1
Hot flush		2					2
Hydrocephalus	1	1			1		1
Hyperaemia		1					1
Hyperaesthesia		1					1
Hyperglycaemia		3		1			2
Hyperhidrosis	2	10	2	2			8
Hypersensitivity		4					4
Hypertension	4	21	2	2	2		19
Hypertensive crisis		1					1
Hyperthermia		7					7
Hyperventilation		1					1
Hypoacusis		3					3
Hypoesthesia	3	10	2	3	1		7
Hypoesthesia oral	2	9	2	3			6
Hypoglycaemia		2					2
Hypoperfusion		1					1
Hypotension	2	9			2		9

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypothermia		2					2
Hypothyroidism		1					1
Hypotonic-hyporesponsive episode		1					1
Impaired work ability		2		1			1
Inappropriate schedule of product administration		3		3			
Incorrect dose administered	2	2	2	2			
Incorrect route of product administration		12		12			
Inflammation		3					3
Influenza	2	5			2		5
Influenza like illness		2		1			1
Injection site pain		3		3			
Insomnia	4	14	2	5	2		9
Inspiratory capacity decreased		1					1
Intercostal neuralgia		2					2
Joint range of motion decreased		2					2
Joint swelling		1					1
Lacrimation increased		1					1
Lacunar stroke	1	1			1		1
Laryngeal oedema		6					6
Libido decreased		1		1			
Limb discomfort	2	4	2	2			2
Lip oedema	1	8	1	1			7
Lip pruritus		1					1
Lip swelling		2					2
Localised oedema	1	4			1		4
Loss of consciousness		2					2
Loss of personal independence in daily activities		2		1			1
Lymphadenitis		4					4
Lymphadenopathy	43	146	11	28	32		118
Lymph node pain		3					3
Lymph node palpable		1		1			
Macule		1					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Magnetic resonance imaging brain abnormal		1		1		
Malaise	8	56	5	12	3	44
Mastitis	1	2			1	2
Maternal exposure during pregnancy		3		3		
Meningitis viral	1	1			1	1
Metrorrhagia		1				1
Migraine	2	5	1	1	1	4
Mobility decreased	3	3	2	2	1	1
Monocyte count increased	1	1	1	1		
Motor dysfunction		1				1
Movement disorder	2	2	2	2		
Muscle contractions involuntary	1	2	1	1		1
Muscle fatigue	1	3	1	1		2
Muscle rigidity		1				1
Muscle spasms		3		1		2
Muscular weakness		7				7
Musculoskeletal discomfort		1				1
Musculoskeletal disorder	1	1			1	1
Musculoskeletal stiffness		4		1		3
Myalgia	76	406	20	73	56	333
Myelitis		1				1
Myelosuppression		1				1
Myocarditis		2				2
Nasal congestion		1				1
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction		1		1		
Nausea	43	140	13	23	30	117
Neck pain	4	10	2	4	2	6
Nervousness		2				2
Neuralgia		1				1
Neuropathy peripheral	1	1			1	1

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Night sweats		2
Non-cardiac chest pain	1	1
Nystagmus		4
Occupational exposure to SARS-CoV-2		1
Ocular discomfort		2
Ocular hyperaemia		2
Odynophagia	1	13
Oedema	1	4
Oedema mouth		2
Oedema peripheral	4	10
Oesophageal disorder		1
Off label use	1	10
Oliguria	1	1
Ophthalmic herpes simplex		1
Oral candidiasis	1	1
Oral herpes		1
Oral pain		1
Oropharyngeal discomfort	1	7
Oropharyngeal oedema		1
Oropharyngeal pain	3	8
Orthopnoea	1	1
Osteitis		1
Overdose	4	14
Oxygen saturation decreased		3
Pain	15	42
Pain in extremity	12	33
Pain in jaw		1
Palatal disorder	1	1
Pallor		6
Palpitations	6	12
Pancytopenia		1
Paraesthesia	12	48

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
1	1		
			4
	1		
	2		
			2
	3	1	10
	1	1	3
			2
1	3	3	7
			1
1	10		
		1	1
			1
		1	1
			1
1	3		4
			1
2	3	1	5
		1	1
			1
4	13		1
			3
4	9	11	33
5	8	7	25
			1
		1	1
	1		5
2	3	4	9
			1
9	17	3	31

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia oral	2	11	2	3		8
Paralysis		2				2
Perineal pain		1				1
Peripheral swelling		3				3
Petechiae		1				1
Pharyngeal cyst	2	2			2	2
Pharyngeal erythema		1				1
Pharyngeal hypoesthesia	2	2	1	1	1	1
Pharyngeal inflammation		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	1	5			1	5
Pharyngeal swelling	1	1			1	1
Pharyngitis		1				1
Phlebitis		1				1
Phonophobia		1				1
Photophobia		5		2		3
Piloerection		4				4
Pityriasis rosea		1				1
Pleuritic pain		2				2
Polydipsia	1	3			1	3
Poor quality sleep		2				2
Postural orthostatic tachycardia syndrome		1				1
Presyncope	7	27	5	6	2	21
Procedural haemorrhage		1				1
Procedural nausea		1				1
Productive cough		3		1		2
Product use issue	1	9	1	9		
Pruritus	2	22		4	2	18
Purpura		1				1
Pyrexia	45	267	12	49	33	218
Rash	7	33	3	6	4	27
Rash erythematous		2		1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash macular	2	5			2	5
Rash maculo-papular		3		1		2
Rash papular		3		2		1
Rash pruritic	2	5	1	2	1	3
Renal tubular necrosis		1				1
Respiratory disorder		1				1
Respiratory distress		2				2
Restlessness	1	1	1	1		
Rhinorrhoea	1	12	1	4		8
Salivary hypersecretion	1	2	1	2		
SARS-CoV-2 test positive		2				2
Scar		1		1		
Seizure		4				4
Sensation of foreign body		1				1
Sensory disturbance		1				1
Sensory loss		6		2		4
Sinusitis		1		1		
Sinus tachycardia		1				1
Skin lesion		1				1
Skin warm	1	2		1	1	1
Sleep disorder		2				2
Somnolence	10	40	6	16	4	24
Speech disorder	1	1			1	1
Status epilepticus	1	1			1	1
Stomatitis		2		1		1
Sudden hearing loss		2				2
Suppressed lactation		1		1		
Swelling	2	5	1	1	1	4
Swelling face		1				1
Syncope	1	11			1	11
Synovial cyst	1	4			1	4
Tachyarrhythmia		2				2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tachycardia	6	41
Tachypnoea		2
Taste disorder		7
Tenosynovitis		1
Terminal ileitis		1
Throat irritation		8
Throat tightness	1	5
Thrombophlebitis	1	2
Thrombotic microangiopathy		1
Thyroid function test abnormal		1
Thyroid mass	1	1
Tinnitus	1	3
Tongue disorder	1	1
Tongue dry	1	1
Tongue eruption		1
Tongue oedema	5	12
Tongue pruritus		1
Tongue rough	1	1
Tonsillar hypertrophy		1
Tonsillar inflammation	1	1
Tonsillitis bacterial		1
Tooth abscess	1	1
Tremor	1	28
Trichoglossia		1
Trigeminal palsy		1
Trismus		1
Urinary tract infection	1	2
Urticaria		9
Urticaria papular		1
Vaccination complication		2
Vaccination failure	2	8
Vaccination site discolouration		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	9	3	32
			2
	2		5
	1		
			1
	3		5
	1	1	4
		1	2
			1
	1		
		1	1
		1	3
		1	1
1	1		
			1
3	3	2	9
			1
1	1		
			1
1	1		
			1
1	1		
1	4		24
	1		
			1
			1
		1	2
	1		8
			1
			2
		2	8
			1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site discomfort	1	3	1	1		2
Vaccination site erythema	15	41	6	13	9	28
Vaccination site haematoma	4	4	2	2	2	2
Vaccination site induration		5				5
Vaccination site inflammation	1	9	1	1		8
Vaccination site injury		1				1
Vaccination site joint movement impairment	2	2			2	2
Vaccination site joint pain	1	1			1	1
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment		1				1
Vaccination site oedema	20	42	7	11	13	31
Vaccination site pain	97	291	53	117	44	174
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus	5	21	3	6	2	15
Vaccination site rash	3	5	1	1	2	4
Vaccination site reaction	3	5	3	3		2
Vaccination site swelling	2	15	1	4	1	11
Vaccination site warmth	1	15	1	6		9
Vaginal haemorrhage	1	1			1	1
Ventricular extrasystoles		1				1
Vertigo	2	12	1	3	1	9
Vertigo positional		1				1
Vision blurred		4		2		2
Visual acuity reduced		1		1		
Visual impairment	1	2			1	2
Vomiting	8	30	2	3	6	27
Vulvovaginal burning sensation		1				1
Vulvovaginal swelling		1				1
Weight decreased		1		1		
	865	3,842	340	874	525	2968

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	4	1	2		2
Abdominal pain	1	4	1	1		3
Abdominal pain upper		1				1
Acidosis	1	1			1	1
Acute myocardial infarction		1				1
Allodynia	1	1			1	1
Amylase increased		1				1
Anaphylactic reaction	1	3			1	3
Angina pectoris		1				1
Angioedema		2				2
Anosmia		2				2
Anxiety	1	4	1	2		2
Aphthous ulcer		1				1
Arrhythmia		2				2
Arthralgia	9	34	1	3	8	31
Asthenia	6	30	1	4	5	26
Asymptomatic COVID-19		1		1		
Aura	1	1	1	1		
Axillary pain	1	4		1	1	3
Back pain		3				3
Balance disorder		3				3
Blood pressure decreased		1				1
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased		3				3
Body temperature abnormal		1				1
Body temperature decreased		1				1
Body temperature increased		1				1
Bone pain		2		1		1
Bradycardia	1	2			1	2
Bradypnoea	1	1			1	1
Breast discomfort	1	1			1	1
Breast pain		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm	1	1			1	1
Burning sensation	3	5	1	1	2	4
Cerebrovascular accident	1	1			1	1
Cheilitis	1	1	1	1		
Chest discomfort		5		1		4
Chest pain	2	5			2	5
Chills	7	37	4	8	3	29
Choking sensation		1				1
Circumoral oedema		1				1
Conjunctival irritation		1				1
Cough	3	8			3	8
COVID-19	4	26	2	8	2	18
Crohn's disease		1				1
Crying		1				1
Death		1				1
Decreased appetite	3	3			3	3
Diarrhoea	6	21		2	6	19
Discomfort	1	1			1	1
Dizziness	5	27	4	5	1	22
Drug ineffective	2	14			2	14
Dry skin	1	1			1	1
Dry throat		1				1
Dysgeusia		3				3
Dyspepsia	1	3			1	3
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	2	4			2	4
Dyspnoea at rest		1				1
Dysstasia		1				1
Ear pain		1				1
Epistaxis	1	2	1	1		1
Erythema	1	8			1	8

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure to SARS-CoV-2		1				1
Extrapyramidal disorder		1				1
Eye irritation	1	3	1	2		1
Eyelid oedema		1				1
Eye pain		1		1		
Eye pruritus		1				1
Face oedema	2	8			2	8
Facial paralysis		2				2
Fall		1		1		
Fatigue	8	35		4	8	31
Feeling abnormal		1				1
Feeling cold	2	5	1	2	1	3
Feeling hot	2	5	2	3		2
Feeling of body temperature change		1				1
Flatulence		1				1
Flushing	1	3	1	2		1
General symptom		1				1
Gynaecomastia	1	1			1	1
Haemoptysis		1				1
Hallucination		1				1
Headache	22	97	8	21	14	76
Head discomfort		1				1
Herpes zoster		1				1
Hot flush		1				1
Hyperhidrosis	1	9		1	1	8
Hyperlactacidaemia	1	1			1	1
Hypersensitivity		1				1
Hypertension	5	12	2	2	3	10
Hypertensive crisis		3				3
Hyperthermia		3		1		2
Hypoaesthesia		2		1		1
Hypoaesthesia oral		3		1		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypokalaemia		1				1
Hypotension		3		1		2
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		4		4		
Injection site pain	1	1	1	1		
Insomnia		7		1		6
Joint range of motion decreased	2	2	1	1	1	1
Lacunar stroke	1	1			1	1
Laryngeal oedema		3				3
Lethargy		2				2
Leukocyturia		1		1		
Lipase increased		1				1
Lip oedema		3				3
Lip swelling		1				1
Localised oedema		1				1
Loss of personal independence in daily activities	1	1			1	1
Lymphadenitis	3	3	2	2	1	1
Lymphadenopathy	5	30	1	2	4	28
Malaise	5	31	3	6	2	25
Mental fatigue	1	1			1	1
Migraine		2		1		1
Mobility decreased		1				1
Motor dysfunction	1	1			1	1
Muscle fatigue	1	2		1	1	1
Muscle tightness		1				1
Muscular weakness		3		1		2
Musculoskeletal disorder	1	1			1	1
Musculoskeletal stiffness		1				1
Myalgia	28	116	8	24	20	92
Myalgia intercostal		1				1
Myoclonus		2				2
Nasal congestion		1		1		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal obstruction		1				1
Nasal oedema	1	1	1	1		
Nasopharyngitis		1				1
Nausea	16	50	9	14	7	36
Neck mass		1		1		
Neuropathy peripheral		1				1
Nipple disorder	1	1	1	1		
Nodule	1	1	1	1		
Odynophagia		1		1		
Oedema	1	3	1	1		2
Oedema mouth		1				1
Oedema mucosal		1				1
Oedema peripheral	2	3		1	2	2
Oesophageal pain		1				1
Oral discomfort	1	1	1	1		
Oral herpes		1				1
Oropharyngeal discomfort	4	9	3	4	1	5
Oropharyngeal pain	2	3			2	3
Overdose	1	4	1	4		
Oxygen saturation decreased	1	1			1	1
Pain	1	4			1	4
Pain in extremity	5	15	1	4	4	11
Pallor		2				2
Palmar-plantar erythrodysesthesia syndrome		1				1
Palpitations		7		2		5
Paraesthesia	6	15	3	3	3	12
Paraesthesia oral	2	7	1	1	1	6
Pericarditis		1				1
Peripheral coldness		3				3
Peripheral swelling	1	1			1	1
Pharyngeal hypoaesthesia		1				1
Polydipsia		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	1	5	1	1		4
Product administered at inappropriate site		1		1		
Proteinuria		1		1		
Pruritus	1	14	1	1		13
Puncture site haematoma		1				1
Purpura		1				1
Pyrexia	14	89	1	12	13	77
Rash	4	16		1	4	15
Rash erythematous	1	2	1	2		
Rash macular	2	2			2	2
Rash maculo-papular		1				1
Rash papular		1				1
Rash pruritic	2	3	1	1	1	2
Respiratory distress	1	1			1	1
Respiratory tract congestion		1				1
Retinal haemorrhage		1				1
Rhinalgia	1	1	1	1		
Rhinitis		1				1
Rhinorrhoea	1	4	1	2		2
SARS-CoV-2 test positive		1				1
Seizure		1				1
Shock	1	1			1	1
Sinus tachycardia		1				1
Skin exfoliation	1	1			1	1
Skin reaction	1	2			1	2
Skin warm		1				1
Sleep disorder	1	3			1	3
Sneezing	1	1	1	1		
Somnolence	8	13	3	7	5	6
Stiff tongue		1				1
Swelling		3				3
Syncope		3				3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Synovial cyst	1	4			1	4
Tachyarrhythmia		1				1
Tachycardia	1	9			1	9
Takayasu's arteritis		1				1
Taste disorder		2				2
Tension headache		1				1
Throat irritation	1	2	1	2		
Throat tightness	1	1			1	1
Thrombophlebitis	1	1			1	1
Tinnitus		1		1		
Tongue coated		1				1
Tongue discomfort		1				1
Tongue dry		2				2
Tongue eruption		1				1
Tongue oedema		2				2
Tremor		3				3
Upper-airway cough syndrome		1				1
Urticaria		3				3
Urticaria cholinergic		1		1		
Vaccination complication		2		1		1
Vaccination failure		4				4
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	5	12	3	6	2	6
Vaccination site haematoma		1				1
Vaccination site induration	3	7	3	5		2
Vaccination site inflammation	2	4			2	4
Vaccination site joint inflammation	1	1			1	1
Vaccination site joint movement impairment	1	1			1	1
Vaccination site movement impairment	2	2	1	1	1	1
Vaccination site nodule		1		1		
Vaccination site oedema	5	13	2	5	3	8
Vaccination site pain	30	74	13	29	17	45

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	3	9	2	3	1	6
Vaccination site rash	1	1	1	1		
Vaccination site reaction		1				1
Vaccination site swelling	1	6			1	6
Vaccination site urticaria		1				1
Vaccination site warmth	2	5	1	2	1	3
Vasculitis		1				1
Vertigo	1	7			1	7
Vision blurred	2	2	2	2		
Vomiting	3	10		1	3	9
Wound		1		1		
	323	1,273	114	269	209	1004

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Anaphylactic reaction		1				1
Arteriosclerosis	1	1	1	1		
Arthralgia		2				2
Asthenia		2				2
Asymptomatic COVID-19	4	6			4	6
Atrial fibrillation	1	1			1	1
Back pain		2				2
Bacterial infection		1				1
Bedridden		1				1
Blood pressure increased	1	1			1	1
Cardiac disorder		1				1
Cardio-respiratory arrest		1				1
Cerebral venous sinus thrombosis	1	1			1	1
Chills		1				1
Condition aggravated	1	1			1	1
Confusional state		1				1
Cough		2				2
COVID-19	2	3		1	2	2
COVID-19 pneumonia		2				2
Deafness neurosensory	1	1			1	1
Deafness unilateral	1	1			1	1
Death		1				1
Decreased appetite		2				2
Diarrhoea		2		1		1
Dizziness	1	2		1	1	1
Drug ineffective	2	2			2	2
Dyspnoea	2	2			2	2
Ecchymosis	1	1			1	1
Epistaxis	1	1			1	1
Fatigue	1	6	1	2		4
Feeling cold		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1			1	1
Gait inability		1		1		
Haematoma	1	1			1	1
Headache	1	3		1	1	2
Hypotension		1				1
Injection site erythema		1		1		
Insomnia		1		1		
International normalised ratio increased	1	1			1	1
Lung infiltration	1	1			1	1
Lymphadenopathy		1				1
Lymphoedema		1				1
Myalgia	2	9	1	4	1	5
Myocardial infarction		1				1
Nausea		3		1		2
Oropharyngeal discomfort		1				1
Overdose	1	1	1	1		
Oxygen saturation decreased		1				1
Pain		1				1
Pain in extremity		2				2
Paraesthesia		1				1
Peripheral artery occlusion	1	1			1	1
Peripheral artery stenosis	1	1			1	1
PO2 decreased	1	1			1	1
Pruritus		3				3
Pyrexia	2	6		1	2	5
Rash		2				2
Rash erythematous		1				1
Rash macular		3		1		2
Rhabdomyolysis		1				1
SARS-CoV-2 test positive		1				1
Sciatica		1				1
Skin burning sensation		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence	1	4	1	1		3
Syncope	1	1			1	1
Tachycardia	1	1			1	1
Tinnitus	1	1			1	1
Urinary tract infection bacterial		1				1
Urticaria	2	2	1	1	1	1
Vaccination failure	5	7			5	7
Vaccination site inflammation		1				1
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema		1		1		
Vaccination site pain	3	5		1	3	4
Vaccination site swelling		1				1
Varicella		1				1
Vision blurred	1	1			1	1
Vomiting		1				1
Wheezing	1	1			1	1
	52	140	6	22	46	118

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute kidney injury	2	2			2	2
Acute myocardial infarction	1	1			1	1
Acute pulmonary oedema	1	1			1	1
Agitation	1	1			1	1
Altered state of consciousness	1	2			1	2
Anaemia		1		1		
Anaphylactic reaction	2	4			2	4
Anaphylactoid reaction		1				1
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Apathy	1	1			1	1
Aphasia	1	1			1	1
Asthenia	2	14		1	2	13
Asymptomatic COVID-19	5	14			5	14
Atrial fibrillation	1	1			1	1
Atrioventricular block complete		2				2
Blindness	2	2			2	2
Blindness unilateral		1				1
Blood glucose fluctuation		1		1		
Blood glucose increased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure increased		1		1		
Blood pressure systolic increased		1		1		
Bradycardia		2				2
Bronchospasm		1				1
Cardiac failure		1				1
Cardio-respiratory arrest	2	3			2	3
Cerebrovascular accident	5	7			5	7
Chest pain	1	1			1	1
Chills		1				1
Cholangitis	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholestasis	1	1			1	1
Chronic kidney disease	1	1			1	1
Condition aggravated	1	1	1	1		
Contusion	1	1			1	1
Cough	2	11			2	11
COVID-19	13	39		4	13	35
COVID-19 pneumonia	1	2			1	2
Cyanosis		1				1
Death	3	5			3	5
Decreased appetite	4	18	1	2	3	16
Deep vein thrombosis	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Diarrhoea	3	4	1	1	2	3
Diplopia	1	1	1	1		
Disorientation	3	3	1	1	2	2
Dizziness	2	3			2	3
Drug-induced liver injury	1	1			1	1
Drug ineffective	10	11			10	11
Drug interaction	1	1			1	1
Dysarthria		1				1
Dyslexia		1				1
Dyspnoea	4	6			4	6
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	1			1	1
Embolic stroke	1	1			1	1
Embolism venous	2	2			2	2
Epistaxis	1	2	1	1		1
Erythema		2		1		1
Escherichia bacteraemia	1	1			1	1
Facial paralysis	1	2			1	2
Fall	1	3		1	1	2
Fatigue	10	12	3	3	7	9

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot	1	1	1	1		
Fibrin D dimer increased	2	2	2	2		
Food refusal	1	1			1	1
Gait disturbance		1				1
Gait inability	1	2			1	2
Gastric disorder		1				1
Haemoglobinuria	1	1			1	1
Haemorrhagic transformation stroke	1	1			1	1
Headache	2	3	1	1	1	2
Head injury		1				1
Heart rate decreased		1				1
Heart rate increased		1		1		
Hemiplegia	1	1			1	1
Hepatitis	1	1			1	1
Hyperglycaemia		1				1
Hyperhidrosis	2	2	1	1	1	1
Hypertension		3				3
Hypopnoea	1	1			1	1
Hypotension	1	8			1	8
Impetigo	1	1			1	1
International normalised ratio decreased	1	1	1	1		
Ischaemic stroke	2	3			2	3
Jaundice	1	1			1	1
Joint swelling	1	1			1	1
Leukaemoid reaction		1				1
Leukocytosis	1	1			1	1
Limb mass		1		1		
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities	1	1			1	1
Lymphadenopathy		1				1
Lymphoproliferative disorder	1	1			1	1
Malaise	2	2			2	2

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased	2	2	1	1	1	1
Movement disorder	1	1			1	1
Muscular weakness	2	2	1	1	1	1
Myalgia	1	2			1	2
Nausea	1	5			1	5
Neutrophilia	1	1			1	1
Oedema peripheral	1	1			1	1
Oliguria	1	1	1	1		
Oropharyngeal discomfort	1	1			1	1
Oxygen saturation decreased	3	6			3	6
Pain	3	3	3	3		
Pain in extremity	2	2	1	1	1	1
Pallor		1				1
Paraesthesia	2	3	1	1	1	2
Patella fracture	1	1			1	1
Pericardial effusion	1	1			1	1
Peripheral swelling	1	1			1	1
Platelet count increased	1	1	1	1		
Pneumonia	1	1			1	1
Pneumonia aspiration	1	2			1	2
Presyncope	2	2	1	1	1	1
Product administered at inappropriate site	1	1	1	1		
Pruritus	1	2	1	2		
Pulmonary embolism	4	4			4	4
Purpura	1	1			1	1
Pyrexia	3	8	1	2	2	6
Rash	2	7		2	2	5
Rash macular	1	1			1	1
Rash maculo-papular	1	1			1	1
Respiratory failure	1	1			1	1
Respiratory tract infection	1	1			1	1
SARS-CoV-2 test positive		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	2	2			2	2
Sepsis	1	1			1	1
Skin lesion		1				1
Sneezing		1				1
Soft tissue haemorrhage		1		1		
Somnolence	2	3			2	3
Speech disorder	1	2		1	1	1
Stroke in evolution		1				1
Sudden cardiac death	1	1			1	1
Syncope	2	4			2	4
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	1	1			1	1
Tachypnoea	1	1			1	1
Thrombosis	2	2			2	2
Transient ischaemic attack	1	1			1	1
Tremor	1	3	1	2		1
Upper gastrointestinal haemorrhage	1	1			1	1
Urinary tract infection		1				1
Vaccination failure	8	27			8	27
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	3	3	2	2	1	1
Vasculitis	1	1			1	1
Visual impairment		1				1
Vomiting	5	8	2	2	3	6
Vulvovaginal burning sensation	1	1	1	1		
Wheezing	2	3		1	2	2
	215	405	36	59	179	346

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		1		1
Abdominal pain	2	4			2	4
Abdominal pain upper		1		1		
Abortion spontaneous		1				1
Amenorrhoea	1	1	1	1		
Amnesia		1		1		
Anaphylactic reaction		1				1
Anxiety		1				1
Arthralgia	2	9	1	3	1	6
Asthenia	3	16	1	3	2	13
Asymptomatic COVID-19		1		1		
Axillary mass		1				1
Axillary pain		3		1		2
Back pain		3		1		2
Chest pain		4		1		3
Chills	3	16		3	3	13
Choroiditis		1				1
Condition aggravated		1				1
Cough		3		1		2
COVID-19		29		6		23
Death		1				1
Decreased appetite		3		1		2
Deep vein thrombosis	2	2			2	2
Diarrhoea	5	10	2	4	3	6
Dizziness		5		2		3
Drug ineffective		17				17
Dysarthria		1		1		
Dysgeusia		1		1		
Dyspepsia	1	1			1	1
Dysphonia		1		1		
Dyspnoea		4		1		3
Ear pain		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Embolism		1
Erythema		4
Exposure during pregnancy	1	3
Exposure via breast milk		3
Face oedema		4
Facial paralysis		1
Fatigue	2	17
Feeling cold		2
Feeling hot		1
Headache	7	48
Hyperglycaemia		1
Hyperhidrosis		3
Hypersensitivity		5
Hypertensive crisis		1
Hyperthermia		2
Hypoaesthesia		3
Hypoaesthesia oral		2
Hypokalaemia		2
Inappropriate schedule of product administration		1
Inflammation		1
Insomnia	1	2
Inspiratory capacity decreased		1
Laryngeal oedema		2
Lethargy		1
Lip oedema		1
Localised oedema		1
Lymphadenitis		1
Lymphadenopathy	1	9
Malaise	2	9
Maternal exposure during pregnancy		2
Menstrual disorder	1	1
Migraine		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	2		2
1	3		
	3		
	1		3
			1
	6	2	11
			2
			1
2	19	5	29
			1
	1		2
	4		1
			1
	2		
	2		1
	1		1
			2
	1		
			1
1	1		1
			1
			2
			1
			1
	1		
	3	1	6
1	6	1	3
	2		
1	1		
	1		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle contractions involuntary		1				1
Muscular weakness		1				1
Musculoskeletal stiffness		1				1
Myalgia	8	55	4	21	4	34
Nausea	3	16	1	8	2	8
Odynophagia		1				1
Off label use		3		3		
Oral disorder		1				1
Oropharyngeal oedema		1		1		
Oropharyngeal pain		3		1		2
Overdose	2	2	2	2		
Oxygen saturation decreased		1				1
Pain	4	6	3	4	1	2
Pain in extremity	1	2		1	1	1
Pallor		1		1		
Pancreatitis		1				1
Paraesthesia	2	7		2	2	5
Paraesthesia oral		2		1		1
Peripheral coldness	1	2			1	2
Pharyngeal inflammation		1		1		
Photophobia		1				1
Pneumonia		1				1
Presyncope		2		1		1
Productive cough		1				1
Product use issue		2		2		
Pruritus		4		1		3
Pyrexia	4	35	1	11	3	24
Rash	1	8	1	6		2
Rash maculo-papular		1		1		
Rash pruritic		1		1		
Rash vesicular	1	1			1	1
Renal colic		1				1

\* I=Interval, C=Cumulative  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea		3		1		2
SARS-CoV-2 test positive		4				4
Sensory loss		1				1
Skin exfoliation		1				1
Somnolence		2		1		1
Stomatitis		1		1		
Swelling		1				1
Syncope	1	2			1	2
Tachycardia		7		3		4
Taste disorder		1		1		
Throat irritation		2		1		1
Tongue discomfort		1				1
Tongue disorder		1		1		
Tongue oedema		1				1
Tonsillitis		1				1
Transaminases increased		1				1
Tremor		4		1		3
Urticaria		1				1
Urticaria cholinergic		1		1		
Vaccination failure		7				7
Vaccination site erythema	1	4	1	2		2
Vaccination site haemorrhage		1		1		
Vaccination site movement impairment		1				1
Vaccination site oedema		4		1		3
Vaccination site pain	6	43	2	28	4	15
Vaccination site pruritus		1				1
Vaccination site reaction		1				1
Vaccination site swelling		2		1		1
Vaccination site warmth	1	1	1	1		
Vitreous floaters	1	1			1	1
Vomiting	3	8	1	2	2	6
	74	559	28	212	46	347

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**PUERTO RICO**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort		1		1
Axillary pain		1		1
Bone disorder		1		1
Bone pain		1		1
Chills		1		1
Fatigue		2		2
Headache		2		2
Inflammation		1		1
Myalgia		1		1
Nodule		1		1
Pain in extremity		1		1
Palpitations		1		1
Pyrexia		1		1
Tachycardia		1		1
Vaccination site erythema		1		1
Vaccination site inflammation		1		1
Vaccination site pain		3		3
Vaccination site swelling		1		1
		22		22

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Antibody test abnormal		1		1		
Antinuclear antibody positive		1		1		
Arthralgia		4		4		
Asthenia		1		1		
Back pain		1		1		
Blood test abnormal		1		1		
Burning sensation		1		1		
Chills		2		2		
Decreased appetite		1		1		
Diarrhoea		2		2		
Dizziness		1		1		
Dry mouth		1		1		
Dyskinesia		1				1
Dyspepsia		1		1		
Dysphonia		1		1		
Erythema		1		1		
Facial pain		1		1		
Facial paralysis	1	3			1	3
Fatigue		7		7		
Flatulence		1		1		
Gait disturbance		1		1		
Gingival bleeding		1		1		
Haematoma		1		1		
Headache		14		14		
Heart rate decreased		1				1
Hypertension		1		1		
Hypoaesthesia	1	4	1	4		
Inappropriate schedule of product administration		2		2		
Limb discomfort		1		1		
Loss of personal independence in daily activities		1		1		
Lymphadenopathy		4		4		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Malaise		1		1			
Migraine		1					1
Movement disorder		1		1			
Muscle twitching		1		1			
Musculoskeletal stiffness		1		1			
Myalgia		6		6			
Nausea		4		4			
Neck pain		2		2			
Neuralgia		1		1			
Night sweats		1					1
Off label use		1		1			
Pain		5		5			
Pain in extremity		3		3			
Paraesthesia		2		2			
Photophobia		1		1			
Pruritus		1		1			
Pyrexia		9		9			
Rash		1		1			
Red blood cell sedimentation rate increased		1		1			
Rhinorrhoea		1		1			
Sinus arrhythmia		1					1
Speech disorder		1		1			
Stress		1		1			
Swelling		1		1			
Swelling face		1		1			
Tachycardia		1		1			
Taste disorder		2		2			
Vaccination site discomfort		1		1			
Vaccination site induration		1		1			
Vaccination site pain		3		3			
Vaccination site swelling		2		2			
	2	125	1	117	1		8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Arthralgia		2		2		
Blood pressure increased		1		1		
Burning sensation		1		1		
Chest pain		1		1		
Chills		2		2		
Death	1	1			1	1
Deep vein thrombosis	1	1			1	1
Depression		1		1		
Diarrhoea		1		1		
Discomfort		1		1		
Dizziness		1		1		
Dysgeusia		1		1		
Dyspnoea		1		1		
Fatigue	1	4	1	4		
Feeling cold	1	1			1	1
Flushing		1		1		
Headache	1	3	1	3		
Head discomfort		1		1		
Heart rate increased		1		1		
Hyperhidrosis	1	1			1	1
Hypertension	1	1			1	1
Hypoaesthesia		1		1		
Insomnia	1	1	1	1		
Joint range of motion decreased		1		1		
Joint swelling		1		1		
Lymphadenopathy	1	2	1	2		
Muscle spasms		1		1		
Myalgia		1		1		
Nausea		2		2		
Oral discomfort		1		1		
Pain in extremity	1	2	1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		1		1		
Product administered at inappropriate site		1		1		
Productive cough		1		1		
Pyrexia	1	4	1	4		
Rash	1	1	1	1		
Tachycardia		1		1		
Thrombosis	1	1			1	1
Vaccination site pain	1	1	1	1		
Vaccination site swelling	1	2	1	2		
	15	56	9	50	6	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Arthralgia		1		1		
Balance disorder		1		1		
Burning sensation		1		1		
Cerebrovascular accident		1				1
Dizziness		1		1		
Headache		2		2		
Hypertension		1		1		
Hypoaesthesia		1		1		
Injection site discomfort		1		1		
Injection site pruritus		1		1		
Injection site swelling		1		1		
Injection site warmth		1		1		
Pruritus	1	1	1	1		
Rash	1	2	1	2		
Somnolence		1		1		
	2	18	2	17		1

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea		1		1
Illness		1		1
Pneumonia		1		1
Urinary tract infection		1		1
		4		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Asymptomatic COVID-19		1		1
Chest discomfort		1		1
Chills		2		2
Dehydration		1		1
Fatigue		2		2
Flushing		1		1
Headache		1		1
Inappropriate schedule of product administration	1	1	1	1
Lymphadenitis		1		1
Maternal exposure during pregnancy		1		1
Muscle spasms		1		1
Myalgia		2		2
Off label use	1	1	1	1
Pain		1		1
Pain in extremity		1		1
Peripheral swelling		1		1
Poor quality product administered		10		10
Pyrexia		2		2
Thirst		1		1
	2	33	2	33

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**QATAR**

Age Range

**18 - 30 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	1	1			1	1
Confusional state	1	1	1	1		
Cough		1				1
COVID-19	1	1			1	1
C-reactive protein increased		1				1
Depressed mood	1	1	1	1		
Dizziness		1				1
Drug ineffective	1	1			1	1
Dysgeusia		1		1		
Dyspepsia		1		1		
Erythema		1				1
Exposure during pregnancy	1	1	1	1		
Facial paralysis		1				1
Headache	1	2	1	2		
Heart rate decreased	1	1	1	1		
Hypertension	1	1	1	1		
Hypotension	1	1	1	1		
Inflammatory marker increased		1				1
Middle insomnia	1	1	1	1		
Mood altered		1		1		
Myalgia		1		1		
Nausea		1				1
Neck pain	1	1			1	1
Neutrophil count increased		1				1
Ocular hyperaemia		1				1
Pain in extremity	1	1			1	1
Peripheral coldness		1		1		
Platelet count increased		1				1
Presyncope		1				1
Product use issue	1	1	1	1		
Pyrexia		1				1
Rash		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Red blood cell sedimentation rate increased		1				1
Rhinovirus infection		1				1
Sleep disorder	1	1	1	1		
Starvation	1	1			1	1
Syncope		1				1
Tachycardia	1	2	1	1		1
White blood cell count increased		1				1
	17	41	11	17	6	24

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance	1	1	1	1		
Herpes zoster		1		1		
Overdose		1		1		
Product preparation error		1		1		
Vertigo	1	1			1	1
	2	5	1	4	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	2		1	1	1
Blood pressure decreased		1		1		
Disturbance in attention	1	1	1	1		
Dizziness		1				1
Dyspnoea		1				1
Erythema	1	1	1	1		
Feeling hot		1				1
Heart rate increased		1		1		
Herpes zoster		1		1		
Hyperhidrosis		1				1
Muscle spasticity	1	1			1	1
Neuralgia		1		1		
Pyrexia	1	1	1	1		
	5	14	3	8	2	6

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	2		1	1	1
Dyspepsia		1		1		
Feeling cold		1		1		
Vaccination failure	1	1			1	1
	2	5		3	2	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ROMANIA**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	1	1			1	1
Loss of consciousness	1	1			1	1
Suffocation feeling	1	1	1	1		
	3	3	1	1	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Administration site pain	1	1	1	1		
Administration site swelling	1	1	1	1		
Adnexa uteri pain		1				1
Angina pectoris		1				1
Anxiety		1				1
Arthralgia	2	9	2	5		4
Asthenia		3		2		1
Back pain	1	1			1	1
Blepharitis		1				1
Blood pressure increased	1	1	1	1		
Bone pain		2		1		1
Breast pain		2		1		1
Burning sensation		1				1
Burn of internal organs		1				1
Cerebrovascular accident		1				1
Chest pain		1				1
Chills	3	18	1	7	2	11
Cold sweat		1				1
Cough		2				2
COVID-19	2	5	1	1	1	4
Cyanosis		1				1
Decreased appetite		1				1
Deep vein thrombosis	1	2			1	2
Dehydration		1				1
Diarrhoea		3				3
Diplopia		1				1
Dizziness	3	7	1	1	2	6
Drug ineffective	1	3			1	3
Dysphagia		1				1
Dyspnoea	1	3	1	1		2
Ear pain		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		2				2
Eye pain		1				1
Fatigue	4	14	4	11		3
Gastric pH decreased		1		1		
Headache	6	21	5	11	1	10
Head discomfort	1	1			1	1
Heart rate increased	2	3	1	1	1	2
Herpes zoster		1				1
Hyperhidrosis		2				2
Hypersensitivity	2	2	2	2		
Hypoacusis	1	1			1	1
Hypoaesthesia	3	3	1	1	2	2
Hypotonia		1				1
Incorrect route of product administration		2		2		
Inflammation		1		1		
Jaw disorder		1				1
Lip oedema		1				1
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities		1		1		
Lymphadenitis		1		1		
Lymphadenopathy		7		3		4
Malaise	1	4	1	1		3
Menstrual disorder		1				1
Migraine		1		1		
Muscular weakness		1		1		
Musculoskeletal chest pain		1				1
Myalgia	5	23	3	8	2	15
Nasal discomfort		1		1		
Nasal vestibulitis		1				1
Nausea	3	14	2	7	1	7
Neurological symptom		1				1
Off label use		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic neuritis	1	1
Oral pigmentation	1	1
Pain	1	1
Pain in extremity		4
Pain of skin	1	1
Pallor	1	1
Palpitations		1
Panic attack		1
Paraesthesia	2	3
Paraplegia		1
Paratracheal lymphadenopathy		1
Parosmia	1	2
Peripheral swelling		1
Pharyngitis		1
Polyuria	1	1
Product use issue		1
Pruritus		2
Pyrexia	3	21
Rash	1	2
Rash vesicular		1
Renal pain		1
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 antibody test positive		2
Scar pain		1
Somnolence	1	5
Suppressed lactation		1
Syncope		1
Tachycardia		3
Taste disorder		1
Tremor	1	1
Urticaria	1	2
Vaccination failure		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
		1	1
	3		1
		1	1
		1	1
			1
	1		
1	1	1	2
			1
			1
	1	1	1
			1
	1		
			2
2	8	1	13
1	2		
			1
			1
	1		
	2		
	1		
1	3		2
	1		
			1
	2		1
	1		
		1	1
1	1		1
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	4	28	3	21	1	7
Vaccination site paraesthesia		1				1
Vaccination site reaction	5	5	5	5		
Vaccination site swelling		1		1		
Vertigo	1	7			1	7
Vision blurred		1				1
Vomiting		3				3
	72	312	43	138	29	174

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	4	6	1	2	3	4
Abdominal pain upper		1				1
Acoustic neuroma	1	1			1	1
Administration site pain	1	1	1	1		
Administration site reaction	2	2	2	2		
Ageusia	1	4	1	3		1
Agitation		1				1
Allergy to vaccine		1		1		
Amenorrhoea	1	1	1	1		
Anaphylactic reaction	2	5			2	5
Anaphylactic shock		2				2
Anaphylactoid reaction	1	1			1	1
Angioedema		2				2
Anosmia	1	2		1	1	1
Anxiety		6		1		5
Arrhythmia	2	4			2	4
Arthralgia	6	26	4	13	2	13
Asphyxia	1	2			1	2
Asthenia	7	21	4	11	3	10
Axillary pain	2	4		2	2	2
Back pain	2	5		2	2	3
Balance disorder	2	2	1	1	1	1
Blister		1				1
Blood pressure fluctuation	1	2			1	2
Blood pressure increased	1	4		1	1	3
Blood pressure systolic increased		1		1		
Body temperature increased	1	1			1	1
Bone pain	3	7		2	3	5
Breast pain		1				1
Bronchitis	1	1			1	1
Bronchospasm		2				2
Burning sensation	1	2		1	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory arrest		1				1
Cataract	1	1			1	1
Chest discomfort	2	4		1	2	3
Chest pain	3	10		3	3	7
Chills	18	52	5	21	13	31
Circumoral oedema		1				1
Cold sweat		2		1		1
Condition aggravated		1				1
Contusion		1		1		
Cough	1	3		1	1	2
COVID-19	3	9		3	3	6
Cyanosis		1				1
Death		1				1
Decreased appetite	3	6	1	2	2	4
Deep vein thrombosis	1	1			1	1
Dermatitis allergic		3				3
Diarrhoea	4	9	3	5	1	4
Diplopia	3	3	1	1	2	2
Discomfort	1	1	1	1		
Disturbance in attention	1	3			1	3
Dizziness	10	25	1	6	9	19
Drug eruption		2				2
Drug ineffective	3	5			3	5
Dysgeusia	1	1			1	1
Dysphagia		2		1		1
Dysphonia		2		2		
Dyspnoea	5	8			5	8
Dysstasia	1	1			1	1
Ear pain		1		1		
Erythema		3				3
Erythema nodosum		1				1
Exposure to SARS-CoV-2	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extensive swelling of vaccinated limb		1				1
Eye haemorrhage	1	1			1	1
Eyelid oedema		1				1
Eyelid ptosis		1				1
Eye pain	1	1			1	1
Face oedema		2				2
Facial pain		1		1		
Facial paralysis	1	6			1	6
Facial paresis	1	1			1	1
Faeces soft		1				1
Fatigue	16	40	6	24	10	16
Feeling cold	1	2		1	1	1
Feeling hot	2	3		1	2	2
Flatulence	1	1			1	1
Foaming at mouth		1				1
General physical health deterioration		3		3		
Goitre		1				1
Guillain-Barre syndrome	1	1			1	1
Headache	30	85	12	44	18	41
Head discomfort	1	1			1	1
Heart rate abnormal		1		1		
Heart rate decreased	1	2			1	2
Heart rate increased	5	9			5	9
Hemianaesthesia	1	1			1	1
Hemiparesis	1	1			1	1
Hepatitis		1				1
Hepatocellular injury		1				1
Herpes zoster		1		1		
Hyperaemia		1				1
Hyperglycaemia		2		1		1
Hyperhidrosis	2	7		3	2	4
Hyperkalaemia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperpyrexia		1				1
Hypersensitivity	13	16	12	13	1	3
Hypertension	11	24	2	3	9	21
Hypertensive crisis		1				1
Hyperthermia		1		1		
Hypoacusis	3	3			3	3
Hypoaesthesia	6	12		4	6	8
Hypoaesthesia oral		2				2
Hypotension	1	6			1	6
Hypothyroidism		1				1
Immobile	1	1			1	1
Impaired work ability		1				1
Incorrect route of product administration	1	4	1	1		3
Influenza		1		1		
Influenza like illness		2		2		
Injected limb mobility decreased		2		2		
Insomnia	1	5		1	1	4
Intracranial pressure increased		1				1
Laryngeal oedema		1				1
Laryngospasm		1				1
Lethargy		1		1		
Lipase increased		1		1		
Lip dry	1	1			1	1
Lip oedema		3		1		2
Lividity	1	1			1	1
Localised oedema		1				1
Local reaction	1	1	1	1		
Loss of consciousness	1	3			1	3
Lymphadenitis	4	6	2	2	2	4
Lymphadenopathy	4	11	1	3	3	8
Lymph node pain		1		1		
Lymph node palpable	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphopenia		1				1
Malaise	6	16	1	7	5	9
Maternal exposure during pregnancy		2		2		
Memory impairment		1				1
Menstruation irregular	1	1			1	1
Mental status changes	1	1			1	1
Metamorphopsia		1				1
Migraine		2				2
Mobility decreased		1		1		
Monoplegia	1	1			1	1
Movement disorder		1				1
Mucosal dryness		1				1
Muscle contractions involuntary		2		1		1
Musculoskeletal stiffness	1	1			1	1
Myalgia	14	56	3	26	11	30
Myoclonus		2				2
Nasal congestion	1	1			1	1
Nasal dryness	1	2		1	1	1
Nausea	12	36	4	15	8	21
Neck pain		1		1		
Nephropathy		1				1
Nervous system disorder		3		3		
Neurological symptom		2				2
Neuropathy peripheral	1	1			1	1
Night sweats	1	1	1	1		
Nystagmus		1		1		
Ocular discomfort	2	2	1	1	1	1
Oedema	1	1	1	1		
Oedema peripheral	1	1			1	1
Oedematous pancreatitis		1				1
Oropharyngeal discomfort		1				1
Oropharyngeal pain	4	4			4	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Overdose		1		1			
Oxygen saturation decreased		2					2
Pain		7		6			1
Pain in extremity	8	17	4	13	4		4
Pain of skin	1	1			1		1
Pallor		1					1
Palpitations	4	7			4		7
Panic attack	1	1	1	1			
Paraesthesia	5	20		6	5		14
Paraesthesia ear		1		1			
Paralysis		1					1
Parosmia	1	1			1		1
Pericarditis		1					1
Peripheral arterial occlusive disease		1					1
Peripheral coldness		1		1			
Photophobia		1					1
Photosensitivity reaction	1	1			1		1
Pleurisy		1					1
Pneumonia		1					1
Polyuria	1	2			1		2
Presyncope		3		2			1
Productive cough		1					1
Pruritus	1	6	1	3			3
Pulse abnormal		1					1
Pulse volume decreased		1		1			
Pyrexia	22	65	9	30	13		35
Rales		1					1
Rash		7		5			2
Rash erythematous		4					4
Rash pruritic		2					2
Raynaud's phenomenon		1					1
Rectal haemorrhage		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Renal pain		2					2
Respiratory disorder		1					1
Respiratory distress		2					2
Rhinorrhoea	2	3	1	2	1		1
SARS-CoV-2 antibody test negative		1		1			
SARS-CoV-2 antibody test positive	1	1	1	1			
Sialoadenitis	1	1			1		1
Sinus tachycardia		2					2
Sitting disability		1					1
Skin burning sensation	1	1			1		1
Skin hypertrophy	1	1			1		1
Skin irritation		2					2
Skin plaque		1					1
Sleep disorder	1	1			1		1
Somnolence	7	17	1	7	6		10
Speech disorder		1					1
Spinal pain		1		1			
Stomatitis	1	1			1		1
Suffocation feeling		2					2
Supraventricular tachycardia		1					1
Suspected COVID-19	1	2			1		2
Sweating fever	1	1			1		1
Syncope	9	18			9		18
Syringe issue		1		1			
Systemic inflammatory response syndrome		1					1
Tachyarrhythmia	1	1			1		1
Tachycardia	5	19	1	3	4		16
Tachypnoea		1					1
Taste disorder	1	1			1		1
Tendon pain	1	1			1		1
Thirst	2	2			2		2
Thyroiditis subacute		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	3	4		1	3	3
Tongue disorder		1		1		
Tongue spasm		1				1
Tremor	2	5		1	2	4
Urticaria	1	5			1	5
Vaccination failure	1	3			1	3
Vaccination site erythema	2	6	2	5		1
Vaccination site induration	2	4	2	4		
Vaccination site inflammation		2		1		1
Vaccination site joint movement impairment		2		1		1
Vaccination site movement impairment	3	5	1	2	2	3
Vaccination site oedema		1		1		
Vaccination site pain	23	65	13	43	10	22
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		2		2		
Vaccination site reaction	9	14	9	14		
Vaccination site swelling	1	2	1	2		
Ventricular extrasystoles		1		1		
Vertigo	4	11		2	4	9
Vestibular disorder		1		1		
Viral infection	1	1			1	1
Vision blurred	1	1			1	1
Visual field defect		1				1
Visual impairment	2	3			2	3
Vomiting	2	13	1	5	1	8
Wheezing		1				1
Wrong technique in product usage process		2		2		
	408	1,147	125	454	283	693

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		1		2
Acute pulmonary oedema		2				2
Administration site pain		1				1
Administration site reaction	2	2	2	2		
Anaphylactic reaction	2	4			2	4
Anaphylactic shock	1	1			1	1
Anaphylactoid reaction		1				1
Angina pectoris		1				1
Angioedema		1				1
Anxiety		3				3
Apnoea	1	1			1	1
Arrhythmia		1				1
Arthralgia	6	12	3	7	3	5
Asthenia	2	5	2	4		1
Asthmatic crisis		1				1
Autoimmune disorder	1	1			1	1
Axillary pain		1		1		
Back pain	2	2			2	2
Balance disorder		2				2
Blood glucose decreased	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure fluctuation		1				1
Blood pressure systolic increased		1				1
Body temperature abnormal		1		1		
Bone pain	1	1			1	1
Breast inflammation	2	2			2	2
Breast pain	1	1			1	1
Bronchospasm		1		1		
Cardiac arrest		1				1
Cerebrovascular accident	2	2			2	2
Chest pain		2				2
Chills	12	23	5	10	7	13

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cold sweat		1		1			
Coma		1					1
Condition aggravated	1	1			1		1
Confusional state		1		1			
Cough		3		2			1
COVID-19	1	2			1		2
Cyanosis		1		1			
Death		1					1
Decreased appetite	2	2	1	1	1		1
Depressed level of consciousness		1					1
Dermatitis allergic	1	1			1		1
Diarrhoea	1	1			1		1
Discomfort		1		1			
Disorientation	1	1			1		1
Dizziness	7	10	2	4	5		6
Drug ineffective	1	2			1		2
Dry mouth	1	2			1		2
Dysgeusia		1					1
Dyspnoea	3	8		1	3		7
Ear discomfort		1		1			
Eructation		1					1
Erythema		6		3			3
Eye haemorrhage	1	1			1		1
Eye pruritus		1		1			
Facial neuralgia		1					1
Facial pain	1	1			1		1
Facial paralysis		1					1
Facial paresis		1					1
Fatigue	2	8	1	4	1		4
Feeling cold	1	2			1		2
Feeling hot		1					1
Headache	16	27	5	8	11		19

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	4			1	4
Horner's syndrome		1				1
Hot flush		1		1		
Hyperaesthesia		1		1		
Hyperglycaemia		1				1
Hyperhidrosis	1	3			1	3
Hyperkalaemia		1				1
Hypersensitivity	4	6	3	5	1	1
Hypertension	6	13	1	1	5	12
Hypoaesthesia	2	5		1	2	4
Hypoaesthesia eye	1	1			1	1
Hypoaesthesia oral	2	2			2	2
Hypocalcaemia		1				1
Hypokinesia		1		1		
Hypotension		1		1		
Hypoxic-ischaemic encephalopathy		1				1
Incorrect route of product administration		1		1		
Insomnia	1	2		1	1	1
Joint ankylosis		1				1
Joint stiffness		1				1
Laryngeal oedema		1				1
Lip oedema		1				1
Lung disorder		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	4	6	1	2	3	4
Malaise	3	6		1	3	5
Mean cell haemoglobin increased		1		1		
Metabolic acidosis		1				1
Mobility decreased	1	1			1	1
Monoplegia		1				1
Mouth swelling	1	1			1	1
Myalgia	10	22	3	9	7	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal dryness		1				1
Nausea	6	13	2	4	4	9
Night sweats	1	1			1	1
Obstructive airways disorder		1				1
Ocular hyperaemia		1		1		
Oxygen saturation decreased	1	1			1	1
Pain	1	1			1	1
Pain in extremity	4	5			4	5
Pallor	1	2		1	1	1
Palpitations	2	3			2	3
Paraesthesia	1	3			1	3
Pelvic pain	1	1			1	1
Petechiae	1	1			1	1
Presyncope		1		1		
Pruritus		1				1
Pulse abnormal		1		1		
Pulse volume decreased		1		1		
Pyrexia	12	23	2	8	10	15
Rash		3		1		2
Rash pruritic		1		1		
Respiration abnormal		1				1
Respiratory disorder		1		1		
Respiratory distress		1				1
Respiratory failure		1				1
Rhinalgia		1				1
Seizure		2				2
Sensory loss		1		1		
Shock		1				1
Somnolence	1	4	1	3		1
Stomatitis	1	1			1	1
Stridor		1		1		
Suffocation feeling	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular tachycardia	1	1			1	1
Swelling		1		1		
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	4	7			4	7
Tachycardia		2		1		1
Taste disorder	1	1	1	1		
Teething	1	1			1	1
Thirst		1				1
Throat tightness		1		1		
Tongue oedema		1				1
Tremor		1				1
Urinary incontinence	1	1			1	1
Urticaria		4		2		2
Use of accessory respiratory muscles		1		1		
Vaccination site erythema	1	4	1	3		1
Vaccination site induration		1				1
Vaccination site nodule		1		1		
Vaccination site pain	4	12	4	10		2
Vaccination site reaction	4	5	4	5		
Vaccination site swelling	2	3	2	3		
Vaccination site urticaria		1		1		
Vertigo	3	5	1	1	2	4
Visual impairment		1				1
Vomiting	3	7	1	2	2	5
Weight increased		1				1
Wheezing		1		1		
Wrong technique in product usage process		1		1		
	174	416	48	144	126	272

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Acute coronary syndrome		1				1
Angina pectoris		1				1
Aphonia		1		1		
Arthralgia		4		3		1
Asthenia	1	1	1	1		
Atrial fibrillation		1				1
Atrioventricular block		1				1
Back disorder		1		1		
Back pain	1	1			1	1
Blood fibrinogen increased	1	1	1	1		
Blood glucose increased	1	1			1	1
Blood pressure abnormal	1	1	1	1		
Blood pressure diastolic increased		1				1
Blood pressure increased	1	4		2	1	2
Blood pressure systolic increased		1				1
Blood uric acid increased	1	1	1	1		
Bone pain		1		1		
Bronchospasm	1	1			1	1
Cardiac fibrillation		1				1
Cerebral small vessel ischaemic disease		1				1
Cerebrovascular accident		1				1
Chills	1	4		2	1	2
Coma		1				1
Condition aggravated		1		1		
Cough	1	1	1	1		
COVID-19	4	8			4	8
Death		1				1
Dementia	1	1			1	1
Diabetes mellitus	1	1			1	1
Diarrhoea		2				2
Disease recurrence		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	4	1	3
		2	3
			1
		1	1
		1	1
	1		
	1		
		1	1
			1
1	2		
			1
		1	2
	1		
	3	2	4
			1
1	1		
		2	3
	3	2	3
		1	1
	1	1	1
1	1		
1	1		
	1		
	1		
		1	2
		1	1
		1	1
		1	1
			1
2	5	1	4
		1	1
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	3		1	1	2
Nitrite urine present	1	1	1	1		
Oedema peripheral		1				1
Off label use	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain in extremity	1	1			1	1
Palpitations	1	1	1	1		
Parkinson's disease	1	1			1	1
Peripheral coldness		1				1
Pollakiuria	1	1			1	1
Presyncope	1	1			1	1
Protein urine present	1	1	1	1		
Pruritus		1		1		
Pulse abnormal	1	2	1	1		1
Pyrexia		3		1		2
Rash	1	1			1	1
Red blood cells urine positive	1	1	1	1		
Rheumatic disorder		1		1		
Somnolence	2	3	1	1	1	2
Spinal pain	1	1			1	1
Stress		1		1		
Swelling		1		1		
Syncope	2	5			2	5
Thirst	1	1			1	1
Thrombosis	1	1			1	1
Type 2 diabetes mellitus	1	1			1	1
Urine ketone body present	1	1	1	1		
Urticaria	1	1			1	1
Vaccination failure	2	3			2	3
Vaccination site joint movement impairment		1				1
Vaccination site pain		2				2
Vertigo		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	1	1			1	1
Visual acuity reduced		1				1
Visual impairment	1	1	1	1		
Walking disability		1		1		
White blood cells urine positive	1	1	1	1		
Wrong product administered		2		2		
	73	167	22	62	51	105

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills	1	1			1	1
COVID-19	2	3			2	3
Disease recurrence	1	1			1	1
Drug ineffective		1				1
Fatigue	2	2			2	2
Hypertension	2	2			2	2
Myalgia	1	1			1	1
Neuronal neuropathy	1	1			1	1
Peripheral swelling		1		1		
Pyrexia	1	1			1	1
Seizure		1				1
Somnolence	1	1			1	1
Syncope	1	1			1	1
	15	19		1	15	18

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		1				1
Adverse event		1		1		
Adverse reaction		1		1		
Ageusia		2		1		1
Anaphylactic shock		1				1
Angioedema		1				1
Angle closure glaucoma		1				1
Anosmia		2		1		1
Anxiety		3		3		
Arthralgia		6		6		
Asthenia	6	12	6	12		
Asthma		1				1
Asymptomatic COVID-19		2				2
Back pain		1		1		
Blood pressure abnormal		1		1		
Blood pressure decreased		1				1
Blood pressure increased		1				1
Body temperature abnormal		2		2		
Body temperature increased		1		1		
Bronchospasm	1	2	1	1		1
Burning sensation		1				1
Chest discomfort	2	3	2	3		
Chest pain	1	1			1	1
Chills	9	21	9	20		1
Circumstance or information capable of leading to medication error		3		3		
Condition aggravated		1				1
Coronavirus infection		1				1
Cough		3		2		1
COVID-19	108	155	3	6	105	149
Crying		1		1		
Death	6	6			6	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	1	1	1		
Dermatitis allergic	1	1	1	1		
Diarrhoea		1		1		
Disturbance in attention		1		1		
Dizziness	2	11	2	11		
Drug ineffective	25	76			25	76
Dyspnoea		2		1		1
Dyspnoea exertional	1	1			1	1
Emotional distress		1		1		
Epiglottic oedema		1				1
Erythema		10		9		1
Erythema nodosum		1		1		
Exposure during pregnancy	1	2	1	2		
Exposure via breast milk		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		1		1		
Facial paralysis		2				2
Facial paresis	2	2	2	2		
Fatigue	9	22	9	22		
Fear		1		1		
Feeling abnormal	2	4	2	3		1
Feeling cold		1		1		
Feeling hot		1		1		
Flushing		1		1		
General physical condition abnormal		1		1		
Headache	11	32	11	32		
Heart rate increased		2		1		1
Hemiparaesthesia	1	1			1	1
Herpes virus test	1	1	1	1		
Hyperhidrosis		5		4		1
Hypertension	2	3	1	1	1	2
Hypoaesthesia	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness		1				1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1		1		
Infarction		1				1
Inflammation		1		1		
Influenza like illness	5	5	5	5		
Injected limb mobility decreased		2		2		
Intercepted medication error		1		1		
Laboratory test abnormal	1	1	1	1		
Lethargy		1		1		
Limb injury		1				1
Lip oedema		1		1		
Lip swelling		1				1
Listeria test positive	1	1	1	1		
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenopathy	3	12	3	12		
Malaise		5		5		
Maternal exposure during pregnancy	1	1	1	1		
Medication error		3		3		
Muscle contracture		1		1		
Muscle spasms		1				1
Muscle swelling		1		1		
Muscular weakness	2	4	2	4		
Myalgia	14	26	14	26		
Nasal discomfort		1		1		
Nasal oedema		1				1
Nausea	1	4	1	4		
Neuralgia		1				1
Neuropathy peripheral		1				1
No adverse event		2		2		
Ocular discomfort	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Odynophagia		1		1			
Oedema		2		1			1
Oedema peripheral		1					1
Off label use		2		2			
Oropharyngeal discomfort		1					1
Oxygen saturation abnormal	1	1			1		1
Oxygen saturation decreased		1		1			
Pain	1	7	1	7			
Pain in extremity	2	21	2	21			
Panic attack		1		1			
Paraesthesia	1	8		5	1		3
Paraesthesia oral		1		1			
Presyncope		1		1			
Product preparation error	1	13	1	13			
Product preparation issue	3	9	3	9			
Product quality issue		1		1			
Product use issue		1		1			
Pruritus		2		2			
Pyrexia	10	35	10	35			
Rash		2		2			
Rash pruritic		1		1			
Rhinorrhoea	2	2	2	2			
SARS-CoV-2 antibody test negative		5		5			
SARS-CoV-2 antibody test positive	1	6	1	6			
SARS-CoV-2 test positive		9		3			6
Skin discolouration	1	2	1	2			
Somnolence	2	4	2	4			
Suspected COVID-19		3		1			2
Syncope		4					4
Systolic hypertension		1					1
Tachycardia		4		3			1
Toxocariasis	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxoplasma serology positive	1	1	1	1		
Transaminases increased		1		1		
Tremor		1		1		
Underdose	2	3	2	3		
Urticaria		4		3		1
Urticaria papular		1		1		
Vaccination failure	4	8			4	8
Vaccination site discolouration		1		1		
Vaccination site discomfort		3		3		
Vaccination site erythema	1	15	1	14		1
Vaccination site granuloma	1	1	1	1		
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy		2		2		
Vaccination site macule	1	1	1	1		
Vaccination site movement impairment		2		2		
Vaccination site nodule		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	8	39	8	38		1
Vaccination site papule	1	1	1	1		
Vaccination site pruritus	2	2	2	2		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
Vertigo	1	2	1	2		
Vomiting		1		1		
Weight decreased		1				1
Wrong technique in product usage process	3	14	3	14		
	277	780	129	476	148	304

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**SAUDI ARABIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Fatigue		1				1
Menstruation irregular	1	1	1	1		
Seizure	1	1			1	1
Vomiting		1				1
	2	5	1	1	1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anaphylactic shock		1				1
Arthralgia		2		2		
Chills		2		2		
COVID-19	1	2	1	2		
Dizziness		2		1		1
Fatigue		3		3		
Headache	1	4	1	4		
Hyperhidrosis		3		3		
Hypotension		1				1
Lymphadenopathy		2		2		
Lymphoma	1	1			1	1
Malaise		1		1		
Mastication disorder		1		1		
Mouth ulceration		1		1		
Myalgia	1	4	1	4		
Nausea		1		1		
Oropharyngeal pain		1		1		
Pain in jaw		1		1		
Pain of skin		1		1		
Peripheral coldness		1		1		
Pollakiuria		1		1		
Pyrexia	1	5	1	5		
Seizure		1				1
Syncope		2				2
Tremor	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain		3		3		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vaginal infection		1		1		
Vomiting		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	6	54	5	46	1	8

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Asthenia		1		1
COVID-19		1		1
C-reactive protein increased		1		1
Fatigue		1		1
Headache		1		1
Herpes zoster		1		1
Lymphadenopathy		1		1
Myalgia		1		1
Nasopharyngitis		1		1
Pain		1		1
Pain in extremity		1		1
Peripheral coldness		1		1
Red blood cell sedimentation rate increased		1		1
Rhinorrhoea		1		1
Sleep disorder	1	1	1	1
Vaccination site pain		2		2
	1	18	1	18

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		1				1
Cardiac arrest		1				1
Carotid artery stenosis		1				1
Gait inability		1				1
Heart rate decreased		1				1
Hyperhidrosis		1				1
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Pyrexia		1				1
Sitting disability		1				1
Syncope		1				1
Vomiting		1				1
		12		2		10

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Feeling hot	1	1	1	1
Gait disturbance		1		1
Hot flush	1	1	1	1
Night sweats	1	1	1	1
Somnolence		1		1
Temperature intolerance	1	1	1	1
	4	7	4	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
Asthenia		1		1		
Axillary pain	1	1	1	1		
Dysstasia		1				1
Fatigue		1		1		
Gait disturbance		1				1
Headache		1		1		
Inappropriate schedule of product administration		1		1		
Lymphadenopathy		1		1		
Malaise	1	1	1	1		
Mobility decreased		4		3		1
Myalgia		2		1		1
Pain	1	5	1	4		1
Pain in extremity		3		1		2
Product preparation issue		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia		1		1		
Sciatica		2		2		
Vaccination site pain	1	1	1	1		
	5	30	4	22	1	8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SERBIA**

Age Range

**18 - 30 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	2	1	2
	1	2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		2		1		1
Anaphylactoid reaction		1				1
Anosmia		1		1		
Arthralgia		9		8		1
Asphyxia		2				2
Asthenia		4		4		
Axillary pain		1		1		
Back pain	1	2		1	1	1
Blepharospasm		1				1
Body temperature increased	2	9	2	8		1
Bone pain		1		1		
Bronchospasm		2		1		1
Chest pain		2				2
Chills		5		4		1
Confusional state		1		1		
Conjunctivitis		1		1		
Cough		2				2
COVID-19	1	1	1	1		
COVID-19 pneumonia		1				1
Decreased appetite		1		1		
Diarrhoea		1		1		
Dizziness	1	2	1	2		
Dysgeusia		1				1
Dyspnoea		2				2
Erythema		5		4		1
Eyelid ptosis		1				1
Eye pain	1	1	1	1		
Facial paresis		1				1
Fatigue	1	5	1	5		
Fear	1	1			1	1
Feeling cold		1		1		
Feeling hot		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Headache	4	15
Herpes zoster		1
Hyperhidrosis		3
Hypertension		3
Hypoaesthesia		1
Hypoaesthesia oral		2
Inappropriate schedule of product administration	1	1
Inflammatory marker increased		1
Influenza like illness		2
Insomnia	1	2
Joint stiffness		1
Localised oedema		1
Loss of consciousness		1
Lymphadenopathy		1
Malaise	2	11
Monocyte count increased		1
Movement disorder		1
Muscular weakness		2
Myalgia	1	13
Nasal congestion		2
Nausea	2	10
Neck pain		1
Nervousness		1
Oedema mucosal		1
Oedema peripheral		1
Off label use	1	1
Overdose	1	1
Pain		1
Pain in extremity	1	7
Pallor		1
Paraesthesia		2
Peripheral swelling		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	13	1	2
	1		
	2		1
			3
	1		
	1		1
1	1		
	1		
	2		
1	1		1
			1
	1		
			1
2	10		1
	1		
	1		
	2		
1	12		1
	1		1
2	9		1
			1
			1
	1		
1	1		
		1	1
	1		
1	7		
	1		
	2		
			1

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 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus		1		1		
Pulmonary pain		2		1		1
Pyrexia	2	23	1	21	1	2
Rash		1		1		
Rash macular		1				1
Rhinorrhoea		1				1
SARS-CoV-2 test positive		2		1		1
Skin reaction		1				1
Sleep disorder		1		1		
Sneezing		1				1
Somnolence		2		1		1
Swollen tongue		1		1		
Syncope		2				2
Tachycardia		2				2
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus		1		1		
Tremor		1		1		
Urticaria		1		1		
Vaccination complication		4		4		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		9		9		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vomiting		2		2		
Wrong product administered		1		1		
	26	231	19	175	7	56

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess		1				1
Asthenia	2	4	1	3	1	1
Axillary pain		1				1
Blood pressure increased		1				1
Body temperature increased	1	1	1	1		
Bone pain		1		1		
Burning sensation	1	1	1	1		
Chest discomfort		1		1		
Chills		3		2		1
COVID-19		2		1		1
Disease recurrence	1	1	1	1		
Dizziness	1	2	1	2		
Drug ineffective		1				1
Dry mouth		1		1		
Erythema		2		2		
Eyelid oedema		1		1		
Fatigue	1	3	1	2		1
Feeling abnormal		1		1		
Feeling cold		1		1		
Feeling hot	1	1	1	1		
Haematoma		1		1		
Headache		5		4		1
Heart rate increased	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypertension	1	4		2	1	2
Lip disorder	1	1	1	1		
Lymphadenitis		1				1
Lymphadenopathy		2		1		1
Malaise	2	6	2	5		1
Myalgia		1		1		
Myositis		1				1
Nasopharyngitis		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		4		3		1
Oedema peripheral	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain		1				1
Pain in extremity	2	2	2	2		
Pain in jaw		1		1		
Pallor		1		1		
Palpitations		1		1		
Phlebitis		1				1
Pruritus	1	1	1	1		
Pyrexia		4		3		1
Rash	1	1	1	1		
Superficial vein prominence	1	1	1	1		
Swelling		2		1		1
Syncope	2	2			2	2
Tremor	1	1	1	1		
Urticaria		1		1		
Vaccination complication		1		1		
Vaccination site pain		1		1		
Vision blurred		2		1		1
	24	85	20	62	4	23

\* I=Interval, C=Cumulative  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Anxiety		1		1		
Arthralgia		1		1		
Blood lactate dehydrogenase increased		1				1
C-reactive protein increased	1	2	1	1		1
Drug ineffective	1	1			1	1
Dyspnoea		1				1
Fall		1		1		
Fatigue	1	1	1	1		
Fear of death		1		1		
Fibrin D dimer increased	1	1	1	1		
Headache		1		1		
Huntington's disease		1				1
Hypertension		1				1
Lacrimation increased		1		1		
Lip pruritus		1		1		
Lip swelling		1		1		
Malaise		2		1		1
Oedema mouth		1		1		
Oxygen saturation decreased		1				1
Pneumonia		1		1		
Pyrexia		3		2		1
Red blood cell count increased	1	1	1	1		
Red blood cell sedimentation rate increased		1				1
Vaccination site erythema		1		1		
Vaccination site pruritus		1		1		
Wheezing		1				1
	6	31	5	20	1	11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1				1
Deafness		1				1
Deafness unilateral		1				1
Face oedema		1				1
Facial paralysis		1				1
Fall		1				1
Haematemesis		1				1
Headache		1		1		
Ischaemic stroke		1				1
Myocardial infarction	1	1			1	1
Nausea		1				1
Pain		1		1		
Pain in extremity		1		1		
Pancreatitis acute		1				1
Pyrexia		2		1		1
Tongue oedema		1				1
Urticaria		1		1		
Vaccination site erythema		1		1		
Vaccination site haematoma		1				1
Vaccination site oedema		1		1		
Vaccination site reaction		1		1		
Vomiting		1				1
	1	23		8	1	15

\* I=Interval, C=Cumulative  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Anxiety		1		1		
Arthralgia		2		2		
Asthenia		1		1		
Blood pressure increased		1		1		
Body temperature increased		4		4		
Chest pain		1		1		
Chills	1	3	1	3		
Cough	1	1	1	1		
COVID-19	2	5	2	4		1
Diarrhoea		1		1		
Dizziness		2		1		1
Drug ineffective		1				1
Erythema		1		1		
Exposure during pregnancy		1		1		
Fatigue		1		1		
Headache	1	2	1	2		
Hyperaesthesia	1	1	1	1		
Hypersensitivity		3		2		1
Hypopnoea		1				1
Inappropriate schedule of product administration		1		1		
Intraocular pressure increased		1				1
Joint stiffness		1		1		
Malaise		1		1		
Maternal exposure during pregnancy		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	1	1	1		
Nausea	1	4	1	4		
No adverse event		3		3		
Oropharyngeal pain		1		1		
Pain in extremity		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia oral		1		1		
Product supply issue		1		1		
Pyrexia	1	6	1	6		
Rash		1				1
Rash macular		1				1
SARS-CoV-2 antibody test negative		1		1		
SARS-CoV-2 test positive		1				1
Skin burning sensation	1	2	1	1		1
Somnolence	1	1	1	1		
Swelling of eyelid		1		1		
Urticaria		1		1		
Vaccination failure		1				1
Vaccination site erythema		1		1		
Vaccination site pain		6		6		
Vomiting		1		1		
	13	78	13	67		11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SINGAPORE**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2			1	2
Anaphylactic reaction	5	6			5	6
Anaphylactic shock		2				2
Angioedema		2				2
Arthralgia	1	1			1	1
Asthenia	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	2	2			2	2
Cellulitis	1	1			1	1
Chest discomfort	4	5			4	5
Chills	2	2			2	2
Complement factor C3 increased	1	1			1	1
Cough		1				1
Dermatitis bullous	1	1			1	1
Diarrhoea		1				1
Dizziness	5	6	1	1	4	5
Dry eye	1	1			1	1
Dyskinesia	1	1			1	1
Dysphonia	2	3			2	3
Dyspnoea	6	7			6	7
Dysstasia	1	1			1	1
Enlarged uvula		1				1
Erythema	1	1			1	1
Eye disorder	1	1			1	1
Eye movement disorder	1	1			1	1
Fall	1	1			1	1
Flushing	2	2			2	2
Gait disturbance	1	1			1	1
Headache	1	1	1	1		
Hepatitis	1	1			1	1
Hunger	1	1	1	1		
Hyperhidrosis	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		2	2
		1	1
		1	1
		4	4
		1	1
		1	1
		1	3
		1	1
		1	1
1	1		
2	2	1	2
		1	1
		1	1
		1	1
1	1		
		1	1
		2	3
			1
1	1		
		3	4
		1	1
1	1	3	3
		1	1
2	3	3	3
			2
		1	1
		1	1
		1	1
		1	1
		3	3
		1	1

Hypersensitivity	1	1
Hypertension	2	2
Hyperthyroidism	1	1
Hypoaesthesia	1	1
Hypotension	4	4
Lacrimation increased	1	1
Laryngeal oedema	1	1
Lip swelling	1	3
Muscular weakness	1	1
Musculoskeletal stiffness	1	1
Myalgia	1	1
Nausea	3	4
Nerve injury	1	1
Odynophagia	1	1
Pain	1	1
Pain in extremity	2	2
Palatal oedema	1	1
Palpitations	2	3
Periorbital swelling		1
Peripheral coldness	1	1
Pruritus	3	4
Pupillary light reflex tests abnormal	1	1
Pyrexia	4	4
Radiculopathy	1	1
Rash	5	6
Rash macular		2
Respiratory tract infection	1	1
Seizure	1	1
Sensation of foreign body	1	1
Somnolence	1	1
Syncope	3	3
Tachycardia	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation	1	1			1	1
Throat tightness	2	3			2	3
Tic	1	1			1	1
Tonic clonic movements	1	1			1	1
Tonic convulsion	1	1			1	1
Transaminases increased	1	1			1	1
Troponin increased	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Urticaria	3	4	1	1	2	3
Vaccination site erythema	1	1	1	1		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site pain	2	2			2	2
Vaccination site paraesthesia	1	1			1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site urticaria	1	1			1	1
Vestibular neuronitis	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	3	3	1	1	2	2
	120	144	17	18	103	126

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2			2	2
Abdominal tenderness	1	1			1	1
Acute kidney injury	1	1			1	1
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	4	5			4	5
Anaphylactic shock		2				2
Angioedema	2	2			2	2
Arthralgia	1	1			1	1
Aspartate aminotransferase increased	1	1			1	1
Asthma	2	2			2	2
Bicytopenia	1	1			1	1
Blepharospasm	1	1	1	1		
Blood alkaline phosphatase increased	1	1			1	1
Blood bilirubin increased	1	1			1	1
Blood pressure increased	1	1			1	1
Blood pressure systolic increased	1	1			1	1
Body temperature increased	1	1			1	1
Chest discomfort	5	5	1	1	4	4
Chest pain	2	2			2	2
Chills	1	2		1	1	1
Cough	1	2			1	2
Diarrhoea	1	2		1	1	1
Disease progression	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness	5	5	2	2	3	3
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia	3	4	1	1	2	3
Dyspnoea	9	10	1	1	8	9
Dyspnoea exertional	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enlarged uvula	1	2			1	2
Eosinophilia	1	1			1	1
Erythema multiforme	1	1			1	1
Extrasystoles	1	1			1	1
Eye pruritus	2	2	1	1	1	1
Facial paralysis	1	1			1	1
Fatigue	3	3	2	2	1	1
Flushing	1	1			1	1
Gastrooesophageal reflux disease	1	1			1	1
Haematuria	1	1			1	1
Hand dermatitis	1	1	1	1		
Headache	2	2	2	2		
Head discomfort		1		1		
Heart rate increased	2	3			2	3
Hyperhidrosis	1	1			1	1
Hypertension		1				1
Hypoaesthesia	1	1			1	1
Hypotension	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	2			1	2
Muscular weakness	1	1			1	1
Myalgia	1	1			1	1
Nausea	5	5	2	2	3	3
Oedema peripheral	1	1	1	1		
Oropharyngeal pain	1	1			1	1
Palatal oedema	1	1			1	1
Palpitations	4	5			4	5
Parosmia	2	2	2	2		
Periorbital swelling	3	3	1	1	2	2
Peripheral swelling	1	1			1	1
Petit mal epilepsy	1	1			1	1
Pharyngeal mass	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling	1	1			1	1
Postural orthostatic tachycardia syndrome	1	1			1	1
Proteinuria	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	4	4	1	1	3	3
Rash	5	6	1	2	4	4
Rash erythematous	1	1	1	1		
Rash macular	1	1			1	1
Rash maculo-papular	1	2		1	1	1
Rash pruritic	1	1			1	1
Renal impairment	1	1			1	1
Secretion discharge	1	1	1	1		
Seizure	1	1			1	1
Sensation of foreign body	2	2			2	2
Sensory disturbance	1	1			1	1
Sinus tachycardia	1	1			1	1
Swelling face	1	1			1	1
Swelling of eyelid	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachycardia	2	2			2	2
Throat irritation	3	3	2	2	1	1
Throat tightness	5	5	1	1	4	4
Transaminases increased	1	1			1	1
Upper respiratory tract congestion	1	1	1	1		
Urticaria	7	8			7	8
Vaccination complication	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site mass		1		1		
Vertigo	1	1	1	1		
Vomiting	2	3	1	1	1	2
Wheezing	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term

Interval Total #  
Spontaneous AE

153

Cumulative Total #  
Spontaneous AE

173

Spontaneous			
Nonserious		Serious	
I	C	I	C
33	40	120	133

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute psychosis	1	1			1	1
Anaphylactic reaction	4	4			4	4
Angioedema	2	3			2	3
Arthritis	1	1			1	1
Asthenia	1	1			1	1
Blood pressure systolic increased	2	2			2	2
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	1	1			1	1
Confusional state	1	1			1	1
Deafness neurosensory	1	1			1	1
Decreased appetite	1	1			1	1
Dehydration	1	1			1	1
Diarrhoea	2	2			2	2
Dizziness	6	6			6	6
Drooling	1	1			1	1
Dyskinesia	2	2			2	2
Dysphagia	1	1			1	1
Dysphonia	2	2			2	2
Dyspnoea	2	2			2	2
Enlarged uvula	1	1			1	1
Erythema	1	1			1	1
Eye movement disorder	2	2			2	2
Eye swelling	1	1			1	1
Facial asymmetry	1	1			1	1
Facial paralysis	1	1			1	1
Feeding disorder	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Gianotti-Crosti syndrome		1		1		
Haematocrit increased	1	1			1	1
Haemoglobin increased	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	2	2			2	2
Hypersensitivity	1	2		1	1	1
Hypoaesthesia	3	3			3	3
Hypotension	1	1			1	1
Influenza like illness	1	1	1	1		
Mental status changes	1	1			1	1
Neck pain	1	1			1	1
Optic neuritis	1	1			1	1
Oropharyngeal pain	1	1			1	1
Palpitations	1	1			1	1
Periorbital swelling	2	2			2	2
Pharyngeal swelling	1	1			1	1
Rash	1	2		1	1	1
Rash macular	1	1			1	1
Rash papular	1	1			1	1
Respiratory rate decreased	1	1			1	1
Respiratory rate increased	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	1	1			1	1
Seizure	2	2			2	2
Sensation of foreign body	2	2			2	2
Status epilepticus	1	1			1	1
Tachycardia	1	1			1	1
Tenosynovitis	1	1			1	1
Throat tightness	1	1			1	1
Tongue biting	1	1			1	1
Toxic neuropathy	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Vision blurred	2	2			2	2
Vomiting	2	2			2	2
	84	88	1	4	83	84

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Anaphylactic reaction	2	2			2	2
Breath sounds abnormal	1	1			1	1
Chest discomfort	1	1	1	1		
Chills	1	1			1	1
Confusional state	1	1			1	1
Cough	1	1			1	1
Diplopia	1	1			1	1
Dizziness	2	2	1	1	1	1
Dry mouth	1	1	1	1		
Dyskinesia	1	1			1	1
Dyspnoea	2	2			2	2
Facial paralysis	1	1			1	1
Fall	1	1			1	1
Fatigue	2	2	2	2		
Femoral neck fracture	1	1			1	1
Fibroma		1		1		
Generalised tonic-clonic seizure	1	1			1	1
Headache		1		1		
Hypertension	2	2			2	2
Injection site swelling		1		1		
Migraine	1	1			1	1
Nausea	2	2	1	1	1	1
Oxygen saturation decreased	2	2			2	2
Pain in extremity	2	2	2	2		
Palpitations	1	1	1	1		
Pneumonia aspiration	1	1			1	1
Poor quality product administered		2		2		
Rash	2	2			2	2
Skin abrasion	1	1			1	1
Skin lesion		1		1		
Somnolence	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Unresponsive to stimuli	1	1			1	1
Vaccination site rash	1	1			1	1
Vaccination site reaction		1		1		
Vlth nerve paralysis	1	1			1	1
Vomiting	1	1			1	1
Wheezing	2	2			2	2
	41	49	9	17	32	32

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat	1	1			1	1
Deep vein thrombosis	1	1			1	1
Dysacusis		1		1		
Dyspnoea	1	1			1	1
Dyspnoea exertional	1	1			1	1
Myocardial infarction	1	1			1	1
Pallor	1	1			1	1
Pulmonary embolism	1	1			1	1
Vaccination site pain		1		1		
	7	9		2	7	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute generalised exanthematous pustulosis	1	1			1	1
Anaphylactic shock		1				1
Chills		1		1		
Dizziness	1	1	1	1		
Eye swelling		1		1		
Headache	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Injection site pruritus	1	1	1	1		
Lip swelling	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Myalgia	1	1	1	1		
Pain	1	1	1	1		
Poor quality product administered	1	1	1	1		
Pyrexia	1	2	1	2		
Syncope	1	1			1	1
Taste disorder		1		1		
Urticaria		1		1		
Vaccination site pain		1		1		
	11	19	9	16	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SLOVAKIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		1		1		
Altered state of consciousness		1				1
Arthralgia	1	5	1	4		1
Asthenia	3	8	3	7		1
Axillary pain		1		1		
Back pain	1	1	1	1		
Blood pressure decreased		2				2
Blood pressure increased		3		1		2
Body temperature fluctuation	1	1	1	1		
Body temperature increased	4	8	4	7		1
Bone pain	1	1	1	1		
Brain contusion		1				1
Chest discomfort		1		1		
Chest pain	1	1	1	1		
Chills	6	14	6	12		2
Cold sweat		1		1		
Cough	1	2	1	2		
COVID-19		1		1		
Decreased appetite	1	1	1	1		
Dehydration	1	1	1	1		
Diarrhoea	1	1	1	1		
Dizziness	2	7	2	7		
Dry throat		1		1		
Dyskinesia	1	1	1	1		
Erythema		1				1
Eye irritation	1	1	1	1		
Eyelid rash		1		1		
Eye pain	1	1	1	1		
Fall	1	2	1	1		1
Fatigue	6	12	6	12		
Feeling hot		1		1		
Flushing	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	2	9	2	8		1
Head discomfort	1	1	1	1		
Hot flush		1		1		
Hyperhidrosis	1	5	1	4		1
Hypersensitivity		1		1		
Inflammation		1		1		
Insomnia		1		1		
Loss of consciousness	1	2			1	2
Lymphadenopathy	1	2	1	2		
Malaise	2	5	2	5		
Maternal exposure during pregnancy		1		1		
Migraine		1		1		
Myalgia	2	6	2	6		
Mydriasis		1		1		
Nausea	1	6	1	6		
Neck pain	1	1	1	1		
Oropharyngeal pain	1	2	1	2		
Pain	1	2	1	2		
Pain in extremity	7	12	7	12		
Pallor		2		1		1
Palpitations	1	1	1	1		
Paraesthesia	2	3	2	2		1
Peripheral coldness		1		1		
Photophobia		1		1		
Presyncope		1				1
Pruritus		1				1
Pyrexia	3	10	3	9		1
Rash papular		1		1		
Rash pustular		1		1		
Rhinalgia	1	1	1	1		
Rhinitis		1		1		
Sudden hearing loss	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		4				4
Tachycardia	1	3	1	2		1
Tension headache	1	2	1	2		
Throat tightness		1		1		
Tinnitus	1	2	1	2		
Tongue discolouration	1	1	1	1		
Tonic convulsion		1				1
Vaccination site erythema	2	3	2	3		
Vaccination site hypersensitivity		1		1		
Vaccination site induration	1	2	1	2		
Vaccination site inflammation	1	1	1	1		
Vaccination site oedema	4	5	4	5		
Vaccination site pain	9	23	9	22		1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	2	1	1		1
Vaccination site warmth	1	1	1	1		
Vertigo	1	5	1	5		
Vision blurred	1	1	1	1		
	90	229	88	198	2	31

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	2	1	2		
Angioedema		1				1
Aphasia	1	1	1	1		
Arthralgia	9	16	9	16		
Asthenia	7	19	6	18	1	1
Atrial fibrillation		1				1
Axillary pain	1	1	1	1		
Back pain	1	3	1	3		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	2	7		3	2	4
Body temperature increased	13	15	12	14	1	1
Brachial plexus injury	1	1			1	1
Bradycardia		1				1
Burning sensation		2		2		
Cardiac discomfort	1	1	1	1		
Cervicobrachial syndrome	1	1			1	1
Chest discomfort		2		2		
Chills	14	41	14	39		2
Conjunctivitis		2		1		1
Cough		2		2		
COVID-19	2	5		1	2	4
Cutaneous vasculitis		1		1		
Deafness	1	1			1	1
Decreased appetite		2		2		
Diarrhoea		1		1		
Diplopia		1		1		
Disorientation	1	1	1	1		
Dizziness	4	8	4	8		
Drug ineffective	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth	1	2	1	1		1
Dysaesthesia		1		1		
Dysarthria	1	1	1	1		
Dyspnoea	1	7	1	5		2
Erythema	1	4	1	4		
Eye allergy		1		1		
Eye irritation		1		1		
Eye oedema		3		1		2
Eye pain		1		1		
Eye pruritus		1		1		
Face oedema	1	3	1	2		1
Fatigue	8	21	8	21		
Feeling abnormal		1		1		
Feeling hot	2	4	2	4		
Feeling of body temperature change		1		1		
Gait disturbance		1		1		
Headache	12	35	12	35		
Heart rate increased	1	2	1	2		
Hot flush	2	4	2	3		1
Hyperhidrosis	1	2	1	1		1
Hypersensitivity		1				1
Hypertension		3		2		1
Hypoaesthesia		1		1		
Influenza like illness		1		1		
Insomnia	1	1	1	1		
Insulin resistance		1				1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	3	8	3	8		
Lymphangitis	1	1			1	1
Lymph node pain	1	1	1	1		
Malaise	1	3	1	3		
Movement disorder	1	2	1	2		

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
	1		
1	1		
1	5		2
1	4		
	1		
	1		
	1		2
	1		
	1		
1	2		1
8	21		
	1		
2	4		
	1		
	1		
12	35		
1	2		
2	3		1
1	1		1
			1
	2		1
	1		
	1		
1	1		
			1
1	1		
3	8		
		1	1
1	1		
1	3		
1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscular weakness		1		1			
Musculoskeletal stiffness	1	1	1	1			
Myalgia	10	27	10	27			
Nausea	7	16	7	14		2	
Ocular hyperaemia		1		1			
Oedema		1		1			
Oedema peripheral		1		1			
Oral discomfort		1		1			
Pain	1	4	1	4			
Pain in extremity	5	16	5	16			
Pallor	1	1	1	1			
Palpitations		5		5			
Pancreatitis acute	1	1			1	1	
Paraesthesia	5	12	5	9		3	
Paraesthesia oral		3		2		1	
Peripheral coldness		2		2			
Peripheral swelling	2	2	2	2			
Petechiae		1		1			
Presyncope	2	5	2	3		2	
Product administered at inappropriate site		2		2			
Product administration error	1	1			1	1	
Pruritus		1		1			
Pyrexia	12	25	12	25			
Rash	1	2	1	2			
Restlessness		1				1	
Retching	2	2	2	2			
SARS-CoV-2 test positive		1		1			
Sinus tachycardia		2					2
Somnolence		1		1			
Sudden hearing loss	1	1			1	1	
Syncope	2	3			2	3	
Synovitis		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	3	6	3	5		1
Tachypnoea		1				1
Tendonitis	1	1	1	1		
Thirst	1	1	1	1		
Throat irritation		2		2		
Tinnitus	2	2	2	2		
Tissue infiltration		1		1		
Tryptase decreased		1		1		
Vaccination failure	1	1			1	1
Vaccination site bruising	1	1	1	1		
Vaccination site erythema	1	3	1	3		
Vaccination site joint movement impairment		1		1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	7	26	7	26		
Vaccination site pruritus		1		1		
Vertigo	2	6	2	6		
Viral infection	1	1			1	1
Vision blurred	1	1	1	1		
Vomiting	2	4	2	3		1
	183	469	164	414	19	55

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		1				1
Arthralgia	4	9	4	9		
Asthenia	5	8	5	7		1
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Axillary vein thrombosis		1				1
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	1	5			1	5
Body temperature increased	2	6	2	5		1
Chills	7	19	7	17		2
Condition aggravated	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	1			1	1
Decreased appetite	2	2	2	2		
Diarrhoea	1	3	1	3		
Dizziness		1				1
Drug ineffective	1	1			1	1
Dysphagia	1	1	1	1		
Enlarged uvula	1	1	1	1		
Facial paresis		1				1
Fatigue	4	9	4	9		
Headache	8	18	8	18		
Head discomfort		1		1		
Heart rate increased		1		1		
Hot flush		2		1		1
Hyperhidrosis		1		1		
Hypertension		1		1		
Incorrect dose administered		1		1		
Influenza like illness		1		1		
Insomnia		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	1	1	1		
Malaise	2	5	2	5		
Medication error		1		1		
Micturition urgency		1				1
Muscular weakness	1	1			1	1
Musculoskeletal discomfort		1		1		
Myalgia	4	9	4	9		
Nausea	3	4	3	4		
Neck pain	1	1	1	1		
No adverse event		1		1		
Pain		1		1		
Pain in extremity	4	10	4	10		
Palpitations		1		1		
Paraesthesia		2		1		1
Pruritus		1		1		
Pyrexia	9	19	9	18		1
Rash	1	2	1	2		
Rash vesicular	1	1	1	1		
Rhinitis		1		1		
Somnolence	1	2	1	2		
Subclavian vein thrombosis		1				1
Syncope		1				1
Tachycardia		1				1
Thrombosis		1				1
Vaccination failure		1				1
Vaccination site movement impairment		1		1		
Vaccination site oedema	1	3	1	3		
Vaccination site pain	4	10	4	10		
Venous thrombosis limb		1				1
Vertigo	1	2	1	2		
Visual impairment	1	1			1	1
Vomiting		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
71	162	6	30

77

192

71

162

6

30

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute myocardial infarction		1				1	
Altered state of consciousness	1	1			1	1	
Amnesia	1	1			1	1	
Anaphylactic reaction		1				1	
Aphasia	1	1			1	1	
Asthenia	1	3			1	3	
Balance disorder	1	1	1	1			
Blood pressure decreased	1	2		1	1	1	
Blood pressure increased	3	3	1	1	2	2	
Body temperature increased	1	1			1	1	
Cerebral ischaemia	1	1			1	1	
COVID-19	1	2			1	2	
Cyanosis	1	1			1	1	
Dehydration	1	1			1	1	
Diarrhoea	1	1			1	1	
Dizziness	2	3	1	1	1	2	
Drug ineffective	1	1			1	1	
Dyspnoea	1	1	1	1			
Eye irritation	1	1	1	1			
Feeling hot	1	1	1	1			
Heart rate decreased		1		1			
Hyperhidrosis		1					1
Lacrimation increased	1	1	1	1			
Loss of consciousness		1					1
Malaise		1					1
Nausea	1	2	1	1		1	
Pyrexia		1					1
Restlessness		1					1
Somnolence	1	1			1	1	
Speech disorder	1	1			1	1	
Subclavian vein stenosis	1	1			1	1	
Syncope	1	3			1	3	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombosis	1	1			1	1
Tinnitus	1	1	1	1		
Tongue dry	1	1			1	1
Tremor		1				1
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	3	3	3	3		
Vaccination site pruritus	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vertigo	1	1			1	1
Vision blurred	1	1	1	1		
Vomiting	1	1			1	1
Wheezing	1	1			1	1
	42	59	17	19	25	40

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	3	1	3		
Asphyxia	1	1			1	1
Blood pressure decreased		1				1
Blood pressure increased	2	2	2	2		
Bone pain	1	1	1	1		
Cardiac failure		1				1
Cardiac fibrillation		1				1
Chest discomfort	1	1			1	1
Chest pain	1	1	1	1		
Diarrhoea		1				1
Dizziness		1				1
Dyspnoea	1	1			1	1
Eye pruritus	1	1	1	1		
Headache	1	1	1	1		
Heart rate increased	1	1	1	1		
Malaise	1	1	1	1		
Musculoskeletal chest pain	1	1	1	1		
Myalgia		1		1		
Myocardial ischaemia		1				1
Pain in extremity	2	2	2	2		
Pruritus	1	1	1	1		
Thirst	1	1	1	1		
Vaccination site pain		1		1		
Vomiting		1				1
	17	28	14	18	3	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Angioedema		1				1
Asthenia		1		1		
Axillary pain		1		1		
Blood pressure decreased		1		1		
Body temperature increased		3		3		
Burning sensation		1		1		
Chills		5		5		
Cough		3		3		
COVID-19	2	4		1	2	3
Dermatitis allergic		1		1		
Diarrhoea		1		1		
Drug ineffective	2	4			2	4
Dry mouth		1		1		
Epilepsy	1	1			1	1
Erysipelas		1				1
Erythema		1		1		
Fatigue		4		4		
Feeling hot		2		2		
Flatulence		1		1		
Headache		4		4		
Head discomfort		1		1		
Hypertensive crisis		1				1
Limb discomfort		1		1		
Lip oedema		1		1		
Lymphadenopathy		2		2		
Malaise		1		1		
Maternal exposure during pregnancy		1		1		
Myalgia		3		3		
Nausea		3		3		
Ocular discomfort		1		1		
Pain		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	2	9	2	9		
Pain of skin		1		1		
Paraesthesia		2		2		
Photophobia		1		1		
Presyncope		1		1		
Pyrexia		7		7		
Rash		1		1		
Rash pruritic		2		2		
SARS-CoV-2 antibody test positive		1				1
SARS-CoV-2 test positive		1				1
Somnolence		1		1		
Urticaria		1				1
Vaccination site dermatitis		1		1		
Vaccination site erythema		1		1		
Vaccination site oedema		2		2		
Vaccination site pain	1	6	1	6		
Vaccination site urticaria		1		1		
Vomiting		1		1		
	8	98	3	83	5	15

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SLOVENIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anaphylactic reaction		1				1
Angioedema		1				1
Arthralgia		2		2		
Blindness unilateral		1				1
Body temperature increased		2		2		
Chills		1		1		
Diarrhoea	1	1	1	1		
Dizziness		1		1		
Erythema		1				1
Exposure during pregnancy	1	1	1	1		
Eye pruritus		1		1		
Fatigue		5		5		
Headache		7		7		
Hypertension		1				1
Hyperventilation		1				1
Hypoaesthesia		2		1		1
Lip swelling		1		1		
Lymphadenopathy		1		1		
Malaise		1				1
Migraine		1				1
Migraine with aura		1				1
Myalgia		4		4		
Nausea		2		1		1
Neurological symptom		1		1		
Paraesthesia		3		3		
Paraesthesia oral		1		1		
Pyrexia		2		2		
Rash	1	1	1	1		
Sensory disturbance		1		1		
Sinus tachycardia		1				1
Somnolence		3		3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder		1		1		
Swollen tongue		2		2		
Tachycardia		1		1		
Thinking abnormal		1		1		
Throat tightness		1		1		
Tongue pruritus		2		2		
Urticaria		1				1
Vaccination site erythema		2		2		
Vaccination site oedema		1		1		
Vaccination site pain	1	10	1	10		
Vaccination site pruritus		1		1		
Vaccination site swelling	1	1	1	1		
Vertigo		1		1		
	5	79	5	66		13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain lower		1		1		
Angina pectoris		1				1
Arthralgia		1		1		
Asthenia	1	1	1	1		
Atrial fibrillation		1				1
Atrial tachycardia		1				1
Body temperature increased	1	2		1	1	1
Bone pain		1		1		
Bronchial disorder		1				1
Chest discomfort	1	2			1	2
Chest pain		1		1		
Chills		1		1		
Circulatory collapse		1				1
Confusional state		1				1
COVID-19		1				1
Deep vein thrombosis		1				1
Diarrhoea	1	4		3	1	1
Dizziness	1	3			1	3
Dysgeusia		2		2		
Dyspnoea		2		1		1
Epilepsy		1				1
Fatigue	3	11	1	7	2	4
Feeling abnormal	1	1	1	1		
Feeling hot	1	1			1	1
Gait inability	1	1			1	1
Guillain-Barre syndrome		2				2
Headache	1	7		5	1	2
Hot flush	1	1			1	1
Hypokalaemia		1				1
Hyposmia		2		2		
Insomnia		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema	1	1			1	1
Loss of consciousness	2	8			2	8
Lymphadenitis		1		1		
Lymphadenopathy		3		3		
Malaise		2		1		1
Migraine		1		1		
Myalgia		2		1		1
Nasopharyngitis		2		2		
Nausea		2		1		1
Oedema peripheral		1				1
Pain in extremity		1		1		
Paraesthesia		3				3
Paraesthesia oral	1	1			1	1
Pityriasis rosea		1		1		
Pneumothorax spontaneous	1	1			1	1
Pulmonary embolism		1				1
Pyrexia		1		1		
Rash		1		1		
Rash pruritic		2		2		
Seizure		1				1
Sensation of foreign body	1	1			1	1
Somnolence	1	3		2	1	1
Syncope		2				2
Tongue biting		1				1
Total lung capacity decreased	1	1			1	1
Uterine spasm		1				1
Vaccination failure		1				1
Vaccination site pain	3	11	1	8	2	3
Vaccination site pruritus		2		2		
Vaccination site warmth	1	1			1	1
Ventricular extrasystoles		1		1		
Vertigo	2	5	1	3	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Walking disability	1	1				
	28	126	5	62	23	64

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		1				1
Arthralgia		1		1		
Asthenia		1				1
Aura		1		1		
Axillary pain		1				1
Basilar artery thrombosis		1				1
B-cell lymphoma		1				1
B-cell type acute leukaemia		1				1
Blood pressure increased		1		1		
Body temperature increased		2		2		
Bradycardia	1	1			1	1
Cardiac tamponade		1				1
Cerebral thrombosis		1				1
Chest discomfort		1		1		
Chest pain		1				1
Chills		2		2		
Diarrhoea		1		1		
Ear pain		1				1
Erythema		1		1		
Eyelid oedema		1		1		
Facial paralysis		1				1
Fatigue		3		2		1
Feeling hot		1		1		
Headache	1	6	1	4		2
Hypertension		2				2
Inappropriate schedule of product administration		1		1		
Ischaemic cerebral infarction		1				1
Malaise		4		3		1
Muscular weakness	1	1	1	1		
Myalgia		1		1		
Myocardial infarction		1				1
Myocardial rupture		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nausea		1		1			
Neutropenia		1					1
Night sweats		1					1
Off label use		1		1			
Oral herpes		1					1
Pain		1		1			
Paraesthesia oral		1					1
Presyncope	1	1	1	1			
Protein total increased		1		1			
Pyrexia		1		1			
Quadripareisis		1					1
Restlessness		1		1			
Sensory disturbance		1					1
Speech disorder		1					1
Suffocation feeling		1					1
Tachycardia		1		1			
Thrombocytopenia		2					2
Transient ischaemic attack		1					1
Vaccination site pain	2	9	2	7			2
Vertebral artery thrombosis		1					1
Vomiting		1		1			
	6	75	5	40	1		35

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Cardiac failure congestive	1	1			1	1
Cardiopulmonary failure		1				1
Cerebral haemorrhage	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Dyspnoea	1	1			1	1
Extrasystoles	1	1			1	1
Hypersensitivity		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Irritability	1	1			1	1
Loss of consciousness	1	1			1	1
Lower respiratory tract infection	1	1			1	1
Mood altered	1	1			1	1
Off label use	1	1	1	1		
Pneumonia		1				1
Pulmonary oedema	1	1			1	1
Sudden cardiac death	2	2			2	2
Sudden death		1				1
Thrombophlebitis superficial	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site pain		7		7		
Ventricular extrasystoles	1	1			1	1
	19	31	2	11	17	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acute myocardial infarction	1	2			1	2
Aphasia	1	1			1	1
Asthenia		2		2		
Asymptomatic bacteriuria		1				1
Atrial fibrillation	1	2			1	2
Bedridden		1				1
Body temperature increased		4		3		1
Bradycardia	2	2			2	2
Cardiac arrest		1				1
Cardiac failure	1	1			1	1
Cardiopulmonary failure	1	1			1	1
Cerebrovascular accident		1				1
Chest pain	2	3	1	1	1	2
Circulatory collapse	2	2			2	2
Confusional state	1	1	1	1		
Coordination abnormal		1				1
Cough		1				1
COVID-19		3				3
COVID-19 pneumonia		1				1
Death		1				1
Deep vein thrombosis	1	1			1	1
Dementia		1				1
Diabetes mellitus	1	1			1	1
Diarrhoea		1		1		
Disease recurrence		1				1
Drug ineffective		1				1
Dysarthria	1	1			1	1
Dyspnoea	1	4			1	4
Epilepsy	1	2			1	2
Fall	2	3	1	1	1	2
Fatigue		3		3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold	1	1	1	1		
Feeling hot		1				1
Gait disturbance		1				1
Gastrointestinal haemorrhage	1	1			1	1
General physical health deterioration		1				1
Headache		1		1		
Head injury	1	1	1	1		
Hypertension	1	2			1	2
Hypotension		1				1
Infection		1				1
Ischaemic stroke	1	1			1	1
Loss of consciousness		2				2
Malaise		6		2		4
Miosis		1				1
Monoparesis	1	1			1	1
Myalgia		1				1
Myocardial infarction		1				1
Nausea	1	2	1	1		1
Oedema peripheral	1	1			1	1
Oropharyngeal pain		1		1		
Oxygen saturation decreased		3				3
Pain in extremity		1				1
Paresis		1				1
Peripheral coldness		1		1		
Pharyngeal erythema		1		1		
Pneumonia		1				1
Pulmonary embolism	1	2			1	2
Pyrexia		2				2
Skin disorder		1				1
Soliloquy	1	1	1	1		
Somnolence		2				2
Sudden death		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Superficial vein prominence	1	1			1	1
Syncope		3				3
Tachycardia	1	1			1	1
Tongue movement disturbance		1		1		
Unresponsive to stimuli		2				2
Vaccination failure		1				1
Vaccination site erythema		7		7		
Vaccination site oedema		3		3		
Vaccination site pain	1	13	1	13		
Vertigo	2	5	1	1	1	4
Vomiting		3		1		2
Wheezing		1				1
White blood cell count increased		1		1		
	34	139	9	50	25	89

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain upper	1	1	1	1		
Arthralgia		2		2		
Autoimmune thyroiditis		1				1
Body temperature increased		2		2		
Chest pain		1		1		
Chills		3		3		
Dizziness		2		2		
Drug ineffective	1	1			1	1
Eyelid disorder		1		1		
Fatigue		3		3		
Headache		3		3		
Inappropriate schedule of product administration		1		1		
Insomnia		2		2		
Lymphadenopathy		1		1		
Malaise		6		6		
Myalgia		4		4		
Nausea		1		1		
Neck pain		1		1		
Nightmare		1		1		
Off label use		1		1		
Pain		1		1		
Paraesthesia		1		1		
Pyrexia		5		5		
Sinusitis		1		1		
Skin burning sensation		1		1		
Suspected COVID-19	1	1			1	1
Vaccination site pain		1		1		
Vaccination site swelling		1		1		
	3	51	1	48	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SPAIN**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	1	1	1	1		
Condition aggravated	1	1	1	1		
Exposure via breast milk		4		2		2
Faeces discoloured		1				1
Gait disturbance		1				1
Headache		1				1
Infant irritability		1				1
Insomnia	1	1	1	1		
Psychotic disorder	1	1	1	1		
Seizure		1				1
Vomiting		1				1
	4	14	4	6		8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain	2	5	2	3		2
Abdominal pain lower	1	1	1	1		
Abortion missed	1	1			1	1
Ageusia		1				1
Allergic cough		1		1		
Allergy to vaccine		1				1
Amnesia	1	2		1	1	1
Anaphylactic reaction	1	10			1	10
Anaphylactic shock		3				3
Angioedema	1	6			1	6
Anosmia		1				1
Anxiety	1	4	1	4		
Aphasia		3				3
Aphonia		1				1
Appendicitis	1	2			1	2
Arthralgia	7	16	7	9		7
Asthenia	4	13	3	6	1	7
Asthma		2				2
Asthmatic crisis		1				1
Asymptomatic COVID-19	1	1			1	1
Autoimmune demyelinating disease		1				1
Axillary pain	1	4	1	4		
Back pain		1		1		
Balance disorder		1				1
Base excess decreased	1	1	1	1		
Bedridden		1				1
Blood bicarbonate increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood lactate dehydrogenase increased	1	1	1	1		
Blood pressure decreased		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased		1		1		
Body temperature increased		1		1		
Bradykinesia		1		1		
Bradyphrenia		1		1		
Breast mass		1		1		
Bronchial hyperreactivity		1				1
Bronchospasm		3				3
Burning sensation		1				1
Butterfly rash		1		1		
Cellulitis		1				1
Chest discomfort		2		1		1
Chest pain	2	5	1	1	1	4
Chills	4	20	4	9		11
Choking		1				1
Choking sensation	1	2			1	2
Chromaturia		1		1		
Circumoral swelling		1		1		
Cold sweat		2		1		1
Colitis	1	1	1	1		
Condition aggravated		3		1		2
Confusional state		1		1		
Conjunctival hyperaemia	1	1			1	1
Conjunctival laceration		1		1		
Contusion	1	1			1	1
Cough		3		1		2
COVID-19		6				6
Craniocerebral injury		1				1
Decreased appetite		3		1		2
Depressed level of consciousness		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	7	17	6	9	1	8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort	1	1	1	1		
Disturbance in attention		2		1		1
Dizziness	11	25	7	12	4	13
Drug ineffective		3				3
Dry eye		1		1		
Dry throat		1		1		
Dysgeusia	1	1			1	1
Dysmenorrhoea		1		1		
Dysphagia	1	3			1	3
Dyspnoea	2	14	1	1	1	13
Dyspnoea exertional		2				2
Encephalitis		2				2
Epigastric discomfort		1				1
Epilepsy	1	1			1	1
Episcleritis		1				1
Epstein-Barr virus infection reactivation		1				1
Erythema	3	14	3	8		6
Eye discharge	1	1			1	1
Eye pain	1	3		1	1	2
Eye pruritus	1	2			1	2
Face oedema	1	3			1	3
Facial paralysis	1	7			1	7
Fatigue	5	24	5	12		12
Feeling cold		2				2
Feeling hot		2		1		1
Fibrin D dimer increased	1	1			1	1
Flatulence	1	1	1	1		
Flushing		1		1		
Gait disturbance		1				1
Gait inability		1				1
Galactorrhoea		1				1
Gastrooesophageal reflux disease		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General physical health deterioration	1	2	1	1		1
Groin pain		1				1
Haemoglobin decreased	1	1	1	1		
Haemoglobin increased	1	1	1	1		
Haemophagocytic lymphohistiocytosis		1				1
Hallucination	1	1			1	1
Headache	25	62	22	35	3	27
Head injury	1	2			1	2
Heart rate increased		1				1
Hemiparaesthesia		1				1
Hemiplegia		2				2
Hepatic failure		1				1
Hepatitis acute		2				2
Hepatomegaly		1				1
Herpes simplex		1				1
Herpes virus infection		1				1
Herpes zoster		2				2
Hyperglycaemia		1				1
Hyperhidrosis		1				1
Hypersensitivity	1	3		1	1	2
Hyperthyroidism		1				1
Hyperventilation		1				1
Hypoaesthesia	1	5	1	1		4
Hypoaesthesia oral	1	1			1	1
Hypoglycaemia	1	2			1	2
Hypokinesia	2	2	1	1	1	1
Hypotension		7		1		6
Hypoxia		1				1
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration		2		2		
Infectious mononucleosis		1				1
Influenza		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site erythema		1		1		
Injection site haematoma		1		1		
Injection site pain		1		1		
Injection site paraesthesia		1		1		
Ischaemic stroke		1				1
Lacrimation increased		1				1
Laryngeal oedema		3				3
Leukocytosis		1				1
Limb discomfort		1		1		
Lipase decreased	1	1	1	1		
Lip blister		1		1		
Lip oedema		2		1		1
Lip pruritus		3		3		
Lip swelling	1	2			1	2
Loss of consciousness		3				3
Loss of personal independence in daily activities	1	1			1	1
Lymphadenitis	1	3	1	2		1
Lymphadenopathy	3	22	2	7	1	15
Lymph node pain		1				1
Lymphocyte count increased	1	1	1	1		
Macroglossia	1	1			1	1
Malaise	11	29	10	17	1	12
Meniere's disease	1	1			1	1
Meningism		1				1
Mental impairment	1	1			1	1
Metrorrhagia		2				2
Middle insomnia		1		1		
Migraine		2		1		1
Migraine with aura	1	1	1	1		
Mobility decreased		3		1		2
Monoparesis	1	1			1	1
Monoplegia	1	1			1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Movement disorder		1				1
Multiple organ dysfunction syndrome		1				1
Muscular weakness		1		1		
Musculoskeletal chest pain		1		1		
Musculoskeletal pain		6		2		4
Musculoskeletal stiffness		2				2
Myalgia	12	35	9	15	3	20
Myocarditis		1				1
Nasal congestion	1	2	1	2		
Nasal pruritus		1				1
Nasopharyngitis	1	1	1	1		
Nausea	13	36	11	21	2	15
Neuropathy peripheral	1	1			1	1
Neutrophil count increased	1	1	1	1		
Night sweats		3		1		2
Nuchal rigidity		2				2
Oculofacial paralysis	1	1			1	1
Odynophagia		2		1		1
Off label use	1	2	1	2		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	1	1	1	1		
Ovarian cyst		1				1
Overdose	1	1	1	1		
Oxygen saturation decreased	1	1	1	1		
Pain	1	5	1	1		4
Pain in extremity	3	13	3	9		4
Palatal oedema	1	4			1	4
Pallor		2		1		1
Palpitations	1	2		1	1	1
Pancytopenia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Papule		1				
Paraesthesia	2	10		1		
Paraesthesia mucosal		1		2	2	8
Paraesthesia oral		4				1
Parosmia	1	1			1	1
Periarthritis		1				1
Pericarditis	1	1			1	1
Periorbital swelling		1		1		
Peripheral swelling		1		1		
Petit mal epilepsy		1				1
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation	1	1			1	1
Pharyngeal swelling	1	1			1	1
Pharyngotonsillitis		1				1
Photophobia		1		1		
Pleural effusion		1		1		
PO2 decreased	1	1	1	1		
Polymenorrhoea	1	1	1	1		
Presyncope	1	2	1	2		
Proctitis		1				1
Productive cough	1	1	1	1		
Pruritus	5	12	4	5	1	7
Psychomotor hyperactivity		1				1
Pulmonary embolism	3	4			3	4
Pyelonephritis	1	1			1	1
Pyrexia	29	76	25	44	4	32
Rash	5	11	4	6	1	5
Rash erythematous		2				2
Rash papular	2	3			2	3
Rash pruritic	1	2			1	2
Raynaud's phenomenon		2				2
Rectal discharge		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rectal haemorrhage		1
Respiratory disorder	1	1
Respiratory distress	1	4
Respiratory failure		1
Rhinorrhoea	1	1
Scleritis		1
Sensation of foreign body		1
Sensory loss	2	2
Shock		1
Sinus bradycardia		1
Sinus tachycardia	1	1
Skin lesion		1
Somnolence		6
Speech disorder		1
Spinal cord injury		1
Swelling		2
Swelling face		1
Swollen tongue	1	1
Syncope	2	11
Tachycardia	1	10
Temperature regulation disorder		3
Throat irritation	2	4
Throat tightness		1
Thrombophlebitis superficial	1	1
Tongue oedema		2
Tongue pruritus		1
Tonsillitis		2
Toxic skin eruption		1
Transaminases increased		1
Transient ischaemic attack		1
Tremor		2
Underdose		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
		1	4
			1
1	1		
			1
1	1	1	1
			1
	1		
		1	1
			1
	3		3
			1
			1
	2		
			1
		1	1
		2	11
		1	10
	1		2
1	2	1	2
			1
		1	1
			2
			1
			2
			1
			1
			1
			2
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Urinary sediment abnormal		1		1			
Urinary tract infection		2		1			1
Urticaria	3	8	2	2	1		6
Uterine haemorrhage		1					1
Uvulitis	1	1			1		1
Vaccination complication		1					1
Vaccination failure	1	2			1		2
Vaccination site discomfort		1		1			
Vaccination site erythema	1	7	1	3			4
Vaccination site haemorrhage		1		1			
Vaccination site induration		1		1			
Vaccination site inflammation	5	6	5	6			
Vaccination site lymphadenopathy		2					2
Vaccination site movement impairment	1	1	1	1			
Vaccination site oedema	1	2	1	1			1
Vaccination site pain	11	26	10	15	1		11
Vaccination site paraesthesia		1					1
Vaccination site pruritus	1	6	1	3			3
Vaccination site rash		1					1
Vaccination site reaction		1		1			
Vaccination site swelling		1		1			
Vaccination site warmth	1	3	1	1			2
Vaginal discharge		1		1			
Ventricular extrasystoles		1					1
Vertigo	1	3		1	1		2
Vestibular neuritis	1	1			1		1
Viral rash		1					1
Vision blurred		2					2
Visual impairment		1					1
Vomiting	8	20	5	7	3		13
Wheezing		2					2
White matter lesion	1	1	1	1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	285	972	192	397	93	575

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal discomfort		2				1			1
Abdominal mass	1	1			1	1			
Abdominal pain	6	13			5	7	1		6
Abdominal pain lower		1							1
Abdominal pain upper		7				4			3
Abnormal faeces		1				1			
Abortion induced		1							1
Abortion missed		1							1
Abortion spontaneous		3							3
Acoustic neuritis		1							1
Acute myocardial infarction		1							1
Adnexa uteri pain	1	1			1	1			
Ageusia	4	8			3	3	1		5
Allergic reaction to excipient		1							1
Allergy to vaccine	1	4				1	1		3
Allodynia		1				1			
Alopecia	1	1					1		1
Amaurosis fugax	1	1					1		1
Amenorrhoea	1	1					1		1
Amnesia		2				1			1
Anaphylactic reaction	3	16					3		16
Androgenetic alopecia	1	1					1		1
Angina pectoris		1							1
Angioedema	2	12					2		12
Anosmia	4	7			3	3	1		4
Antipsychotic drug level increased		1							1
Anuria	1	1					1		1
Anxiety		2				2			
Aphonia		2							2
Aphthous ulcer		4				2			2
Appendicitis		1							1
Arrhythmia	1	1					1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthralgia	16	53
Arthritis	1	1
Arthritis reactive		1
Asphyxia		2
Asthenia	17	57
Asthma		1
Asymptomatic COVID-19	3	5
Atelectasis	1	1
Atrophic glossitis		1
Atypical haemolytic uraemic syndrome	1	1
Autoimmune hepatitis		1
Autoimmune hypothyroidism	1	1
Axillary pain	1	9
Axonal neuropathy	1	1
Bacille Calmette-Guerin scar reactivation		1
Back pain	2	14
Balance disorder	1	8
Biliary colic		1
Bladder spasm		1
Blepharitis	1	1
Blepharospasm		1
Blindness transient		1
Blindness unilateral	1	1
Blister		1
Blood fibrinogen decreased	1	1
Blood fibrinogen increased		1
Blood glucose decreased		1
Blood iron decreased		1
Blood pressure abnormal	1	2
Blood pressure increased	1	4
Blood pressure systolic increased		1
Body temperature increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	28	4	25
				1	1
					1
					2
		11	25	6	32
					1
		1	1	2	4
		1	1		
					1
				1	1
					1
				1	1
		1	3		6
		1	1		
			1		
		2	6		8
			2	1	6
					1
					1
		1	1		
			1		
					1
				1	1
					1
		1	1		
			1		
					1
		1	1		1
			1	1	3
			1		
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brachial plexus injury		1
Bradycardia		3
Bradyphrenia		2
Brain oedema		1
Breast oedema		1
Bronchitis bacterial		1
Bronchospasm		5
Bundle branch block right	1	1
Burning sensation		1
Bursitis		1
Cardiac failure acute		1
Cardio-respiratory arrest		1
Catarrh	1	2
Cellulitis		3
Cerebral disorder		1
Cerebral haemorrhage	1	1
Cerebral ischaemia	1	1
Cerebral venous thrombosis	1	2
Cervicobrachial syndrome		1
Cheilitis		2
Chest discomfort	2	12
Chest pain	4	19
Chills	11	56
Choking sensation		3
Chronic lymphocytic leukaemia	1	1
Citrobacter infection		1
Cold sweat	1	2
Concomitant disease aggravated	1	3
Condition aggravated	1	9
Confusional state		1
Conjunctival haemorrhage	1	1
Constipation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
					2
					1
					1
					1
					5
				1	1
					1
					1
					1
		1	1		1
					3
					1
				1	1
				1	1
				1	2
					1
					2
		1	1	1	11
		2	7	2	12
		8	29	3	27
					3
				1	1
					1
		1	1		1
				1	3
		1	2		7
					1
				1	1
		1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Contusion	1	3
Corneal reflex decreased		1
Costochondritis		1
Cough	5	25
COVID-19	6	26
COVID-19 pneumonia		1
Craniocerebral injury		1
C-reactive protein increased		1
Cytomegalovirus test positive	1	1
Deafness		1
Deafness unilateral		1
Death		1
Decreased appetite		4
Decreased nasolabial fold		1
Deep vein thrombosis		2
Dehydration		1
Delirium febrile		1
Demyelination	1	1
Depressed level of consciousness		5
Depressed mood		1
Dermatitis allergic	1	3
Dermatitis atopic	1	1
Dermatitis bullous		1
Diabetes mellitus inadequate control	1	2
Diaphragmalgia	1	1
Diarrhoea	12	52
Diarrhoea haemorrhagic		1
Diplopia	1	3
Discomfort	2	9
Disease recurrence	1	3
Disorganised speech		1
Disturbance in attention		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
					1
					1
		4	12	1	13
		4	10	2	16
					1
					1
			1		
				1	1
					1
					1
					4
					1
					2
					1
					1
				1	1
					5
			1		
				1	3
				1	1
					1
				1	2
				1	1
		11	29	1	23
					1
		1	1		2
		1	5	1	4
		1	1		2
					1
					4

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dizziness	18	81
Dizziness postural	1	2
Drowning		2
Drug hypersensitivity		2
Drug ineffective		11
Dry eye	1	1
Dry mouth	1	5
Dry skin	1	1
Dry throat		1
Dysaesthesia		5
Dysarthria	1	1
Dysgeusia		6
Dyspepsia	1	2
Dysphagia	1	6
Dysphonia	4	6
Dyspnoea	11	42
Dyspnoea exertional	1	5
Dystonia		1
Dysuria	1	3
Ear infection		1
Ear pain	1	7
Ecchymosis		1
Eczema		1
Electrocardiogram ST segment elevation	1	1
Encephalopathy	1	1
Epilepsy	2	3
Epistaxis	1	1
Epstein-Barr virus antibody positive	1	1
Erythema	5	22
Erythema multiforme		1
Essential tremor	1	2
Euphoric mood		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	40	4	41
			1	1	1
					2
					2
					11
				1	1
			1	1	4
				1	1
					1
					5
				1	1
			3		3
		1	1		1
		1	2		4
		2	2	2	4
		6	9	5	33
				1	5
					1
		1	2		1
					1
		1	2		5
					1
					1
				1	1
				1	1
				2	3
		1	1		
				1	1
		4	7	1	15
					1
		1	1		1
					1

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exposure during pregnancy		1
Eyelid oedema		1
Eye pain	1	2
Eye swelling		1
Face oedema	1	7
Facial neuralgia	1	1
Facial pain		1
Facial paralysis	4	23
Facial paresis	1	2
Fall		3
Fatigue	20	62
Febrile convulsion		2
Feeling abnormal	1	4
Feeling cold		3
Feeling drunk		1
Feeling hot	1	7
Flatulence		1
Floppy eyelid syndrome		1
Flushing		2
Foreign body in throat		1
Foreign body sensation in eyes	1	1
Formication	1	5
Fracture		1
Fumbling		1
Fungal skin infection		1
Gait disturbance		4
Gait inability	1	2
Gastroenteritis	2	3
Gastrointestinal disorder	1	1
Gastrointestinal somatic symptom disorder	1	1
Generalised oedema		2
Generalised tonic-clonic seizure		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	2
					1
				1	7
		1	1		
					1
				4	23
			1	1	1
					3
		15	33	5	29
					2
		1	1		3
			1		3
			1		4
		1	3		1
					1
					2
					1
					1
					2
					1
					1
			2		2
				1	2
		2	2		1
		1	1		
		1	1		
					2
					1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
General physical health deterioration	1	2					1	2
Genital ulceration		1						1
Gingival bleeding	1	1					1	1
Gingival discolouration		1				1		
Gingivitis		1				1		
Glossitis		4						4
Glossodynia		1						1
Goitre		1				1		
Guillain-Barre syndrome		1						1
Haematochezia		1						1
Haematoma		2				1		1
Haemoptysis		1						1
Haemorrhage		2						2
Haemorrhagic diathesis		1						1
Hallucination	1	1					1	1
Hallucination, visual		1						1
Headache	75	215			60	110	15	105
Heart rate increased	1	2					1	2
Heart rate irregular	1	1					1	1
Hemianaesthesia		1						1
Hemiparaesthesia		1						1
Hepatic enzyme abnormal	1	1					1	1
Hepatitis	1	2					1	2
Hepatitis acute	1	1					1	1
Hepatitis B virus test positive	1	1			1	1		
Herpes ophthalmic		1						1
Herpes simplex	1	1			1	1		
Herpes virus infection	1	1			1	1		
Herpes zoster	5	21	1	1	1	2	4	19
Herpes zoster reactivation		2						2
Hot flush		2				1		1
Hyperaesthesia	1	2			1	1		1

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperdynamic left ventricle		1
Hyperglycaemia	1	4
Hyperhidrosis	2	9
Hyperpyrexia		1
Hypersensitivity	1	11
Hypersomnia		1
Hypertension	6	18
Hypertensive crisis	1	10
Hypertensive urgency		1
Hyperthermia		1
Hypertransaminasaemia		2
Hypoacusis		3
Hypoaesthesia	4	18
Hypoaesthesia oral	1	5
Hypocalcaemia	1	2
Hypoglycaemia		4
Hypophosphataemia		1
Hyporeflexia		2
Hypotension		7
Hypothermia		1
Hypotonia		1
Idiopathic angioedema		1
Immune thrombocytopenia	3	4
Immunisation reaction		1
Inappropriate schedule of product administration		2
Incorrect dose administered	1	1
Induration		1
Inflammation	1	5
Influenza		3
Influenza like illness		3
Injection site erythema		1
Injection site inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	3
		1	2	1	7
					1
			1	1	10
					1
		2	5	4	13
				1	10
					1
					1
					2
					3
		2	5	2	13
		1	2		3
			1	1	1
			1		3
					1
			1		1
					5
					1
			1		
					1
				3	4
			1		
			2		
		1	1		
					1
		1	3		2
					3
			2		1
			1		
			1		

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Insomnia	1	3
Insulin resistance		1
Interstitial lung disease		1
Intraventricular haemorrhage	1	1
Iron deficiency		1
Joint contracture		2
Joint injury		1
Joint range of motion decreased		1
Joint swelling		1
Joint warmth		1
Keratitis	1	1
Lacrimation increased		1
Laryngeal disorder		1
Laryngeal oedema	1	5
Laryngitis		1
Larynx irritation		1
Leukocytosis	1	1
Leukopenia		1
Lichen planus		1
Limb discomfort	1	2
Limb immobilisation		1
Lip erythema		1
Lip oedema		4
Lipoma	1	1
Lip pruritus		1
Lip swelling	1	5
Lividity		1
Local reaction	2	3
Loss of consciousness	1	7
Loss of personal independence in daily activities		1
Lymphadenitis	4	7
Lymphadenopathy	20	74

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
			1		
					1
				1	1
			1		
			2		
					1
					1
					1
				1	1
					1
					1
					1
		1	1		
					1
					1
				1	2
					1
					1
			1		3
		1	1		
					1
		1	1		4
					1
				2	3
				1	7
			1		
		3	4	1	3
		7	24	13	50

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphocytosis	1	1
Lymphopenia		2
Macular oedema		1
Malaise	20	79
Mass		1
Maternal exposure during pregnancy		2
Memory impairment		1
Meningoradiculitis	1	1
Menometrorrhagia		1
Menorrhagia		1
Menstruation delayed		2
Mental impairment		2
Metrorrhagia	1	6
Migraine		6
Migraine with aura		1
Migraine without aura	1	1
Misophonia		1
Mobility decreased		3
Mononeuropathy		1
Monoparesis	1	1
Monoplegia		1
Mouth swelling		1
Movement disorder		1
Mucosal dryness		1
Multiple sclerosis		1
Muscle contractions involuntary		3
Muscle contracture		3
Muscle fatigue		1
Muscle rigidity		1
Muscle spasms	1	5
Muscle tightness	1	3
Muscular weakness	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		
					1
		18	45	2	34
					1
			2		
					1
				1	1
					1
					2
					2
				1	6
			1		5
					1
				1	1
					1
			1		2
					1
				1	1
					1
			1		1
					1
			1		
			2		1
			1		
					1
		1	3		2
				1	3
		1	3		4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal chest pain		1
Musculoskeletal discomfort		2
Musculoskeletal pain	3	18
Musculoskeletal stiffness		4
Myalgia	45	117
Myelitis		1
Myocardial ischaemia		1
Myocarditis		1
Myoclonic dystonia		2
Myositis		1
Nasal congestion	2	6
Nasal disorder	1	1
Nasopharyngitis		1
Nausea	19	76
Neck mass		1
Neck pain	1	10
Nervousness	1	4
Neuralgia		4
Neuropathy peripheral	1	4
Neurosensory hypoacusis		1
Neutrophilic dermatosis	1	1
Nodule		1
Nuchal rigidity		1
Ocular hyperaemia		2
Odynophagia	1	12
Oedema		5
Oedema mouth	1	1
Oedema peripheral		5
Off label use		5
Oral candidiasis		3
Oral discomfort	1	1
Oral dysaesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
		1	4	2	14
			2		2
		40	74	5	43
					1
					1
					1
					2
					1
		2	3		3
		1	1		
			1		
		19	45		31
			1		
		1	5		5
			2	1	2
			1		3
				1	4
					1
				1	1
			1		
					1
					2
		1	2		10
			3		2
				1	1
					5
			5		
			2		1
		1	1		
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral herpes	3	7
Oral pain		1
Oral pruritus	1	3
Oropharyngeal discomfort	1	2
Oropharyngeal pain	3	9
Orthostatic hypotension		1
Osteoarthritis	1	1
Overdose	2	2
Oxygen saturation decreased	1	2
Pain	7	15
Pain in extremity	7	26
Palatal oedema		7
Palatal swelling	1	2
Pallor		1
Palpitations	4	11
Papule		1
Paraesthesia	13	62
Paraesthesia oral		8
Paresis		1
Parotid gland enlargement	2	2
Parotitis		2
Pelvic pain		1
Periarthritis		1
Pericarditis	2	5
Periorbital abscess		1
Periorbital oedema		1
Periorbital pain		1
Peripheral artery thrombosis		1
Peripheral coldness		1
Peripheral swelling		3
Peripheral venous disease	1	1
Pernio-like erythema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	6
			1		
		1	1		2
				1	2
		1	3	2	6
					1
		1	1		
		2	2		
				1	2
		6	12	1	3
		3	14	4	12
					7
		1	1		1
					1
		1	1	3	10
					1
		4	15	9	47
					8
			1		
		2	2		
					2
			1		
					1
				2	5
					1
			1		
					1
					1
				1	1
			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Persistent depressive disorder		1
Petechiae	1	2
Petit mal epilepsy		1
Pharyngeal inflammation	1	2
Pharyngeal oedema	1	4
Pharyngeal swelling	1	3
Phlebitis	1	1
Phlebitis superficial		1
Phonophobia		1
Photophobia		3
Photopsia		1
Pityriasis rosea	1	3
Pleuritic pain		1
Poor peripheral circulation	1	1
Post thrombotic syndrome	1	1
Presyncope	4	12
Proctalgia		1
Productive cough	1	2
Product use issue		3
Pruritus	9	40
Psoriatic arthropathy		1
Psychomotor hyperactivity		1
Pulmonary embolism	1	3
Pulmonary infarction	1	1
Pulse abnormal		1
Purpura		1
Pustule		1
Pyrexia	63	199
Rash	5	29
Rash erythematous	1	4
Rash macular		1
Rash maculo-papular		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
					1
		1	1		1
		1	1		3
				1	3
				1	1
					1
					1
					3
			1		
				1	3
					1
		1	1		
				1	1
		1	3	3	9
			1		
				1	2
			3		
		6	12	3	28
					1
					1
				1	3
				1	1
					1
					1
		51	97	12	102
		4	7	1	22
				1	4
			1		
			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Rash papular	1	2
Rash pruritic		4
Rash vesicular	1	1
Raynaud's phenomenon		2
Rectal haemorrhage	1	1
Red blood cell sedimentation rate increased		1
Respiratory distress		8
Respiratory rate decreased	1	1
Restless legs syndrome		1
Restlessness	1	1
Retinal vein occlusion		1
Rhinitis		2
Rhinorrhoea	1	7
Rotator cuff syndrome	2	2
SARS-CoV-2 antibody test positive		2
SARS-CoV-2 test positive		2
Seizure	1	2
Sensation of foreign body		2
Sense of oppression		1
Sensory disturbance		1
Sensory loss	1	7
Serum ferritin abnormal		1
Sialoadenitis	1	1
Sinusitis	1	2
Sinus tachycardia	3	4
Skeletal injury		1
Skin exfoliation		2
Skin lesion		2
Skin odour abnormal		1
Skin reaction	1	2
Slow speech		1
Sneezing	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		3
		1	1		
					2
				1	1
			1		
					8
				1	1
					1
				1	1
					1
			1		1
		1	4		3
				2	2
			1		1
			1		1
				1	2
					2
					1
					1
			3	1	4
			1		
				1	1
		1	2		
				3	4
					1
					2
					2
					1
		1	2		
					1
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somnolence	2	9
Spinal pain		1
Spontaneous haematoma		1
Stomatitis		4
Stridor		1
Subcutaneous abscess		1
Suffocation feeling		2
Supraventricular extrasystoles	1	1
Supraventricular tachycardia	1	1
Swelling	1	2
Swelling face	2	4
Swollen tongue	1	5
Syncope	1	25
Systemic lupus erythematosus		1
Systemic lupus erythematosus rash	1	1
Tachycardia	9	35
Tachycardia paroxysmal		1
Tachypnoea		2
Temperature regulation disorder	1	17
Tenderness		1
Tendon disorder		1
Tension headache	1	2
Testicular pain	1	1
Thirst	1	1
Throat irritation		7
Throat tightness	1	3
Thrombocytopenia	1	2
Thrombophlebitis	1	1
Thrombophlebitis superficial	3	3
Thunderclap headache		1
Tic		2
Tinnitus	2	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		3
					1
					1
			3		1
					1
					1
					2
				1	1
				1	1
		1	1		1
		2	2		2
				1	5
				1	25
					1
		1	1		
		4	10	5	25
					1
					2
			7	1	10
					1
					1
		1	1		1
		1	1		
		1	1		
			2		5
		1	1		2
				1	2
				1	1
		1	1	2	2
					1
					2
		1	3	1	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue disorder	1	1
Tongue erythema		1
Tongue injury		1
Tongue oedema		5
Tongue pruritus		2
Tongue ulceration		1
Tooth avulsion		1
Toxicity to various agents		1
Transferrin abnormal		1
Tremor		8
Trigeminal neuralgia		2
Tunnel vision		1
Underdose		2
Urinary tract infection	1	2
Urinary tract infection bacterial		1
Urticaria	10	30
Uterine haemorrhage		1
Vaccination failure	4	5
Vaccination site abscess		1
Vaccination site discomfort	2	4
Vaccination site erythema		5
Vaccination site haematoma	1	5
Vaccination site hyperaesthesia	1	2
Vaccination site hypoaesthesia	1	3
Vaccination site induration		3
Vaccination site inflammation	6	10
Vaccination site joint erythema	3	7
Vaccination site joint inflammation		2
Vaccination site joint movement impairment		1
Vaccination site joint swelling	1	1
Vaccination site lymphadenopathy	1	13
Vaccination site movement impairment	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
			1		
			1		4
					2
			1		
					1
					1
			1		
			2		6
					2
					1
			2		
				1	2
					1
		8	13	2	17
					1
				4	5
					1
		1	2	1	2
			2		3
				1	5
		1	1		1
			1	1	2
			2		1
		5	5	1	5
		2	3	1	4
					2
					1
		1	1		
			5	1	8
		2	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site oedema	1	2			1	1		1
Vaccination site pain	34	86			28	54	6	32
Vaccination site paraesthesia	1	5				1	1	4
Vaccination site pruritus	3	7			3	4		3
Vaccination site rash	1	1			1	1		
Vaccination site reaction		2				1		1
Vaccination site swelling	2	5				1	2	4
Vaccination site warmth	1	4			1	1		3
Vaginal haemorrhage		2				1		1
Vasculitis	1	2					1	2
Venous thrombosis limb	1	1					1	1
Vertigo	1	13				3	1	10
Vertigo positional	1	1					1	1
Vestibular migraine	1	1					1	1
Vision blurred	1	8				2	1	6
Vitamin B12 decreased		1				1		
Vitamin D decreased		1				1		
Vomiting	8	40			8	19		21
Vulval ulceration		1						1
Vulvovaginal candidiasis	1	1					1	1
Wheezing		3						3
White matter lesion	1	1					1	1
	769	2,971	1	1	483	1125	286	1846

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension	1	2	1	2		
Abdominal pain	2	8	2	4		4
Abdominal pain lower		1		1		
Abdominal pain upper		3		3		
Abdominal symptom		1		1		
Acute kidney injury		1				1
Acute myocardial infarction	1	2			1	2
Acute respiratory failure		1				1
Adrenal mass		1		1		
Ageusia		1				1
Agitation	1	1			1	1
Allergic oedema		1				1
Allergy to vaccine		4				4
Amaurosis fugax	1	1			1	1
Amnesia		2				2
Anal sphincter atony		2				2
Anaphylactic reaction		17				17
Anaphylactic shock		3				3
Angina pectoris		1				1
Angioedema		11				11
Anisometropia	1	1	1	1		
Anosmia		1				1
Anxiety		1		1		
Aortic dissection		1				1
Aphonia	1	3	1	2		1
Aphthous ulcer	1	3	1	2		1
Arrhythmia		1				1
Arthralgia	14	38	12	24	2	14
Arthritis		1				1
Arthritis allergic		1				1
Asphyxia		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenia	11	40
Asthenopia		2
Asthma		1
Asthmatic crisis		1
Asymptomatic COVID-19	1	3
Ataxia	1	1
Atelectasis		1
Atrial fibrillation		1
Axillary pain	1	3
Back pain	2	5
Balance disorder	1	3
Biliary colic		1
Bladder spasm		1
Bladder sphincter atony		2
Blepharospasm	1	1
Blister		1
Blood pressure increased	1	7
Blood pressure systolic increased	1	1
Body temperature decreased		1
Bradycardia		2
Bradyphrenia		1
Bronchiectasis		1
Bronchospasm		3
Burning sensation		1
Burning sensation mucosal		1
Bursitis		1
Cardiac tamponade		1
Carotid bruit		1
Cellulitis		1
Cerebellar syndrome		1
Cerebral venous thrombosis	1	1
Cerebrovascular accident	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
9	18	2	22
			2
	1		
			1
		1	3
		1	1
			1
			1
1	3		
2	3		2
1	2		1
			1
			1
			2
		1	1
			1
1	6		1
1	1		
	1		
			2
			1
			1
			3
			1
	1		
			1
			1
			1
			1
		1	1
		1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cervicobrachial syndrome	1	1	1	1		
Cheilitis		2				2
Chest discomfort		6		1		5
Chest pain	1	9			1	9
Chills	8	35	8	27		8
Choking sensation		2		1		1
Chorioretinopathy		1				1
Colitis ulcerative		1				1
Concomitant disease aggravated		1				1
Condition aggravated	2	5			2	5
Conjunctival haemorrhage		4				4
Constipation		2		2		
Cough	1	7	1	1		6
COVID-19	3	16		2	3	14
Craniocerebral injury		2				2
Cyanosis	1	1	1	1		
Deafness unilateral		1				1
Decreased appetite		3		1		2
Deep vein thrombosis	3	4			3	4
Demyelination		1				1
Dental caries		1		1		
Depressed level of consciousness		4				4
Depressed mood	1	1	1	1		
Dermatitis allergic	1	3			1	3
Dermatitis bullous		1				1
Dermatitis contact		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	4	23	4	10		13
Diarrhoea haemorrhagic		1				1
Diplopia	3	5	1	1	2	4
Discomfort		3		2		1
Disease recurrence		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention		1				1
Dizziness	6	44	5	17	1	27
Dizziness postural	1	1	1	1		
Drug eruption	1	1	1	1		
Drug ineffective	1	9			1	9
Drug interaction		1				1
Dry mouth		1				1
Dysaesthesia		3		1		2
Dysarthria		1		1		
Dyschromatopsia	1	1			1	1
Dysgeusia		3		1		2
Dysphagia		4		1		3
Dysphonia		2				2
Dyspnoea	3	23		1	3	22
Dyspnoea at rest		1				1
Dyspnoea exertional	1	2	1	1		1
Dysuria		1				1
Ear discomfort		1				1
Eczema herpeticum		1				1
Electrocardiogram QRS complex shortened		2				2
Electrocardiogram T wave inversion		1				1
Encephalitis	1	2			1	2
Epiglottitis		1				1
Epilepsy	1	2			1	2
Erythema	1	14		3	1	11
Erythema nodosum		1				1
Essential hypertension		1				1
Extensive swelling of vaccinated limb	1	1	1	1		
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Extrasystoles	1	2			1	2
Eye haemorrhage	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid oedema		2
Eye pain		3
Eye pruritus		3
Face injury		1
Face oedema		2
Facial bones fracture	1	2
Facial pain		1
Facial paralysis	2	10
Facial paresis	1	2
Faeces soft		1
Fall		1
Fatigue	10	27
Febrile convulsion	1	1
Feeling abnormal		2
Feeling cold		2
Feeling hot	2	5
Fibrin D dimer increased		2
Fibromyalgia	1	1
Flatulence	1	2
Flushing		1
Folate deficiency		1
Foreign body sensation in eyes		2
Gait disturbance	1	3
Gallbladder enlargement		1
Gastroenteritis	1	2
Gastrooesophageal reflux disease		1
Generalised tonic-clonic seizure		1
General physical health deterioration		2
Genital herpes		1
Giant papillary conjunctivitis		1
Gingival bleeding	1	1
Granulomatous liver disease		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
	1		2
	2		1
			1
			2
		1	2
	1		
	1		
7	16	3	11
		1	1
	1		1
	2		
2	2		3
			2
		1	1
1	2		
	1		
	1		
	2		
		1	3
			1
	1	1	1
			1
	1		1
	1		
1	1		1
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Guillain-Barre syndrome		1					1
Haematoma	2	3	2	2			1
Headache	26	106	22	54	4		52
Heart rate increased		1		1			
Hemidysaesthesia		1					1
Hemiparaesthesia		3					3
Hemiparesis		2					2
Hepatic cyst		1		1			
Herpes ophthalmic		1					1
Herpes simplex		1					1
Herpes zoster	3	19	1	5	2		14
Herpes zoster oticus		1					1
Herpes zoster reactivation		1					1
Hyperaemia		1		1			
Hyperaesthesia	1	2	1	1			1
Hyperfibrinogenaemia		1					1
Hyperglycaemia		1					1
Hyperhidrosis	1	3	1	1			2
Hypersensitivity		9					9
Hypertension	4	23	2	6	2		17
Hypertensive crisis		11					11
Hypertransaminasaemia		1		1			
Hypoacusis		3					3
Hypoaesthesia	1	7		1	1		6
Hypoaesthesia oral	1	2			1		2
Hypotension	3	6		1	3		5
Hypothermia	4	7			4		7
Hypothyroidism		1					1
Hypoxia		1					1
Ileus paralytic		1					1
Inappropriate schedule of product administration		1		1			
Incorrect route of product administration	1	2	1	2			

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Induration		1
Inflammation	2	5
Influenza		1
Injury	1	1
Insomnia		3
Intestinal ischaemia		1
Intestinal obstruction		1
Iridocyclitis	1	1
Ischaemic stroke		3
Jaw fracture		1
Joint range of motion decreased		1
Labyrinthitis		1
Lacrimation increased		3
Laryngeal erythema		1
Laryngeal oedema		5
Laryngeal pain		1
Laryngospasm		1
Lip oedema		4
Lip pruritus		1
Localised oedema		1
Local reaction		2
Loss of consciousness	1	6
Lymphadenitis	2	4
Lymphadenopathy	4	39
Lymphangitis		2
Malaise	11	47
Malnutrition		1
Mass		1
Maternal exposure timing unspecified	1	1
Mechanical urticaria		1
Mental impairment		2
Micturition urgency		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	2	1	3
			1
		1	1
	1		2
			1
			1
		1	1
			3
			1
			1
	1		2
			1
			5
			1
			1
			4
			1
			1
	1		1
		1	6
		2	4
	15	4	24
11	30		17
	1		
			1
1	1		
			1
			2
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	1	1			1	1
Migraine with aura		1				1
Mobility decreased		3				3
Monoplegia		1				1
Mouth swelling		1				1
Mouth ulceration		1				1
Movement disorder		1				1
Muscle contractions involuntary	1	1	1	1		
Muscle contracture		1		1		
Muscle spasms		1		1		
Muscular weakness		4		2		2
Musculoskeletal discomfort		2				2
Musculoskeletal disorder	1	1			1	1
Musculoskeletal pain		8		3		5
Myalgia	23	79	20	48	3	31
Myocardial infarction	1	1			1	1
Myositis		2				2
Nasal congestion	1	3	1	1		2
Nausea	16	53	16	33		20
Neck pain		4				4
Nervousness	1	3		1	1	2
Neuralgic amyotrophy	2	2			2	2
Neurogenic shock		1				1
Neutropenia		1				1
Night sweats	2	2	1	1	1	1
Noninfective gingivitis		1				1
Normochromic normocytic anaemia		1		1		
Nuchal rigidity		1				1
Ocular dysmetria	1	1	1	1		
Odynophagia	2	3	2	2		1
Oedema		1		1		
Oedema mouth		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral		4		1		3
Ophthalmic herpes zoster		1				1
Optic neuritis		1				1
Oral candidiasis	1	1	1	1		
Oral herpes		2		2		
Oral pruritus		1				1
Oropharyngeal discomfort		2				2
Oropharyngeal oedema		3				3
Oropharyngeal pain		2		2		
Oxygen saturation decreased	1	3		1	1	2
Pain	2	11	2	8		3
Pain in extremity	4	19	3	10	1	9
Pain in jaw		1		1		
Palatal oedema		2				2
Palatal swelling		1				1
Pallor		2		1		1
Palpitations		6		2		4
Panniculitis		1				1
Paraesthesia	5	26	1	5	4	21
Paraesthesia oral	1	6	1	2		4
Paraparesis		2				2
Partial seizures		1				1
Pericarditis		3				3
Periorbital haematoma		1				1
Peripheral coldness	1	2	1	1		1
Peripheral paralysis		1				1
Peripheral swelling		1				1
Persistent generalised lymphadenopathy	1	1			1	1
Petechiae		3				3
Pharyngeal erythema		3				3
Pharyngitis		1				1
Pharyngotonsillitis	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Phlebitis		1		1		
Phlebitis superficial	1	1	1	1		
Photophobia	1	3	1	1		2
Photopsia	1	1	1	1		
Pigmentation disorder		1		1		
Pityriasis rosea		1				1
Pleuropericarditis		1				1
Pneumonia		3				3
Pneumonia aspiration	1	2			1	2
Polyarthritis		1				1
Poor peripheral circulation	1	1	1	1		
Poor quality sleep		1				1
Post viral fatigue syndrome		1				1
Presyncope	1	8			1	8
Pruritus	3	24	3	7		17
Psoriasis		1				1
Pulmonary embolism	3	5			3	5
Pyrexia	43	144	40	90	3	54
Rash		12		2		10
Rash erythematous		2				2
Rash maculo-papular		1				1
Rash pruritic		2				2
Raynaud's phenomenon		1				1
Reaction to excipient		1				1
Rectal haemorrhage		1				1
Rectal tenesmus		1				1
Renal cyst		1		1		
Renal impairment		1				1
Respiratory arrest		1				1
Respiratory disorder		2				2
Respiratory distress		3				3
Respiratory failure		3				3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retinal artery occlusion	1	1
Rhinalgia		1
Rhinorrhoea	2	2
SARS-CoV-2 antibody test negative		1
Sensation of foreign body		1
Sensory disturbance		1
Septic arthritis staphylococcal	1	1
Shoulder injury related to vaccine administration		1
Sinus tachycardia	2	3
Skin lesion		1
Skin reaction		1
Somnolence		2
Spasmodic dysphonia		1
Speech disorder		1
Spinal pain		1
Subarachnoid haemorrhage	1	1
Sudden death		3
Sudden visual loss	1	1
Superinfection bacterial		1
Supraventricular tachycardia		1
Swelling face		1
Swollen tongue		1
Syncope	4	20
Systemic inflammatory response syndrome		1
Tachycardia	3	17
Temperature regulation disorder	3	8
Tendonitis	1	2
Tenosynovitis		1
Tension headache		2
Throat irritation		7
Throat tightness		1
Thrombophlebitis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
2	2		
	1		
			1
			1
		1	1
	1		
	1	2	2
			1
			1
			2
	1		
	1		
			1
		1	1
			3
		1	1
			1
			1
			1
		4	20
			1
	2	3	15
3	6		2
1	1		1
			1
	1		1
	1		6
			1
1	1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombophlebitis superficial	1	2			1	2
Tic		1				1
Tinnitus	1	5		2	1	3
Tongue discomfort		1		1		
Tongue eruption		1		1		
Tongue oedema		5				5
Tongue pruritus	1	2	1	1		1
Tonic clonic movements		1				1
Transient global amnesia		1				1
Transient ischaemic attack	1	2			1	2
Tremor		2				2
Type IV hypersensitivity reaction		1				1
Underdose		2		2		
Upper respiratory tract infection		1				1
Urinary retention		1				1
Urticaria	5	16	4	5	1	11
Uvulitis		1				1
Vaccination complication		2		1		1
Vaccination failure	2	2			2	2
Vaccination site cellulitis		2				2
Vaccination site erosion		1		1		
Vaccination site erythema		1		1		
Vaccination site haematoma	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration	1	2	1	1		1
Vaccination site inflammation	6	14	5	9	1	5
Vaccination site joint erythema		3		2		1
Vaccination site joint inflammation	1	1	1	1		
Vaccination site joint swelling		1		1		
Vaccination site lymphadenopathy	2	5	1	2	1	3
Vaccination site movement impairment		1				1

\* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site oedema		1					1
Vaccination site pain	21	53	20	39	1		14
Vaccination site paraesthesia	1	1	1	1			
Vaccination site reaction		1					1
Vaccination site swelling		3		2			1
Vasculitis	1	1			1		1
Vertigo		3		1			2
Vision blurred		4		1			3
Visual acuity reduced		1					1
Visual impairment		1					1
Vitamin D deficiency		1		1			
Vitreous detachment		2					2
Vitreous floaters		1					1
Volvulus		1					1
Vomiting	5	26	5	13			13
Wheezing		1					1
White blood cell count decreased		1					1
Wound	1	1			1		1
Wrong technique in product usage process		1		1			
Yawning		1		1			
	383	1,757	260	685	123		1072

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower		1		1		
Acute generalised exanthematous pustulosis		1				1
Acute kidney injury		1				1
Acute myocardial infarction	1	1			1	1
Acute respiratory failure		1				1
Agitation		1				1
Alcohol poisoning		1				1
Anal sphincter atony		1				1
Angioedema		2				2
Antibody test abnormal		1		1		
Aphasia	1	1			1	1
Arthralgia		2		1		1
Asthenia	1	4	1	3		1
Asymptomatic COVID-19		1		1		
Back pain		1		1		
Blepharitis		1		1		
Blood chloride decreased		1		1		
Blood pressure decreased		1				1
Blood sodium decreased		1		1		
Bradycardia		1				1
Bradykinesia		1				1
Breath sounds abnormal		1				1
Bronchospasm		1				1
Cardiac failure acute		1				1
Cardio-respiratory arrest		1				1
Cellulitis	1	1			1	1
Cerebral haematoma		1				1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident		1				1
Chills		1				1
Chronic respiratory failure		1				1
Condition aggravated		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state		3		1		2
Conjunctival haemorrhage	1	1			1	1
Contusion		1		1		
Coordination abnormal		1		1		
Cough	1	2	1	2		
COVID-19	2	9	1	2	1	7
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Death		2				2
Decreased appetite	1	1	1	1		
Dehydration		1		1		
Depressed level of consciousness	1	3			1	3
Diabetes mellitus		1				1
Diarrhoea	5	11	3	6	2	5
Disorientation		1		1		
Dizziness		5		1		4
Drug ineffective	1	2			1	2
Dyslexia	1	1			1	1
Dyspnoea	1	6			1	6
Dysstasia		1		1		
Eczema		1		1		
Encephalitis		1				1
Encephalopathy		1				1
Epilepsy		1				1
Erythema		1		1		
Extensive swelling of vaccinated limb		1		1		
Face oedema		1				1
Facial paralysis		1				1
Fall		6		4		2
Fatigue	2	3			2	3
Febrile convulsion		1				1
Fibrin D dimer increased		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gait disturbance		1					1
Gait inability	1	1			1		1
Gastrointestinal disorder	1	1	1	1			
Generalised tonic-clonic seizure		1					1
Gingival swelling	1	1			1		1
Haematuria		1		1			
Haemoglobin decreased		1		1			
Headache	3	8	3	5			3
Head injury		1		1			
Hemiparaesthesia		1					1
Herpes ophthalmic	1	1			1		1
Herpes zoster	1	3		1	1		2
Hot flush		1					1
Hyperhidrosis		1					1
Hypersensitivity		1					1
Hypertension	2	6	1	1	1		5
Hypertransaminasaemia		1					1
Hypoaesthesia		1		1			
Hypotension	2	3		1	2		2
Hypoxia		3					3
Incoherent		1					1
Incorrect route of product administration	1	1	1	1			
Increased bronchial secretion		1					1
Infection	1	1	1	1			
Inflammatory bowel disease	1	1			1		1
Influenza like illness		1		1			
Ischaemic stroke	1	2			1		2
Laryngeal oedema	1	1			1		1
Leukoencephalopathy		1					1
Ligament sprain		1		1			
Lip oedema		1					1
Lip swelling	1	1			1		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness	1	5			1	5
Lung disorder		1				1
Lung infiltration		1		1		
Lymphangitis		1				1
Lymphocyte percentage decreased		1		1		
Lymphopenia		1		1		
Malaise	3	7	3	4		3
Mobility decreased	1	1	1	1		
Multiple organ dysfunction syndrome		1				1
Muscular weakness		2		1		1
Myalgia	2	4	2	3		1
Myocardial rupture	1	1			1	1
Myocarditis		1				1
Nasal congestion		1		1		
Nausea		2		2		
Neutrophil count increased		1		1		
Neutrophilia		1		1		
Neutrophil percentage increased		1		1		
Oedema		1		1		
Oedema peripheral		1				1
Off label use		1		1		
Ophthalmic herpes zoster		1				1
Overdose		4		4		
Oxygen saturation decreased		3				3
Pain	2	3	1	1	1	2
Pallor		1				1
Palpitations	1	1	1	1		
Pericardial haemorrhage	1	1			1	1
Peripheral coldness		1				1
Peripheral ischaemia		1				1
Petechiae	1	2	1	2		
Petit mal epilepsy		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia	1	5
Portal vein thrombosis	1	1
Product preparation issue		4
Product use issue		1
Pruritus		1
Pulmonary haemorrhage	1	1
Pulmonary thrombosis	1	1
Pulse abnormal		1
Pyrexia	16	39
Rash		3
Renal failure	1	2
Renal impairment		1
Respiratory distress		1
Retinal vein thrombosis	1	1
Rhinorrhoea		1
Salivary hypersecretion	1	1
Seizure	1	4
Sensation of foreign body	1	1
Silent thyroiditis	1	1
Sinus tachycardia		1
Skin necrosis		1
Skin reaction		1
Slow speech		1
Somnolence		1
Status epilepticus		1
Sudden cardiac death	1	1
Sudden death	1	2
Syncope	1	9
Tachypnoea		1
Tension headache	1	1
Thrombocytopenia	1	1
Thrombophlebitis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	5
		1	1
	4		
	1		
			1
		1	1
		1	1
			1
13	24	3	15
			3
		1	2
			1
			1
	1	1	1
		1	1
		1	4
		1	1
		1	1
			1
			1
	1		
			1
		1	1
		1	2
		1	9
			1
1	1		
		1	1
		1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue coated		1				1
Tremor		1				1
Urinary sediment present		1		1		
Urinary tract infection		3				3
Urticaria	1	3	1	1		2
Vaccination failure		1				1
Vaccination site inflammation	1	2	1	2		
Vaccination site joint erythema	1	2	1	1		1
Vaccination site pain	1	8	1	7		1
Vaccination site rash	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vision blurred		1				1
Vomiting	4	8	2	4	2	4
White blood cell count increased		1		1		
	94	342	44	132	50	210

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2		1	1	1
Abdominal pain	2	4	2	2		2
Abdominal pain upper	1	1			1	1
Activated partial thromboplastin time prolonged	1	1			1	1
Activated partial thromboplastin time shortened	1	1	1	1		
Acute coronary syndrome	1	1			1	1
Acute hepatic failure	1	1			1	1
Acute kidney injury	1	4			1	4
Acute leukaemia		1				1
Acute myocardial infarction	2	3			2	3
Acute psychosis	1	1			1	1
Acute pulmonary oedema	1	1			1	1
Acute respiratory distress syndrome		1				1
Acute respiratory failure	5	10			5	10
Ageusia	1	1			1	1
Agitation	3	3			3	3
Amnesia		2		2		
Anaemia	2	2			2	2
Anal incontinence	1	2	1	1		1
Anaphylactic reaction	1	6			1	6
Angioedema	2	4			2	4
Angular cheilitis		1		1		
Anxiety	1	1			1	1
Aortic valve calcification	1	1			1	1
Apathy	1	1			1	1
Aphasia	1	4		1	1	3
Apnoea		1				1
Arrhythmia	1	2			1	2
Arthralgia	3	5	1	3	2	2
Aspiration		1				1
Asthenia	9	16	5	8	4	8
Asthenopia	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	2	11	1	3	1	8
Atelectasis		1				1
Atrial fibrillation	4	9			4	9
Atrioventricular block first degree		1		1		
Autoantibody negative		1				1
Autoimmune haemolytic anaemia	1	1			1	1
Autoimmune hepatitis	1	1			1	1
Back pain		1		1		
Bacteraemia	1	1			1	1
Bacterial disease carrier		1				1
Bacterial test	1	1			1	1
Balance disorder	3	4	1	2	2	2
Basal ganglia stroke	1	1			1	1
Basilar artery thrombosis	1	1			1	1
Bedridden	1	1			1	1
Biliary cyst	1	1	1	1		
Blister	1	1	1	1		
Blood bicarbonate decreased	1	1			1	1
Blood creatinine increased	1	1	1	1		
Blood fibrinogen increased	1	1	1	1		
Blood gases abnormal	1	1			1	1
Blood glucose increased		1		1		
Blood lactate dehydrogenase increased	1	1			1	1
Blood pressure abnormal	1	1			1	1
Blood pressure diastolic decreased		1				1
Blood pressure increased		1		1		
Blood thyroid stimulating hormone increased		1		1		
Blood urea increased	1	1			1	1
Body temperature decreased	1	1			1	1
Bradycardia		3				3
Bradyphrenia	3	3	2	2	1	1
Breast haematoma	1	1			1	1

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\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bronchial hyperreactivity		1					1
Bronchitis		1					1
Bronchospasm	3	6			3		6
Bundle branch block left	1	1			1		1
Cachexia		1					1
Cardiac arrest	1	3			1		3
Cardiac disorder	1	2	1	1			1
Cardiac failure	8	16			8		16
Cardiac failure acute	2	5			2		5
Cardiac failure congestive	2	2			2		2
Cardiomegaly	2	2			2		2
Cardio-respiratory arrest	3	11			3		11
Cardio-respiratory distress		1					1
Cardiothoracic ratio increased	1	1			1		1
Cell death	1	1			1		1
Cellulitis	1	2			1		2
Cellulitis staphylococcal		1					1
Cephalhaematoma	1	1			1		1
Cerebellar infarction	1	1			1		1
Cerebral haematoma	2	2			2		2
Cerebral haemorrhage	4	4			4		4
Cerebral infarction	2	2			2		2
Cerebral venous sinus thrombosis	1	1			1		1
Cerebrovascular accident	3	5			3		5
Cerebrovascular disorder	1	1			1		1
Chest discomfort		1					1
Chest injury		1					1
Chest pain	1	3			1		3
Chills	2	5	1	1	1		4
Choking		1					1
Cholestasis	1	1			1		1
Chronic kidney disease	2	2			2		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic obstructive pulmonary disease	1	1			1	1
Chronic respiratory failure		1				1
Circadian rhythm sleep disorder	1	1			1	1
Circulatory collapse	1	1			1	1
Clostridium difficile colitis		1				1
Cognitive disorder	3	4		1	3	3
Condition aggravated	1	3			1	3
Confusional state	4	9	1	2	3	7
Conjunctival haemorrhage	1	1			1	1
Conjunctival hyperaemia	1	1			1	1
Constipation	4	5	2	2	2	3
Coombs positive haemolytic anaemia	1	1			1	1
Coordination abnormal	1	1			1	1
Cough	2	7	2	3		4
COVID-19	12	23	8	8	4	15
COVID-19 pneumonia	2	10			2	10
Craniocerebral injury	2	2			2	2
C-reactive protein increased	1	2	1	2		
Cyanosis		4		1		3
Death	1	4			1	4
Decreased appetite	3	3	1	1	2	2
Deep vein thrombosis	8	10			8	10
Dehydration		1		1		
Delirium	3	3			3	3
Delusion	1	1			1	1
Depressed level of consciousness	2	9			2	9
Depressed mood		1		1		
Dermatitis allergic	1	1			1	1
Dermatitis bullous		1				1
Diarrhoea	14	26	10	16	4	10
Dilatation atrial	1	1			1	1
Dilatation ventricular	1	1			1	1

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\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort	2	3			2	3
Disease recurrence	3	3			3	3
Disorientation	5	12	1	4	4	8
Dizziness	6	9	2	4	4	5
Drug ineffective	3	12			3	12
Drug interaction		1		1		
Dry mouth	1	1			1	1
Duodenal ulcer haemorrhage		1				1
Dysarthria	1	5		2	1	3
Dyskinesia		1				1
Dyspepsia	1	1			1	1
Dysphagia	4	4	1	1	3	3
Dyspnoea	6	27	1	3	5	24
Dyspnoea exertional		2		2		
Dysuria	2	2	1	1	1	1
Ear pain	1	1			1	1
Eating disorder		1		1		
Electrocardiogram normal	1	1			1	1
Electrocardiogram QRS complex prolonged		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST-T change		1				1
Electrolyte imbalance		1				1
Embolic stroke	2	2			2	2
Embolism		1				1
Enterococcal infection	1	1			1	1
Epidermal necrosis		1				1
Epistaxis	1	2			1	2
Erythema	3	5	3	5		
Escherichia infection	1	2			1	2
Euphoric mood		2		1		1
Eyelid oedema	1	2			1	2
Face oedema	1	2			1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	3
		3	3
1	4	4	8
2	4	4	5
		3	12
	1		
		1	1
			1
	2	1	3
			1
		1	1
1	1	3	3
1	3	5	24
	2		
1	1	1	1
		1	1
	1		
		1	1
			1
			1
			1
		2	2
			1
		1	1
			1
		1	2
3	5		
		1	2
	1		1
		1	2
		1	2

\* I=Interval, C=Cumulative  
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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis	4	5			4	5
Faeces soft	1	1	1	1		
Fall	4	8		2	4	6
Fatigue		7		5		2
Febrile convulsion		1				1
Feeling abnormal	1	1	1	1		
Feeling cold		1				1
Feeling hot	2	3	2	3		
Femur fracture	1	1			1	1
Fibrin D dimer increased	3	3	1	1	2	2
Fibrinolysis	1	1			1	1
Fluid overload	1	1			1	1
Flushing		1				1
Gait disturbance	1	4		1	1	3
Gait inability	1	4		2	1	2
Gamma-glutamyltransferase increased		1		1		
Gastric disorder		1				1
Gastritis	1	1			1	1
Gastrointestinal haemorrhage	2	3			2	3
Gaze palsy		1				1
Generalised tonic-clonic seizure	2	4			2	4
General physical health deterioration	1	4	1	2		2
Genital blister		1		1		
Giant cell arteritis	1	1			1	1
Glomerular filtration rate decreased	1	1	1	1		
Guillain-Barre syndrome	4	4			4	4
Haematocrit decreased		1		1		
Haematoma	3	4	1	2	2	2
Haematoma muscle	2	3			2	3
Haematuria	2	2			2	2
Haemoglobin decreased		2		1		1
Haemoptysis	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Haemorrhage		1					1
Haemorrhage intracranial	1	1			1		1
Haemorrhagic stroke	1	2			1		2
Hallucination	1	2			1		2
Hallucination, auditory	1	1			1		1
Hallucinations, mixed	1	1			1		1
Hallucination, visual	1	1			1		1
Headache	8	15	3	9	5		6
Head discomfort	1	1			1		1
Head injury	1	1			1		1
Heart rate decreased	1	1			1		1
Hemihyperaesthesia	1	1			1		1
Hemiparesis	1	2			1		2
Hemiplegia	2	2			2		2
Hepatic cyst	1	1	1	1			
Hepatic steatosis	1	1			1		1
Hepatitis acute	1	2			1		2
Hepatitis cholestatic	1	1			1		1
Herpes zoster	10	11	1	1	9		10
Herpes zoster cutaneous disseminated	1	2			1		2
Hiatus hernia	2	3		1	2		2
Hypercholesterolaemia	1	1	1	1			
Hyperglycaemia	3	3			3		3
Hyperhidrosis		2		2			
Hyperkalaemia	1	1			1		1
Hypernatraemia		3		1			2
Hypersensitivity	1	2	1	1			1
Hypersensitivity vasculitis	2	2			2		2
Hypersexuality		1					1
Hypertension	2	3			2		3
Hypertensive crisis	2	5			2		5
Hypertensive emergency	1	1			1		1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive encephalopathy	1	1			1	1
Hypertensive urgency	1	2			1	2
Hypoacusis		1				1
Hypoaesthesia	1	1			1	1
Hypoaesthesia eye	1	1			1	1
Hypokalaemia		1				1
Hyponatraemia	2	3			2	3
Hyporesponsive to stimuli		1				1
Hypotension	3	10	1	3	2	7
Hypovolaemic shock		1				1
Hypoxia	1	8			1	8
Ileus paralytic	1	1			1	1
Ill-defined disorder	1	1			1	1
Immobilisation syndrome	1	1	1	1		
Immune system disorder		1				1
Immune thrombocytopenia	1	2			1	2
Inappropriate schedule of product administration		2		2		
Incoherent	1	1			1	1
Incorrect dose administered	1	2	1	2		
Incorrect route of product administration	1	2	1	2		
Infection		1				1
Infective exacerbation of bronchiectasis	1	1			1	1
Inflammatory bowel disease		1				1
Injury	1	1	1	1		
Insomnia	1	1			1	1
Interstitial lung disease		1				1
Intestinal ischaemia		1				1
Intestinal obstruction	1	2			1	2
Ischaemia	1	1			1	1
Ischaemic cerebral infarction		1				1
Ischaemic stroke	9	13			9	13
Joint injury	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Kaposi's sarcoma AIDS related		1					1
Keratitis	1	1			1		1
Lacunar stroke		1					1
Large intestine infection	1	1			1		1
Laryngospasm		1		1			
Lethargy	1	1			1		1
Limb discomfort	1	1	1	1			
Lip oedema	1	1			1		1
Liver function test abnormal	1	1			1		1
Localised infection		1					1
Localised oedema	1	1			1		1
Loss of consciousness	1	3			1		3
Lower respiratory tract infection		1					1
Lung disorder		1					1
Lung infiltration		2		1			1
Lymphocyte count decreased	1	1	1	1			
Malaise	15	31	9	15	6		16
Mean cell haemoglobin concentration decreased	1	1	1	1			
Melaena	1	3			1		3
Meningitis herpes	1	1			1		1
Mental disorder		1					1
Mental impairment		1					1
Micturition urgency	1	1			1		1
Miosis		1					1
Mobility decreased	2	3		1	2		2
Mood altered		1					1
Morganella infection	1	1			1		1
Multiple organ dysfunction syndrome		3					3
Muscle contractions involuntary		1		1			
Muscle rigidity	1	1			1		1
Muscle spasms		1					1
Musculoskeletal pain	2	2			2		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	3	6		2	3	4
Myocardial infarction		1				1
Myocardial ischaemia	1	1			1	1
Myositis	1	1			1	1
Nasal herpes		1				1
Nausea	3	5	2	2	1	3
Neck pain	1	1			1	1
Necrosis		1				1
Neoplasm		1		1		
Nervous system disorder	1	2			1	2
Neuralgia	1	1	1	1		
Neuralgic amyotrophy	1	1			1	1
Neutrophil count increased	1	2	1	2		
Neutrophilia	1	1			1	1
N-terminal prohormone brain natriuretic peptide increased	1	1			1	1
Odynophagia		2				2
Oedema peripheral	5	5	2	2	3	3
Off label use	1	3	1	3		
Oral disorder		1				1
Oral mucosal blistering		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	1			1	1
Orthopnoea	1	1			1	1
Overdose	1	2	1	2		
Oxygen saturation decreased	2	8			2	8
Pain	1	3			1	3
Pain in extremity	3	3	2	2	1	1
Pallor		1				1
Palpitations		1				1
Pancreatitis chronic	1	1			1	1
Pancytopenia		1				1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	1	2		1	1	1
Paraesthesia oral		1				1
Partial seizures		1				1
Patella fracture	1	1			1	1
PCO2 decreased	1	1	1	1		
Penile discomfort		1		1		
Peripheral coldness	2	2	2	2		
Peripheral embolism	1	1			1	1
Peripheral ischaemia		1				1
Peripheral swelling	2	2	2	2		
Petechiae	1	1			1	1
Petit mal epilepsy		3				3
Platelet count decreased	1	1			1	1
Platelet count increased		1		1		
Pleural effusion	1	4			1	4
Pleuritic pain	1	1	1	1		
Pneumonia	2	5			2	5
Pneumonia aspiration	1	2			1	2
Pneumonitis	1	2			1	2
Pneumothorax	1	1			1	1
PO2 decreased	2	2	2	2		
Pollakiuria	1	1			1	1
Polyuria	1	1			1	1
Poor quality product administered	5	5	5	5		
Positron emission tomogram	1	1			1	1
Prerenal failure	1	1			1	1
Presyncope	1	2	1	1		1
Productive cough		1		1		
Product preparation error	5	5	5	5		
Product use issue		1		1		
Prothrombin level decreased	1	1			1	1
Prothrombin time prolonged	2	3	1	2	1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	3	5		1	3	4
Psychomotor hyperactivity		2		1		1
Pulmonary embolism	22	26			22	26
Pulmonary hypertension	1	1			1	1
Pulmonary infarction	1	2			1	2
Pulmonary sepsis	1	1			1	1
Pulmonary thrombosis		1				1
Pyrexia	40	87	31	53	9	34
Rales	1	1			1	1
Rash	3	5	1	2	2	3
Rash maculo-papular	1	1			1	1
Rash pruritic	1	1			1	1
Rectal haemorrhage	1	3			1	3
Red blood cell sedimentation rate increased		1		1		
Renal cyst	1	1	1	1		
Renal failure	2	3			2	3
Renal impairment	1	1			1	1
Respiration abnormal		1				1
Respiratory acidosis	1	2			1	2
Respiratory disorder	1	1	1	1		
Respiratory distress	5	6			5	6
Respiratory failure	4	7			4	7
Respiratory tract infection	3	6			3	6
Restlessness	1	4		2	1	2
Retinal artery occlusion	1	1			1	1
Rhinitis	4	4	4	4		
Rib fracture	1	1			1	1
SARS-CoV-2 test positive	2	3	2	3		
Scab	1	1	1	1		
Scoliosis	1	1			1	1
Seizure	2	4			2	4
Sepsis		2				2

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Septic shock	2	2			2	2
Severe acute respiratory syndrome		1				1
Sinus arrest		1				1
Skin lesion		1		1		
Skin necrosis		1				1
Skin ulcer	2	4	2	3		1
SLE arthritis		1				1
Slow speech	1	1	1	1		
Sneezing	1	1	1	1		
Somnolence	1	4	1	2		2
Speech disorder	1	1			1	1
Spinal osteoarthritis	1	1			1	1
Staphylococcal infection	1	1			1	1
Stupor		1				1
Subcutaneous haematoma	1	1			1	1
Sudden death	3	11			3	11
Suicide attempt		1				1
Swollen tongue		1				1
Syncope	7	8			7	8
Tachyarrhythmia		1				1
Tachycardia		5		2		3
Tachypnoea		4		2		2
Thalamic infarction	1	1			1	1
Thrombocytopenia	5	5			5	5
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	2	2			2	2
Thrombotic microangiopathy		1				1
Thrombotic thrombocytopenic purpura		1				1
Thyroxine decreased		1		1		
Toxic skin eruption	1	1			1	1
Transient ischaemic attack	3	5			3	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tremor		1		1			
Tricuspid valve incompetence	1	1		1		1	1
Troponin I increased	1	1				1	1
Troponin T increased	1	2				1	2
Upper gastrointestinal haemorrhage	1	1				1	1
Upper limb fracture	1	2		1		1	1
Urinary incontinence	1	1	1	1			
Urinary retention		1					1
Urinary tract infection	2	6		1		2	5
Urinary tract infection pseudomonal	1	1				1	1
Urosepsis	1	1				1	1
Urticaria	6	6	4	4		2	2
Vaccination complication		1					1
Vaccination failure	3	13				3	13
Vaccination site erythema	4	4	4	4			
Vaccination site haematoma		1					1
Vaccination site hypoaesthesia	1	1				1	1
Vaccination site induration	2	2	2	2			
Vaccination site inflammation		5		5			
Vaccination site joint erythema	1	2	1	2			
Vaccination site pain	3	7	3	7			
Vaccination site rash	1	1				1	1
Vaccination site swelling	1	1	1	1			
Vaccination site warmth	1	2	1	2			
Vasoplegia syndrome	1	1				1	1
Venous thrombosis limb	2	3				2	3
Ventricular dysfunction	1	1				1	1
Ventricular enlargement	1	1				1	1
Ventricular fibrillation	1	1				1	1
Vertigo		1					1
Viral keratouveitis	1	1				1	1
Vision blurred	1	1				1	1

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Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	1	1			1	1
Vomiting	15	28	11	15	4	13
Wheezing	3	3	3	3		
White blood cell count increased		1		1		
X-ray abnormal	1	1			1	1
	669	1,261	193	354	476	907

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain upper		1				1
Allergic oedema		1				1
Aphonia		1				1
Arthralgia	7	15	6	13	1	2
Arthritis reactive	1	1			1	1
Asthenia	3	4		1	3	3
Asymptomatic COVID-19		2				2
Back pain		1		1		
Blood glucose increased		1				1
Blood pressure abnormal		1		1		
Blood pressure increased		1				1
Bradyphrenia		1		1		
Bruxism		1		1		
Carotid bruit		1				1
Cellulitis		1				1
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain		3				3
Chills	3	6	3	6		
Confusional state		1				1
Conjunctival haemorrhage		1				1
Cough		3		1		2
COVID-19	4	19	2	5	2	14
Diabetes mellitus		1				1
Diabetic ketoacidosis		1				1
Diarrhoea	2	7	2	5		2
Discomfort	1	2	1	2		
Disease recurrence		1				1
Dizziness	4	10	4	6		4
Drug ineffective	2	16			2	16
Dry mouth		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysgeusia		1
Dysphonia		1
Dyspnoea	1	5
Epistaxis	1	2
Erythema		1
Exposure during pregnancy		1
Exposure via breast milk	1	3
Extensive swelling of vaccinated limb	1	1
Eyelid oedema		1
Facial paralysis		2
Fatigue	5	19
Feeling abnormal		1
Feeling hot	1	3
Foetal heart rate abnormal		1
Food allergy		1
Gastric disorder	1	1
Gastritis	1	1
Gastroenteritis	1	1
Gingival bleeding		1
Gingivitis		1
Headache	6	27
Heart rate increased		1
Hemiparaesthesia	1	1
Hyperhidrosis		1
Hypersensitivity	2	3
Hypertension		4
Hypertensive crisis	1	1
Hypoaesthesia		2
Hypoaesthesia oral		1
Inappropriate schedule of product administration	2	3
Incorrect dose administered		1
Inflammation	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
		1	5
1	1		1
			1
	1		
1	3		
1	1		
			1
			2
4	13	1	6
	1		
1	3		
			1
			1
1	1		
1	1		
1	1		
			1
	1		
6	23		4
	1		
		1	1
			1
1	1	1	2
	1		3
		1	1
	2		
	1		
2	3		
	1		
1	1		

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\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza	1	1
Influenza like illness		1
Insomnia	1	1
Jaw disorder		1
Loss of consciousness		2
Lymphadenitis		1
Lymphadenopathy		6
Malaise	5	15
Maternal exposure during pregnancy	1	3
Medication error		1
Muscle contracture		1
Muscle spasms		1
Muscle tightness		1
Muscular weakness		1
Musculoskeletal pain	1	2
Myalgia	6	17
Myoclonus		1
Nasal congestion	1	2
Nasopharyngitis		1
Nausea		4
Neoplasm	1	1
No adverse event	1	1
Oedema peripheral		1
Off label use		2
Oral discomfort		1
Oropharyngeal pain		1
Pain		1
Pain in extremity	1	3
Palpitations		3
Panic reaction		1
Paraesthesia	2	7
Paraesthesia oral		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1		
1	1		
	1		
			2
			1
	4		2
4	13	1	2
1	2		1
	1		
	1		
	1		
			1
1	1		1
6	12		5
			1
1	2		
	1		
	3		1
1	1		
1	1		
			1
	2		
	1		
	1		
	1		
1	3		
			3
			1
1	3	1	4
	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral sensory neuropathy	1	1
Peripheral swelling		1
Pertussis		2
Pleuritic pain		1
Pneumonia	1	1
Presyncope		1
Product use issue		3
Pruritus	1	3
Pulmonary embolism		1
Pulmonary thrombosis	1	1
Pyrexia	10	30
Rash	2	4
Rash macular	1	1
Rash pruritic	1	1
Respiratory arrest		1
Respiratory distress		1
SARS-CoV-2 antibody test negative		1
SARS-CoV-2 antibody test positive		2
SARS-CoV-2 test positive		2
Seizure		1
Sense of oppression		1
Serology negative		1
Skin lesion		1
Skin tightness		1
Somnolence		2
Speech disorder		1
Stomatitis		1
Suspected COVID-19	1	1
Syncope		2
Tachycardia	2	7
Temperature intolerance	1	1
Tenderness		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
			2
			1
		1	1
			1
	3		
	1	1	2
			1
		1	1
10	22		8
1	2	1	2
		1	1
		1	1
			1
	1		
	2		
	2		
			1
			1
	1		
	1		
	1		
	2		
			1
	1		
		1	1
			2
2	2		5
1	1		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tension headache		2		1			1
Throat irritation		1		1			
Tongue eruption		1		1			
Tongue pruritus		1		1			
Tuberculosis		1					1
Urinary tract infection		1		1			
Urine output decreased		1		1			
Vaccination failure	1	1			1		1
Vaccination site inflammation	3	4	3	4			
Vaccination site joint erythema		1		1			
Vaccination site lymphadenopathy	1	2	1	1			1
Vaccination site movement impairment	1	1	1	1			
Vaccination site pain	4	16	4	14			2
Vaccination site rash	1	1	1	1			
Vaccination site reaction	1	1	1	1			
Vomiting	3	5	3	5			
Wrong technique in product usage process	1	1	1	1			
	112	408	87	246	25		162

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**SWAZILAND**

Age Range

**65 - 79 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
Angioedema		1				1
Death		1				1
Dermatitis allergic		1		1		
Dyspnoea		1		1		
Headache		1		1		
Influenza like illness		1		1		
Nasopharyngitis		1		1		
Pyrexia		1		1		
Skin swelling		1		1		
		10		7		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SWEDEN**

Age Range

**Less than or equal to 17 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Feeling abnormal		1		1
Nausea		1		1
Peripheral swelling		1		1
Pharyngeal swelling		1		1
Rash		1		1
Vaccination site movement impairment		1		1
		6		6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain upper		2				2
Abnormal dreams	1	1	1	1		
Abortion spontaneous		1				1
Acne		1		1		
Allodynia		1		1		
Anaphylactic reaction	1	4			1	4
Anxiety		1		1		
Arrhythmia		1				1
Arthralgia	1	6		2	1	4
Asthenia	1	1	1	1		
Axillary pain		3		3		
Back pain		3		1		2
Balance disorder	1	1	1	1		
Blindness	1	1			1	1
Blood pressure decreased		1				1
Blood pressure increased	1	2			1	2
Body temperature increased		1		1		
Burning sensation		1				1
Cardiac arrest	1	1			1	1
Chest pain		3		1		2
Chills	1	15		9	1	6
Concussion	1	1	1	1		
Condition aggravated	1	2			1	2
Confusional state		1				1
Cough	1	3		2	1	1
COVID-19		2		1		1
Decreased appetite		1				1
Diarrhoea	1	5	1	3		2
Discomfort	1	1			1	1
Disease recurrence		2		1		1
Disturbance in attention		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Dizziness	1	12
Drug ineffective		1
Dry mouth		1
Dysphagia	2	2
Dyspnoea	3	10
Dysstasia		1
Epilepsy	1	1
Epistaxis		1
Eye inflammation		1
Facial paralysis		2
Facial paresis		2
Fatigue	4	25
Feeding disorder	1	1
Feeling abnormal	1	1
Feeling cold		1
Feeling hot	1	5
Feeling of body temperature change		1
Fluid retention		1
Flushing		1
Furuncle		1
Gastric disorder		1
Gastroenteritis	1	1
Glossodynia		1
Haematoma		1
Haemorrhage	1	1
Hallucination, auditory		1
Headache	3	41
Head discomfort	1	1
Heart rate increased		4
Heart rate irregular		1
Hot flush		1
Hyperhidrosis		4

Spontaneous			
Nonserious		Serious	
I	C	I	C
	7	1	5
			1
			1
		2	2
	2	3	8
			1
		1	1
	1		
			1
			2
			2
1	17	3	8
1	1		
		1	1
	1		
	3	1	2
			1
			1
			1
			1
	1		
		1	1
	1		
			1
		1	1
			1
2	30	1	11
		1	1
			4
	1		
	1		
	2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	1	3		1	1	2
Hypersomnia-bulimia syndrome		1				1
Hyperventilation		1				1
Hypoacusis		1				1
Hypoaesthesia	1	9		2	1	7
Hypoaesthesia oral		1		1		
Immune thrombocytopenia		1				1
Initial insomnia		1				1
Insomnia		2		2		
Joint stiffness		1		1		
Lip swelling		1				1
Local reaction		1		1		
Lymphadenopathy		2		2		
Lymph node pain		1		1		
Malaise	1	7		3	1	4
Metrorrhagia		1				1
Muscle contractions involuntary		1				1
Muscle spasms	1	3			1	3
Muscle twitching		3				3
Muscular weakness	1	5			1	5
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness		1		1		
Myalgia	3	13	1	7	2	6
Nasal congestion		2		1		1
Nasopharyngitis	1	1			1	1
Nausea	1	13	1	7		6
Neck pain		1		1		
Neuralgia	1	1	1	1		
Night sweats		1		1		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	5	1	3
1	11		3
3	17	1	10
	2	1	4
			1
			1
	1		
			1
1		1	1
1		1	1
3		3	7
1	1		1
	1		
2		2	2
1		1	1
			2
			1
1	22	1	11
	1		1
			1
			1
	1		
	3		
1		1	3
1		1	1
			1
	1		
2		2	2
1		1	8
	1		
			1

Oropharyngeal pain 1 8

Pain 1 14

Pain in extremity 4 27

Palpitations 1 6

Panic attack 1 1

Paraesthesia 1 1

Periorbital pain 1 1

Pharyngeal disorder 1 1

Pharyngeal mass 1 1

Pharyngeal oedema 1 1

Pharyngeal swelling 3 7

Poor quality sleep 1 2

Product preparation issue 1 1

Pruritus 2 2

Pulmonary embolism 1 1

Pulmonary pain 2 2

Purpura 1 1

Pyrexia 1 33

Rash 2 2

Rash erythematous 1 1

Rash pruritic 1 1

Respiratory rate increased 1 1

Rhinitis 1 1

Rhinorrhoea 3 3

Seizure 1 3

Septic shock 1 1

Skin ulcer 1 1

Swelling 1 1

Swollen tongue 2 2

Syncope 1 8

Tachycardia 1 1

Taste disorder 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation	2	3		1	2	2
Tremor		4				4
Underdose		1		1		
Urticaria	1	4		1	1	3
Vaccination site erythema		1		1		
Vaccination site haematoma		1				1
Vaccination site induration		1		1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	2	21	2	18		3
Vaccination site pruritus		2		2		
Vaccination site swelling		2		2		
Vaccination site urticaria		1		1		
Vaccination site warmth		1		1		
Vision blurred		1				1
Visual impairment		2		1		1
Vomiting	2	6	1	1	1	5
	75	473	21	236	54	237

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		1		1
Abdominal distension		1				1
Abdominal pain		3		2		1
Abdominal pain lower		1				1
Abdominal pain upper		3		2		1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Ageusia		3		2		1
Amenorrhoea		1		1		
Amnesia		2				2
Anaphylactic reaction	2	11			2	11
Anaphylactic shock		1				1
Angioedema		3				3
Anosmia		4		2		2
Anxiety	1	4		1	1	3
Apathy		1				1
Aphasia		1				1
Areflexia		1				1
Arrhythmia		1				1
Arthralgia	1	17		9	1	8
Arthritis	1	2			1	2
Asthenia	2	15		4	2	11
Asthenopia		2				2
Atrial fibrillation		1				1
Axillary pain	1	6		3	1	3
Back pain	1	12	1	8		4
Bedridden		1		1		
Blindness		2				2
Blister		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood pressure decreased		4		1			3
Blood pressure increased		1		1			
Blood pressure systolic increased		1		1			
Cardiac arrest		1					1
Cardiac flutter		1					1
Cardiac murmur	1	1			1		1
Central pain syndrome		1					1
Cerebrovascular accident		1					1
Chest discomfort	2	13	1	6	1		7
Chest pain	3	12	1	4	2		8
Chills	5	40		17	5		23
Cholecystitis		1					1
Chronic fatigue syndrome	1	1			1		1
Cognitive disorder		1					1
Cold sweat	1	7		2	1		5
Condition aggravated		2		1			1
Cough		9		4			5
COVID-19	2	4			2		4
Cranial nerve disorder		1					1
C-reactive protein abnormal		1		1			
C-reactive protein increased	2	3			2		3
Decreased appetite		1					1
Deep vein thrombosis	2	3			2		3
Depressed mood		4		1			3
Diarrhoea		6		5			1
Diplopia	1	1	1	1			
Discomfort		2		1			1
Disease recurrence		1					1
Disturbance in attention		3		1			2
Dizziness	3	46	1	15	2		31
Dizziness exertional	1	1			1		1
Drug ineffective		1					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry skin		1		1		
Dysaesthesia	1	1	1	1		
Dysarthria		1				1
Dysgeusia	1	5		1	1	4
Dyspepsia		1		1		
Dysphagia		2				2
Dysphonia	1	3		1	1	2
Dyspnoea	1	23		7	1	16
Dyspnoea exertional	1	3			1	3
Dystonia	1	1			1	1
Ear discomfort		2				2
Ear pain		2				2
Eczema		1		1		
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram T wave inversion		1				1
Erythema	1	11	1	5		6
Escherichia urinary tract infection		1				1
Extrasystoles		2				2
Eye disorder		1				1
Eye irritation		2				2
Eye pain		3		1		2
Eye pruritus		2				2
Eye swelling		1				1
Face injury		1				1
Facial discomfort	1	1	1	1		
Facial neuralgia		1				1
Facial pain		1				1
Facial paralysis	1	6			1	6
Facial paresis	1	6			1	6
Fall	1	4			1	4
Fatigue	11	82	3	40	8	42
Fear of death	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		7		3		4
Feeling cold	1	10	1	7		3
Feeling hot	1	12	1	6		6
Feeling of body temperature change		2				2
Feeling of despair		1				1
Flank pain		1		1		
Flushing		1				1
Formication		2				2
Gait disturbance		2		1		1
Gallbladder disorder		1				1
Gallbladder oedema		1				1
Generalised oedema		1				1
General physical health deterioration		1				1
Guillain-Barre syndrome		1				1
Haematoma		1				1
Hallucination		1				1
Headache	7	96	3	52	4	44
Head discomfort		6		3		3
Heart rate increased		5		1		4
Heart rate irregular		1				1
Hemiparesis		1				1
Hepatitis acute		1				1
Herpes simplex	1	1			1	1
Horner's syndrome	1	1			1	1
Hyperacusis		1				1
Hyperaesthesia		1		1		
Hyperhidrosis		5		1		4
Hypersensitivity	1	15			1	15
Hypersomnia		2		1		1
Hypertension	1	4		2	1	2
Hyperventilation		2				2
Hypoacusis		2				2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia	3	35
Hypoaesthesia oral		7
Hypoglycaemia		1
Hypokinesia		1
Hypotension	3	4
Illness		1
Immunisation reaction		1
Incorrect route of product administration		1
Increased upper airway secretion		1
Inflammation		2
Influenza like illness		5
Injected limb mobility decreased		1
Insomnia		3
Intention tremor		1
Joint stiffness	1	3
Joint swelling		2
Lacrimation increased		1
Laziness		1
Lethargy	1	1
Leukopenia	2	2
Limb discomfort		2
Lip pruritus	1	1
Lip swelling		2
Liver disorder		1
Loose tooth	1	1
Loss of personal independence in daily activities		1
Lymphadenitis		1
Lymphadenopathy	3	14
Lymphadenopathy mediastinal		1
Lymph node pain		6
Lymphoedema		1
Malaise	2	14

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	9	1	26
	1		6
			1
			1
	1	3	3
	1		
			1
	1		
			2
	3		2
	1		
	1		2
			1
	1	1	2
	1		1
			1
	1		
		1	1
		2	2
	1		1
		1	1
			1
		1	1
	1		
1	7	2	7
	1		
	4		2
			1
1	9	1	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Memory impairment		3
Mental fatigue		4
Metabolic acidosis	1	1
Migraine		7
Multiple sclerosis		2
Muscle spasms	2	6
Muscle tightness		1
Muscle twitching		2
Muscular weakness		7
Musculoskeletal discomfort		1
Musculoskeletal stiffness	1	12
Myalgia	3	41
Myelitis		1
Myocarditis	3	3
Myopia		1
Nasal congestion	1	6
Nasopharyngitis	1	3
Nausea	3	38
Neck pain		10
Nervousness		1
Neuropathy peripheral		1
Nightmare		3
Nodule		1
Obstructive airways disorder		1
Ocular discomfort		2
Oedema peripheral		1
Off label use		1
Oral mucosal blistering	1	1
Oral pruritus	1	2
Oropharyngeal pain	1	8
Oropharyngeal spasm		1
Overdose		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		1
	1		3
		1	1
	3		4
			2
2	3		3
			1
			2
	2		5
			1
	3	1	9
1	18	2	23
			1
		3	3
			1
1	2		4
		1	3
1	22	2	16
	5		5
			1
			1
			3
	1		
			1
			2
			1
	1	1	1
1	1		1
	6	1	2
			1
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain	2	25
Painful respiration		1
Pain in extremity	4	48
Pain in jaw		2
Pain of skin		2
Pallor		3
Palpitations	1	14
Panic attack		1
Panic reaction		1
Paraesthesia	2	26
Paraesthesia oral	1	8
Parosmia	1	2
Periarthritis	1	1
Pericardial effusion		2
Periorbital discomfort		1
Peripheral coldness		2
Peripheral motor neuropathy		1
Peripheral sensory neuropathy		1
Peripheral swelling		2
Pharyngeal erythema		1
Pharyngeal hypoaesthesia		1
Pharyngeal paraesthesia		2
Pharyngeal swelling		6
Photophobia		2
Physical deconditioning		2
Pleural effusion		3
Pleurisy		1
Pneumonia		1
Polyarthritis	1	1
Poor quality product administered		3
Post viral fatigue syndrome		1
Presyncope		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	10		15
	1		
3	35	1	13
	1		1
	1		1
	1		2
	3	1	11
			1
			1
1	8	1	18
	3	1	5
		1	2
		1	1
			2
	1		1
			1
	1		1
			2
	4		2
			2
	1		1
	1		2
			1
		1	1
	3		
	1		
			2

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Procalcitonin increased	2	2			2	2
Product colour issue		2		2		
Productive cough		1				1
Product preparation issue		3		3		
Product storage error		1		1		
Product use issue		1		1		
Pruritus	1	13	1	5		8
Psoriasis		1		1		
Pulmonary embolism	2	4			2	4
Pulmonary infarction	1	1			1	1
Pulmonary pain		1		1		
Pulse pressure decreased		1		1		
Pyrexia	10	84	2	39	8	45
Rash	2	10	1	5	1	5
Rash erythematous		4		1		3
Rash maculo-papular		1				1
Rash pruritic		1		1		
Renal pain		1		1		
Renal tubular necrosis	1	1			1	1
Respiratory distress	2	7			2	7
Restless legs syndrome		1				1
Rhinorrhoea		4		4		
Sciatica		1				1
Seizure	1	1			1	1
Sensation of foreign body		1				1
Sensory disturbance		1				1
Sinus disorder		1		1		
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin discolouration		1		1		
Skin warm		1		1		
Sleep disorder		2				2

\* I=Interval, C=Cumulative  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep paralysis		1
Somnolence		4
Spinal pain		1
Subarachnoid haemorrhage		1
Sudden hearing loss		1
Supraventricular extrasystoles		1
Supraventricular tachycardia		1
Swelling	1	5
Swelling face		4
Swollen tongue		4
Syncope	3	10
Systemic lupus erythematosus	1	1
Tachycardia		9
Taste disorder		1
Throat irritation		4
Throat tightness		3
Thrombocytopenia	1	1
Thrombosis	1	3
Tinnitus	1	9
Tongue discomfort		1
Tongue pruritus	1	1
Transient ischaemic attack		1
Tremor		5
Trigeminal nerve paresis	1	1
Underdose		2
Upper respiratory tract congestion		1
Upper respiratory tract infection		1
Urticaria	2	15
Uterine inflammation		1
Vaccination failure	2	2
Vaccination site bruising		1
Vaccination site erythema		13

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	2		2
	1		
			1
			1
			1
1	2		3
	1		3
			4
		3	10
		1	1
	2		7
			1
	1		3
	1		2
		1	1
		1	3
		1	9
	1		
		1	1
			1
	1		4
		1	1
	2		
	1		
			1
	5	2	10
	1		
		2	2
			1
	9		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		1		1
Vaccination site movement impairment		2		2		
Vaccination site nodule		1		1		
Vaccination site pain	4	63	4	52		11
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		6		4		2
Vaccination site reaction		1		1		
Vaccination site swelling	1	19	1	12		7
Vaccination site warmth		4		4		
Vaginal haemorrhage		1				1
Venous thrombosis		1				1
Vertigo		2				2
Vertigo positional		1		1		
Vision blurred		2				2
Visual field defect		3				3
Visual impairment		3				3
Vomiting	3	10		3	3	7
	165	1,494	42	612	123	882

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	1		1
Abdominal infection	1	1			1	1
Abdominal pain		8		6		2
Abdominal pain lower		1				1
Abdominal pain upper		1				1
Acute myocardial infarction	1	2			1	2
Ageusia		1				1
Allergy to vaccine		2				2
Amnesia		1				1
Anaphylactic reaction		5				5
Anaphylactoid reaction	1	1			1	1
Angioedema	1	1			1	1
Anosmia		1				1
Anxiety		2		2		
Apathy	1	1			1	1
Arrhythmia		1				1
Arthralgia		19		10		9
Asthenia	2	11		6	2	5
Asthenopia		2				2
Atrial fibrillation	1	1			1	1
Atrial septal defect		1				1
Axillary pain		2		1		1
Back pain		1		1		
Balance disorder	2	3			2	3
Bedridden		1		1		
Blepharospasm		1				1
Blindness transient		1				1
Blood creatinine increased	1	1	1	1		
Blood fibrinogen decreased	1	1			1	1
Blood lactate dehydrogenase increased	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood pressure increased	1	3			1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature increased	1	1
Brain stem syndrome		1
Breast pain	1	1
Bronchospasm		1
Cardiac arrest		2
Cardiac discomfort	2	2
Cardiac disorder	1	1
Cardiogenic shock	1	1
Cardiovascular disorder	1	1
Cerebellar syndrome		1
Cerebral microangiopathy	1	1
Cerebrovascular accident		1
Chest discomfort	2	4
Chest pain	1	3
Chills	1	31
Circulatory collapse		1
Coagulopathy	1	1
Cold sweat	1	3
Concomitant disease aggravated		1
Condition aggravated	1	2
Confusional state		2
Constipation		1
Cough		6
COVID-19	1	1
Deafness unilateral		2
Death		1
Decreased appetite		1
Deep vein thrombosis	3	4
Depressed level of consciousness		3
Depression		1
Derealisation		1
Dermatitis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
			1
		1	1
			1
			2
		2	2
		1	1
		1	1
		1	1
			1
		1	1
			1
1	2	1	2
	1	1	2
1	22		9
			1
		1	1
	1	1	2
			1
		1	2
			2
	1		
	4		2
1	1		
			2
			1
		3	4
			3
	1		
			1
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	2	16		11	2	5
Discomfort	1	3		2	1	1
Disease recurrence	2	2	1	1	1	1
Disturbance in attention	2	3			2	3
Dizziness	5	21		4	5	17
Dry mouth	1	1			1	1
Dysgeusia		3		1		2
Dysphagia	1	2			1	2
Dysphonia	1	4		2	1	2
Dyspnoea	3	17		4	3	13
Ear pain	1	1			1	1
Encephalitis		1				1
Encephalopathy		1				1
Epilepsy		2				2
Epistaxis		2		2		
Erysipelas		1				1
Erythema		9		5		4
Extrasystoles	1	1			1	1
Eye irritation		1				1
Eye pain		4				4
Eye swelling		1				1
Facial pain		2				2
Facial paralysis	1	2			1	2
Facial paresis	2	4			2	4
Fatigue	8	45	1	27	7	18
Feeling abnormal		3		1		2
Feeling cold	4	6	1	3	3	3
Feeling drunk		1		1		
Feeling hot		7		1		6
Flatulence		1		1		
Flushing		1				1
Formication		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance	1	1			1	1
Gait inability		1				1
Gastritis		1		1		
General physical health deterioration		1				1
Goitre	1	1			1	1
Haematuria	1	1			1	1
Haemorrhage	2	2			2	2
Hallucination, visual		1				1
Headache	8	64	1	38	7	26
Head discomfort		2		1		1
Heart rate increased		7		3		4
Heat stroke		1				1
Herpes zoster	1	2		1	1	1
Hot flush		1				1
Hyperhidrosis		3		1		2
Hypersensitivity	1	10		3	1	7
Hypertension	1	5	1	2		3
Hypoacusis		4				4
Hypoaesthesia	2	20		6	2	14
Hypoaesthesia oral		2				2
Hypoxia		1				1
Illness	1	2			1	2
Influenza like illness	1	4	1	3		1
Insomnia	1	3			1	3
Jaw disorder		1				1
Joint lock		1				1
Joint range of motion decreased	1	2		1	1	1
Lip swelling		4		1		3
Lip ulceration	1	1	1	1		
Loss of consciousness	1	2			1	2
Lymphadenopathy		6		4		2
Lymph node pain		2		2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise		17		11		6
Mass		1				1
Memory impairment		2				2
Meningitis herpes		1				1
Mental fatigue	1	4			1	4
Metabolic disorder	1	2	1	1		1
Metastasis	1	1			1	1
Migraine	3	5		2	3	3
Mobility decreased		2		1		1
Monoparesis	1	1			1	1
Mouth swelling		1				1
Mouth ulceration	1	1	1	1		
Muscle fatigue		1				1
Muscle spasms		3		1		2
Muscular weakness	1	3		1	1	2
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness		7		2		5
Myalgia	3	29		16	3	13
Myocarditis		1				1
Nasal congestion		2		1		1
Nausea	5	26	1	12	4	14
Neck pain		3		2		1
Neuralgia		1				1
Ocular discomfort		1		1		
Oral herpes		2		1		1
Oral mucosal blistering		1				1
Oral pruritus		5		3		2
Oral viral infection		1				1
Oropharyngeal pain		5		3		2
Overdose		1		1		
Pain	4	24	1	11	3	13
Pain in extremity	4	29	2	17	2	12

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain in jaw		1
Pain of skin		1
Palatal swelling		1
Palpitations		6
Panic reaction		1
Paraesthesia		10
Paraesthesia ear		1
Paraesthesia oral		2
Parosmia		1
Periorbital oedema		1
Periorbital pain		1
Periorbital swelling		2
Peripheral coldness		1
Peripheral swelling	2	7
Pharyngeal erythema		1
Pharyngeal hypoaesthesia		2
Pharyngeal swelling		1
Photophobia		2
Platelet count decreased	1	1
Pneumonia	1	2
Polymyalgia rheumatica		1
Presyncope		1
Product administered at inappropriate site		1
Pruritus		5
Pulmonary embolism	3	3
Pulmonary hypertension	1	1
Pyrexia	6	61
Rash	1	2
Rash erythematous		1
Rash macular		1
Rash pruritic		1
Reading disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	1		
			1
	1		5
			1
	2		8
			1
	1		1
			1
			1
	1		1
			1
	1		1
	2		5
	1		
			2
			1
			2
		1	1
		1	2
			1
			1
	1		
	3		2
		3	3
		1	1
3	38	3	23
		1	2
			1
	1		
	1		
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Reduced facial expression		1				1
Renal impairment		1				1
Renal pain		2		1		1
Respiration abnormal		1				1
Respiratory arrest	1	1			1	1
Respiratory disorder	1	1			1	1
Respiratory distress		2				2
Retinal haemorrhage	1	1			1	1
Rhinalgia		2		1		1
Rhinorrhoea	2	7		5	2	2
Seizure		1				1
Seizure like phenomena		2				2
Sensory disturbance		1		1		
Sinus congestion		1		1		
Skin discolouration		1		1		
Skin reaction		1		1		
Skin tightness	1	1			1	1
Sleep disorder	1	2			1	2
Sleep talking		1				1
Sluggishness	1	1			1	1
Sneezing		1		1		
Somnolence		1		1		
Stomatitis		1				1
Stress	1	2	1	2		
Subarachnoid haemorrhage	1	1			1	1
Sudden visual loss	1	1			1	1
Suspected COVID-19		1		1		
Swelling		1				1
Swelling face		4		2		2
Swollen tongue		3				3
Syncope		2				2
Tachycardia	1	5		1	1	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		1				1
Tenderness	1	1			1	1
Throat irritation		4		1		3
Throat tightness		1				1
Thrombocytopenia	3	3			3	3
Thrombophlebitis	1	2	1	1		1
Thrombosis	3	4			3	4
Tinnitus	2	7			2	7
Tongue movement disturbance		1				1
Tongue pruritus		2				2
Transient ischaemic attack	2	2			2	2
Unresponsive to stimuli		1				1
Upper respiratory tract infection		1				1
Urticaria		9		4		5
Vaccination site bruising	1	1	1	1		
Vaccination site discolouration		1				1
Vaccination site erythema	1	6	1	5		1
Vaccination site induration	1	2	1	2		
Vaccination site lymphadenopathy		1				1
Vaccination site mass		1		1		
Vaccination site movement impairment		2		2		
Vaccination site pain	2	33	2	23		10
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling	2	12	2	10		2
Vaccination site warmth		4		3		1
Vasodilatation	1	1	1	1		
Vertigo	1	2		1	1	1
Vision blurred	1	4		1	1	3
Visual impairment	2	4			2	4
Vomiting	4	8	1	3	3	5
Weight decreased		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wound	1	1				
	175	981	33	419	142	562

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	7			3	7
Abdominal pain upper		1		1		
Abnormal behaviour		1		1		
Acute kidney injury		1				1
Acute left ventricular failure		1				1
Acute myocardial infarction		1				1
Adrenocortical insufficiency acute		1				1
Ageusia		1		1		
Altered state of consciousness	1	1			1	1
Anaemia	1	1			1	1
Anaphylactic reaction	2	4			2	4
Anaphylactic shock	1	2			1	2
Angina pectoris	1	2			1	2
Angioedema		1				1
Anosmia		1		1		
Anxiety		2				2
Arrhythmia		1				1
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	1	4		2	1	2
Arthritis		2		2		
Ascites		1				1
Asthenia	2	4	1	1	1	3
Asthma		1				1
Atrial fibrillation	1	1			1	1
Atrial flutter	1	1			1	1
Atrioventricular block complete		1				1
Autonomic nervous system imbalance		1				1
Back pain	1	3		1	1	2
Balance disorder		3				3
Basedow's disease		1				1
Basilar artery thrombosis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	1			1	1
Biliary tract disorder		1				1
Blister		1				1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood glucose increased		1				1
Blood pressure abnormal		1				1
Blood pressure decreased		1				1
Blood pressure fluctuation		1				1
Blood pressure increased		1		1		
Body temperature increased		1				1
Breath sounds abnormal		1				1
Bundle branch block right		1				1
Cardiac arrest	2	4			2	4
Cardiac failure		2				2
Cardiac failure acute		2				2
Cardiac fibrillation		1				1
Cardiogenic shock		1				1
Cerebral haemorrhage	3	4			3	4
Cerebral infarction	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident	2	3			2	3
Chest pain	2	4			2	4
Chills	4	5	1	2	3	3
Chronic obstructive pulmonary disease		2				2
Circulatory collapse		1				1
Cold sweat		1				1
Condition aggravated	2	3		1	2	2
Confusional state	2	5			2	5
Coronary artery stenosis		1				1
Cough	2	3		1	2	2
COVID-19	2	3			2	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19 pneumonia		1				1
C-reactive protein increased	1	1	1	1		
Crying		1		1		
Cyanosis		1				1
Death	1	12			1	12
Deep vein thrombosis	3	5			3	5
Dehydration	2	4	1	1	1	3
Delirium	1	1			1	1
Depressed level of consciousness		3				3
Dermatitis		1		1		
Diarrhoea	1	7	1	4		3
Discomfort	1	2			1	2
Disease recurrence		2				2
Dizziness	5	12	1	2	4	10
Drug ineffective	1	1			1	1
Dysarthria		1				1
Dysphagia	3	6	1	4	2	2
Dysphonia		2		1		1
Dyspnoea	3	17	1	2	2	15
Dysstasia		1				1
Eating disorder	1	1			1	1
Embolism		1				1
Epilepsy	1	1			1	1
Epistaxis	2	2			2	2
Erythema	1	4	1	2		2
Eye haemorrhage	1	1			1	1
Eye pain		2				2
Facial paralysis		1				1
Facial paresis	1	1			1	1
Fall	1	3	1	1		2
Fatigue	7	21	4	9	3	12
Feeding disorder	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		2		1		1
Feeling cold		1		1		
Fibromyalgia		1				1
Fluid intake reduced		1				1
Gamma-glutamyltransferase increased		1				1
Gastric disorder	1	1			1	1
General physical health deterioration	3	9	1	3	2	6
Goitre		1				1
Graft versus host disease		1				1
Haematemesis	1	3			1	3
Haematoma	1	2			1	2
Haemoglobin decreased		1				1
Haemorrhage intracranial	1	1			1	1
Hallucination		1				1
Headache	4	11	1	3	3	8
Head injury	1	2	1	1		1
Heart rate increased	1	2			1	2
Hemiparaesthesia		1				1
Hemiparesis	1	1			1	1
Herpes zoster	2	5			2	5
Hiccups		1				1
Hip fracture		1				1
Hot flush		1				1
Hydrothorax		1				1
Hyperhidrosis	1	2	1	2		
Hypersensitivity		4				4
Hypertension	2	4			2	4
Hypoaesthesia	2	4			2	4
Hypoaesthesia oral		1		1		
Hypoglycaemia		2				2
Hypokinesia		1				1
Hypophagia		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	2	4		1	2	3
Hypothermia		1				1
Illness	1	1			1	1
Inappropriate schedule of product administration	3	3	3	3		
Incorrect route of product administration	1	2	1	2		
Infection	2	5			2	5
Inflammation	1	1			1	1
Influenza like illness	1	1			1	1
Infrequent bowel movements		1		1		
Insomnia		1		1		
Intestinal haemorrhage	1	2			1	2
Intestinal ischaemia	1	2			1	2
Ischaemic stroke	2	2			2	2
Jaundice		1				1
Lactic acidosis		1				1
Lethargy	1	2	1	1		1
Lip pruritus		1				1
Lip swelling		1				1
Liver disorder		1				1
Loss of consciousness	2	3			2	3
Loss of personal independence in daily activities	1	1			1	1
Lung disorder	1	1			1	1
Lung infiltration	1	1			1	1
Lung transplant rejection		1				1
Lymphadenopathy		1		1		
Malaise	1	6		1	1	5
Meningitis		1				1
Motor dysfunction		1				1
Multiple sclerosis	1	1			1	1
Muscle tone disorder		1				1
Muscular weakness	1	3			1	3
Musculoskeletal stiffness		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	1	6		2	1	4
Myelitis		1				1
Myocardial fibrosis		1				1
Myocardial infarction		3				3
Myocardial ischaemia		2				2
Nail discolouration		1				1
Nasopharyngitis	1	4	1	4		
Nausea	5	16	1	5	4	11
Neck pain	2	2			2	2
Nephrolithiasis	1	1			1	1
Nervousness		1		1		
Neuralgia		1		1		
Nightmare	1	1	1	1		
Off label use	3	3	3	3		
Ophthalmic herpes zoster		1				1
Oral discomfort		1				1
Oropharyngeal pain	1	1			1	1
Oxygen saturation decreased		4		1		3
Pain	2	3			2	3
Pain in extremity	1	1			1	1
Pain of skin	1	1			1	1
Palpitations	3	6			3	6
Pancytopenia	1	1			1	1
Paraesthesia	1	3	1	2		1
Paraesthesia oral		2		1		1
Parkinson's disease	1	1			1	1
Periorbital oedema		1				1
Peripheral swelling	2	3		1	2	2
Petechiae	3	3	1	1	2	2
Pharyngitis		1		1		
Pneumonia		3				3
Pneumonia aspiration	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Poor quality product administered		1		1		
Presyncope	1	2		1	1	1
Productive cough	1	1			1	1
Pruritus	1	6		1	1	5
Psychotic disorder	1	1			1	1
Pulmonary artery thrombosis		1				1
Pulmonary embolism	10	13			10	13
Pulmonary oedema		3				3
Pulse abnormal		1				1
Pyrexia	12	30	2	11	10	19
Rash		2		1		1
Renal failure		1				1
Renal haemorrhage	1	1			1	1
Respiratory arrest		2				2
Respiratory distress		1				1
Respiratory failure	1	1			1	1
Respiratory rate increased		1				1
Restless legs syndrome		1				1
Rhinorrhoea	1	2		1	1	1
Sciatica		1		1		
Screaming	1	1	1	1		
Seizure	2	4			2	4
Sense of oppression		1				1
Sepsis	1	2			1	2
Septic shock		1				1
Skin ulcer		1				1
Sleep disorder	1	1			1	1
Sleep paralysis	1	1	1	1		
Solar dermatitis	1	1			1	1
Somnolence	1	2	1	1		1
Speech disorder	2	2	1	1	1	1
Spleen disorder	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spontaneous haematoma	1	1			1	1
Status epilepticus	1	1			1	1
Subarachnoid haemorrhage		1				1
Subdural haematoma	1	1			1	1
Sudden death		1				1
Swelling face	1	3	1	1		2
Swollen tongue		1				1
Syncope	1	1			1	1
Tachypnoea	1	3		1	1	2
Temperature regulation disorder		1		1		
Throat tightness		1				1
Thrombocytopenia	6	6			6	6
Thrombocytopenic purpura	1	1			1	1
Thrombosis	2	3			2	3
Tongue discomfort		1				1
Tongue pruritus		1				1
Transaminases increased		1				1
Tremor	1	2	1	1		1
Troponin increased	1	1	1	1		
Underdose		1		1		
Urinary incontinence		1				1
Urinary tract infection	1	1			1	1
Urticaria	2	5	1	2	1	3
Vaccination failure	1	2			1	2
Vaccination site discomfort		1				1
Vaccination site erythema		4		1		3
Vaccination site pain	2	5	1	4	1	1
Vaccination site rash		1				1
Vertigo		1		1		
Vision blurred		1				1
Visual impairment	1	1			1	1
Vomiting	3	11	1	5	2	6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wheezing	220	602	43	133	177	469

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain	1	3	1	1		2
Abdominal pain upper		1				1
Abdominal symptom		1				1
Abdominal wall haemorrhage	1	1			1	1
Abnormal behaviour		2				2
Abnormal sensation in eye		1				1
Acute kidney injury	1	3			1	3
Acute myocardial infarction	2	4			2	4
Ageusia		1				1
Aggression		1				1
Agitation	1	2			1	2
Akinesia		1				1
Altered state of consciousness	1	1			1	1
Amnesia	2	2			2	2
Anaphylactic reaction	1	2			1	2
Angina pectoris	1	2			1	2
Angioedema		1				1
Anosmia		1				1
Anxiety	1	5		1	1	4
Aortic aneurysm rupture		1				1
Aortic arteriosclerosis	1	2		1	1	1
Aphasia	1	2			1	2
Apnoea		2				2
Arrhythmia	1	1			1	1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		1				1
Arthralgia	2	4	1	1	1	3
Arthritis		2				2
Aspiration	1	1			1	1
Asthenia	3	10	1	3	2	7
Atelectasis		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial fibrillation	3	7			3	7
Atrial flutter		1				1
Atrial thrombosis		1				1
Atrioventricular block complete		1				1
Atypical pneumonia	1	1			1	1
Back pain	3	4		1	3	3
Balance disorder	4	5			4	5
Biliary colic	1	1			1	1
Biliary dilatation	1	1			1	1
Blood creatinine increased	1	2		1	1	1
Blood glucose increased		1		1		
Blood phosphorus decreased		1		1		
Blood potassium increased	1	1			1	1
Blood pressure decreased	1	7	1	2		5
Blood pressure diastolic decreased		1		1		
Blood pressure increased		1				1
Blood pressure systolic increased		1				1
Body temperature decreased		2				2
Body temperature increased	1	2		1	1	1
Bone disorder		1		1		
Bradycardia	1	1			1	1
Brain herniation	1	1			1	1
Brain injury		1				1
Brain scan abnormal		1				1
Bronchial haemorrhage		1				1
Bronchitis		1				1
Bundle branch block left	1	2	1	1		1
Bursitis	1	1			1	1
Cachexia		1				1
Cardiac arrest	7	12			7	12
Cardiac death	1	1			1	1
Cardiac disorder		3				3

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure	5	13			5	13
Cardiac failure chronic		1				1
Cardiopulmonary failure		1				1
Catheter site haemorrhage		1		1		
Cerebellar haemorrhage	1	1			1	1
Cerebral artery embolism	1	2			1	2
Cerebral atrophy		1				1
Cerebral haemorrhage	2	4			2	4
Cerebral infarction	2	4			2	4
Cerebrovascular accident	7	16			7	16
Cerebrovascular disorder		1				1
Chest discomfort		2		1		1
Chest pain	3	10		3	3	7
Chills	1	10		1	1	9
Chronic gastritis		1				1
Chronic obstructive pulmonary disease		3				3
Chronic respiratory failure		1				1
Circulatory collapse	1	4			1	4
Clostridium difficile colitis	1	1			1	1
Coeliac artery stenosis		1				1
Cognitive disorder	1	1			1	1
Condition aggravated	4	11	1	2	3	9
Confusional state	1	10	1	1		9
Constipation		1		1		
Contusion	2	2			2	2
Coordination abnormal	1	3			1	3
Coronary artery occlusion	1	1			1	1
Cor pulmonale acute		1				1
Cough	4	13	2	5	2	8
COVID-19	2	13			2	13
C-reactive protein increased	2	8	1	5	1	3
Crepitations		2		1		1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis	1	3	1	2		1
Death	2	27			2	27
Decreased appetite	3	14	1	7	2	7
Decubitus ulcer		1		1		
Deep vein thrombosis	8	11			8	11
Dehydration	1	3		1	1	2
Delusional disorder, unspecified type		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	3	13			3	13
Depression	1	1			1	1
Device related infection		1				1
Diarrhoea	2	14		3	2	11
Discomfort		1				1
Disease recurrence	3	5		1	3	4
Disorganised speech		1				1
Disorientation		1				1
Dissociation		1				1
Diverticulitis		1				1
Diverticulum		1		1		
Dizziness	8	19	1	4	7	15
Drug eruption		2		1		1
Drug ineffective		7				7
Dry mouth		1				1
Dysarthria	1	5		1	1	4
Dysphagia		3				3
Dyspnoea	12	43	1	5	11	38
Dyspnoea exertional	1	1			1	1
Dysstasia		1				1
Ear swelling	1	1			1	1
Eczema		1				1
Electrocardiogram ST segment elevation	1	1			1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Embolism cerebral infarction	1	1			1	1
Embolism	1	2			1	2
Embolism arterial	1	1			1	1
Encephalitis	1	1			1	1
Energy increased	1	1			1	1
Epilepsy	1	1			1	1
Epistaxis	2	2			2	2
Erysipelas	4	5			4	5
Erythema	5	9	2	5	3	4
Escherichia infection		1				1
Escherichia sepsis		1				1
Eye disorder		2				2
Eye haemorrhage	1	1			1	1
Facial paralysis		4				4
Facial paresis		3				3
Fall	6	9	1	2	5	7
Fatigue	4	40	3	18	1	22
Feeling abnormal	1	1	1	1		
Feeling cold	1	2		1	1	1
Feeling hot	1	2	1	2		
Femoral neck fracture		1				1
Fluid retention	1	1			1	1
Food refusal		1				1
Gait disturbance		1				1
Gastric haemorrhage	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Generalised oedema		1				1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration	6	34	1	7	5	27
Glomerular filtration rate decreased	2	2	1	1	1	1
Gout		1				1
Haematemesis	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematochezia		1				1
Haematoma	1	2			1	2
Haemoglobin decreased		1				1
Haemolytic anaemia	1	2			1	2
Haemoptysis	1	2			1	2
Haemorrhage	1	2			1	2
Haemorrhage subcutaneous	1	1			1	1
Hallucination		2				2
Hallucination, visual	1	2			1	2
Headache	6	13	3	4	3	9
Head discomfort		1				1
Head injury	1	2		1	1	1
Heart rate decreased		3		2		1
Heart rate increased	1	3			1	3
Heart rate irregular		2		2		
Helplessness	1	1			1	1
Hemiparesis	2	6			2	6
Hepatic enzyme increased	1	1			1	1
Herpes ophthalmic	1	1			1	1
Herpes zoster	2	6		1	2	5
Hypercalcaemia		1				1
Hyperglycaemia		1				1
Hyperhidrosis		1				1
Hypernatraemia		1				1
Hyperparathyroidism primary		1		1		
Hypersensitivity		6				6
Hypersomnia	1	1			1	1
Hypertension	1	4			1	4
Hypoaesthesia	1	4		2	1	2
Hypoaesthesia oral		2		1		1
Hypoalbuminaemia		1		1		
Hypoglycaemia		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypokalaemia	1	2			1	2
Hypoperfusion	1	1			1	1
Hypophagia		1				1
Hypopnoea		1				1
Hypotension	2	15	1	2	1	13
Hypothermia		2				2
Idiopathic pulmonary fibrosis		1				1
Illness		1				1
Immune thrombocytopenia	1	1			1	1
Incontinence		1		1		
Incorrect route of product administration	1	3	1	3		
Increased upper airway secretion		1		1		
Infection	2	7		1	2	6
Influenza like illness		1				1
International normalised ratio increased	1	1			1	1
Intestinal haemorrhage		1				1
Intestinal ischaemia		1				1
Irregular breathing		1		1		
Ischaemic stroke	4	6			4	6
Laryngeal oedema		1				1
Left ventricular hypertrophy		1				1
Leukocytosis		1				1
Limb injury	1	1			1	1
Livedo reticularis		1		1		
Loss of consciousness	3	11			3	11
Lung disorder		1				1
Lymphadenopathy		1				1
Malaise	3	9	2	4	1	5
Memory impairment	1	2			1	2
Meningism	1	1			1	1
Mesenteric artery embolism		1				1
Monoplegia		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	2	2	1	1	1	1
Muscular weakness	5	8			5	8
Musculoskeletal stiffness	1	2			1	2
Myalgia	4	8	1	2	3	6
Myelosuppression		1				1
Myocardial infarction	3	10			3	10
Myocardial ischaemia		1				1
Myocardial rupture		1				1
Nasal congestion		2		1		1
Nasopharyngitis	3	5	1	1	2	4
Nausea	3	18	1	6	2	12
Neck pain	1	1			1	1
Neoplasm progression		1				1
Neuropathy peripheral		1				1
Obstructive airways disorder	1	2			1	2
Oedema peripheral	1	1	1	1		
Oesophageal ulcer haemorrhage	1	1			1	1
Oral discomfort		2				2
Oropharyngeal pain		1		1		
Orthostatic hypotension		1				1
Oxygen saturation abnormal		1		1		
Oxygen saturation decreased	3	19		3	3	16
Pain	8	16	2	4	6	12
Painful respiration	1	1	1	1		
Pain in extremity	6	10	1	3	5	7
Pallor	1	5	1	3		2
Palpitations		1		1		
Pancytopenia	1	1			1	1
Paraesthesia	1	4			1	4
Paresis		1				1
Pemphigoid		2				2
Penile haemorrhage	1	1			1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pericardial effusion		1					1
Pericardial haemorrhage		1					1
Pericarditis		1					1
Periorbital oedema		1					1
Peripheral coldness		1					1
Peripheral embolism	1	1			1		1
Peripheral swelling	8	9	1	1	7		8
Petechiae	1	2			1		2
Petit mal epilepsy		2					2
Pharyngeal swelling		1					1
Phlebitis	1	1			1		1
Pleural effusion	1	2			1		2
Pneumonia	1	8			1		8
Pneumonia aspiration	1	1			1		1
Pneumonia bacterial		1					1
Pneumonia pneumococcal		1					1
Pneumonia streptococcal		1					1
Polyneuropathy	1	1			1		1
Postoperative wound complication		1					1
Post stroke epilepsy	1	1			1		1
Product administered at inappropriate site	1	1	1	1			
Productive cough	1	3			1		3
Pruritus	3	6	1	1	2		5
Psychotic disorder	1	2			1		2
Pulmonary embolism	18	28			18		28
Pulmonary oedema	1	6			1		6
Pulmonary thrombosis	1	2			1		2
Pulse abnormal		2		2			
Pyrexia	11	63	5	21	6		42
Rash	1	3		1	1		2
Rash erythematous		1					1
Rash macular	1	1	1	1			

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic		1				1
Red blood cell sedimentation rate increased		1				1
Renal failure	1	1			1	1
Renal infarct		1				1
Respiratory arrest		2				2
Respiratory distress		5				5
Respiratory failure	1	2			1	2
Respiratory rate increased		6		1		5
Retinal artery occlusion	1	1			1	1
Retinal vein occlusion	1	1			1	1
Retroperitoneal haemorrhage	1	1			1	1
Rhinitis		1		1		
Rhinorrhoea	1	1			1	1
Rib fracture	1	1			1	1
Scapula fracture	1	1			1	1
Seizure		2				2
Sepsis		5				5
Skin discolouration	1	3			1	3
Skin disorder	1	1			1	1
Skin turgor decreased		1				1
Skin ulcer	1	2			1	2
Skin wound	1	1			1	1
Slow speech		1				1
Somnolence		3				3
Speech disorder		2		1		1
Stevens-Johnson syndrome		1				1
Streptococcal bacteraemia		1				1
Subarachnoid haemorrhage	1	1			1	1
Subdural haematoma	1	1			1	1
Sudden death	2	5			2	5
Suspected COVID-19		1				1
Swelling		2		1		1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling face	1	3		1	1	2
Swollen tongue		2		1		1
Syncope	2	6			2	6
Systemic inflammatory response syndrome		1				1
Tachycardia		2		1		1
Tachypnoea		2		1		1
Tenderness	1	2		1	1	1
Tenosynovitis		1				1
Throat irritation		1				1
Throat tightness		1				1
Thrombocytopenia	4	4			4	4
Thrombophlebitis	3	3			3	3
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	2			1	2
Toxic epidermal necrolysis		1				1
Tracheal haemorrhage		1				1
Transient ischaemic attack	4	6			4	6
Tremor		2				2
Unresponsive to stimuli	1	2			1	2
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract infection		1				1
Urinary retention		1				1
Urinary tract infection	2	9	1	5	1	4
Urine output decreased		2				2
Urosepsis		3				3
Urticaria	1	6		2	1	4
Vaccination failure	1	2			1	2
Vaccination site erythema	2	9		4	2	5
Vaccination site haematoma		1				1
Vaccination site infection		1				1
Vaccination site pain	2	4	1	2	1	2
Vaccination site phlebitis		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		1				1
Vaccination site reaction		2				2
Vaccination site swelling	2	5	1	2	1	3
Vaccination site thrombosis		1				1
Vaccination site warmth	1	1	1	1		
Vascular dementia		1				1
Vasculitis		1				1
Ventricular fibrillation	2	2			2	2
Ventricular hypokinesia	1	1			1	1
Ventricular tachycardia		1				1
Visual field defect	1	1			1	1
Vomiting	4	30	1	4	3	26
Wheezing	3	7	1	2	2	5
White blood cell count increased	1	2	1	2		
White blood cells urine positive		1		1		
Wound		1		1		
Wound necrosis		1				1
	390	1,245	57	224	333	1021

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Allergy to vaccine		1		1		
Arthralgia		1		1		
Asthenia		1		1		
Chills		2		2		
Circumstance or information capable of leading to medication error		29		29		
COVID-19	3	23	2	21	1	2
Death		2				2
Diarrhoea	1	1	1	1		
Dizziness		1		1		
Dysphonia		1		1		
Dyspnoea		1				1
Erythema		1		1		
Facial paresis		1				1
Fatigue		1		1		
Gastrointestinal pain	1	1	1	1		
Headache	1	4	1	4		
Herpes zoster		1		1		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Incorrect route of product administration		3		3		
Malaise		3		3		
Muscular weakness		1		1		
Musculoskeletal stiffness		1		1		
Myalgia		3		3		
Nausea		1		1		
Neck pain		1		1		
Neurological symptom		1				1
Pain	1	1	1	1		
Pain in extremity		8		8		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		1		1		
Paralysis		1				1
Poor quality product administered		33		33		
Product colour issue		34		34		
Pruritus		1		1		
Pyrexia	1	4	1	4		
Rhinorrhoea	1	1	1	1		
Throat irritation		1		1		
Underdose		1		1		
Vaccination failure	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site joint movement impairment		3		3		
Vaccination site pain	2	7	2	7		
Vaccination site swelling		3		2		1
Vaccination site warmth		1		1		
Weight decreased		1		1		
	14	195	12	183	2	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SWITZERLAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute stress disorder		1				1	
Angioedema	1	1			1		1
Arthralgia	1	1	1	1			
Asthenia	1	1			1		1
Cardiovascular disorder	1	1			1		1
Chest discomfort	1	1			1		1
Chills	2	2			2		2
Cough	1	1			1		1
COVID-19	1	1			1		1
Diarrhoea	1	1			1		1
Dissociative disorder		1					1
Dizziness	1	2	1	1			1
Dyspnoea	1	2	1	1			1
Erythema	1	1	1	1			
Exposure during pregnancy	1	1			1		1
Eye pain	1	1	1	1			
Fatigue	5	5	3	3	2		2
Gait disturbance		1					1
Headache	2	3	1	1	1		2
Herpes zoster	1	1			1		1
Hyperhidrosis		1					1
Hypersensitivity		1					1
Hypertension	1	2			1		2
Hypoaesthesia oral	1	1	1	1			
Hypotension		1					1
Influenza like illness	1	1	1	1			
Lymphadenopathy	1	1			1		1
Muscle spasms		1					1
Myalgia		1					1
Nasopharyngitis	1	1			1		1
Nausea	2	3	1	1	1		2
Oral herpes	1	1			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	1	1	1	1		
Pain in extremity	4	4	2	2	2	2
Pallor		1				1
Paraesthesia	1	2	1	1		1
Paraesthesia oral	1	1	1	1		
Peripheral coldness		1				1
Presyncope	1	2			1	2
Pruritus		1				1
Pyrexia	4	5	2	2	2	3
Rash	1	2	1	1		1
Swelling of eyelid	1	1			1	1
Syncope	2	3			2	3
Tachycardia	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site pain	1	1	1	1		
Vomiting	1	2			1	2
	51	73	22	22	29	51

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Acute stress disorder		1				1
Anaphylactic reaction	2	3			2	3
Anaphylactic shock		1				1
Angina pectoris		1				1
Angioedema	3	4			3	4
Arthralgia	4	4	2	2	2	2
Asthenia	5	5			5	5
Asthma		3				3
Asymptomatic COVID-19	1	1	1	1		
Axillary lymphadenectomy	1	1			1	1
Back pain		1		1		
Blood pressure decreased		1		1		
Blood pressure increased	1	2			1	2
Breast haematoma	1	1			1	1
Breast pain	1	1			1	1
Chest discomfort	1	3			1	3
Chest pain		1				1
Chills	4	6			4	6
Circulatory collapse	1	1			1	1
Cough		2		2		
COVID-19	4	6			4	6
Deep vein thrombosis		1				1
Diarrhoea	3	3	1	1	2	2
Diplopia	1	1			1	1
Disease recurrence	2	2			2	2
Disturbance in attention		1		1		
Dizziness	2	6			2	6
Drug eruption	1	1			1	1
Drug ineffective	2	3			2	3
Drug interaction		1		1		
Dysaesthesia	1	2			1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia		1		1		
Dyspnoea		2				2
Erythema		2				2
Fatigue	7	8	3	4	4	4
Feeling cold	1	1	1	1		
Feeling hot	2	4		1	2	3
Flushing		2				2
Gastrointestinal disorder		1				1
Hair growth abnormal		1		1		
Headache	8	13	1	4	7	9
Heart rate increased		1				1
Herpes zoster	1	3			1	3
Hyperhidrosis	1	2			1	2
Hypersensitivity	5	9	3	3	2	6
Hypertension	1	4		1	1	3
Hyperventilation	2	4			2	4
Hypoaesthesia oral	1	1			1	1
Hypotension	1	1			1	1
Illusion		1		1		
Immunisation anxiety related reaction	2	2			2	2
Incorrect route of product administration		2		1		1
Influenza	1	1			1	1
Insomnia	1	1	1	1		
Joint range of motion decreased		1				1
Lethargy		1		1		
Lymph node pain	1	1			1	1
Malaise	6	11	1	2	5	9
Monoplegia	1	1			1	1
Muscle spasms		2				2
Muscular weakness	1	1			1	1
Myalgia	5	7	2	3	3	4
Myelitis	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Nausea	1	3
Neuralgia	1	1
Neuralgic amyotrophy	2	2
Obstructive airways disorder		1
Oropharyngeal pain		1
Pain	4	4
Pain in extremity	3	3
Palpitations	2	3
Paraesthesia	2	2
Peripheral coldness		1
Photophobia	1	1
Pneumonia		1
Presyncope	1	3
Pruritus	2	2
Pyrexia	10	13
Rash	4	5
Rash erythematous		1
Rash papular	1	1
Respiratory distress	1	1
Rhinitis		1
Sense of oppression		1
Sensory disturbance	1	1
Sickle cell anaemia with crisis	1	1
Sinus tachycardia	1	1
Sudden death		1
Syncope	2	2
Tachycardia	5	10
Tachypnoea	1	1
Therapeutic response unexpected		1
Throat irritation	1	1
Throat tightness		1
Tremor		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		2
		1	1
		2	2
			1
	1		
		4	4
		3	3
		2	3
		2	2
			1
		1	1
			1
		1	3
		2	2
2	3	8	10
3	4	1	1
			1
		1	1
		1	1
	1		
			1
		1	1
		1	1
		1	1
		2	2
	1	5	9
		1	1
	1		
		1	1
			1
			2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal neuralgia	1	1			1	1
Type II hypersensitivity	1	1			1	1
Urticaria	1	1			1	1
Vaccination failure	2	2			2	2
Vaccination site erythema		2		1		1
Vaccination site induration		1				1
Vaccination site lymphadenopathy	1	1			1	1
Vaccination site oedema		1		1		
Vaccination site pain	4	6	2	3	2	3
Vaccination site pruritus		1		1		
Vaccination site warmth		2		1		1
Vertigo		1				1
Visual impairment	1	2			1	2
Vomiting	1	2			1	2
	150	261	24	54	126	207

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Anaphylactic reaction	1	7			1	7
Angioedema		3				3
Asthenia	2	4	2	3		1
Blindness transient		1				1
Blood glucose increased		1		1		
Blood pressure increased		1		1		
Cerebrovascular accident		1				1
Chest discomfort	1	1			1	1
Chills	1	3			1	3
Cholecystitis acute	1	1			1	1
Cough	1	1			1	1
COVID-19	1	1			1	1
Deep vein thrombosis	1	1			1	1
Diarrhoea	1	2			1	2
Dizziness	1	5		1	1	4
Dyspnoea	1	5		2	1	3
Epilepsy		1				1
Erythema	1	2			1	2
Erythema annulare	1	1			1	1
Eye haemorrhage	1	1			1	1
Eyelid oedema		2				2
Facial paralysis		1				1
Facial paresis	2	2			2	2
Fatigue	2	3	1	2	1	1
Feeling cold		2		2		
Gastritis	1	1			1	1
Gastroesophageal reflux disease	1	1			1	1
Haemophagocytic lymphohistiocytosis	1	1			1	1
Headache	3	5	1	2	2	3
Herpes zoster	1	2			1	2
Hyperhidrosis		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	4	8		1	4	7
Hypertension	2	5		1	2	4
Hypotension	1	1			1	1
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Influenza like illness	1	1	1	1		
Lip oedema		1				1
Lip swelling	1	1			1	1
Lymphadenopathy	2	3		1	2	2
Malaise		2		1		1
Middle insomnia		1		1		
Mobility decreased	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Myalgia	3	5			3	5
Nausea	2	4			2	4
Oedema peripheral		2		1		1
Oesophageal perforation		1				1
Off label use	1	1	1	1		
Oropharyngeal oedema	1	1			1	1
Paraesthesia		2		1		1
Paraesthesia oral	1	1			1	1
Peripheral swelling		1				1
Pharyngeal paraesthesia	1	1			1	1
Platelet count increased		1		1		
Presyncope	1	1			1	1
Pruritus		3		2		1
Pulmonary embolism	1	1			1	1
Pyrexia	1	4		1	1	3
Rash		2				2
SARS-CoV-2 antibody test negative		1		1		
Sedation	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sense of oppression		1				1	
Septic shock		1				1	
Skin lesion		1				1	
Sleep disorder		1		1			
Sudden hearing loss		1				1	
Throat tightness	1	1			1	1	
Thrombocytopenia	1	1			1	1	
Tinnitus		1				1	
Tongue oedema		1				1	
Underdose		1		1			
Urticaria		1				1	
Vaccination site erythema		1				1	
Vaccination site haematoma		1				1	
Vaccination site pain		2		1		1	
Vaccination site reaction	1	1			1	1	
Vaccination site swelling		1				1	
Vaccination site urticaria		1				1	
Vertigo	1	1	1	1			
Vomiting	2	5			2	5	
Wrong technique in product usage process		1		1			
	63	152	13	39	50	113	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2			1	2
Abdominal pain lower		1				1
Agitation		1				1
Alanine aminotransferase increased		1		1		
Amnesia	1	1	1	1		
Anaemia		1				1
Anaphylactic reaction		3				3
Anti-myelin-associated glycoprotein antibodies positive		1				1
Aphasia		2				2
Arrhythmia	2	2			2	2
Arthralgia	2	5			2	5
Ascites		1				1
Atrial fibrillation	2	2			2	2
Blood alkaline phosphatase increased		1		1		
Blood pressure increased	1	2			1	2
Cardiac failure acute	1	1			1	1
Cardiovascular disorder	1	1			1	1
Central nervous system lesion		1				1
Cerebrovascular accident		1				1
Cheilitis		1		1		
Chest pain	2	2			2	2
Chills		3				3
Cholestasis		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse	1	1			1	1
Cold sweat	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state		1				1
Conjunctivitis bacterial		1				1
Cough		1				1
COVID-19		3				3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19 pneumonia	1	1
C-reactive protein increased		1
Cystitis	1	1
Deafness unilateral		1
Decreased appetite		1
Deep vein thrombosis	1	1
Delirium	1	2
Dermatitis allergic		1
Diarrhoea		1
Discomfort	1	1
Disease recurrence	1	1
Disturbance in attention	2	2
Dizziness	3	5
Drug ineffective		1
Dysarthria	1	1
Dysgeusia		2
Dyspnoea	2	4
Embolic stroke		1
Encephalitis		1
Encephalopathy		1
Eosinophilia		1
Epilepsy	1	3
Epistaxis		1
Erysipeloid		1
Erythema	1	2
Eyelids pruritus		1
Facial paresis	1	1
Fall	3	3
Fatigue	1	1
Gait disturbance		2
Generalised tonic-clonic seizure		1
General physical health deterioration		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
		1	1
			1
			1
		1	1
		1	2
	1		
			1
1	1		
		1	1
		2	2
	2	3	3
			1
		1	1
	2		
1	1	1	3
			1
			1
	1		
		1	3
	1		
			1
	1	1	1
	1		
		1	1
1	1	2	2
		1	1
			1
	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gout		1				1
Haematemesis	1	1			1	1
Hallucination, visual	1	1			1	1
Headache	2	8		1	2	7
Herpes zoster	7	7			7	7
Hypersensitivity	2	3			2	3
Hypertension	3	4			3	4
Hypertensive crisis		1				1
Hypertensive emergency		1				1
Hypotension		1		1		
Immune thrombocytopenia		1				1
Infection		1		1		
Inflammation		1				1
Influenza like illness		1				1
Ischaemic cerebral infarction	1	1			1	1
Joint dislocation	1	1			1	1
Loss of consciousness	1	1			1	1
Lung disorder	1	1			1	1
Malaise	2	4			2	4
Metabolic syndrome		1				1
Monocytosis		1		1		
Musculoskeletal stiffness		1				1
Myalgia	1	3			1	3
Myocardial infarction	1	1			1	1
Nausea	1	3		2	1	1
Neuralgia	1	1			1	1
NIH stroke scale score decreased	1	1			1	1
Ophthalmic herpes zoster	1	1			1	1
Pain		1		1		
Pain in extremity	2	2	1	1	1	1
Pallor	1	1			1	1
Palpitations		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatitis		1				1
Paraesthesia		1				1
Paraesthesia oral		1				1
Parotitis	1	1			1	1
Pleocytosis		1				1
Pleural effusion		1		1		
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Polyneuropathy		1				1
Presyncope	1	1			1	1
Pruritus	1	6		2	1	4
Pulmonary embolism	1	1			1	1
Pulmonary fibrosis	1	1			1	1
Pyrexia	2	8	1	3	1	5
Rash		2		1		1
Rash erythematous		1				1
Rash maculo-papular	1	2		1	1	1
Rash pustular		1				1
Respiratory failure	1	1			1	1
Rheumatoid arthritis		2				2
Road traffic accident	1	1			1	1
Salivary hypersecretion		1				1
Scratch		1		1		
Sensory disturbance	1	1			1	1
Sepsis		1				1
Skin disorder	1	1			1	1
Skin reaction	1	1			1	1
Somnolence		2				2
Speech disorder		1				1
Stress cardiomyopathy	1	1			1	1
Sudden death	1	2			1	2
Syncope	2	3			2	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	2			1	2
Tendon rupture	1	1			1	1
Thrombocytopenia		1				1
Transient ischaemic attack		2				2
Urinary incontinence		1				1
Urticaria		1		1		
Vaccination failure	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site pain		2		1		1
Vaccination site pruritus		1				1
Varicella zoster virus infection	1	1			1	1
Vascular encephalopathy		1				1
Vertigo	1	1			1	1
Vertigo positional		1				1
Visual impairment	1	1			1	1
Vomiting		3		2		1
White matter lesion		1		1		
	91	226	6	41	85	185

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal infection		1				1
Abdominal pain	2	4		1	2	3
Acute kidney injury	1	2			1	2
Acute myocardial infarction	1	2			1	2
Acute pulmonary oedema	1	2			1	2
Alopecia	1	1			1	1
Altered state of consciousness		1				1
Anal haemorrhage		1		1		
Anaphylactic reaction		1				1
Angioedema		1				1
Aphasia		2				2
Aphthous ulcer	1	1			1	1
Apnoea	1	1			1	1
Appendicitis		1				1
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia		1				1
Asthenia	2	5			2	5
Atrial fibrillation	2	2			2	2
Atrophy		1				1
Back pain	1	2		1	1	1
Blister		1		1		
Blood pressure decreased		1				1
Brain hypoxia		1				1
Cardiac arrest	1	2			1	2
Cardiac failure	3	5			3	5
Cardiac failure acute	1	1			1	1
Cardiac failure chronic		1				1
Cardiac failure congestive	1	1			1	1
Cardiac fibrillation		1				1
Cardio-respiratory arrest		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cerebral infarction		1					1
Cerebrovascular accident	1	2			1		2
Chills	1	2		1	1		1
Cholestasis	1	1			1		1
Chronic obstructive pulmonary disease		1					1
Circulatory collapse	1	1			1		1
Coma		2					2
Condition aggravated	1	1			1		1
Confusional state	1	2			1		2
Cough	1	2			1		2
COVID-19	1	6		1	1		5
Craniocerebral injury	1	1			1		1
C-reactive protein increased	1	3	1	1			2
CSF test abnormal		1					1
Death	1	6			1		6
Decreased appetite	1	2		1	1		1
Dehydration	1	2			1		2
Delirium	1	2			1		2
Dementia		1					1
Diabetic ketoacidosis		1					1
Diabetic metabolic decompensation		1					1
Diarrhoea	1	4		2	1		2
Discomfort		1					1
Disorientation		2					2
Disturbance in attention		1					1
Dizziness	2	4		1	2		3
Dysarthria		1					1
Dyspnoea	4	5			4		5
Ear pain		1					1
Embolism		1					1
Enuresis	1	1			1		1
Epilepsy		2					2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Erysipelas	2	2
Erythema		1
Facial paralysis		1
Facial paresis	1	1
Fall	1	3
Fatigue	3	6
Feeding disorder	1	2
Fluid overload	1	1
Gait disturbance		1
Gastric disorder		1
Generalised tonic-clonic seizure		1
General physical health deterioration	3	7
Glomerulonephritis minimal lesion		1
Haemorrhagic stroke		1
Headache		3
Heart rate decreased		1
Hemiplegia		1
Hepatic cirrhosis		1
Hepatocellular injury	1	1
Herpes zoster	3	5
Hyperglycaemia		1
Hypersensitivity		1
Hypertension	1	3
Hypertensive crisis		1
Hyperthermia		1
Hypoglycaemic coma		1
Hypotension	3	3
Incorrect route of product administration	2	3
Inflammation		2
Insomnia		1
Ischaemic cerebral infarction		2
Joint swelling		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	2
			1
			1
		1	1
		1	3
	1	3	5
1	1		1
		1	1
			1
			1
			1
2	2	1	5
			1
			1
	3		
			1
			1
		1	1
		3	5
			1
		1	3
			1
	1		
			1
		3	3
2	3		
			2
	1		
			2
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liver disorder	1	1			1	1
Liver injury		1				1
Loss of consciousness	1	2			1	2
Lymphangiectasia	1	1			1	1
Lymphopenia		1				1
Malaise	1	4		1	1	3
Meniere's disease	1	1			1	1
Meningioma	1	1			1	1
Muscle disorder		1				1
Muscular weakness		1				1
Myalgia		1		1		
Nausea	3	7		1	3	6
Neck pain		1				1
Nervous system disorder		1				1
Neuralgia	1	1			1	1
Neutrophilia		1				1
Oedema peripheral	1	1			1	1
Ophthalmic herpes zoster	1	1			1	1
Oropharyngeal pain		1				1
Oxygen saturation decreased	1	3			1	3
Pain	1	2		1	1	1
Paranoia		1				1
Performance status decreased	1	1			1	1
Pericardial effusion	1	1			1	1
Peripheral vascular disorder		1				1
Pleural effusion	1	1			1	1
Pneumonia	2	3			2	3
Pruritus	1	3			1	3
Pulmonary embolism	3	3			3	3
Pulmonary oedema	1	1			1	1
Purpura	1	1			1	1
Pyrexia	5	15	1	1	4	14

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Rash		1				1	
Rash pruritic	1	1			1	1	
Renal failure		2				2	
Renal impairment	1	1			1	1	
Respiratory depression		1				1	
Respiratory distress		1				1	
Respiratory failure		2				2	
Respiratory paralysis		1				1	
Respiratory tract infection		1				1	
Scratch	1	1	1	1			
Seizure		1				1	
Sensory disturbance		1				1	
Sepsis		1				1	
Skull fracture	1	1			1	1	
Somnolence		2				2	
Spinal cord ischaemia	1	1			1	1	
Subdural haematoma	1	1			1	1	
Sudden death	1	1			1	1	
Swelling face		1		1			
Swollen tongue		1				1	
Tachycardia	1	2			1	2	
Tachypnoea		1				1	
Tremor		1				1	
Type I hypersensitivity		1				1	
Urinary tract infection	1	2			1	2	
Urinary tract infection bacterial		1				1	
Urogenital haemorrhage		1				1	
Urticaria		2				2	
Vaccination failure	1	1			1	1	
Vaccination site erythema	1	2		1	1	1	
Vaccination site pain	2	4		2	2	2	
Vaccination site rash		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	1	1			1	1
Ventricular fibrillation		1				1
Vertigo		1				1
Vomiting	4	8		1	4	7
Weight decreased	1	1	1	1		
	113	294	10	37	103	257

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Amnesia		1		1		
Arrhythmia		2				2
Asthenia	1	1			1	1
Body temperature increased		1		1		
Bone formation increased		1		1		
Bone pain	1	1	1	1		
Chest pain	1	1			1	1
Chills	1	4	1	3		1
COVID-19	1	3			1	3
Depressed mood	1	1	1	1		
Diarrhoea	1	1			1	1
Dizziness		1				1
Drug ineffective	1	3			1	3
Dyspnoea	1	1			1	1
Ear pruritus	1	1			1	1
Fatigue		1		1		
Gastrointestinal disorder	2	2	2	2		
Gastrooesophageal reflux disease	1	1			1	1
Genital herpes	1	1			1	1
Headache	1	1	1	1		
Influenza like illness		1				1
Migraine	1	1	1	1		
Myalgia	2	3	2	3		
Nausea	1	2	1	1		1
Odynophagia		1				1
Pain in extremity		2		2		
Peak expiratory flow rate decreased	1	1			1	1
Pyrexia	2	4	1	2	1	2
Swelling face	1	1	1	1		
Tendon pain	1	1	1	1		
Therapeutic response unexpected		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tumour marker increased	2	2	2	2		
Underdose		1		1		
Viral infection	1	1	1	1		
Vomiting		1				1
Wrong product administered		1		1		
	27	54	16	30	11	24

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**TUNISIA**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	2	2	2	2
Chills	1	1	1	1
Cough	1	1	1	1
Dizziness	2	2	2	2
Dysgeusia	1	1	1	1
Fatigue	1	1	1	1
Headache	1	1	1	1
Hypertension	1	1	1	1
Influenza like illness	1	1	1	1
Injection site pain	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
Paraesthesia	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	2	2	2	2
	19	19	19	19

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
Fatigue	1	1	1	1
Joint range of motion decreased	1	1	1	1
Vertigo	1	1	1	1
	4	4	4	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**TURKEY**

Age Range

**18 - 30 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Incorrect dose administered	1	1	1	1		
Product preparation error	1	1	1	1		
	5	5	3	3	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Chills	1	1	1	1		
COVID-19	1	1	1	1		
Dizziness	2	2	2	2		
Dry skin	1	1	1	1		
Dyspnoea	1	1	1	1		
Erythema	2	2	2	2		
Fatigue	1	1	1	1		
Headache	4	4	4	4		
Inappropriate schedule of product administration	1	1	1	1		
Meningitis	1	1			1	1
Nausea	1	1	1	1		
Off label use	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	1	1	1	1		
Swelling face	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vomiting	1	1	1	1		
	26	26	24	24	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
COVID-19	2	2	2	2		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Herpes zoster	1	1	1	1		
Invasive ductal breast carcinoma	1	1			1	1
Malaise	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Pyrexia	1	1	1	1		
Tonsillar hypertrophy	1	1	1	1		
Vaccination site pain	2	2	2	2		
	14	14	13	13	1	1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Cough	1	1	1	1
Maternal exposure during pregnancy	1	1	1	1
Overdose	1	1	1	1
Product preparation error	1	1	1	1
Pyrexia	1	1	1	1
Toothache	2	2	2	2
Vaccination site pain	1	1	1	1
	9	9	9	9

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred  
**TURKS AND CAICOS ISLANDS**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Myalgia		1		1		
Nodule		1		1		
Seizure		1				1
		5		3		2

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Haemorrhagic stroke	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UKRAINE**

Age Range

**31 - 50 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED ARAB EMIRATES**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Pain		1		1		
Swelling		1				1
		3		2		1

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Back pain	1	1	1	1		
Chills	1	1	1	1		
COVID-19		1				1
Dizziness		1		1		
Drug ineffective		1				1
Headache	1	2	1	2		
Myalgia	1	1	1	1		
Nausea	1	3	1	3		
Pyrexia	1	2	1	2		
Vomiting		2		2		
	7	16	7	14		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Arthralgia		1		1		
Back pain		1		1		
Chest pain	1	2			1	2
Chills	1	2	1	2		
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Depressed mood		1				1
Dizziness		1				1
Dysgeusia	1	1	1	1		
Dyspnoea		1		1		
Erythropeia		1				1
Facial paralysis	1	1			1	1
Fatigue	1	4	1	4		
Feeling abnormal		1		1		
Fibromyalgia		1		1		
Headache	2	3	2	2		1
Head injury	1	1			1	1
Hypertension		1				1
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy		1		1		
Nausea		3		2		1
Neurotoxicity		1				1
Pain in extremity	1	1	1	1		
Pruritus		1		1		
Pyrexia	2	4	2	4		
Rash	1	2	1	2		
Skin irritation		1		1		
Sleep deficit		1		1		
Somnolence		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sudden death		1				1	
Thrombosis	1	1			1	1	
Vaccination site pain	1	2	1	2			
	15	49	10	34	5	15	

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Back pain		1		1			
Blindness unilateral	1	1			1	1	
Cough		1		1			
COVID-19	1	2	1	1		1	
Dyspnoea		1				1	
Fatigue	1	2	1	2			
Hypoxia		1				1	
Inappropriate schedule of product administration	1	1	1	1			
Ocular vascular disorder	1	1			1	1	
Pyrexia		2		2			
Tachypnoea		1		1			
Thrombosis	1	1			1	1	
Vaccination site pain	1	1	1	1			
	7	16	4	10	3	6	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
COVID-19		1				1
Dizziness		1		1		
Drug ineffective		1				1
Gait disturbance		1		1		
Ophthalmic herpes zoster	1	1			1	1
Pyrexia		1		1		
Rectal haemorrhage		1				1
Vaccination site pain		2		2		
Vision blurred		1		1		
	1	11		6	1	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Arthralgia		1		1		
Asthenia	1	1	1	1		
Babesiosis		1				1
Bone pain	1	1	1	1		
Chest discomfort		1		1		
COVID-19	2	6	1	1	1	5
Death		1				1
Dizziness		1		1		
Drug ineffective	1	5			1	5
Dysgeusia	1	1	1	1		
Erectile dysfunction		1				1
Facial paralysis		1				1
Fatigue	1	1	1	1		
Feeling abnormal		1		1		
Headache		2		2		
Hyperhidrosis	1	1	1	1		
Hypertension		1		1		
Hypoacusis		1				1
Hypoaesthesia		1				1
Lyme disease		1				1
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Maternal exposure timing unspecified		1		1		
Muscle fatigue		1		1		
Myalgia	1	1	1	1		
Nasopharyngitis		1		1		
Neuralgia		1		1		
Off label use		1		1		
Pain	1	2	1	2		
Paraesthesia		1		1		
Pneumonia	1	1			1	1

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 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue		1		1		
Pyrexia	1	2	1	2		
Rash		1				1
Respiratory tract irritation		1		1		
SARS-CoV-2 antibody test negative		3		3		
Sciatica		2		2		
Suspected COVID-19	1	1			1	1
Tremor	1	1	1	1		
Urticaria		1				1
Vaccination failure	1	1			1	1
Vaccination site pain	1	2	1	2		
Vision blurred		1		1		
	18	60	13	38	5	22

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**UNITED KINGDOM**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	3		2	1	1
Abnormal faeces		1				1
Acne	1	1	1	1		
Agitation	1	1			1	1
Anaphylactic reaction	1	2			1	2
Anaphylactoid reaction	1	1			1	1
Angina pectoris		1				1
Angioedema	1	3			1	3
Anxiety	1	1	1	1		
Arteriospasm coronary		1				1
Arthralgia	4	12	3	5	1	7
Asthenia		5		1		4
Asthma	1	1			1	1
Axillary pain		1				1
Balance disorder		1		1		
Blood urine present		1				1
Body temperature increased	1	3	1	2		1
Breath odour	1	1	1	1		
Cardiac discomfort		1				1
Cellulitis		1				1
Cerebral infarction	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest discomfort	1	2	1	1		1
Chest pain	2	3	1	1	1	2
Chills	2	11	2	6		5
Constipation	1	1			1	1
Contusion		1		1		
Cough	1	2	1	2		
COVID-19		2				2
Crying		1				1
Decreased appetite	1	2			1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration	1	1			1	1
Diarrhoea		5		3		2
Diarrhoea haemorrhagic	1	1			1	1
Discomfort	1	2		1	1	1
Disease recurrence	2	3			2	3
Dizziness	7	11	3	4	4	7
Dizziness exertional		1		1		
Dizziness postural		1				1
Drug ineffective		2				2
Dry mouth		1				1
Dry throat	1	2	1	1		1
Dysgeusia		2		1		1
Dyspnoea	2	4		1	2	3
Dysuria		1				1
Ear pain		1		1		
Epilepsy		2				2
Epileptic encephalopathy		1				1
Epistaxis	1	1			1	1
Erythema	1	2	1	1		1
Exertional headache		1		1		
Exposure via breast milk	13	33	9	20	4	13
External ear pain		1				1
Facial paralysis	1	3			1	3
Fall		1		1		
Fatigue	7	20	4	10	3	10
Feeling abnormal		2		2		
Feeling cold	1	1	1	1		
Feeling hot		2		1		1
Feeling of body temperature change		1		1		
Flushing		2				2
Gait disturbance		1		1		
Generalised tonic-clonic seizure		1				1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glossodynia	1	1	1	1		
Headache	11	31	5	13	6	18
Heart rate increased		1				1
Hot flush	1	2		1	1	1
Hyperacusis		1				1
Hyperhidrosis	1	3		1	1	2
Hypersensitivity	1	1			1	1
Hypoaesthesia	1	2			1	2
Hypotension	1	1			1	1
Illness	3	6			3	6
Inappropriate schedule of product administration		1		1		
Increased appetite	1	1	1	1		
Infantile vomiting		1				1
Infant irritability	1	2	1	1		1
Infection	1	1	1	1		
Influenza		1				1
Influenza like illness	1	1	1	1		
Insomnia	1	2	1	1		1
Joint swelling	1	1	1	1		
Jugular vein thrombosis	1	1			1	1
Lacrimation increased	1	1	1	1		
Lennox-Gastaut syndrome		1				1
Lip swelling	1	1			1	1
Loss of consciousness		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	2	6	1	1	1	5
Malaise	5	7	4	5	1	2
Mastitis		1				1
Maternal exposure during breast feeding	1	1			1	1
Maternal exposure during pregnancy		1				1
Menorrhagia	1	1	1	1		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	1	3			1	3
Miliaria	1	1	1	1		
Mobility decreased		2		2		
Musculoskeletal stiffness	1	3	1	1		2
Myalgia	5	10	4	7	1	3
Nasopharyngitis	1	2	1	1		1
Nausea	8	20	3	7	5	13
Neonatal pneumothorax		1				1
Neonatal respiratory distress		1				1
Nervousness	1	1			1	1
Neuralgia	1	1			1	1
Off label use	8	23	8	23		
Oral pain	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain	5	13	3	7	2	6
Pain in extremity	6	16	5	8	1	8
Palpitations	1	2	1	1		1
Paraesthesia	3	4	2	2	1	2
Parosmia		1				1
Peripheral swelling		3		2		1
Pharyngeal leukoplakia		1		1		
Photophobia		1				1
Pineal gland cyst	1	1			1	1
Platelet count decreased	1	1			1	1
Poor feeding infant	1	1			1	1
Post laminectomy syndrome		1				1
Premature baby		1				1
Product administered at inappropriate site		1		1		
Product administered to patient of inappropriate age	7	30	7	28		2
Product use issue	9	17	9	16		1
Pruritus	2	6	1	2	1	4

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Psychogenic seizure		1					1
Pyrexia	2	23	1	11	1		12
Rash	4	8	2	4	2		4
Rash papular		1					1
Rash pruritic		1					1
Respiratory rate decreased		1					1
Screaming	1	1	1	1			
Seasonal allergy	1	1			1		1
Seizure		5					5
Sinus disorder		1					1
Sinusitis		1		1			
Sinus tachycardia		1		1			
Skin exfoliation		1					1
Sleep disorder		1		1			
Sleep disorder due to general medical condition, insomnia type	1	1			1		1
Sneezing	1	1	1	1			
Somnolence		2					2
Spinal pain		1		1			
Status epilepticus		1					1
Suspected COVID-19		2		1			1
Swelling	2	5	1	3	1		2
Swollen tongue		1					1
Syncope	1	5			1		5
Tachycardia	1	1			1		1
Tenderness		1		1			
Thermal burn		1		1			
Thirst		1		1			
Thrombosis	1	1			1		1
Tongue ulceration	2	3	2	2			1
Tonsillar hypertrophy		1		1			
Tremor	1	2	1	1			1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Urine analysis abnormal		1					1
Urticaria		2		1			1
Vaccination site erythema	2	3	2	3			
Vaccination site movement impairment		1		1			
Vaccination site pain	3	9	3	7			2
Vaccination site pruritus		1		1			
Vaccination site rash	2	2	1	1	1		1
Vaccination site reaction		1					1
Vaccination site swelling	1	2	1	2			
Vaccination site warmth	1	1	1	1			
Vertigo	1	1			1		1
Viral infection		1					1
Vision blurred	1	1			1		1
Vomiting	4	11			4		11
Weight decreased	1	1			1		1
Wheezing	2	3			2		3
Yellow skin		1		1			
	1	3	1	3			
	204	560	116	275	88		285

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	5	18			2	6	3	12
Abdominal distension	3	13			1	5	2	8
Abdominal pain	17	63			6	16	11	47
Abdominal pain lower		3				2		1
Abdominal pain upper	28	96			10	37	18	59
Abdominal rigidity		1						1
Abdominal tenderness		1						1
Abnormal behaviour		1				1		
Abnormal dreams	1	8				5	1	3
Abnormal sensation in eye		2				1		1
Abortion spontaneous	7	16					7	16
Abscess	1	1					1	1
Accidental exposure to product		2				1		1
Acne	2	3			2	2		1
Acute abdomen		1						1
Acute kidney injury		2						2
Acute myocardial infarction	1	2					1	2
Administration site joint movement impairment		2						2
Adverse drug reaction	1	3				2	1	1
Ageusia	8	24			5	11	3	13
Agitation		8				4		4
Akathisia		1						1
Alanine aminotransferase increased		2						2
Alexithymia		1				1		
Allergic reaction to excipient		2						2
Allergy to vaccine		3				1		2
Allodynia	1	2					1	2
Alopecia		1						1
Altered state of consciousness	1	2					1	2
Amenorrhoea	2	4				1	2	3
Ammonia abnormal		1				1		
Amnesia	1	5					1	5

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaemia		1
Anal haemorrhage	1	2
Anal incontinence		1
Anaphylactic reaction	5	30
Anaphylactoid reaction		3
Anger	1	2
Angina pectoris	2	2
Angioedema	3	13
Anisomastia		1
Ankylosing spondylitis		1
Anosmia	2	10
Anovulatory cycle		1
Anticholinergic syndrome		1
Anxiety	7	29
Aphasia		1
Aphonia	2	4
Aphthous ulcer	1	3
Appendicitis		1
Application site vesicles	1	1
Arthralgia	139	463
Arthritis	2	3
Aspartate aminotransferase increased		1
Asthenia	39	128
Asthenopia	2	9
Asthma	3	18
Asymptomatic COVID-19		1
Atonic seizures		2
Atrial fibrillation		1
Atrial tachycardia		1
Auditory disorder		1
Aura		3
Autoimmune disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
					1
				5	30
					3
			1	1	1
				2	2
				3	13
			1		
					1
		1	5	1	5
					1
					1
		2	14	5	15
					1
		2	3		1
				1	3
					1
				1	1
		87	208	52	255
		1	1	1	2
					1
		18	51	21	77
		1	3	1	6
			3	3	15
			1		
					2
					1
					1
			1		
			3		
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Autoimmune neutropenia	1	1
Autonomic nervous system imbalance		1
Axillary mass	6	17
Axillary pain	66	132
Bacille Calmette-Guerin scar reactivation	1	3
Back pain	31	132
Balance disorder	3	9
Basedow's disease	1	1
Bedridden		1
Behaviour disorder		2
Behcet's syndrome	2	4
Binocular eye movement disorder		1
Bipolar I disorder	1	1
Blepharospasm		2
Blindness	2	3
Blister	3	5
Blood blister		1
Blood creatine phosphokinase increased		1
Blood glucose decreased	1	2
Blood glucose fluctuation		2
Blood glucose increased	1	8
Blood heavy metal increased		1
Blood immunoglobulin E increased	1	1
Blood ketone body increased		1
Blood ketone body present		1
Blood potassium decreased		1
Blood pressure decreased	1	9
Blood pressure increased	4	9
Blood pressure orthostatic decreased		1
Blood prolactin increased		1
Blood test abnormal	1	2
Blood testosterone increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		3	8	3	9
		16	43	50	89
			2	1	1
		20	57	11	75
		3	4		5
				1	1
			1		
					2
				2	4
					1
				1	1
					2
				2	3
		1	2	2	3
					1
					1
				1	2
					2
			2	1	6
			1		
				1	1
					1
					1
					1
			4	1	5
		2	5	2	4
					1
			1		
				1	2
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood thyroid stimulating hormone increased		1
Blood urine present		1
Blue toe syndrome	1	2
Body temperature	3	4
Body temperature abnormal	3	6
Body temperature decreased	1	4
Body temperature fluctuation	4	8
Body temperature increased	11	27
Bone disorder	1	1
Bone pain	3	25
Bradycardia		3
Bradykinesia	1	2
Bradyphrenia		2
Brain neoplasm		1
Brain oedema		1
Breast cancer	1	1
Breast mass		1
Breast pain	3	13
Breast swelling	1	4
Breast tenderness	2	4
Breath odour	1	4
Burning sensation	11	21
Bursitis		1
Candida infection		1
Cardiac arrest		2
Cardiac disorder	1	2
Cardiac flutter		4
Cardiovascular disorder		1
Carpal tunnel syndrome	1	2
Cellulitis	4	9
Cerebellar haemorrhage	1	1
Cerebral venous sinus thrombosis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				1	2
		3	4		
		2	3	1	3
			1	1	3
		2	3	2	5
		7	17	4	10
				1	1
		2	11	1	14
					3
				1	2
					2
					1
					1
				1	1
					1
		1	2	2	11
			1	1	3
		1	1	1	3
			1	1	3
		4	7	7	14
					1
					1
					2
		1	1		1
					4
					1
				1	2
				4	9
				1	1
				2	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral venous thrombosis	1	1
Cerebrovascular accident	3	4
Chapped lips		2
Cheilitis	1	2
Chest crushing	1	1
Chest discomfort	23	77
Chest pain	31	115
Chillblains	2	2
Chills	219	738
Choking		1
Choking sensation		1
Chondritis		1
Chromaturia	2	6
Chronic fatigue syndrome		2
Chronic gastritis	1	1
Circulatory collapse	1	2
Clavicle fracture	1	1
Cluster headache	7	11
Coeliac disease		2
Cold sweat	12	51
Cold urticaria	1	1
Colitis		1
Colitis ulcerative	1	1
Condition aggravated	12	26
Confusional state	5	26
Congenital cystic lung		1
Congestive hepatopathy		1
Conjunctival haemorrhage	1	2
Conjunctival hyperaemia		1
Constipation	4	14
Constricted affect		1
Contusion	15	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				3	4
			1		1
		1	2		
				1	1
		10	26	13	51
		12	31	19	84
		2	2		
		149	385	70	353
					1
					1
					1
		1	4	1	2
					2
				1	1
				1	2
				1	1
		3	3	4	8
					2
		5	24	7	27
		1	1		
					1
				1	1
		5	8	7	18
		2	4	3	22
					1
					1
				1	2
					1
		3	5	1	9
					1
		9	20	6	13

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coordination abnormal	2	5
Coronavirus test positive		1
Cortisol decreased		1
Costochondritis		4
Cough	29	106
COVID-19	16	69
C-reactive protein increased	1	1
Crohn's disease		1
Crying	2	10
Cyanosis	3	5
Cyst	1	1
Cystitis		1
Deafness		5
Deafness unilateral	1	1
Death		2
Decreased appetite	24	95
Decreased interest		1
Deep vein thrombosis	2	3
Defaecation urgency		1
Dehydration		6
Delirium	3	6
Delusion		1
Depressed level of consciousness	1	1
Depressed mood	2	9
Depression	2	2
Depression suicidal	1	2
Derealisation		1
Dermatitis	2	11
Dermatitis allergic	1	8
Dermatitis exfoliative		1
Device infusion issue		1
Diabetes mellitus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	3
			1		
					1
			1		3
		20	44	9	62
		8	24	8	45
				1	1
					1
			5	2	5
		2	2	1	3
		1	1		
			1		
					5
				1	1
					2
		14	45	10	50
			1		
				2	3
					1
			1		5
				3	6
					1
				1	1
		1	4	1	5
		1	1	1	1
				1	2
			1		
		1	5	1	6
		1	1		7
					1
					1
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diabetes mellitus inadequate control		2
Diabetic complication	1	2
Diabetic ketoacidosis	1	3
Diaphragmalgia	2	2
Diarrhoea	55	194
Diarrhoea haemorrhagic		2
Diplegia	1	1
Diplopia	1	3
Discharge		1
Discoloured vomit		1
Discomfort	6	22
Disease recurrence	7	30
Disorientation	2	10
Dissociation	1	2
Dissociative disorder		1
Disturbance in attention	8	25
Dizziness	155	495
Dizziness postural	13	41
Drooling	2	2
Drooping shoulder syndrome		1
Drug eruption	1	2
Drug hypersensitivity	1	3
Drug ineffective	13	72
Dry eye		4
Dry mouth	5	21
Dry skin	4	11
Dry throat	3	6
Dysarthria	2	3
Dysgeusia	8	31
Dyskinesia	2	6
Dysmenorrhoea	3	8
Dyspepsia	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	2
				1	3
		1	1	1	1
		27	71	28	123
					2
				1	1
		1	3		
					1
			1		
		2	9	4	13
		1	5	6	25
			2	2	8
			1	1	1
			1		
		3	8	5	17
	1	91	220	64	275
		8	17	5	24
		1	1	1	1
			1		
		1	2		
			1	1	2
				13	72
			2		2
		4	13	1	8
		2	5	2	6
		3	5		1
				2	3
		5	16	3	15
			3	2	3
		1	4	2	4
		1	3	1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysphagia	7	18
Dysphemia		1
Dysphonia	1	8
Dyspnoea	35	157
Dyspnoea at rest		1
Dyspnoea exertional	2	6
Dysstasia	1	7
Dystonia	1	3
Dysuria		1
Ear discomfort		5
Ear disorder	1	2
Ear infection	2	3
Ear pain	11	34
Ear pruritus		1
Ear swelling		1
Eating disorder symptom		1
Eczema	1	5
Embolism	2	2
Emotional disorder	2	3
Emotional distress	2	3
Encephalitis	2	3
Encephalopathy		1
Endometriosis	2	2
Energy increased	1	1
Enlarged uvula		1
Eosinophil count increased		1
Epilepsy	2	7
Epinephrine increased		1
Epistaxis	9	22
Erectile dysfunction		2
Eructation		2
Erythema	42	124

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7	4	11
					1
		1	2		6
		13	35	22	122
					1
			2	2	4
			2	1	5
				1	3
			1		
			2		3
		1	2		
		1	1	1	2
		4	7	7	27
					1
					1
					1
			1	1	4
				2	2
		2	2		1
		1	2	1	1
				2	3
					1
		1	1	1	1
		1	1		
					1
			1		
				2	7
					1
		4	9	5	13
					2
			1		1
		28	70	14	54

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema multiforme		5
Erythema nodosum	2	2
Erythema of eyelid		1
Euphoric mood	1	3
Eustachian tube dysfunction		1
Exercise tolerance decreased	2	2
Exfoliative rash	1	4
Expired product administered		1
Exposure during pregnancy		3
Exposure to SARS-CoV-2		1
Exposure via breast milk	1	1
Extensive swelling of vaccinated limb	1	3
Extrasystoles	1	1
Eye contusion		1
Eye discharge		1
Eye disorder		2
Eye infection	1	1
Eye injury		1
Eye irritation	1	8
Eyelid function disorder		1
Eyelid pain		1
Eyelid rash	1	2
Eye oedema	1	1
Eye pain	15	60
Eye pruritus	4	17
Eye swelling	3	18
Face injury		1
Face oedema		1
Facial discomfort	1	1
Facial pain	1	10
Facial paralysis	5	24
Facial paresis	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
		1	1	1	1
			1		
				1	3
					1
				2	2
				1	4
			1		
			3		
					1
		1	1		
		1	2		1
				1	1
			1		
					1
					2
				1	1
					1
		1	1		1
		1	1		
		8	18	7	42
		4	11		6
		3	7		11
			1		
					1
		1	1		
		1	4		6
				5	24
		1	1		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial spasm	1	3
Faecaloma		2
Faeces discoloured		2
Fall	1	4
Fatigue	355	1,225
Fear		1
Febrile convulsion	1	2
Feeding disorder		4
Feeling abnormal	21	62
Feeling cold	26	87
Feeling drunk		4
Feeling hot	22	94
Feeling jittery		2
Feeling of body temperature change	9	36
Feeling of despair		1
Fibrin D dimer increased	1	1
Fibromyalgia	2	2
Fine motor skill dysfunction	1	1
Flank pain	2	3
Flat affect		1
Flatulence		4
Fluid imbalance	1	1
Fluid intake reduced		1
Flushing	4	22
Foetal death	1	1
Folliculitis		1
Food allergy	1	1
Food refusal		1
Foreign body sensation in eyes		1
Formication		1
Frequent bowel movements		4
Frustration tolerance decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					2
					2
		1	3		1
1	4	225	581	130	644
			1		
		1	2		
			4		
		10	20	11	42
		9	39	17	48
			1		3
		15	57	7	37
			1		1
		2	17	7	19
					1
		1	1		
		1	1	1	1
				1	1
		2	2		1
			1		
			4		
				1	1
					1
		4	10		12
				1	1
			1		
				1	1
					1
			1		
					1
					4
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait disturbance	12	21
Gait inability	1	9
Galactorrhoea		1
Gastric disorder		1
Gastric ulcer		1
Gastritis		2
Gastroenteritis		1
Gastroenteritis norovirus	1	1
Gastroenteritis viral		2
Gastrointestinal disorder	1	3
Gastrointestinal motility disorder		1
Gastrointestinal pain	2	3
Gastrointestinal wall thickening		1
Gastrooesophageal reflux disease	2	5
Generalised tonic-clonic seizure		4
Genital herpes	2	3
Genital pain		2
Genital tract inflammation		1
Gingival bleeding	1	1
Gingival pain	2	5
Gingivitis		1
Glomerulonephritis		1
Glomerulonephritis rapidly progressive		1
Glossodynia	1	3
Glucose tolerance impaired		1
Grip strength decreased	1	2
Groin pain	1	6
Haematemesis		4
Haematochezia		2
Haematoma		1
Haematuria	1	5
Haemoglobin decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	11	18
		1	2		7
					1
			1		
					1
					2
					1
				1	1
			2		
			2	1	1
			1		
				2	3
			1		
		1	1	1	4
					4
		1	2	1	1
					2
			1		
				1	1
			2	2	3
			1		
					1
					1
		1	3		
			1		
		1	1		1
		1	3		3
					4
					2
					1
			1	1	4
				1	1

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemolytic anaemia		1
Haemoptysis	1	4
Haemorrhage	7	13
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		1
Haemorrhagic stroke	2	2
Haemorrhoids		1
Hair texture abnormal	1	1
Hallucination	4	15
Hallucination, auditory	1	2
Hallucination, olfactory		1
Hallucinations, mixed		1
Hallucination, tactile		1
Hallucination, visual		1
Hangover		2
Headache	450	1,574
Head discomfort	7	16
Head injury	1	6
Heart rate		1
Heart rate abnormal	2	6
Heart rate decreased		2
Heart rate increased	16	47
Heat oedema	1	1
Heat stroke		1
Hemianopia homonymous	1	1
Hemiparesis	2	2
Hemiplegia	1	2
Hemiplegic migraine		1
Hepatitis	1	1
Hepatitis viral	1	1
Herpes zoster	3	16
Hiccups		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	4
				7	13
					1
					1
				2	2
					1
				1	1
				4	15
				1	2
					1
					1
					1
					2
	1	281	768	169	806
		2	7	5	9
		1	4		2
					1
		1	1	1	5
			2		
		6	15	10	32
				1	1
			1		
				1	1
				2	2
				1	2
					1
				1	1
				1	1
			6	3	10
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hidradenitis		1
Hormone level abnormal		1
Hot flush	33	77
Hunger		3
Hyperacusis	1	3
Hyperaesthesia	6	16
Hyperaesthesia teeth		1
Hyperglycaemia		2
Hyperhidrosis	39	137
Hyperintensity in brain deep nuclei	1	1
Hyperpyrexia		1
Hypersensitivity	6	36
Hypersomnia	4	10
Hypertension	3	18
Hyperthyroidism		1
Hyperventilation	1	2
Hypoacusis	5	8
Hypoaesthesia	36	109
Hypoaesthesia oral	4	16
Hypoglycaemia		9
Hypoglycaemic coma		1
Hypokinesia	5	13
Hypomenorrhoea	2	3
Hypophagia		1
Hypopnoea		4
Hyporeflexia		1
Hyposomnia		1
Hypotension	11	21
Hypothermia	1	2
Hypotonia		1
Hypovitaminosis		1
Idiopathic intracranial hypertension	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		17	36	16	41
			1		2
				1	3
		2	7	4	9
					1
			1		1
		17	56	22	81
				1	1
					1
		3	10	3	26
		2	3	2	7
		2	8	1	10
					1
				1	2
		2	3	3	5
		23	39	13	70
		1	7	3	9
			1		8
					1
		3	7	2	6
		1	2	1	1
					1
					4
					1
					1
		5	8	6	13
				1	2
			1		
					1
				1	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Illness	39	112
Immune-mediated adverse reaction		1
Immune thrombocytopenia	3	6
Immunodeficiency		1
Impaired driving ability	1	1
Impaired healing	1	1
Impaired self-care		1
Impaired work ability	4	6
Inappropriate schedule of product administration	61	82
Incontinence		1
Incorrect dose administered	3	3
Incorrect route of product administration		8
Induration		1
Infected skin ulcer		1
Infection	4	7
Infectious mononucleosis		2
Inflammation	4	10
Influenza	21	65
Influenza like illness	39	122
Initial insomnia		1
Injected limb mobility decreased	1	2
Injection related reaction		1
Injection site erythema	2	3
Injection site mass	1	1
Injection site pain	10	16
Injection site pruritus	1	1
Injection site swelling	1	1
Insomnia	36	107
Insulin resistance		1
International normalised ratio fluctuation		1
Intestinal obstruction		2
Irregular breathing		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	23	42	16	70
				3	6
		1	1		1
			1	1	1
		1	2	3	4
		59	79	2	3
					1
		2	2	1	1
			8		
					1
					1
		1	2	3	5
					2
		2	4	2	6
1	2	8	25	13	40
		23	57	16	65
			1		
		1	1		1
					1
		2	3		
				1	1
		9	13	1	3
				1	1
		1	1		
		19	50	17	57
			1		
					1
					2
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Irritability	4	10
Irritable bowel syndrome		4
Ischaemia	1	1
Itching scar		2
Jaundice	1	1
Jaw disorder	1	1
Joint dislocation		1
Joint range of motion decreased	5	13
Joint stiffness	2	9
Joint swelling	3	9
Ketoacidosis		1
Kidney infection	1	1
Labyrinthitis	3	4
Lacrimation increased		6
Lacunar infarction		1
Laryngeal obstruction		1
Laryngospasm		1
Laziness		1
Learning disability		1
Lethargy	44	148
Limb discomfort	25	85
Limb injury		1
Limb mass		4
Lip blister	1	1
Lip dry	3	8
Lip erythema		2
Lip exfoliation		1
Lipoma	1	1
Lip pain	1	4
Lip pruritus	1	1
Lip swelling	10	30
Lip ulceration		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	7		3
			1		3
				1	1
			1		1
				1	1
				1	1
		1	4	4	9
		1	3	1	6
		1	3	2	6
					1
				1	1
				3	4
			4		2
					1
					1
					1
					1
1	2	32	69	12	79
		17	45	8	40
					1
			3		1
		1	1		
		1	5	2	3
			2		
					1
		1	1		
			2	1	2
		1	1		
		4	8	6	22
					2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Livedo reticularis		2
Liver function test increased	1	1
Liver injury	1	1
Localised infection		3
Local reaction	1	5
Loss of consciousness	2	32
Loss of libido		1
Loss of personal independence in daily activities	7	15
Loss of proprioception		1
Lower respiratory tract infection	1	5
Lung disorder	1	1
Lymphadenitis	2	10
Lymphadenopathy	160	393
Lymphangitis	1	2
Lymph gland infection	3	3
Lymph node pain	38	80
Lymph node palpable		1
Lymphoedema	1	6
Lymphoma		2
Lymphopenia		1
Maculopathy	1	1
Magnetic resonance imaging abnormal	1	1
Malaise	86	323
Mandibular mass		1
Mania	1	1
Mass		2
Mastitis	2	2
Mastocytosis		1
Maternal exposure during breast feeding	2	4
Maternal exposure during pregnancy	6	21
Medication error		1
Melaena		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	1
				1	1
			1		2
		1	1		4
				2	32
					1
		1	4	6	11
					1
				1	5
				1	1
		1	6	1	4
		65	164	95	229
				1	2
		1	1	2	2
		10	28	28	52
			1		
			1	1	5
					2
					1
				1	1
				1	1
1	1	50	145	36	178
			1		
				1	1
			2		
				2	2
					1
		1	2	1	2
1	1	2	9	4	12
			1		
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Memory impairment	4	7
Menopausal symptoms		1
Menorrhagia	5	8
Menstrual disorder	3	4
Menstruation delayed	7	13
Menstruation irregular	4	8
Mental disorder	2	3
Mental fatigue	3	11
Mental impairment		3
Metastases to lymph nodes		1
Metrorrhagia		1
Middle ear effusion		1
Middle insomnia	3	11
Migraine	53	191
Migraine with aura	6	13
Migraine without aura	1	1
Miliaria	5	8
Mobility decreased	4	21
Monoparesis	1	1
Monoplegia		3
Mood altered		3
Mood swings		1
Morose		2
Motion sickness	2	3
Motor dysfunction	1	1
Mouth swelling	1	3
Mouth ulceration	4	16
Movement disorder	2	10
Mucosal haemorrhage		1
Mumps		1
Muscle atrophy	1	1
Muscle contractions involuntary		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4	1	3
			1		
		1	2	4	6
		1	2	2	2
		2	4	5	9
			1	4	7
		2	2		1
		1	2	2	9
					3
					1
			1		
					1
		1	7	2	4
		19	51	34	140
		1	3	5	10
				1	1
		4	5	1	3
		1	7	3	14
				1	1
					3
			2		1
					1
			2		
			1	2	2
				1	1
				1	3
		1	3	3	13
		1	1	1	9
					1
					1
		1	1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle fatigue	8	24
Muscle rigidity		1
Muscle rupture	1	1
Muscle spasms	8	35
Muscle strain	2	3
Muscle swelling		1
Muscle tightness	1	3
Muscle twitching	6	10
Muscular weakness	19	61
Musculoskeletal chest pain	3	10
Musculoskeletal discomfort	3	6
Musculoskeletal pain	1	3
Musculoskeletal stiffness	19	73
Myalgia	240	824
Mydriasis	1	2
Myelitis	1	1
Myocardial infarction	2	2
Myocarditis	1	2
Myoclonus		1
Myofascial pain syndrome		1
Myositis		1
Nail discolouration	1	1
Nasal congestion	5	10
Nasal dryness		1
Nasopharyngitis	16	50
Nausea	267	904
Neck mass		1
Neck pain	38	116
Neoplasm	1	1
Nephrotic syndrome		1
Nerve compression		2
Nerve injury	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6	6	18
	1				1
				1	1
			9	8	26
		1	1	1	2
					1
			1	1	2
		3	3	3	7
		7	22	12	39
			2	3	8
		1	2	2	4
		1	2		1
		9	27	10	46
1	3	165	408	75	416
		1	1		1
				1	1
				2	2
				1	2
			1		
					1
					1
		1	1		
		3	6	2	4
			1		
		9	27	7	23
	2	165	404	102	500
					1
		22	48	16	68
				1	1
					1
					2
		1	2		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervousness	3	9
Neuralgia	3	10
Neurogenic shock		2
Neurological symptom		1
Neuropathy peripheral		2
Neutropenia		3
Neutrophil count decreased	1	1
Nightmare	4	11
Night sweats	10	43
Nipple pain	2	3
Nipple swelling	1	1
Nodule	2	3
Non-cardiac chest pain		1
Noninfective encephalitis		1
No reaction on previous exposure to drug	1	1
Nuchal rigidity		1
Numb chin syndrome		1
Ocular discomfort		4
Ocular hyperaemia	2	7
Odynophagia		7
Oedema		2
Oedema peripheral	1	4
Oesophagitis	1	1
Off label use	71	131
Oligomenorrhoea	1	1
Optic neuritis	1	1
Oral blood blister		1
Oral candidiasis	1	4
Oral discomfort		1
Oral herpes	1	3
Oral mucosal eruption	1	1
Oral mucosal erythema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4		5
			4	3	6
					2
			1		
					2
					3
		1	1		
		3	7	1	4
		8	25	2	18
				2	3
				1	1
		1	2	1	1
					1
					1
		1	1		
					1
					1
			1		3
		1	2	1	5
			2		5
					2
				1	4
		1	1		
		66	124	5	7
				1	1
				1	1
			1		
		1	2		2
					1
		1	3		
		1	1		
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral mucosal exfoliation		1
Oral pain	1	5
Oropharyngeal blistering		2
Oropharyngeal discomfort	1	6
Oropharyngeal pain	50	148
Oropharyngeal spasm		1
Orthostatic hypotension		1
Oversensing		2
Ovulation pain		1
Oxygen saturation decreased		2
Pain	181	537
Painful respiration	2	6
Pain in extremity	217	694
Pain in jaw	3	15
Pain of skin	7	22
Palatal swelling		1
Palatal ulcer		1
Pallor	3	19
Palpitations	18	81
Pancreatitis		2
Pancreatitis acute		1
Panic attack	3	6
Panic disorder	1	1
Papilloedema		1
Papule		2
Paraesthesia	38	133
Paraesthesia oral	14	43
Paralysis	2	4
Paranasal sinus discomfort		2
Paranasal sinus inflammation		1
Paranoia		1
Paresis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	3
					2
		1	3		3
		31	69	19	79
					1
					1
					2
					1
			2		
		111	269	70	268
				2	6
1	2	146	350	71	344
			3	3	12
		3	7	4	15
					1
					1
		1	11	2	8
		5	25	13	56
					2
					1
		2	2	1	4
		1	1		
					1
					2
		26	66	12	67
		11	17	3	26
				2	4
			1		1
					1
					1
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Parosmia	2	6
Partial seizures		2
Pelvic haemorrhage		2
Pelvic pain	1	3
Pemphigoid		1
Pericardial effusion	1	2
Pericarditis		2
Periorbital oedema		1
Periorbital swelling		3
Peripheral coldness	5	15
Peripheral swelling	49	135
Peripheral vascular disorder		1
Persistent postural-perceptual dizziness		1
Personality change		3
Petechiae	1	3
Petit mal epilepsy	2	2
Pharyngeal hypoaesthesia	1	2
Pharyngeal inflammation		1
Pharyngeal oedema	2	3
Pharyngeal paraesthesia	1	2
Pharyngeal swelling	2	13
Pharyngeal ulceration		1
Pharyngitis	1	2
Pharyngitis streptococcal		1
Phonophobia		1
Photophobia	5	37
Photopsia	1	4
Photosensitivity reaction	1	9
Piloerection		1
Pityriasis		1
Pityriasis rosea	1	2
Plantar fasciitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	4
					2
					2
		1	2		1
				1	2
					2
					1
					3
		1	5	4	10
		27	56	22	79
			1		
					1
			1		2
			1	1	2
				2	2
				1	2
					1
				2	3
		1	1		1
		1	1	1	12
					1
				1	2
					1
			1		
		1	8	4	29
		1	1		3
			1	1	8
					1
			1		
				1	2
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Platelet count decreased	4	4
Pleural effusion	1	2
Pleurisy		3
Pleuritic pain	1	2
Pneumonia		1
Pollakiuria		3
Polymenorrhoea	1	1
Polymerase chain reaction positive		1
Poor feeding infant	1	1
Poor quality sleep	1	13
Postural orthostatic tachycardia syndrome		1
Post viral fatigue syndrome		2
Potentiating drug interaction	1	1
Pregnancy with contraceptive device	1	1
Premenstrual syndrome	1	1
Presyncope	8	42
Primary cough headache		1
Prion disease		1
Procedural dizziness	1	1
Proctalgia		1
Product administered at inappropriate site		2
Product administration error	1	1
Productive cough	1	4
Product use issue	11	51
Proteinuria		1
Pruritus	42	142
Pruritus genital		1
Psoriasis		2
Psychogenic seizure		2
Psychomotor hyperactivity	1	2
Psychotic disorder		1
Pulmonary artery dilatation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	2	2
				1	2
					3
				1	2
					1
			1		2
		1	1		
					1
		1	1		
		1	6		7
			1		
					2
				1	1
				1	1
		7	20	1	22
			1		
					1
		1	1		
			1		
			1		1
				1	1
		1	2		2
		8	47	3	4
			1		
		27	73	15	69
			1		
			1		1
			1		1
		1	2		
					1
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary embolism	3	6
Pulmonary pain		7
Pulmonary thrombosis	1	2
Pulpitis dental		1
Pulse abnormal	1	3
Puncture site bruise	1	2
Pupillary reflex impaired	1	2
Pupils unequal		2
Purpura		2
Pustule	1	1
Pyrexia	318	1,192
Rash	63	166
Rash erythematous	16	51
Rash macular	3	21
Rash maculo-papular	2	5
Rash papular	6	14
Rash pruritic	8	33
Rash vesicular		1
Raynaud's phenomenon		1
Reaction to excipient	1	1
Rectal discharge		1
Rectal haemorrhage		2
Reduced facial expression	1	3
Renal pain	3	6
Respiration abnormal		1
Respiratory disorder		1
Respiratory rate increased	3	5
Restless legs syndrome	1	3
Restlessness	3	8
Retching	2	7
Rhabdomyolysis		3
Rheumatoid arthritis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	6
			2		5
				1	2
					1
		1	2		1
				1	2
		1	1		1
					2
			1		1
		1	1		
1	2	201	531	117	661
		43	82	20	84
		11	31	5	20
		1	12	2	9
		1	2	1	3
		6	10		4
		5	13	3	20
			1		
					1
				1	1
			1		
					2
		1	3		
		1	3	2	3
					1
			1		
		2	3	1	2
			1	1	2
		1	4	2	4
		2	4		3
					3
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinitis	2	4
Rhinorrhoea	5	26
Right ventricular failure		1
Rosacea		1
Rubber sensitivity		1
Sacroiliitis		1
Salivary hypersecretion	1	2
SARS-CoV-2 antibody test negative		1
Scar pain		1
Sciatica	1	2
Scleral discolouration		3
Scratch		1
Screaming		1
Scrotal pain		1
Seasonal allergy	1	3
Seizure	8	32
Self-injurious ideation	1	1
Sensation of foreign body	1	3
Sense of a foreshortened future		3
Sensitive skin	9	20
Sensory disturbance		4
Sensory loss	2	3
Sepsis	1	1
Serositis		1
Sinonasal obstruction		2
Sinus bradycardia		1
Sinus congestion	2	3
Sinus headache	5	16
Sinusitis		3
Sinus pain	1	11
Sinus tachycardia	2	7
Skin burning sensation	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	1
		4	11	1	15
					1
			1		
					1
			1		
			1	1	1
					1
			1		
		1	1		1
			1		2
					1
					1
			1		
		1	2		1
				8	32
				1	1
		1	1		2
			2		1
		6	9	3	11
			3		1
		1	2	1	1
				1	1
					1
			1		1
		1	2	1	1
		4	9	1	7
					3
				1	11
		1	3	1	4
			1	2	7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin discolouration	1	7
Skin disorder	1	1
Skin exfoliation		2
Skin fissures		1
Skin haemorrhage	1	1
Skin infection	1	3
Skin irritation		1
Skin laceration		1
Skin lesion		2
Skin mass		1
Skin reaction		3
Skin sensitisation	1	1
Skin swelling	1	5
Skin tightness	1	2
Skin ulcer		1
Skin warm	4	20
Sleep disorder	7	26
Sleep disorder due to a general medical condition	1	6
Sleep disorder due to general medical condition, insomnia type		5
Sleep paralysis		1
Sleep talking	1	1
Sluggishness		2
Small intestinal haemorrhage		1
Sneezing		7
Soft tissue swelling	1	1
Somnolence	13	58
Speech disorder	3	5
Spinal pain	1	2
Splinter haemorrhages		1
Staring	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	7
		1	1		
			1		1
			1		
		1	1		
			1	1	2
					1
			1		
			1		1
					1
			2		1
				1	1
		1	4		1
				1	2
					1
		2	11	2	9
		5	16	2	10
		1	5		1
			5		
			1		
		1	1		
			2		
					1
			3		4
		1	1		
		8	26	5	32
		2	2	1	3
				1	2
					1
				1	1

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Status epilepticus	1	2
Steatorrhoea		1
Stillbirth	1	1
Stomatitis		1
Stress	3	6
Stridor		5
Sudden visual loss		1
Suicidal ideation		1
Suicide attempt		1
Supraventricular tachycardia		4
Suspected COVID-19	17	78
Sweating fever	1	15
Swelling	50	119
Swelling face	4	23
Swelling of eyelid		7
Swollen tongue	7	26
Symptom recurrence		1
Syncope	17	101
Synovial cyst		1
Systemic lupus erythematosus		1
Tachycardia	13	59
Tachyphrenia		1
Tachypnoea	1	4
Taste disorder	1	5
Tearfulness		4
Teething		1
Temperature difference of extremities		1
Temperature intolerance	1	2
Temperature regulation disorder		2
Temporomandibular joint syndrome		2
Tenderness	16	36
Tension	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
				1	1
			1		
		1	2	2	4
					5
					1
					1
			1		1
					3
		11	31	6	47
				1	15
		26	56	24	63
		2	4	2	19
			2		5
		4	11	3	15
			1		
				17	101
			1		
					1
		5	19	8	40
					1
			1	1	3
			1	1	4
			1		3
			1		
					1
				1	2
			1		1
			2		
		12	24	4	12
		1	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tension headache	13	38
Testicular pain	2	2
Testis discomfort	1	1
Therapeutic product effect increased		1
Therapeutic response unexpected	1	1
Thermal burn	1	1
Thirst	2	9
Throat irritation	3	14
Throat tightness	2	17
Thrombocytopenia	3	5
Thrombosis	8	9
Thunderclap headache		2
Thyroxine free increased	1	1
Tic	1	1
Tinnitus	7	29
Tongue discolouration		2
Tongue discomfort	1	2
Tongue disorder	2	2
Tongue pruritus	1	1
Tongue spasm		1
Tongue ulceration	1	2
Tonic convulsion		1
Tonsillar erythema	1	1
Tonsillar hypertrophy	3	6
Tonsillar inflammation	1	2
Tonsillitis	1	6
Toothache	2	6
Tracheitis	1	1
Transient ischaemic attack		1
Tremor	25	107
Trigeminal neuralgia	1	1
Trismus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	18	5	20
		2	2		
		1	1		
					1
				1	1
		1	1		
		1	4	1	5
		1	3	2	11
		2	3		14
				3	5
				8	9
					2
				1	1
				1	1
		3	12	4	17
			2		
		1	1		1
		1	1	1	1
		1	1		
					1
			1	1	1
					1
		1	1		
		3	3		3
		1	1		1
				1	6
			2	2	4
		1	1		
					1
		16	45	9	62
		1	1		
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Troponin increased		1						1
Type 1 diabetes mellitus		1						1
Type IV hypersensitivity reaction	1	1					1	1
Ulnar nerve injury		1						1
Unresponsive to stimuli		3						3
Upper-airway cough syndrome		1				1		
Upper airway obstruction		1						1
Upper limb fracture		1						1
Urinary incontinence		1						1
Urinary retention		5						5
Urinary tract infection		3						3
Urine abnormality	1	1			1	1		
Urine odour abnormal		1				1		
Urine output decreased	1	4			1	2		2
Urticaria	21	80			13	34	8	46
Urticaria thermal	1	1			1	1		
Uterine haemorrhage	1	1					1	1
Uterine pain		1						1
Uterine spasm		1				1		
Uveitis		2						2
Vaccination complication	3	5			2	3	1	2
Vaccination site abscess	1	1			1	1		
Vaccination site bruising	8	24			6	16	2	8
Vaccination site discharge		1						1
Vaccination site discolouration		3				2		1
Vaccination site discomfort	2	10			1	6	1	4
Vaccination site erythema	35	120			20	65	15	55
Vaccination site haemorrhage	1	1			1	1		
Vaccination site hypersensitivity		1						1
Vaccination site hypoaesthesia		5				3		2
Vaccination site induration	2	7			1	5	1	2
Vaccination site infection	1	5			1	2		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
					1
					3
			1		
					1
					1
					1
					5
					3
		1	1		
			1		
		1	2		2
		13	34	8	46
		1	1		
				1	1
					1
			1		
					2
		2	3	1	2
		1	1		
		6	16	2	8
					1
			2		1
		1	6	1	4
		20	65	15	55
		1	1		
					1
			3		2
		1	5	1	2
		1	2		3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site inflammation	3	16
Vaccination site joint erythema	1	1
Vaccination site joint movement impairment		4
Vaccination site joint pain		4
Vaccination site lymphadenopathy	2	5
Vaccination site macule		1
Vaccination site mass	20	52
Vaccination site movement impairment	4	18
Vaccination site necrosis		1
Vaccination site oedema	1	2
Vaccination site pain	161	572
Vaccination site papule		1
Vaccination site paraesthesia		4
Vaccination site pruritus	11	42
Vaccination site rash	7	27
Vaccination site reaction		5
Vaccination site swelling	32	114
Vaccination site urticaria		7
Vaccination site warmth	15	62
Vaginal cyst		1
Vaginal haemorrhage	6	13
Varicella	1	1
Vascular headache	1	1
Vasculitis	1	1
Vasodilatation		2
Vasospasm		1
Vein disorder		1
Vein rupture		1
Ventricular fibrillation		1
Ventricular hypertrophy		1
Vertigo	11	40
Vertigo positional	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	1	6
		1	1		
			1		3
			2		2
		1	3	1	2
			1		
	1	11	29	9	23
		2	6	2	12
					1
		1	2		
	1	108	330	53	242
					1
			1		3
		8	22	3	20
		4	12	3	15
			2		3
		23	63	9	51
			4		3
		9	33	6	29
					1
		2	3	4	10
				1	1
		1	1		
				1	1
			1		1
			1		
					1
					1
		1	7	10	33
				1	2

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vestibular migraine		1						1
Vestibular neuronitis		1						1
Viral infection	1	1					1	1
Viral labyrinthitis		1				1		
Viral pharyngitis		1						1
Viral rash		1						1
Visceral pain		1				1		
Vision blurred	5	36			2	9	3	27
Visual field defect	1	1					1	1
Visual impairment	5	18			4	11	1	7
Visual snow syndrome	1	1					1	1
Vitreous floaters		1						1
Vomiting	80	276		1	39	99	41	177
Vomiting projectile		5				2		3
Vulvovaginal candidiasis		1						1
Weight decreased	1	5				1	1	4
Weight increased	1	1			1	1		
Wheezing	3	16			1	3	2	13
Withdrawal syndrome		1						1
Wound complication		2				1		1
Wrong product administered	1	1			1	1		
Yawning	1	2				1	1	1
Yellow skin		3				3		
		1				1		
	5,930	19,846	9	26	3328	8690	2602	11156

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	22	77			12	30	10	47
Abdominal distension	11	31			7	15	4	16
Abdominal mass	1	1					1	1
Abdominal pain	42	139			17	53	25	86
Abdominal pain lower	5	9			2	4	3	5
Abdominal pain upper	66	228			28	60	38	168
Abdominal rigidity		5				2		3
Abdominal tenderness	2	3					2	3
Abnormal behaviour	1	1					1	1
Abnormal dreams	11	24			8	15	3	9
Abnormal faeces	2	3			1	1	1	2
Abnormal sensation in eye	3	8			1	3	2	5
Abortion missed		1						1
Abortion spontaneous	14	29					14	29
Abscess		1						1
Abscess jaw		1						1
Abscess oral	1	1			1	1		
Accident		1				1		
Accidental exposure to product		1				1		
Accidental overdose		1				1		
Achenbach syndrome		1				1		
Acidosis	1	1					1	1
Acne	2	2					2	2
Acne pustular		1				1		
Acute abdomen		1						1
Acute disseminated encephalomyelitis	1	1					1	1
Acute kidney injury	2	3					2	3
Acute myocardial infarction	1	2					1	2
Administration site discomfort	1	1			1	1		
Adnexa uteri pain		3						3
Adrenocortical insufficiency acute	1	2					1	2
Adverse drug reaction	4	10			2	7	2	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aerophagia		2
Affective disorder	1	1
Affect lability	1	2
African trypanosomiasis	1	2
Ageusia	15	56
Aggression	2	5
Agitation	2	14
Airway secretion clearance therapy		1
Alanine aminotransferase increased	1	2
Albuminuria	1	1
Alcohol interaction		2
Alcohol intolerance	2	2
Allergic cough	2	4
Allergy to vaccine	2	21
Allodynia	1	1
Alopecia	3	14
Alopecia areata	2	2
Altered state of consciousness	1	2
Amenorrhoea	1	5
Amnesia	5	9
Anaemia	1	2
Anaemia vitamin B12 deficiency		1
Anal haemorrhage	1	3
Anal incontinence		1
Anal sphincter atony		1
Anaphylactic reaction	12	109
Anaphylactic shock		5
Anaphylactoid reaction	1	6
Anaphylactoid shock	1	2
Anger		2
Angina bullosa haemorrhagica	1	1
Angina pectoris	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	1
		1	1		1
				1	2
		8	23	7	33
			1	2	4
			1	2	13
					1
			1	1	1
				1	1
					2
				2	2
				2	4
		1	7	1	14
				1	1
			3	3	11
				2	2
				1	2
			1	1	4
				5	9
				1	2
					1
				1	3
			1		
					1
				12	109
					5
				1	6
				1	2
			2		
				1	1
				4	9

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angioedema	7	36
Angular cheilitis	1	1
Ankle fracture	1	1
Ankylosing spondylitis		1
Anorectal discomfort	1	1
Anorectal swelling		1
Anorgasmia		1
Anosmia	8	27
Antibody test positive		1
Antiphospholipid syndrome	1	1
Antisynthetase syndrome		1
Anti-thyroid antibody positive	1	1
Anxiety	25	102
Apathy		4
Aphasia	4	11
Aphonia	2	9
Aphthous ulcer	1	3
Apnoea		1
Appendicitis	1	3
Appendicitis perforated	1	1
Appetite disorder	2	4
Apraxia		1
Areflexia		1
Arrhythmia	2	10
Arrhythmia supraventricular		1
Arterial thrombosis	1	1
Arthralgia	393	1,277
Arthritis	11	24
Arthritis bacterial		1
Arthritis reactive	1	6
Arthropathy	1	7
Arthropod bite		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	36
				1	1
				1	1
					1
		1	1		
					1
					1
		3	10	5	17
			1		
				1	1
			1		
				1	1
		11	32	14	70
					4
		2	3	2	8
1	1	2	3		6
		1	1		2
					1
				1	3
				1	1
				2	4
			1		
					1
				2	10
					1
				1	1
2	9	167	426	226	851
		2	2	9	22
					1
				1	6
			2	1	5
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenia	66	272
Asthenopia	9	29
Asthma	9	54
Asthma prophylaxis		1
Asymptomatic COVID-19	1	4
Atonic seizures		1
Atrial fibrillation	2	9
Atrial tachycardia		1
Attention deficit hyperactivity disorder	1	1
Auditory disorder	1	1
Aura	1	4
Auricular swelling		1
Autoimmune disorder	3	4
Autonomic nervous system imbalance		1
Autoscopy	3	3
Axillary lymphadenectomy	1	1
Axillary mass	22	45
Axillary pain	159	327
Bacille Calmette-Guerin scar reactivation	1	4
Back pain	90	316
Balance disorder	14	35
Bedridden	4	9
Behaviour disorder		1
Behcet's syndrome		1
Binge eating		1
Bipolar disorder		1
Bladder disorder	1	4
Bladder pain		2
Bleeding time abnormal		1
Blepharitis		2
Blepharospasm	3	8
Blindness	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	19	87	47	185
		4	8	5	21
			8	9	46
					1
			1	1	3
					1
				2	9
			1		
				1	1
				1	1
			1	1	3
					1
				3	4
					1
		1	1	2	2
				1	1
		5	14	17	31
		37	99	122	228
			1	1	3
		42	121	48	195
		1	4	13	31
		1	2	3	7
					1
					1
					1
				1	4
					2
					1
			1		1
		2	2	1	6
				3	7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blindness transient		3						3
Blindness unilateral		1						1
Blister	15	36			6	13	9	23
Blood blister	3	5			1	1	2	4
Blood cholesterol increased		1						1
Blood folate decreased	1	1			1	1		
Blood glucose abnormal		1						1
Blood glucose decreased	1	2					1	2
Blood glucose fluctuation		4				1		3
Blood glucose increased	2	16			1	8	1	8
Blood immunoglobulin M abnormal	1	1					1	1
Blood lactic acid increased		2						2
Blood oestrogen increased		1						1
Blood phosphorus decreased	1	2					1	2
Blood potassium abnormal		1						1
Blood potassium decreased		2				1		1
Blood potassium increased	1	1					1	1
Blood pressure abnormal	1	2					1	2
Blood pressure decreased	3	10			2	3	1	7
Blood pressure diastolic decreased		1				1		
Blood pressure diastolic increased		1						1
Blood pressure fluctuation	2	3					2	3
Blood pressure increased	13	68			6	38	7	30
Blood pressure systolic increased		2				1		1
Blood test abnormal	1	3					1	3
Blood urine present	3	8			1	3	2	5
Blue toe syndrome	1	2					1	2
Body fat disorder	1	1			1	1		
Body temperature	4	9			4	6		3
Body temperature abnormal	8	28			1	9	7	19
Body temperature decreased	1	12			1	3		9
Body temperature fluctuation	2	7			2	4		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
		6	13	9	23
		1	1	2	4
					1
		1	1		
					1
				1	2
			1		3
		1	8	1	8
				1	1
					2
					1
				1	2
					1
			1		1
				1	1
				1	2
					1
					3
		6	38	7	30
			1		1
				1	3
		1	3	2	5
				1	2
		1	1		
		4	6		3
		1	9	7	19
		1	3		9
		2	4		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature increased	30	100
Bone pain	31	90
Bone swelling	2	6
Bowel movement irregularity		1
Bradycardia		11
Bradykinesia		2
Bradyphrenia	2	5
Breast abscess		1
Breast cancer	3	3
Breast cancer stage III	1	1
Breast cyst		1
Breast discomfort	2	4
Breast disorder	1	1
Breast engorgement	1	1
Breast enlargement	1	2
Breast mass	7	13
Breast milk discolouration		1
Breast pain	32	70
Breast prosthesis user	1	1
Breast swelling	15	25
Breast tenderness	3	7
Breath odour	1	4
Bronchiectasis		1
Bronchitis		1
Bronchospasm	2	7
Bruxism	1	3
Burning sensation	27	74
Burn oral cavity		1
Burns second degree		1
Bursitis	3	4
Butterfly rash		1
Candida infection	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		20	44	10	56
		11	30	20	60
			3	2	3
					1
					11
					2
		1	2	1	3
					1
				3	3
				1	1
					1
		1	2	1	2
				1	1
				1	1
				1	2
		2	4	5	9
			1		
		5	18	27	52
		1	1		
		5	7	10	18
		1	1	2	6
		1	3		1
					1
					1
			1	2	6
				1	3
		9	20	18	54
					1
			1		
				3	4
			1		
			1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac arrest	1	12
Cardiac discomfort		1
Cardiac disorder		2
Cardiac failure	1	3
Cardiac flutter	2	15
Cardiac murmur	1	3
Cardiomyopathy	1	1
Cardiovascular disorder	1	2
Carpal tunnel syndrome	2	2
Cataplexy	1	1
Catarrh		3
Catatonia		1
Cellulitis	12	33
Cerebral artery occlusion	1	1
Cerebral disorder		1
Cerebral haemorrhage	2	4
Cerebral infarction	2	2
Cerebral thrombosis		1
Cerebral venous sinus thrombosis	5	5
Cerebrovascular accident	9	24
Cervical dysplasia	1	1
Cervicogenic headache	1	2
Chalazion	1	2
Change of bowel habit	1	1
Chapped lips		1
Cheilitis	1	4
Chest discomfort	34	200
Chest injury	1	1
Chest pain	90	304
Chillblains	9	10
Chills	368	1,417
Choking		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	12
			1		
			1		1
				1	3
				2	15
			1	1	2
				1	1
				1	2
		2	2		
				1	1
			2		1
					1
				12	33
				1	1
			1		
				2	4
				2	2
					1
				5	5
				9	24
				1	1
		1	1		1
				1	2
		1	1		
		1	2		2
	1	14	57	20	143
				1	1
	1	27	71	63	233
		6	6	3	4
4	12	158	496	210	921
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Choking sensation		2
Cholecystitis infective		1
Chromaturia	2	3
Chronic fatigue syndrome	4	11
Chronic kidney disease	1	2
Chronic obstructive pulmonary disease		1
Chronic spontaneous urticaria		1
Circulatory collapse	1	5
Clavicle fracture		1
Clonic convulsion		2
Clostridium test positive	1	1
Clumsiness	1	2
Cluster headache	6	32
Coagulation time prolonged		1
Coagulopathy	1	3
Coeliac disease	1	2
Cognitive disorder	3	11
Cold-stimulus headache	1	1
Cold sweat	22	109
Colitis	1	1
Colitis ulcerative	4	8
Coma scale abnormal		1
Condition aggravated	32	100
Confusional state	32	104
Congestive cardiomyopathy		1
Conjunctival haemorrhage		3
Conjunctival oedema		1
Conjunctivitis	1	7
Consciousness fluctuating		3
Constipation	6	20
Contraindicated product administered		1
Contusion	36	77

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
					1
		1	1	1	2
				4	11
				1	2
					1
					1
				1	5
					1
					2
				1	1
				1	2
		2	7	4	25
					1
				1	3
				1	2
				3	11
		1	1		
		10	37	12	72
		1	1		
				4	8
					1
		13	27	19	73
	1	7	22	25	82
					1
					3
					1
		1	2		5
					3
		1	3	5	17
					1
		11	27	25	50

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Conversion disorder	1	1
Coordination abnormal	2	8
Corneal erosion		1
Corneal reflex decreased	1	1
Costochondritis	3	6
Costovertebral angle tenderness		1
Cough	67	272
COVID-19	46	145
C-reactive protein abnormal	1	1
C-reactive protein increased	1	2
Creutzfeldt-Jakob disease	1	1
Crohn's disease	2	6
Crying	2	11
Cutaneous sarcoidosis	1	1
Cutaneous symptom		1
Cyanosis	5	10
Cyclothymic disorder		1
Cyst	1	2
Cystitis	3	9
Cytomegalovirus infection reactivation		1
Dairy intolerance	1	1
Dark circles under eyes	1	1
Deafness	10	20
Deafness bilateral		1
Deafness neurosensory	3	6
Deafness unilateral	5	7
Death		9
Decreased activity	1	1
Decreased appetite	49	188
Decreased insulin requirement	1	1
Decreased interest		1
Deep vein thrombosis	11	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2	1	6
					1
				1	1
				3	6
			1		
1	1	25	82	42	190
2	2	15	37	31	108
				1	1
				1	2
				1	1
				2	6
		1	1	1	10
				1	1
					1
		4	6	1	4
					1
				1	2
		1	3	2	6
					1
				1	1
				10	20
					1
				3	6
				5	7
					9
				1	1
	1	18	59	31	129
				1	1
					1
				11	18

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Defaecation urgency		2
Deficiency anaemia	1	1
Dehydration	5	25
Delayed recovery from anaesthesia	2	2
Delirium	2	16
Delusion	1	1
Delusional perception		1
Dementia with Lewy bodies		1
Demyelination		1
Dental caries	1	1
Depersonalisation/derealisation disorder		2
Depressed level of consciousness	1	7
Depressed mood	10	38
Depression	7	22
Derealisation	1	2
Dermal filler injection	1	1
Dermatitis	3	7
Dermatitis allergic	6	19
Dermatitis atopic	1	3
Dermatitis bullous	1	2
Dermatitis diaper	1	1
Dermatomyositis		2
Dermatosis		1
Diabetes mellitus	2	3
Diabetes mellitus inadequate control	1	3
Diabetic eye disease		1
Diabetic ketoacidosis		1
Diarrhoea	153	576
Diarrhoea haemorrhagic		1
Diplegia		1
Diplopia	6	14
Discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
		2	13	3	12
		1	1	1	1
				2	16
				1	1
					1
					1
				1	1
			1		1
				1	7
		4	8	6	30
		1	1	6	21
				1	2
		1	1		
		1	3	2	4
		3	6	3	13
			1	1	2
				1	2
		1	1		
					2
			1		
				2	3
				1	3
			1		
					1
1	2	74	187	79	389
					1
					1
		1	4	5	10
					1

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discoloured vomit		1
Discomfort	21	57
Disease progression		1
Disease recurrence	17	55
Disorganised speech		2
Disorientation	12	38
Dissociation	2	9
Disturbance in attention	16	57
Dizziness	329	1,174
Dizziness exertional	6	10
Dizziness postural	23	81
Dose calculation error		1
Dreamy state		1
Drooling	1	3
Drug eruption		1
Drug hypersensitivity		4
Drug ineffective	31	152
Drug interaction	2	5
Drug level decreased		1
Drug withdrawal syndrome		1
Dry eye	2	13
Dry mouth	15	76
Dry skin	9	21
Dry throat	10	31
Duodenogastric reflux	1	1
Dysaesthesia	1	2
Dysarthria	5	26
Dyschezia		1
Dyschromatopsia	1	1
Dysentery		1
Dysgeusia	46	171
Dyshidrotic eczema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	8	18	13	39
					1
			6	17	49
			1		1
		5	10	7	28
		1	6	1	3
	1	6	19	10	38
	5	147	390	182	784
		1	1	5	9
	1	14	33	9	48
			1		
					1
				1	3
					1
					4
2	2			31	152
			1	2	4
					1
					1
		1	5	1	8
		11	30	4	46
		3	9	6	12
1	1	7	15	3	16
		1	1		
		1	1		1
		2	6	3	20
					1
		1	1		
					1
	1	31	96	15	75
					2

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyskinesia	4	9
Dysmenorrhoea	7	18
Dysmorphism		1
Dyspepsia	8	34
Dysphagia	12	49
Dysphemia	2	2
Dysphonia	5	24
Dysphoria	1	1
Dyspnoea	129	487
Dyspnoea at rest	1	3
Dyspnoea exertional	1	26
Dysstasia	5	16
Dystonia	1	3
Dysuria	3	7
Ear canal erythema	1	1
Ear congestion	1	3
Ear discomfort	4	20
Ear disorder	1	7
Ear infection	7	14
Ear infection bacterial		1
Ear pain	41	129
Ear pruritus		2
Ear swelling	2	6
Eating disorder	1	5
Eczema	4	19
Eczema asteatotic	1	1
Eczema eyelids	1	3
Eczema weeping		1
Electric shock		1
Electrocardiogram abnormal	1	2
Electrocardiogram ST segment elevation		1
Embolism	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	2	6
		2	6	5	12
					1
		4	12	4	22
		7	18	5	31
				2	2
		3	10	2	14
	1	37	120	92	367
				1	3
			7	1	19
		1	6	4	10
				1	3
			1	3	6
		1	1		
			1	1	2
		1	8	3	12
			2	1	5
		1	4	6	10
					1
		13	42	28	87
			2		
		1	1	1	5
				1	5
			4	4	15
				1	1
		1	3		
			1		
			1		
				1	2
					1
				4	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Emotional disorder	5	11
Emotional distress		4
Encephalitis	1	2
Encephalitis viral	1	1
Endometriosis		2
Energy increased	1	2
Enlarged uvula		2
Enuresis		1
Ephelides	1	1
Epicondylitis	1	2
Epididymitis		1
Epigastric discomfort	1	4
Epilepsy	7	18
Episcleritis	1	3
Epistaxis	17	44
Epstein-Barr virus infection		2
Erectile dysfunction	4	6
Eructation	2	5
Erythema	97	290
Erythema annulare		1
Erythema multiforme		3
Erythema nodosum	1	2
Erythema of eyelid	1	2
Erythrospia		2
Essential tremor		1
Euphoric mood	4	6
Eustachian tube disorder		1
Excessive cerumen production	1	1
Exercise tolerance decreased	2	4
Exertional headache	1	1
Expired product administered	2	2
Exposure during pregnancy	11	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4	2	7
			1		3
				1	2
				1	1
					2
				1	2
			1		1
					1
		1	1		
		1	1		1
					1
			1	1	3
				7	18
				1	3
		7	16	10	28
					2
				4	6
				2	5
		60	147	37	143
					1
					3
				1	2
				1	2
			1		1
					1
		2	3	2	3
					1
				1	1
		2	2		2
		1	1		
				2	2
1	1	6	18	5	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exposure to SARS-CoV-2		1
Exposure via breast milk	2	3
Extensive swelling of vaccinated limb	2	5
Extensor plantar response		1
External ear cellulitis		1
Extraocular muscle paresis		1
Extrasystoles	1	13
Eye contusion		4
Eye discharge	1	4
Eye disorder	5	13
Eye haemorrhage		2
Eye infection	1	2
Eye inflammation		3
Eye irritation	6	20
Eyelid disorder		1
Eyelid exfoliation		1
Eyelid function disorder		1
Eyelid irritation		1
Eyelid margin crusting		1
Eyelid oedema		2
Eyelid pain		4
Eyelid ptosis		3
Eyelid rash		2
Eyelids pruritus	1	3
Eye movement disorder	2	4
Eye oedema	2	3
Eye pain	45	147
Eye paraesthesia		1
Eye pruritus	12	38
Eye swelling	22	80
Eye ulcer	1	1
Face crushing		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2	1	1
			3	2	2
					1
					1
					1
			3	1	10
			1		3
				1	4
		1	4	4	9
					2
				1	2
					3
		1	4	5	16
					1
					1
					1
			1		
			1		1
			2		2
			1		2
				1	2
		1	2	1	1
		14	41	31	106
			1		
		3	11	9	27
		9	17	13	63
		1	1		
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Face oedema	1	4
Facial discomfort		3
Facial neuralgia		2
Facial pain	15	47
Facial paralysis	27	118
Facial paresis	3	16
Facial spasm	1	6
Faeces discoloured		4
Faeces pale		1
Failed in vitro fertilisation	1	1
Fall	7	17
False positive investigation result	1	1
Familial hemiplegic migraine		1
Familial periodic paralysis		1
Fatigue	810	2,947
Fear	2	4
Fear of injection		1
Febrile convulsion	4	5
Feeding disorder	1	10
Feeling abnormal	87	283
Feeling cold	42	201
Feeling drunk	6	21
Feeling hot	66	264
Feeling jittery		7
Feeling of body temperature change	15	72
Fibrin D dimer increased	1	2
Fibromyalgia	4	13
Fine motor skill dysfunction	1	1
Finger deformity	1	1
Flank pain	4	8
Flashback	1	1
Flatulence	7	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	2
			1		2
			2		
		6	15	9	32
	1			27	118
			4	3	12
		1	4		2
			3		1
			1		
				1	1
		2	7	5	10
				1	1
					1
					1
6	24	354	984	456	1963
			2	2	2
			1		
		3	3	1	2
			6	1	4
		38	102	49	181
	1	20	75	22	126
		3	7	3	14
		39	127	27	137
			2		5
		6	29	9	43
			1	1	1
		1	1	3	12
		1	1		
		1	1		
		2	4	2	4
				1	1
		3	6	4	17

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fluid imbalance	1	1
Fluid retention	1	3
Flushing	23	101
Focal dyscognitive seizures	1	1
Foetal death	1	1
Food allergy	1	3
Food aversion		1
Food craving		2
Food poisoning		1
Foreign body sensation in eyes	2	4
Formication	3	8
Foveal reflex abnormal	1	1
Fracture blisters		1
Frequent bowel movements	1	5
Furuncle	1	3
Gait disturbance	16	56
Gait inability	6	16
Gastric dilatation		1
Gastric disorder	3	6
Gastric ulcer	1	1
Gastritis	2	5
Gastroenteritis		3
Gastroenteritis viral		1
Gastrointestinal disorder	3	4
Gastrointestinal haemorrhage		1
Gastrointestinal pain	2	6
Gastrointestinal sounds abnormal	2	6
Gastrointestinal stoma complication		1
Gastroesophageal reflux disease	6	17
Generalised oedema	1	1
Generalised tonic-clonic seizure	3	6
General physical health deterioration	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	2		1
	1	12	39	11	62
				1	1
			1	1	2
					1
			1		1
		1	1	1	3
		1	2	2	6
				1	1
			1		
		1	3		2
			1	1	2
		1	7	15	49
		2	4	4	12
					1
			1	3	5
				1	1
				2	5
					3
					1
			1	3	3
					1
		1	1	1	5
		2	3		3
					1
		2	3	4	14
		1	1		
				3	6
		1	1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Genital herpes	1	2
Genital ulceration		1
Genitourinary symptom		1
Gestational diabetes	1	1
Gingival abscess		1
Gingival bleeding	3	6
Gingival blister	1	2
Gingival discomfort		1
Gingival disorder		2
Gingival erythema		1
Gingival pain	1	10
Gingival pruritus	1	1
Gingival swelling	3	4
Gingivitis	1	2
Gingivitis ulcerative		2
Glaucoma		1
Glomerulonephritis minimal lesion	2	3
Glossitis		2
Glossodynia	12	36
Goitre	3	3
Gout	2	6
Graft versus host disease	1	1
Granuloma skin	1	1
Granulomatous lymphadenitis		2
Grief reaction	1	1
Grip strength		1
Grip strength decreased	3	7
Groin pain	7	21
Guillain-Barre syndrome		2
Habit cough	2	2
Haematemesis		2
Haematochezia	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
					1
				1	1
					1
		2	3	1	3
		1	2		
			1		
			1		1
			1	1	9
				1	1
		1	1	2	3
			1	1	1
					2
					1
				2	3
			2		
		8	18	4	18
		1	1	2	2
				2	6
				1	1
		1	1		
					2
				1	1
					1
		2	5	1	2
		2	6	5	15
					2
		1	1	1	1
					2
				1	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematocrit increased		1
Haematoma	1	3
Haematuria		3
Haemoglobin decreased		3
Haemoglobin increased		1
Haemoptysis	5	7
Haemorrhage	9	15
Haemorrhage urinary tract		1
Haemorrhagic diathesis	1	1
Haemorrhoids	1	4
Hallucination	6	21
Hallucination, auditory		1
Hallucination, olfactory	1	2
Hallucination, visual		1
Hand-arm vibration syndrome		1
Hand deformity	2	2
Hangover	1	8
Headache	1,001	3,546
Head banging	2	2
Head discomfort	18	53
Head injury	1	7
Head titubation	1	1
Heart disease congenital		1
Heart injury		2
Heart rate	4	6
Heart rate abnormal	1	10
Heart rate decreased	6	16
Heart rate increased	30	140
Heart rate irregular	2	11
Heat oedema		2
Hemiparaesthesia		1
Hemiparesis	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	3
			1		2
			1		2
					1
		2	2	3	5
1	1			9	15
					1
				1	1
				1	4
				6	21
					1
				1	2
					1
					1
				2	2
			2	1	6
4	15	468	1286	533	2260
		1	1	1	1
		6	18	12	35
			4	1	3
				1	1
					1
					2
		2	2	2	4
		1	5		5
		1	2	5	14
		18	55	12	85
				2	11
			1		1
					1
				2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiplegia	2	5
Hemiplegic migraine	1	3
Hepatic pain		5
Hepatitis	2	2
Hepatitis A	1	1
Hepatitis viral	1	1
Hepatomegaly	1	1
Hereditary neuropathy with liability to pressure palsies	1	1
Herpes simplex	1	5
Herpes simplex reactivation	1	1
Herpes virus infection	1	2
Herpes zoster	16	74
Herpes zoster reactivation		1
Histamine intolerance		1
Histamine level increased		1
Hordeolum		1
Hormone level abnormal		1
Hot flush	38	129
Humerus fracture	1	1
Hunger	1	3
Hyperactive pharyngeal reflex		1
Hyperacusis	5	12
Hyperaesthesia	7	20
Hypercapnia		1
Hyperchlorhydria		4
Hypergeusia		1
Hyperglycaemia	4	18
Hyperhidrosis	76	301
Hyperkalaemia		1
Hyperphagia		1
Hyperreflexia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
				1	3
					5
				2	2
				1	1
				1	1
				1	1
				1	1
		1	3		2
		1	1		
		1	1		1
		3	29	13	45
					1
					1
			1		
					1
		24	51	14	78
				1	1
		1	3		
					1
		2	6	3	6
		3	10	4	10
					1
			1		3
					1
		1	3	3	15
		26	87	50	214
					1
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersensitivity	25	103
Hypersomnia	14	46
Hypertension	17	88
Hypertensive crisis	3	3
Hyperthyroidism	1	2
Hypertonic bladder		1
Hypertrophic cardiomyopathy		1
Hyperventilation	1	5
Hypervigilance		1
Hypnagogic hallucination		1
Hypoacusis	5	13
Hypoaesthesia	100	340
Hypoaesthesia eye	1	3
Hypoaesthesia oral	16	80
Hypoaesthesia teeth		1
Hypoglycaemia	3	11
Hypokalaemia		1
Hypokinesia	14	20
Hypomania		1
Hypomenorrhoea	1	5
Hyponatraemia	1	1
Hyponatraemic syndrome	1	1
Hypoperfusion		1
Hypophagia	1	2
Hypopnoea	7	14
Hyporeflexia		1
Hyposmia		3
Hypotension	9	58
Hypothermia	1	6
Hypothyroidism	3	5
Hypoventilation	2	2
Hypovitaminosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	25	15	78
		9	20	5	26
		6	28	11	60
				3	3
				1	2
			1		
					1
		1	4		1
					1
					1
		2	6	3	7
	3	48	131	52	209
				1	3
		12	37	4	43
			1		
		1	3	2	8
					1
		4	5	10	15
					1
		1	3		2
				1	1
				1	1
					1
				1	2
			1	7	13
			1		
			2		1
		2	17	7	41
				1	6
				3	5
				2	2
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypovolaemic shock	1	1
Hypoxia		3
Illness	70	209
Immediate post-injection reaction		1
Immune system disorder	2	5
Immune thrombocytopenia	3	6
Immunisation anxiety related reaction		1
Immunodeficiency		1
Immunodeficiency common variable	1	1
Immunology test	1	1
Impaired driving ability	2	6
Impaired gastric emptying		1
Impaired quality of life	2	2
Impaired work ability	4	6
Implant site pain		1
Inappropriate affect		1
Inappropriate schedule of product administration	128	161
Incision site pain		2
Incoherent	2	2
Incontinence	1	5
Incorrect dose administered	1	2
Incorrect route of product administration	1	11
Increased appetite		1
Increased bronchial secretion		1
Increased tendency to bruise	2	5
Increased upper airway secretion	1	4
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion		3
Indifference	1	3
Induration		1
Infected dermal cyst		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					3
		29	69	41	140
			1		
				2	5
				3	6
					1
					1
				1	1
		1	1		
			2	2	4
					1
		1	1	1	1
		1	1	3	5
					1
					1
1	1	124	155	4	6
					2
		1	1	1	1
		1	2		3
		1	2		
		1	11		
					1
					1
			2	2	3
			1	1	3
					1
			1		2
				1	3
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infection	14	25
Infectious mononucleosis	1	1
Infectious pleural effusion		1
Infertility		1
Inflammation	13	37
Inflammatory pain		2
Influenza	69	185
Influenza like illness	115	377
Infusion related reaction		1
Initial insomnia	1	3
Injected limb mobility decreased	3	11
Injection related reaction		4
Injection site erythema	1	6
Injection site joint movement impairment		1
Injection site mass		1
Injection site oedema	1	1
Injection site pain	13	22
Injection site pruritus		2
Injection site reaction		2
Injection site swelling	4	6
Injection site urticaria		1
Injection site warmth		1
Injury	3	4
Inner ear disorder	2	4
Inner ear inflammation		1
Insomnia	58	219
Insulin resistance		1
Intentional self-injury	1	2
Internal haemorrhage		1
International normalised ratio abnormal	1	1
International normalised ratio decreased	1	1
Interstitial lung disease	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	7	9	18
				1	1
					1
					1
		10	19	3	18
			1		1
		24	58	45	127
	1	50	147	65	230
					1
		1	2		1
		1	4	2	7
			3		1
		1	6		
					1
			1		
		1	1		
		13	17		5
			2		
			1		1
		4	6		
					1
			1		
				3	4
				2	4
					1
		15	73	43	146
					1
				1	2
					1
		1	1		
				1	1
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intestinal pseudo-obstruction		1
Intranasal hyposaesthesia		1
Intranasal paraesthesia		1
Intrusive thoughts	1	1
Iridocyclitis		2
Iron deficiency anaemia	1	1
Irregular breathing		5
Irritability	7	21
Irritable bowel syndrome	2	10
Itching scar	1	3
Jaundice	1	2
Jaw clicking		1
Joint effusion	1	5
Joint injury	2	6
Joint laxity	1	2
Joint lock		1
Joint noise	2	4
Joint range of motion decreased	15	46
Joint stiffness	13	41
Joint swelling	21	53
Joint warmth	1	4
Keratitis		1
Ketoacidosis		1
Kidney infection		2
Kidney small		1
Labyrinthitis	3	10
Lack of spontaneous speech	1	4
Lacrimal disorder		1
Lacrimation increased	5	24
Lactation disorder	1	2
Lactose intolerance		1
Lagophthalmos	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
				1	1
					2
		1	1		
					5
		3	4	4	17
		1	2	1	8
		1	2		1
				1	2
					1
		1	1		4
		1	3	1	3
				1	2
					1
			1	2	3
		3	12	12	34
		4	10	9	31
		8	13	13	40
			3	1	1
					1
					1
					2
					1
		1	2	2	8
			1	1	3
					1
		2	4	3	20
				1	2
			1		
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Language disorder	1	1
Laryngeal disorder		1
Laryngeal pain		1
Laryngitis		1
Lethargy	105	358
Leukopenia	1	1
Lhermitte's sign	1	1
Ligament sprain		2
Limb discomfort	64	226
Limb immobilisation		2
Limb injury	4	10
Limb mass		7
Lip blister	1	5
Lip discolouration		1
Lip disorder		4
Lip dry	1	6
Lip erythema		1
Lip exfoliation		2
Lip haemorrhage		1
Lip oedema		3
Lip pain	2	9
Lip pruritus	1	1
Lip swelling	32	103
Lip ulceration	2	2
Listless		1
Livedo reticularis	1	6
Liver function test abnormal	1	1
Liver function test increased	1	1
Liver injury	1	1
Localised infection	1	7
Localised oedema	1	2
Local reaction	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					1
	1	49	129	56	229
				1	1
				1	1
					2
	1	34	94	30	132
			2		
		1	2	3	8
			3		4
		1	1		4
					1
			2		2
		1	3		3
					1
			1		1
					3
		1	6	1	3
		1	1		
		18	33	14	70
		2	2		
					1
			1	1	5
				1	1
				1	1
			1	1	6
		1	1		1
		1	3	1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Locked-in syndrome		1
Logorrhoea		1
Long thoracic nerve palsy		1
Loss of consciousness	18	57
Loss of control of legs		2
Loss of personal independence in daily activities	23	57
Lower respiratory tract congestion	1	1
Lower respiratory tract infection	9	26
Lung disorder	1	3
Lupus-like syndrome		1
Lymphadenitis	16	27
Lymphadenopathy	460	1,105
Lymphangiopathy	1	1
Lymphangitis		1
Lymphatic disorder		1
Lymph gland infection	1	1
Lymph node abscess		1
Lymph node pain	97	230
Lymph node palpable	1	3
Lymph nodes scan abnormal		1
Lymphocytosis		1
Lymphoedema	10	23
Lymphoma	1	3
Lymphopenia		1
Macular degeneration		1
Macule	1	2
Maculopathy		1
Malaise	245	922
Malnutrition		1
Mania		2
Mass	3	8
Mast cell activation syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
				18	57
					2
		9	19	14	38
		1	1		
				9	26
		1	1		2
					1
		5	8	11	19
1	3	160	386	300	719
				1	1
					1
			1		
				1	1
					1
		19	59	78	171
		1	2		1
					1
					1
	1	1	5	9	18
				1	3
			1		
					1
		1	1		1
					1
	3	106	337	139	585
					1
					2
				3	8
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mastication disorder	1	2
Mastitis	3	8
Maternal exposure before pregnancy	1	2
Maternal exposure during breast feeding	6	10
Maternal exposure during pregnancy	13	52
Maternal exposure timing unspecified		2
Measles	1	1
Mechanical urticaria		1
Melaena	1	1
Melanocytic naevus		1
Memory impairment	6	16
Meniere's disease		1
Meningitis	2	2
Meningitis aseptic		1
Meningitis viral	1	2
Menorrhagia	21	50
Menstrual discomfort	1	1
Menstrual disorder	4	12
Menstruation delayed	5	23
Menstruation irregular	9	16
Mental disorder		2
Mental fatigue	7	28
Mental impairment	2	5
Mesenteric vein thrombosis	1	1
Metabolic acidosis		2
Metamorphopsia		3
Metastases to lymph nodes		3
Metrorrhagia	2	3
Micturition urgency	2	3
Middle ear inflammation		1
Middle insomnia	2	11
Migraine	105	341

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				3	8
				1	2
		2	4	4	6
2	2	9	41	4	11
			2		
				1	1
			1		
				1	1
					1
			3	6	13
					1
				2	2
					1
				1	2
1	1	7	14	14	36
				1	1
1	1	2	6	2	6
		2	8	3	15
1	1	2	6	7	10
			1		1
		2	5	5	23
				2	5
				1	1
					2
			1		2
					3
		1	2	1	1
				2	3
					1
			3	2	8
1	2	21	78	84	263

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine with aura	5	23
Migraine without aura		1
Miliaria	4	10
Miosis		1
Misophonia	1	1
Mitral valve prolapse		1
Moaning		1
Mobility decreased	11	46
Monocytosis		1
Mononeuropathy		1
Monoparesis	2	8
Monoplegia	3	13
Mood altered	1	6
Mood swings		5
Morning sickness		1
Motion sickness	5	11
Motor dysfunction		1
Mouth breathing		2
Mouth cyst		1
Mouth haemorrhage	1	1
Mouth swelling	3	18
Mouth ulceration	16	51
Movement disorder	13	30
Multiple injuries		1
Multiple sclerosis		7
Multiple sclerosis relapse	3	12
Mumps		1
Muscle atrophy	2	2
Muscle contractions involuntary	1	6
Muscle discomfort	1	1
Muscle disorder	1	1
Muscle fatigue	12	49

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6	5	17
					1
		2	4	2	6
					1
				1	1
					1
					1
		2	15	9	31
			1		
					1
			1	2	7
				3	13
			1	1	5
			3		2
					1
		3	6	2	5
					1
					2
			1		
		1	1		
		2	5	1	13
		7	24	9	27
		1	5	12	25
					1
					7
				3	12
					1
		1	1	1	1
			2	1	4
		1	1		
		1	1		
		7	13	5	36

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle injury		1
Muscle rigidity		1
Muscle rupture		1
Muscle spasms	38	118
Muscle spasticity		2
Muscle strain		3
Muscle swelling	2	5
Muscle tightness	5	16
Muscle twitching	4	42
Muscular weakness	35	123
Musculoskeletal chest pain	4	25
Musculoskeletal discomfort	5	16
Musculoskeletal disorder	1	8
Musculoskeletal pain	2	12
Musculoskeletal stiffness	53	158
Mutism	2	3
Myalgia	442	1,610
Myalgia intercostal	1	1
Myasthenia gravis		2
Mydriasis	1	2
Myelitis transverse	2	9
Myocardial fibrosis		1
Myocardial infarction	3	8
Myocardial oedema		2
Myocarditis	2	9
Myoclonus		2
Myofascial pain syndrome		2
Myositis		2
Nail discolouration		2
Narcolepsy		1
Nasal congestion	10	40
Nasal discharge discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
1	1	14	36	24	82
					2
			1		2
		1	3	1	2
		2	7	3	9
		3	16	1	26
		13	39	22	84
		2	7	2	18
		2	10	3	6
			2	1	6
			3	2	9
		25	56	28	102
		1	2	1	1
2	10	217	592	225	1018
				1	1
					2
				1	2
				2	9
					1
				3	8
					2
				2	9
			1		1
					2
			2		
					2
					1
		3	15	7	25
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal discomfort	4	9
Nasal disorder		1
Nasal dryness	1	2
Nasal herpes	1	2
Nasal oedema		2
Nasal pruritus	1	3
Nasopharyngitis	38	112
Nausea	482	1,824
Near death experience	1	1
Neck mass	2	7
Neck pain	93	310
Necrotising fasciitis	1	1
Negative thoughts		1
Neoplasm	1	1
Neoplasm malignant	1	2
Nephritis		1
Nephrotic syndrome	1	4
Nerve compression		4
Nerve injury	2	5
Nervousness	6	31
Nervous system disorder	2	3
Neuralgia	17	51
Neuritis	1	1
Neurogenic shock		4
Neurological symptom	1	6
Neurologic neglect syndrome		1
Neuromyelitis optica spectrum disorder	1	1
Neuropathy peripheral	3	14
Neutropenia	3	7
Neutrophil count increased		1
New daily persistent headache		1
Nightmare	4	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	3	4
			1		
		1	1		1
		1	2		
			1		1
				1	3
		17	39	21	73
	7	240	652	242	1172
				1	1
			2	2	5
	2	37	108	56	202
				1	1
					1
				1	1
				1	2
					1
				1	4
			2		2
				2	5
		4	9	2	22
		1	2	1	1
		3	11	14	40
		1	1		
					4
				1	6
					1
				1	1
				3	14
				3	7
			1		
			1		
		2	7	2	9

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Night sweats	30	90
Nipple exudate bloody	1	1
Nipple pain	1	6
Nipple swelling	1	3
Nodule	1	2
Non-cardiac chest pain		2
Non-tobacco user	1	1
No reaction on previous exposure to drug	1	1
Nuchal rigidity		1
Nystagmus	2	3
Obstructive airways disorder		2
Occipital neuralgia	1	2
Occupational exposure to product		1
Ocular discomfort	4	9
Ocular hyperaemia	8	30
Ocular sarcoidosis		1
Odynophagia	4	12
Oedema	4	7
Oedema mouth		2
Oedema peripheral	4	8
Oesophageal pain		2
Oesophageal spasm		1
Oesophageal stenosis		1
Off label use	155	357
Oligodendroglioma	1	1
Oligohydramnios		1
Oligomenorrhoea	1	2
Onychoclasia	1	1
Ophthalmic herpes zoster		1
Ophthalmoplegia		1
Optic nerve disorder		1
Optic neuritis	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	15	38	15	52
				1	1
		1	3		3
			2	1	1
				1	2
					2
		1	1		
		1	1		
					1
				2	3
					2
				1	2
			1		
		2	6	2	3
		7	12	1	18
					1
		3	6	1	6
		1	2	3	5
			1		1
			2	4	6
			2		
			1		
					1
1	1	145	332	10	25
				1	1
					1
				1	2
		1	1		
					1
					1
					1
				2	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral blood blister		1
Oral candidiasis	1	1
Oral discomfort	1	15
Oral disorder	4	6
Oral herpes	6	26
Oral mucosa erosion		1
Oral mucosal blistering	3	9
Oral mucosal eruption	1	1
Oral mucosal erythema	1	2
Oral mucosal exfoliation	1	2
Oral pain	7	19
Oral pruritus	3	6
Orchitis		1
Oropharyngeal blistering		5
Oropharyngeal discomfort	7	21
Oropharyngeal oedema		1
Oropharyngeal pain	92	349
Orthostatic hypertension		1
Orthostatic hypotension		2
Oscillopsia		1
Osteonecrosis of jaw	1	1
Otitis externa		1
Overdose	1	6
Oversensing	1	1
Overweight		1
Oxygen saturation decreased	1	16
Pain	372	1,173
Painful respiration	5	13
Pain in extremity	470	1,625
Pain in jaw	10	48
Pain of skin	12	41
Palatal oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
		1	8		7
			2	4	4
	1	3	15	3	11
			1		
		3	5		4
		1	1		
		1	1		1
			1	1	1
		5	10	2	9
		2	3	1	3
					1
					5
		2	5	5	16
					1
	2	48	125	44	224
					1
			1		1
			1		
				1	1
					1
		1	6		
				1	1
					1
			1	1	15
	4	164	444	208	729
			2	5	11
3	13	216	647	254	978
		3	15	7	33
		7	14	5	27
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palatal swelling		2
Pallor	6	36
Palpitations	78	306
Pancreatic disorder		1
Pancreatitis acute	1	1
Panic attack	4	13
Panic disorder		1
Panic reaction	2	6
Papule	1	8
Paraesthesia	117	445
Paraesthesia oral	56	219
Parainfluenzae viral laryngotracheobronchitis	1	1
Paralysis	9	14
Paramnesia	1	1
Paranasal sinus discomfort	2	7
Paranoia		3
Paresis		1
Parosmia	7	21
Partial seizures	2	5
Patient elopement	1	1
Peak expiratory flow rate	1	1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased	2	3
Pelvic haemorrhage		1
Pelvic pain	1	7
Pelvic venous thrombosis		2
Pemphigus		1
Penile swelling		1
Peptic ulcer haemorrhage	1	1
Periarthritis	2	9
Pericarditis	1	4
Perioral dermatitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		4	13	2	23
	1	26	85	52	221
					1
				1	1
		2	4	2	9
					1
				2	6
		1	5		3
	2	62	177	55	268
		39	117	17	102
				1	1
	1			9	14
				1	1
		1	3	1	4
			1		2
					1
		3	10	4	11
				2	5
				1	1
				1	1
					1
					1
				2	3
					1
				1	7
					2
					1
					1
				1	1
		1	3	1	6
				1	4
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Periorbital cellulitis	1	1
Periorbital oedema		2
Periorbital pain	1	2
Periorbital swelling	5	16
Peripheral circulatory failure		2
Peripheral coldness	14	65
Peripheral ischaemia	2	2
Peripheral sensory neuropathy		3
Peripheral swelling	127	358
Peripheral vein stenosis	1	1
Peroneal nerve palsy	1	2
Petechiae	8	18
Petit mal epilepsy	1	5
Phantom limb syndrome		1
Pharyngeal erythema	3	4
Pharyngeal haemorrhage		1
Pharyngeal hypoaesthesia	2	6
Pharyngeal inflammation		5
Pharyngeal oedema		2
Pharyngeal paraesthesia	3	12
Pharyngeal swelling	9	60
Pharyngeal ulceration		2
Pharyngitis	2	4
Phlebitis	1	1
Phobia	1	1
Photophobia	12	66
Photopsia	5	13
Photosensitivity reaction	3	13
Pigmentation disorder	1	2
Piloerection	1	4
Pityriasis		3
Pityriasis lichenoides et varioliformis acuta	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
			1	1	1
		3	4	2	12
					2
		8	21	6	44
		2	2		
					3
1	2	45	119	82	239
				1	1
				1	2
		5	6	3	12
				1	5
					1
		2	2	1	2
					1
		2	3		3
					5
					2
		2	5	1	7
		5	16	4	44
					2
			1	2	3
		1	1		
				1	1
		4	18	8	48
		3	4	2	9
			2	3	11
			1	1	1
				1	4
			1		2
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pityriasis rosea	4	6
Plantar erythema	1	1
Plantar fasciitis	1	1
Platelet count decreased	8	9
Platelet count increased	1	1
Pleural effusion		1
Pleurisy		3
Pleuritic pain		1
Plicated tongue		2
Pneumonia	2	5
Pneumonitis		2
Pneumothorax	1	1
Poisoning	1	3
Pollakiuria	2	6
Polyarthritis	1	2
Polychondritis	1	2
Polydipsia	1	3
Polymenorrhoea	2	7
Polymerase chain reaction positive	1	2
Poor peripheral circulation		1
Poor quality sleep	8	31
Postictal paralysis	1	1
Postictal state		1
Postmenopausal haemorrhage	3	3
Post procedural complication		1
Post-traumatic stress disorder	1	2
Postural orthostatic tachycardia syndrome		3
Posture abnormal	1	1
Post viral fatigue syndrome	4	11
Pre-existing condition improved		1
Pregnancy	1	2
Prehypertension	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	2	3
				1	1
		1	1		
			1	8	8
				1	1
					1
					3
			1		
			1		1
				2	5
					2
				1	1
				1	3
			1	2	5
				1	2
			1	1	2
			2	2	5
		1	2		
			1		
	1	7	17	1	14
				1	1
					1
				3	3
					1
				1	2
					3
		1	1		
			1	4	10
			1		
			1	1	1
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Premature delivery		1
Premature menopause		1
Pressure of speech		1
Presyncope	11	74
Preterm premature rupture of membranes		2
Primary cough headache		1
Procedural dizziness	1	2
Procedural nausea		1
Proctalgia	1	1
Product administered at inappropriate site	1	6
Product dose omission issue		1
Productive cough	4	19
Product preparation error	1	2
Product residue present	1	1
Product taste abnormal		1
Product use issue	26	201
Prophylaxis of nausea and vomiting		1
Proteinuria		1
Pruritus	140	495
Psoriasis	6	11
Psoriatic arthropathy	3	3
Psychogenic seizure	1	1
Psychomotor hyperactivity	3	6
Psychotic disorder	1	3
Pulmonary embolism	5	17
Pulmonary oedema		1
Pulmonary pain	4	10
Pulmonary sarcoidosis		1
Pulmonary sepsis		1
Pulmonary thrombosis		1
Pulse abnormal	1	2
Puncture site swelling	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
	1	8	32	3	42
					2
					1
				1	2
					1
				1	1
		1	5		1
			1		
		1	4	3	15
		1	2		
				1	1
			1		
		21	183	5	18
					1
					1
		72	216	68	279
		1	3	5	8
				3	3
				1	1
				3	6
				1	3
				5	17
					1
		1	2	3	8
					1
					1
				1	2
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pupil fixed	1	1
Purple glove syndrome	1	1
Purpura	2	5
Pustule		2
Pyelonephritis		1
Pylorospasm		1
Pyrexia	527	2,174
Q fever		1
Quality of life decreased	1	1
Radial pulse abnormal		1
Radiculopathy		1
Rales		3
Rash	145	450
Rash erythematous	37	130
Rash macular	17	66
Rash maculo-papular	2	10
Rash morbilliform	2	5
Rash papular	14	38
Rash pruritic	35	115
Rash pustular		2
Rash vesicular	4	11
Raynaud's phenomenon	3	9
Reaction to preservatives		1
Rectal haemorrhage	1	6
Rectal injury	1	1
Rectal spasm		1
Red blood cell sedimentation rate increased	1	2
Reduced facial expression	1	1
Relapsing fever	1	1
Renal colic	1	1
Renal impairment	2	5
Renal pain	5	34

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		2	2		3
					2
					1
			1		
2	11	253	797	274	1377
					1
				1	1
					1
					1
					3
		78	198	67	252
		22	57	15	73
		9	33	8	33
		2	2		8
		1	2	1	3
		6	15	8	23
		18	40	17	75
					2
		1	4	3	7
			3	3	6
					1
				1	6
				1	1
			1		
				1	2
				1	1
				1	1
		1	1		
				2	5
		2	9	3	25

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiration abnormal	2	11
Respiratory arrest	2	5
Respiratory disorder	1	6
Respiratory distress	1	6
Respiratory rate decreased		1
Respiratory rate increased	3	11
Respiratory symptom	1	2
Respiratory tract infection		1
Respiratory tract irritation		2
Respiratory tract oedema		1
Restless legs syndrome	4	17
Restlessness	16	39
Retching	3	11
Retinal aneurysm	1	1
Retinal fovea disorder	1	1
Retinal migraine	1	5
Retinal vein occlusion		1
Retinitis pigmentosa		1
Rheumatoid arthritis	5	12
Rhinalgia	3	6
Rhinitis		7
Rhinitis allergic		1
Rhinorrhoea	19	75
Rosacea	1	1
Rotator cuff syndrome	2	2
Sacroiliitis	1	1
Salivary gland enlargement	1	1
Salivary gland pain		1
Salivary hypersecretion	1	7
Sarcoidosis	1	4
SARS-CoV-2 antibody test negative		3
SARS-CoV-2 antibody test positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	1	6
	1			2	5
			1	1	5
				1	6
					1
			3	3	8
				1	2
					1
			1		1
					1
		1	4	3	13
		4	9	12	30
		2	3	1	8
				1	1
				1	1
				1	5
					1
					1
	1			5	12
		2	3	1	3
			3		4
			1		
2	2	12	28	7	47
				1	1
				2	2
				1	1
				1	1
		1	3		4
				1	4
			1		2
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative		2
SARS-CoV-2 test positive	4	18
Scab	1	1
Scalloped tongue	1	1
Scar	1	4
Schizophrenia	1	1
Sciatica	1	6
Scintillating scotoma	1	1
Scleral discolouration		1
Scleritis		1
Scleroderma associated digital ulcer		1
Scratch		3
Scrotal pain		1
Seasonal allergy	1	1
Secondary transmission	1	1
Secretion discharge		1
Sedation	1	4
Seizure	20	61
Seizure cluster		2
Seizure like phenomena		1
Self-injurious ideation		1
Sensation of foreign body	6	14
Sense of a foreshortened future		1
Sensitive skin	11	30
Sensory disturbance	4	11
Sensory loss	7	16
Sepsis	1	2
Septic shock	1	1
Shock		2
Sinonasal obstruction		2
Sinus congestion		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
		2	4	2	14
		1	1		
				1	1
				1	4
				1	1
			2	1	4
				1	1
			1		
					1
					1
			2		1
					1
		1	1		
				1	1
					1
			1	1	3
				20	61
					2
					1
					1
		3	5	3	9
					1
		6	15	5	15
		3	6	1	5
		3	6	4	10
				1	2
				1	1
					2
					2
			3		5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus headache	18	44
Sinusitis	4	8
Sinus pain	6	22
Sinus tachycardia		11
Skin abrasion		3
Skin burning sensation	11	39
Skin depigmentation		1
Skin discharge		1
Skin discolouration	5	18
Skin disorder	2	6
Skin erosion	1	3
Skin exfoliation	9	15
Skin infection	1	1
Skin irritation	4	10
Skin laceration		1
Skin laxity		1
Skin lesion	1	5
Skin mass		2
Skin odour abnormal	1	2
Skin reaction	5	11
Skin sensitisation	4	7
Skin swelling	5	10
Skin temperature	1	3
Skin tightness	2	13
Skin ulcer		1
Skin warm	10	37
Skin weeping		1
Sleep apnoea syndrome		1
Sleep deficit	1	4
Sleep disorder	23	68
Sleep disorder due to a general medical condition	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	19	9	25
		1	2	3	6
		3	8	3	14
			4		7
			1		2
		4	16	7	23
					1
					1
		2	7	3	11
		1	2	1	4
		1	1		2
		4	5	5	10
		1	1		
		1	4	3	6
					1
					1
		1	2		3
			1		1
		1	2		
		3	5	2	6
		1	1	3	6
		4	8	1	2
		1	1		2
		1	8	1	5
					1
		4	13	6	24
					1
			1	1	3
		9	24	14	44
		1	3		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep disorder due to general medical condition, insomnia type	1	6
Sleep paralysis		2
Sleep terror	1	2
Slow response to stimuli		2
Slow speech	1	2
Sluggishness		4
Sneezing	8	41
Snoring		1
Soft tissue injury	1	1
Soft tissue swelling	1	1
Solar lentigo	1	1
Somatic symptom disorder		1
Somnolence	53	160
Speech disorder	1	3
Spinal disorder	1	2
Spinal pain	5	13
Spleen atrophy		1
Splenomegaly	1	2
Sputum abnormal		1
Sputum discoloured		2
Sputum purulent		1
Staphylococcal abscess	1	1
Staphylococcal infection		2
Staring	1	1
Status epilepticus	4	10
Steatorrhoea	1	1
Stiff leg syndrome		1
Stiff tongue		1
Stomatitis	4	8
Strabismus	1	1
Stress	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	5
			1		1
			1	1	1
					2
				1	2
					4
		5	15	3	26
					1
				1	1
		1	1		
				1	1
					1
		27	63	26	97
			1	1	2
			1	1	1
		2	5	3	8
					1
				1	2
					1
			1		1
		1	1		
					2
				1	1
				4	10
		1	1		
					1
					1
		4	6		2
				1	1
		1	1	3	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stridor	2	3
Subarachnoid haemorrhage	1	1
Subclavian vein thrombosis		2
Subcutaneous abscess		2
Subcutaneous haematoma	1	1
Subdural haematoma	1	1
Sudden hearing loss		2
Sudden visual loss	1	1
Suicidal ideation	5	10
Sunburn	1	1
Superficial injury of eye		1
Superficial vein prominence		1
Suppressed lactation		2
Supraventricular tachycardia	3	9
Suspected COVID-19	28	148
Sweating fever	4	18
Swelling	156	337
Swelling face	40	143
Swelling of eyelid	8	20
Swollen joint count increased		1
Swollen tongue	20	84
Symphysis		1
Symptom recurrence	1	1
Syncope	37	167
Synovial cyst		2
Syringe issue		1
Systemic candida		1
Systemic immune activation	1	1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	1	4
Systemic lupus erythematosus rash		2
Tachycardia	28	169

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	2
				1	1
					2
			1		1
		1	1		
				1	1
					2
				1	1
				5	10
		1	1		
					1
			1		
					2
		2	3	1	6
		14	55	14	93
				4	18
		56	136	100	201
		17	40	23	103
		1	5	7	15
					1
		10	25	10	59
					1
				1	1
				37	167
					2
			1		
					1
				1	1
					1
				1	4
			1		1
		15	50	13	119

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tachyphrenia		1
Tachypnoea		7
Taste disorder	14	36
Tearfulness	6	10
Teething		1
Telangiectasia	1	1
Temperature difference of extremities		2
Temperature intolerance	3	4
Temperature regulation disorder	1	2
Temporomandibular joint syndrome		1
Tenderness	22	53
Tendon injury		1
Tendonitis	3	6
Tendon pain		1
Tension		2
Tension headache	19	50
Terminal insomnia	1	3
Testicular pain		1
Testicular torsion		1
Therapeutic product effect delayed	1	1
Therapeutic response unexpected	2	5
Thermal burns of eye	1	3
Thinking abnormal	2	7
Thirst	19	54
Throat clearing		1
Throat irritation	14	50
Throat tightness	14	83
Thrombocytopenia	10	13
Thrombophlebitis	1	2
Thrombophlebitis superficial	1	2
Thrombosis	14	22
Thrombotic microangiopathy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		5
		10	25	4	11
		2	4	4	6
					1
				1	1
					2
		1	1	2	3
				1	2
			1		
	1	15	27	7	26
					1
		1	1	2	5
			1		
			1		1
		7	16	12	34
		1	1		2
					1
					1
				1	1
		1	1	1	4
				1	3
		1	3	1	4
		7	17	12	37
					1
		9	20	5	30
		6	25	8	58
				10	13
		1	1		1
		1	1		1
	1			14	22
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombotic thrombocytopenic purpura	2	3
Thyroid disorder	1	1
Thyroid function test abnormal		1
Tinnitus	54	114
Tongue biting		1
Tongue blistering	1	1
Tongue coated	1	2
Tongue cyst	1	1
Tongue discolouration	3	5
Tongue discomfort	3	10
Tongue disorder	2	8
Tongue dry		2
Tongue eruption	1	3
Tongue erythema		1
Tongue injury		1
Tongue movement disturbance	1	2
Tongue oedema	2	7
Tongue paralysis		1
Tongue pruritus		4
Tongue rough		1
Tongue spasm	1	1
Tongue ulceration		4
Tonic convulsion	1	5
Tonsillar erythema		1
Tonsillar haemorrhage		1
Tonsillar hypertrophy	1	6
Tonsillar inflammation		1
Tonsillar ulcer		1
Tonsillitis	5	9
Tonsillitis bacterial	1	3
Toothache	2	8
Torticollis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
				1	1
			1		
		15	29	39	85
					1
		1	1		
		1	2		
				1	1
		1	1	2	4
		1	4	2	6
			2	2	6
			2		
		1	2		1
			1		
					1
				1	2
		1	2	1	5
					1
			1		3
			1		
				1	1
			2		2
				1	5
					1
					1
		1	1		5
			1		
					1
1	1	2	2	3	7
				1	3
		1	4	1	4
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Toxicity to various agents		1
Transient ischaemic attack	4	6
Tremor	55	209
Trichodynia		1
Trigeminal neuralgia	3	8
Trigger finger		1
Trismus	4	7
Troponin increased		3
Tumefactive multiple sclerosis	1	1
Tunnel vision	1	2
Type 1 diabetes mellitus	1	3
Type 2 diabetes mellitus	1	1
Type III immune complex mediated reaction	1	1
Type IV hypersensitivity reaction		2
Typical aura without headache	1	1
Ulcer		1
Ulcerative keratitis		2
Ulnar nerve injury		1
Underdose		2
Unresponsive to stimuli	2	4
Upper respiratory tract congestion	1	1
Upper respiratory tract infection	1	2
Urinary incontinence		6
Urinary retention	2	6
Urinary tract infection	5	17
Urine abnormality	1	1
Urine analysis abnormal		1
Urine flow decreased		1
Urine ketone body present	1	1
Urine output	1	1
Urine output increased		1
Urticaria	60	202

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				4	6
		27	65	28	144
					1
				3	8
					1
		1	1	3	6
					3
				1	1
				1	2
				1	3
				1	1
				1	1
					2
				1	1
					1
					2
					1
			2		
				2	4
				1	1
		1	1		1
			2		4
				2	6
		2	2	3	15
				1	1
					1
					1
				1	1
		1	1		
					1
		34	83	26	119

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urticaria chronic	1	1
Urticaria thermal		1
Uterine haemorrhage	1	1
Uveitis		2
Uvulitis	1	1
Vaccination complication	3	11
Vaccination failure	2	2
Vaccination site abscess		3
Vaccination site bruising	15	46
Vaccination site cellulitis	2	13
Vaccination site discolouration	1	5
Vaccination site discomfort	6	23
Vaccination site dryness		1
Vaccination site eczema	1	1
Vaccination site erythema	61	228
Vaccination site haemorrhage	4	8
Vaccination site hyperaesthesia		3
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia	2	13
Vaccination site induration	8	32
Vaccination site infection	2	9
Vaccination site inflammation	8	16
Vaccination site irritation	2	3
Vaccination site joint discomfort	1	1
Vaccination site joint erythema	1	1
Vaccination site joint movement impairment		6
Vaccination site joint pain		5
Vaccination site joint swelling	1	1
Vaccination site lymphadenopathy	5	14
Vaccination site macule		1
Vaccination site mass	27	94
Vaccination site movement impairment	9	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
				1	1
					2
		1	1		
		1	3	2	8
				2	2
			1		2
		7	20	8	26
		1	2	1	11
		1	2		3
		2	11	4	12
					1
		1	1		
		40	129	21	99
			1	4	7
			1		2
		1	1		
		1	5	1	8
		5	18	3	14
		1	3	1	6
		7	9	1	7
		1	2	1	1
		1	1		
				1	1
			3		3
			2		3
		1	1		
			3	5	11
			1		
		14	46	13	48
		2	14	7	17

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site necrosis		1
Vaccination site oedema	2	2
Vaccination site pain	331	1,195
Vaccination site paraesthesia	1	12
Vaccination site pruritus	29	96
Vaccination site rash	18	48
Vaccination site reaction	5	25
Vaccination site scar		2
Vaccination site swelling	72	287
Vaccination site urticaria	2	5
Vaccination site vesicles	2	5
Vaccination site warmth	33	134
Vaginal discharge		2
Vaginal disorder		1
Vaginal haemorrhage	6	25
Vaginal ulceration	1	1
Varicella	2	2
Varicose vein	1	1
Vascular headache		1
Vascular pain	1	2
Vasculitic rash	1	1
Vasculitis	2	2
Vein discolouration	1	1
Vein disorder	1	2
Vein rupture		1
Venous injury	3	3
Venous thrombosis	1	1
Ventricular arrhythmia		2
Ventricular extrasystoles		9
Ventricular fibrillation		1
Ventricular tachycardia		1
Vertebral lesion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	1	1
	2	198	564	133	631
		1	8		4
		21	61	8	35
		11	26	7	22
			13	5	12
			1		1
		40	129	32	158
		1	4	1	1
		1	1	1	4
		21	68	12	66
			1		1
			1		
		2	6	4	19
				1	1
				2	2
				1	1
					1
				1	2
					1
				1	1
		1	1	1	1
		1	1		
				1	2
					1
				3	3
				1	1
					2
			1		8
					1
					1
				1	1

\* I=Interval, C=Cumulative

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo	39	110
Vertigo positional	1	7
Vestibular disorder	1	2
Vestibular migraine		2
Viral infection	4	5
Viral labyrinthitis	1	2
Viral pericarditis		1
Viral pharyngitis		2
Viral rash	1	7
Viral test		1
Vision blurred	39	124
Visual acuity reduced	1	2
Visual field defect		4
Visual impairment	16	42
Vital capacity		1
Vitamin B12 decreased	1	1
Vitamin D	1	1
Vitreous detachment		1
Vitreous floaters	1	4
Vocal cord disorder		1
Vomiting	117	455
Vomiting projectile	2	7
Vth nerve injury		1
Vulval haemorrhage	1	2
Vulval oedema		1
Vulval ulceration	1	1
Vulvovaginal burning sensation	1	1
Vulvovaginal candidiasis	3	4
Vulvovaginal pain	1	3
Vulvovaginal swelling		1
Vulvovaginal ulceration	2	2
Weight bearing difficulty		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	19	29	91
				1	7
			1	1	1
					2
		1	2	3	3
			1	1	1
					1
					2
		1	4		3
					1
		12	38	27	86
				1	2
			2		2
		3	11	13	31
					1
				1	1
				1	1
					1
			3	1	1
					1
1	2	36	137	81	318
		1	2	1	5
					1
				1	2
			1		
		1	1		
				1	1
		1	2	2	2
			1	1	2
					1
				2	2
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Weight decreased	2	10				1	2	9
Weight increased		1						1
Wheat-free diet	1	1					1	1
Wheezing	15	77			8	22	7	55
White blood cell count decreased		1						1
White blood cell count increased	2	4			1	3	1	1
Withdrawal syndrome		1				1		
Wound		1				1		
Wrong product administered	2	2			2	2		
Yawning	2	7			1	1	1	6
Yellow skin		1				1		
		4				4		
	14,320	48,848	48	182	6141	17206	8179	31642

\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	15	61	1	2	2	13	13	48
Abdominal distension	10	28			3	7	7	21
Abdominal infection	1	1					1	1
Abdominal lymphadenopathy	1	1					1	1
Abdominal migraine	1	1					1	1
Abdominal pain	39	108		1	13	33	26	75
Abdominal pain lower	2	11				1	2	10
Abdominal pain upper	34	158		1	11	37	23	121
Abdominal tenderness		2				2		
Abnormal behaviour		1						1
Abnormal dreams	4	13			3	5	1	8
Abnormal faeces		1						1
Abnormal loss of weight		1						1
Abnormal sensation in eye		1						1
Abscess	2	4				2	2	2
Abscess oral		1						1
Acne	2	3					2	3
Acne pustular		1						1
Activated partial thromboplastin time prolonged	2	2					2	2
Activated partial thromboplastin time shortened	1	1					1	1
Acute abdomen	1	1					1	1
Acute cardiac event		1						1
Acute coronary syndrome	2	2					2	2
Acute kidney injury	2	6					2	6
Acute leukaemia		1						1
Acute motor axonal neuropathy		1						1
Acute myocardial infarction	1	2					1	2
Acute vestibular syndrome		1				1		
Addison's disease		1						1
Adrenocortical insufficiency acute		3						3
Adverse drug reaction	2	10			1	5	1	5
Affect lability		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ageusia	14	37
Agitated depression		1
Agitation	1	5
Airway burns		1
Alanine aminotransferase increased	2	4
Alcohol poisoning		1
Allergic cough		1
Allergic oedema	1	4
Allergy to arthropod bite	1	1
Allergy to arthropod sting	1	1
Allergy to vaccine	3	13
Allodynia		2
Alopecia	7	8
Altered state of consciousness	1	3
Amblyopia		1
Amenorrhoea	1	1
Amnesia	2	4
Anaemia	3	5
Anal fissure		1
Analgesic drug level		1
Anal pruritus	1	2
Anaphylactic reaction	7	57
Anaphylactic shock	2	5
Anaphylactoid reaction		3
Anaphylaxis prophylaxis	1	1
Androgenetic alopecia	1	1
Angina pectoris	3	6
Angina unstable		1
Angioedema	6	28
Anisocytosis		1
Ankle fracture	1	1
Ankylosing spondylitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	14	5	23
					1
			1	1	4
					1
			1	2	3
					1
					1
		1	1		3
		1	1		
				1	1
		2	8	1	5
					2
				7	8
				1	3
			1		
				1	1
			1	2	3
			1	3	4
					1
					1
			1	1	1
				7	57
				2	5
					3
				1	1
				1	1
				3	6
					1
				6	28
					1
				1	1
				1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anorectal discomfort		1
Anosmia	4	22
Antiphospholipid syndrome		1
Anxiety	12	41
Aortic embolus	2	2
Aortic stenosis		1
Apathy	2	3
Aphasia	3	5
Aphonia		6
Aphthous ulcer	1	4
Apnoea	1	1
Apparent death		1
Appendicitis	2	2
Appendicitis perforated	1	1
Appetite disorder		2
Arrhythmia		4
Arrhythmia supraventricular		2
Arterial disorder	1	1
Arteritis		1
Arthralgia	249	888
Arthritis	6	15
Arthritis reactive		1
Arthropathy		3
Ascites		1
Aspiration		1
Asthenia	60	206
Asthenopia	4	13
Asthma	7	28
Ataxia		1
Atonic seizures	1	1
Atopy		1
Atrial fibrillation	11	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	8	2	14
					1
		1	12	11	29
				2	2
					1
		2	3		
			1	3	4
					6
		1	2		2
				1	1
					1
				2	2
				1	1
					2
					4
			1		1
				1	1
					1
	7	78	240	171	648
		1	3	5	12
					1
			1		2
					1
					1
	1	21	54	39	152
		3	5	1	8
		3	7	4	21
					1
				1	1
					1
				11	24

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atrial flutter		1
Atypical femur fracture		1
Auditory disorder		1
Aura	1	2
Auricular swelling		1
Autoimmune disorder		5
Autoimmune haemolytic anaemia		1
Autonomic nervous system imbalance	1	1
Autoscopy		1
Axillary mass	8	18
Axillary pain	51	130
Back pain	60	214
Bacterial diarrhoea		1
Balance disorder	10	41
Basal cell carcinoma	1	2
Bedridden	1	2
Bladder discomfort		1
Bladder disorder		1
Bladder irritation		1
Bladder pain		1
Blepharitis	1	1
Blepharospasm	2	4
Blindness	2	5
Blindness transient	1	3
Blister	10	27
Blood albumin decreased		1
Blood alkaline phosphatase increased	1	2
Blood blister		3
Blood count abnormal	2	2
Blood creatine phosphokinase increased	1	1
Blood creatinine increased		1
Blood glucose abnormal		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
				1	2
					1
					5
					1
				1	1
					1
		1	4	7	14
		11	39	40	91
	1	18	52	42	162
					1
		1	6	9	35
				1	2
				1	2
			1		
					1
					1
				1	1
		1	1	1	3
				2	5
				1	3
		3	8	7	19
					1
			1	1	1
					3
				2	2
				1	1
			1		
			2		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood glucose decreased	1	6
Blood glucose fluctuation	2	6
Blood glucose increased	3	20
Blood iron decreased	1	1
Blood pH		1
Blood pH increased		1
Blood potassium decreased	1	1
Blood pressure decreased	5	16
Blood pressure diastolic decreased	1	1
Blood pressure fluctuation		2
Blood pressure increased	13	47
Blood pressure systolic decreased		2
Blood pressure systolic increased		2
Blood sodium decreased	1	1
Blood test abnormal	2	2
Blood urine present	1	2
Blue toe syndrome	1	2
Body temperature	5	6
Body temperature abnormal	4	19
Body temperature decreased	1	8
Body temperature fluctuation	2	11
Body temperature increased	23	82
Bone neoplasm		1
Bone pain	11	40
Bone swelling	1	2
Bowel movement irregularity		2
Brachial plexus injury	1	1
Bradycardia	2	3
Bradykinesia	1	1
Bradyphrenia	2	5
Brain injury		1
Brain neoplasm	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	4
		1	2	1	4
			4	3	16
		1	1		
					1
			1		
		1	1		
		2	4	3	12
		1	1		
			1		1
		4	14	9	33
					2
			1		1
				1	1
				2	2
				1	2
		1	2		
		2	2	3	4
		1	5	3	14
		1	1		7
			2	2	9
	2	9	38	14	44
					1
		4	9	7	31
		1	1		1
			1		1
				1	1
				2	3
		1	1		
			1	2	4
					1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brain stem syndrome		1
Breast cancer		1
Breast cyst	1	1
Breast discomfort	1	2
Breast mass	2	3
Breast pain	13	29
Breast swelling	1	8
Breast tenderness	2	4
Breath sounds abnormal	1	2
Bronchial disorder		1
Bronchial secretion retention	1	1
Bronchiectasis	1	2
Bronchitis		3
Bronchopulmonary aspergillosis		1
Bronchospasm	1	1
Bruxism	1	1
Bulbar palsy	1	1
Burning feet syndrome		1
Burning sensation	12	44
Burn oesophageal		1
Burns second degree	1	2
Bursitis		2
Candida infection	1	2
Cardiac arrest	4	8
Cardiac discomfort	1	1
Cardiac disorder		1
Cardiac failure		2
Cardiac failure acute	1	1
Cardiac flutter	7	15
Carotid artery dissection		1
Cataplexy		1
Cataract	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	1		
		1	1		1
				2	3
		1	5	12	24
			5	1	3
			1	2	3
		1	1		1
					1
		1	1		
				1	2
					3
					1
		1	1		
				1	1
				1	1
					1
		3	13	9	31
					1
		1	1		1
					2
			1	1	1
				4	8
				1	1
					1
					2
				1	1
				7	15
					1
					1
				1	1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Catarrh	1	1
Cellulitis	5	21
Central nervous system lesion	1	1
Cerebellar infarction		1
Cerebral artery thrombosis	1	1
Cerebral haemorrhage	3	5
Cerebral infarction	4	6
Cerebral thrombosis	1	2
Cerebral venous sinus thrombosis	2	2
Cerebrospinal fluid leakage		1
Cerebrovascular accident	12	23
Cervical radiculopathy	1	1
Change of bowel habit	1	1
Chapped lips	2	4
Cheilitis		1
Chest crushing	1	2
Chest discomfort	29	98
Chest injury	1	1
Chest pain	40	157
Chillblains	4	4
Chills	258	993
Choking	3	4
Chorea		1
Choroidal neovascularisation		2
Chromaturia	1	6
Chronic fatigue syndrome	5	8
Chronic kidney disease	1	1
Chronic lymphocytic leukaemia	1	1
Chronic obstructive pulmonary disease	3	5
Circulatory collapse	3	11
Clostridium difficile colitis		1
Clumsiness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				5	21
		1	1		
					1
				1	1
				3	5
				4	6
				1	2
				2	2
					1
				12	23
				1	1
				1	1
		1	2	1	2
					1
				1	2
		8	27	21	71
				1	1
		6	29	34	128
		3	3	1	1
	3	114	315	144	678
				3	4
					1
					2
			4	1	2
			1	5	7
				1	1
				1	1
				3	5
				3	11
					1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cluster headache	6	13
Coagulopathy		1
Coccydynia	1	2
Coeliac disease		1
Cognitive disorder	1	7
Cold-stimulus headache	1	3
Cold sweat	17	61
Colitis	4	6
Colitis ischaemic	1	1
Colitis microscopic		1
Colitis ulcerative	1	3
Colon cancer	1	1
Coma		1
Communication disorder		1
Condition aggravated	20	48
Confusional state	21	54
Conjunctival haemorrhage	4	6
Conjunctivitis	2	8
Conjunctivitis viral	1	1
Constipation	7	13
Contusion	20	48
Coordination abnormal	4	11
Corneal disorder		1
Corneal reflex decreased		1
Coronary artery disease	1	2
Coronary artery thrombosis	1	1
Coronavirus infection	1	2
Costochondritis	3	5
Cough	46	190
COVID-19	12	77
COVID-19 immunisation	2	2
COVID-19 pneumonia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	4	10
					1
		1	2		
					1
			1	1	6
				1	3
		3	13	14	48
				4	6
				1	1
					1
				1	3
				1	1
					1
					1
		2	7	18	41
		2	6	19	48
				4	6
		2	3		5
		1	1		
		1	1	6	12
		8	18	12	30
		1	1	3	10
					1
			1		
				1	2
				1	1
			1	1	1
				3	5
	2	22	61	24	129
		5	23	7	54
				2	2
				1	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cranial nerve disorder		1
C-reactive protein increased	6	8
Crohn's disease	1	6
Crying		4
Cutaneous sarcoidosis		1
Cyanopsia		1
Cyanosis	2	6
Cyanosis central		1
Cyclic vomiting syndrome		1
Cystitis	2	4
Cystitis interstitial	1	1
Deafness	12	21
Deafness neurosensory	1	4
Deafness transitory		1
Deafness unilateral	3	3
Death	2	5
Decreased activity	1	1
Decreased appetite	42	162
Decreased immune responsiveness		2
Decreased interest	2	3
Decubitus ulcer	1	1
Deep vein thrombosis	21	26
Defaecation urgency	2	3
Dehydration	3	12
Deja vu	1	1
Delirium	1	6
Dementia		1
Dental discomfort		1
Depersonalisation/derealisation disorder	1	1
Depressed level of consciousness	1	4
Depressed mood	6	25
Depression	7	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	5	7
				1	6
			1		3
					1
				2	6
					1
					1
				2	4
				1	1
				12	21
				1	4
					1
				3	3
				2	5
		1	1		
		14	48	28	114
					2
			1	2	2
				1	1
	1			21	26
				2	3
		1	3	2	9
				1	1
				1	6
					1
					1
				1	1
				1	4
			2	6	23
				7	17

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Derealisation		1
Dermatitis	2	5
Dermatitis allergic	5	15
Dermatitis atopic	1	2
Dermatitis bullous		1
Dermatitis infected		1
Dermatomyositis		1
Device pacing issue	1	1
Device stimulation issue		1
Diabetes mellitus	3	9
Diabetes mellitus inadequate control	1	1
Diabetic coma	1	1
Diabetic ketoacidosis		1
Diarrhoea	97	406
Diarrhoea haemorrhagic	1	4
Diplegia	1	1
Diplopia	5	16
Discoloured vomit		2
Discomfort	9	29
Disease progression		1
Disease recurrence	19	57
Disorientation	5	24
Dissociation	1	5
Dissociative amnesia	1	1
Disturbance in attention	16	53
Dizziness	155	619
Dizziness exertional	1	7
Dizziness postural	18	78
Dreamy state		1
Droling		3
Drug eruption		1
Drug hypersensitivity	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2	1	3
		1	5	4	10
				1	2
					1
					1
				1	1
			1		
				3	9
				1	1
				1	1
					1
	2	36	101	61	305
				1	4
				1	1
		2	3	3	13
			1		1
		2	9	7	20
					1
1	1	1	4	18	53
			2	5	22
			1	1	4
		1	1		
		2	9	14	44
	5	57	167	98	452
				1	7
		4	14	14	64
			1		
			1		2
					1
				2	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug-induced liver injury	1	1
Drug ineffective	12	71
Drug interaction	1	1
Dry eye	2	9
Dry mouth	6	37
Dry skin	5	9
Dry throat	6	16
Duodenal ulcer haemorrhage	1	1
Duodenal ulcer perforation		1
Dysarthria	2	10
Dyschezia	1	2
Dysgeusia	28	94
Dyshidrotic eczema		2
Dyskinesia	4	9
Dyspepsia	7	21
Dysphagia	5	24
Dysphemia	1	1
Dysphonia	8	19
Dyspnoea	71	278
Dyspnoea exertional	2	8
Dysstasia	3	14
Dystonia		2
Dysuria	2	5
Ear congestion		1
Ear discomfort	1	6
Ear haemorrhage	1	1
Ear infection	4	7
Ear pain	18	65
Ear pruritus		2
Ear swelling	3	5
Eating disorder	2	5
Eating disorder symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				12	71
				1	1
			2	2	7
		2	10	4	27
		1	1	4	8
		5	6	1	10
				1	1
					1
			3	2	7
		1	2		
		19	52	9	42
					2
			1	4	8
		3	7	4	14
		1	6	4	18
		1	1		
		2	5	6	14
		12	45	59	233
			2	2	6
			5	3	9
					2
		1	1	1	4
					1
			2	1	4
				1	1
			1	4	6
		8	20	10	45
					2
			1	3	4
				2	5
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema	4	9
Eczema herpeticum	1	2
Ehlers-Danlos syndrome		1
Electric shock	1	2
Electrocardiogram abnormal	1	1
Electrocardiogram change		1
Embolism	11	13
Emotional disorder		2
Emotional distress	2	5
Encephalitis	1	2
Enlarged uvula		3
Enteritis	2	3
Enthesopathy		1
Enuresis	1	2
Eosinophil count increased	1	1
Eosinophilia		1
Epicondylitis		1
Epigastric discomfort		2
Epiglottitis	1	1
Epilepsy	8	17
Epileptic aura		1
Epiphyses premature fusion		1
Episcleritis		1
Epistaxis	27	45
Erectile dysfunction		3
Erection increased	1	1
Eructation	2	8
Erythema	31	132
Erythema multiforme	2	4
Erythema nodosum	1	2
Essential hypertension		1
Essential thrombocythaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	4	7
				1	2
					1
				1	2
		1	1		
			1		
				11	13
			1		1
			1	2	4
				1	2
			1		2
				2	3
					1
				1	2
				1	1
			1		
					1
					2
				1	1
				8	17
					1
					1
			1		
		10	18	17	27
					3
				1	1
			2	2	6
		16	51	15	81
				2	4
				1	2
					1
					1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Euphoric mood	1	3
Eustachian tube dysfunction		1
Evans syndrome	1	1
Excessive cerumen production	1	1
Exercise tolerance decreased	2	2
Exophthalmos		1
Exploding head syndrome		1
Exposure during pregnancy	2	6
Exposure to SARS-CoV-2		1
Extensive swelling of vaccinated limb		1
External ear pain		1
Extraocular muscle disorder	1	1
Extrasystoles	1	2
Eye colour change		1
Eye discharge	1	3
Eye disorder		5
Eye haematoma		1
Eye haemorrhage	2	6
Eye infection	1	1
Eye inflammation	3	5
Eye injury		1
Eye irritation	4	11
Eyelid bleeding	1	1
Eyelid cyst		1
Eyelid disorder		1
Eyelid function disorder	1	2
Eyelid pain		1
Eyelid ptosis		4
Eyelids pruritus	1	2
Eye movement disorder		5
Eye pain	20	85
Eye pruritus	5	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
					1
				1	1
				1	1
		1	1	1	1
					1
					1
		2	5		1
			1		
			1		
			1		
				1	1
				1	2
					1
		1	1		2
			2		3
					1
				2	6
				1	1
		2	2	1	3
					1
		1	2	3	9
				1	1
					1
			1		
			1	1	1
					1
			4		
			1	1	1
					5
		4	18	16	67
		4	7	1	10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye swelling	15	45
Face injury	1	1
Face oedema		1
Facial asymmetry		1
Facial discomfort		2
Facial nerve disorder	1	1
Facial neuralgia		2
Facial pain	7	27
Facial paralysis	24	88
Facial paresis	1	9
Facial spasm		2
Faecal calprotectin		1
Faecal calprotectin increased	1	1
Faeces discoloured	2	3
Faeces hard	1	1
Faeces pale		1
Faeces soft	1	1
Fall	6	18
Fatigue	501	1,857
Fear	2	3
Febrile convulsion	1	1
Feeding disorder	1	17
Feeling abnormal	59	192
Feeling cold	50	182
Feeling drunk	2	9
Feeling hot	32	135
Feeling jittery		2
Feeling of body temperature change	23	54
Feeling of despair	2	2
Fibrin D dimer increased	2	2
Fibromyalgia	2	9
Fine motor skill dysfunction	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	17	5	28
				1	1
			1		1
			1		1
		1	1		
					2
		2	7	5	20
				24	88
		1	5		4
			2		
					1
				1	1
			1	2	2
				1	1
			1		
				1	1
		1	2	5	16
2	16	183	527	318	1330
				2	3
		1	1		
			6	1	11
1	1	16	55	43	137
	1	23	65	27	117
		1	1	1	8
		16	60	16	75
					2
		7	13	16	41
				2	2
		1	1	1	1
			2	2	7
				1	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fixed eruption		1
Flank pain		2
Flat affect		1
Flatulence	6	17
Fluid retention	1	1
Flushing	9	45
Foaming at mouth	1	1
Folliculitis		1
Food allergy		1
Food aversion		1
Food craving		1
Food intolerance	1	1
Food refusal		1
Forced expiratory volume increased		2
Foreign body sensation in eyes	2	7
Formication	1	2
Freezing phenomenon	1	1
Frequent bowel movements	1	5
Full blood count abnormal		1
Fungal infection	1	1
Furuncle	2	4
Gait disturbance	16	46
Gait inability	5	18
Galactorrhoea	2	2
Gallbladder disorder	1	1
Gamma-glutamyltransferase increased	1	1
Gastric antral vascular ectasia	1	1
Gastric disorder	1	4
Gastric varices haemorrhage		1
Gastritis	1	4
Gastroenteritis	1	2
Gastroenteritis viral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
					1
		2	4	4	13
				1	1
		7	26	2	19
				1	1
					1
					1
					1
				1	1
					1
					2
		1	2	1	5
		1	1		1
				1	1
				1	5
					1
				1	1
			1	2	3
		4	14	12	32
			1	5	17
				2	2
				1	1
				1	1
		1	2		2
					1
			2	1	2
				1	2
					1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal disorder		2
Gastrointestinal haemorrhage		1
Gastrointestinal pain	7	12
Gastrointestinal sounds abnormal	1	3
Gastrooesophageal reflux disease	1	9
Gastroschisis	1	1
Generalised oedema	1	1
Generalised tonic-clonic seizure	1	9
General physical health deterioration	1	1
Genital herpes		1
Giant cell arteritis		1
Gingival bleeding	1	3
Gingival discomfort		1
Gingival disorder		2
Gingival pain	4	12
Gingival swelling	1	4
Glaucoma	2	2
Glossitis		2
Glossodynia	5	21
Goitre		1
Gout		5
Grip strength decreased	3	8
Groin pain	2	9
Guillain-Barre syndrome	6	10
Haemangioma		1
Haemarthrosis	2	2
Haematemesis		1
Haematochezia	3	7
Haematoma		2
Haematospermia	1	1
Haematuria	2	5
Haemodynamic instability		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
		2	3	5	9
				1	3
				1	9
				1	1
				1	1
				1	9
				1	1
					1
					1
				1	3
					1
			1		1
		3	3	1	9
			1	1	3
				2	2
			1		1
		1	5	4	16
					1
					5
		1	1	2	7
		1	5	1	4
				6	10
			1		
				2	2
					1
				3	7
			1		1
				1	1
				2	5
					1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoglobin decreased		1
Haemoglobin increased		1
Haemoperitoneum	1	1
Haemoptysis	2	4
Haemorrhage	11	16
Haemorrhage urinary tract	1	1
Haemorrhagic diathesis		1
Haemorrhagic stroke	1	1
Haemorrhoids	1	3
Hallucination	5	18
Hallucination, olfactory		1
Hallucinations, mixed		1
Hallucination, visual	2	2
Hangover	2	9
Headache	587	2,264
Head banging		1
Head discomfort	13	32
Head injury	1	6
Heart injury	1	1
Heart rate		1
Heart rate abnormal	3	5
Heart rate decreased	2	6
Heart rate increased	17	89
Heart rate irregular	3	6
Heart sounds abnormal	1	1
Heat illness		1
Hemianopia		1
Hemiparesis	1	1
Hemiplegia	3	5
Hemiplegic migraine	1	1
Hepatic cirrhosis		1
Hepatic enzyme increased	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				1	1
		1	1	1	3
				11	16
				1	1
					1
				1	1
				1	3
				5	18
					1
					1
				2	2
		1	3	1	6
	9	243	688	344	1576
			1		
		3	7	10	25
			2	1	4
				1	1
					1
	1			3	5
			1	2	5
		6	26	11	63
				3	6
				1	1
					1
					1
				1	1
				3	5
				1	1
					1
		1	2	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatic failure		1
Hepatic function abnormal		1
Hepatic lesion		1
Hepatic pain		2
Hepatitis		3
Hepatitis viral		1
Herpes simplex	2	3
Herpes virus infection		2
Herpes zoster	11	83
Herpes zoster oticus		2
Herpes zoster reactivation		1
Hip fracture		1
Hordeolum	1	3
Horner's syndrome		1
Hot flush	19	59
Hunger	1	1
Hyperacusis	1	3
Hyperaesthesia	5	11
Hyperaesthesia teeth	1	2
Hyperchlorhydria		1
Hyperglycaemia	1	6
Hyperhidrosis	49	198
Hyperoxia	1	1
Hyperpyrexia		2
Hypersensitivity	14	59
Hypersomnia	14	53
Hypertension	18	80
Hypertensive crisis		1
Hyperthermia		2
Hyperthyroidism	1	1
Hypertonic bladder		1
Hyperventilation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					2
					3
					1
				2	3
					2
			17	11	66
					2
					1
					1
			1	1	2
					1
		9	22	10	37
		1	1		
		1	1		2
		2	5	3	6
		1	1		1
					1
				1	6
		14	60	35	138
				1	1
					2
		5	17	9	42
		6	21	8	32
		7	23	11	57
					1
					2
				1	1
			1		
			1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypaema		1
Hypoacusis	3	6
Hypoaesthesia	46	155
Hypoaesthesia eye		2
Hypoaesthesia oral	12	44
Hypocalcaemia		1
Hypoglycaemia	1	6
Hypokinesia	3	4
Hypomenorrhoea		1
Hypophagia	4	6
Hypopnoea		5
Hyposmia		2
Hypotension	10	38
Hypothermia	1	5
Hypothyroidism	2	2
Hypoxia	1	5
Illrd nerve disorder		1
Illrd nerve paralysis		2
Ileus paralytic	1	1
Illness	47	134
Immobile	2	3
Immune-mediated adverse reaction		1
Immune system disorder	2	4
Immune thrombocytopenia	3	7
Immunodeficiency		1
Impaired driving ability	1	6
Impaired work ability	1	6
Impetigo		1
Inappropriate schedule of product administration	81	102
Incision site pain	1	1
Incoherent		1
Incontinence		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	3	1	3
		14	55	32	100
			1		1
		9	23	3	21
					1
				1	6
			1	3	3
			1		
				4	6
					5
					2
		5	8	5	30
				1	5
				2	2
				1	5
					1
					2
				1	1
		20	37	27	97
				2	3
			1		
		1	1	1	3
				3	7
					1
		1	3		3
			2	1	4
					1
		78	99	3	3
				1	1
					1
					2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect dose administered		1
Incorrect route of product administration	1	8
Increased upper airway secretion		1
Increased viscosity of upper respiratory secretion	1	1
Infection	4	13
Inflammation	8	26
Inflammatory bowel disease	1	1
Inflammatory marker increased		2
Influenza	52	133
Influenza like illness	82	323
Inhibitory drug interaction		1
Initial insomnia	1	3
Injection related reaction	4	6
Injection site erythema	1	3
Injection site mass	1	1
Injection site pain	4	10
Injection site pruritus	1	1
Injection site reaction		1
Injection site swelling	2	3
Injury	1	1
Injury corneal		1
Insomnia	36	137
Insulin resistance		1
Intentional self-injury		1
Internal hernia	1	1
International normalised ratio decreased	1	3
International normalised ratio increased	1	2
Intervertebral disc compression	1	1
Intervertebral disc protrusion		1
Intestinal ischaemia	1	1
Intestinal obstruction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	7		1
					1
				1	1
		1	4	3	9
		3	8	5	18
				1	1
			1		1
	2	17	32	35	101
	2	25	105	57	218
					1
			1	1	2
		1	1	3	5
		1	3		
				1	1
		4	6		4
		1	1		
			1		
		1	2	1	1
				1	1
					1
		5	35	31	102
					1
					1
				1	1
				1	3
				1	2
				1	1
					1
				1	1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intracranial pressure increased	1	1
Intraocular pressure increased		1
Iodine uptake increased		1
Iridocyclitis		2
Iritis		1
Iron deficiency	1	1
Irregular breathing	1	2
Irritability	2	8
Irritable bowel syndrome	3	8
Ischaemic stroke	2	5
Jaundice	1	2
Joint destruction		1
Joint effusion		3
Joint lock	1	2
Joint noise		1
Joint range of motion decreased	9	32
Joint stiffness	7	29
Joint swelling	14	43
Joint warmth	1	1
Ketoacidosis		1
Kidney infection	2	3
Labile blood pressure		1
Labyrinthitis	5	10
Lacrimation increased	1	13
Lagophthalmos		1
Language disorder	1	1
Laryngeal pain		1
Latent autoimmune diabetes in adults		1
Lateral medullary syndrome	1	1
Left ventricular failure		1
Lethargy	55	196
Leukopenia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					2
			1		
				1	1
		1	2		
		1	1	1	7
		1	1	2	7
				2	5
				1	2
					1
			1		2
				1	2
					1
		1	7	8	25
			3	7	26
		4	15	10	28
				1	1
					1
				2	3
					1
		2	3	3	7
			3	1	10
					1
				1	1
					1
				1	1
					1
		16	56	39	140
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lichenoid keratosis	1	2
Ligament sprain	1	3
Limbal swelling	1	1
Limb discomfort	34	142
Limb injury	2	4
Limb mass	1	4
Limb operation	1	1
Lip blister		4
Lip disorder		2
Lip dry	1	6
Lip pain	3	5
Lip pruritus	1	3
Lip scab		1
Lip swelling	9	52
Livedo reticularis	2	5
Liver function test abnormal	3	5
Liver function test increased	2	4
Liver injury		1
Liver tenderness	1	1
Localised infection	1	2
Localised oedema	1	3
Local reaction	2	8
Loss of bladder sensation		2
Loss of consciousness	15	46
Loss of control of legs		2
Loss of personal independence in daily activities	8	28
Lower respiratory tract infection	9	20
Lung disorder	1	2
Lung opacity	1	1
Lymphadenitis	4	9
Lymphadenopathy	174	465
Lymphangioma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	3
				1	1
		13	62	21	80
			1	2	3
				1	4
				1	1
					4
			2		
			2	1	4
		1	2	2	3
			2	1	1
					1
		5	14	4	38
		2	2		3
		1	2	2	3
			2	2	2
					1
				1	1
				1	2
		1	1		2
		2	4		4
					2
				15	46
					2
			8	8	20
				9	20
			1	1	1
				1	1
		1	2	3	7
	1	50	143	124	322
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymph gland infection		1
Lymph node pain	31	101
Lymphocytosis	1	1
Lymphoedema	4	11
Lymphoma	1	3
Macular rupture	1	1
Macule		2
Madarosis		1
MAGIC syndrome		1
Magnetic resonance imaging brain abnormal	1	1
Malaise	164	705
Malignant hypertension	1	1
Mania		1
Mass	1	4
Mast cell activation syndrome		1
Mastication disorder		1
Mastitis	3	5
Maternal exposure during pregnancy	1	6
Measles	1	1
Medial tibial stress syndrome		1
Medication error		2
Medication overuse headache		1
Melaena		1
Memory impairment	2	6
Meniere's disease	1	1
Meningitis		2
Meningitis bacterial		1
Meningitis pneumococcal		1
Meniscus injury		1
Menopausal symptoms	1	2
Menopause	1	1
Menorrhagia	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	5	27	26	74
				1	1
			4	4	7
				1	3
				1	1
			1		1
					1
					1
				1	1
	1	56	195	108	510
				1	1
					1
			1	1	3
					1
					1
				3	5
		1	6		
				1	1
					1
					2
					1
					1
			1	2	5
				1	1
					2
					1
			1		
			1	1	1
				1	1
		1	1	2	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Menstrual disorder	2	2
Menstruation irregular	1	1
Mental disorder	2	3
Mental fatigue	4	13
Mental impairment	1	4
Mesenteric vein thrombosis	2	2
Metamorphopsia	1	2
Metastasis		1
Metrorrhagia	1	1
Micturition disorder		1
Micturition urgency	3	4
Middle insomnia	2	9
Migraine	58	172
Migraine prophylaxis	1	1
Migraine with aura	6	16
Migraine without aura	2	2
Miliaria	4	9
Miosis		1
Moaning		1
Mobility decreased	11	49
Monoparesis	2	7
Monoplegia	1	4
Mood altered	1	1
Mood disorder due to a general medical condition		1
Morning sickness		3
Motion sickness	2	4
Motor dysfunction	1	3
Mouth haemorrhage	2	4
Mouth swelling	1	11
Mouth ulceration	5	21
Movement disorder	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				1	1
			1	2	2
		1	4	3	9
				1	4
				2	2
				1	2
					1
				1	1
					1
		1	1	2	3
		1	2	1	7
1	2	7	21	51	151
				1	1
	1	2	4	4	12
				2	2
		1	1	3	8
					1
					1
		4	9	7	40
			1	2	6
				1	4
				1	1
					1
					3
		1	2	1	2
			1	1	2
			1	2	3
			2	1	9
			3	5	18
		1	3	2	10

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mucous stools	3	3
Multiple sclerosis	2	7
Multiple sclerosis relapse	1	6
Multiple sclerosis relapse prophylaxis	1	1
Mumps	1	1
Muscle contractions involuntary		1
Muscle discomfort		1
Muscle disorder		2
Muscle fatigue	13	33
Muscle injury		1
Muscle rigidity		3
Muscle spasms	16	61
Muscle strain	2	5
Muscle swelling	2	4
Muscle tightness	3	12
Muscle twitching	4	16
Muscular weakness	25	83
Musculoskeletal chest pain	7	19
Musculoskeletal discomfort	4	14
Musculoskeletal disorder	2	3
Musculoskeletal pain	1	10
Musculoskeletal stiffness	35	125
Mutism		2
Myalgia	258	996
Myelitis		1
Myelitis transverse		4
Myocardial infarction	8	13
Myocardial ischaemia		1
Myocarditis	1	3
Myoclonus	2	2
Myofascial pain syndrome		1
Myositis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
				2	7
				1	6
				1	1
				1	1
					1
					1
			1		1
		6	8	7	25
					1
					3
		3	15	13	46
				2	5
		1	1	1	3
			3	3	9
		1	9	3	7
		7	24	18	59
		1	2	6	17
		1	5	3	9
			1	2	2
		1	2		8
		15	40	20	85
			1		1
2	7	104	296	154	700
					1
					4
				8	13
					1
				1	3
				2	2
			1		
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nail discolouration		1
Nasal congestion	6	18
Nasal discomfort	2	10
Nasal disorder		1
Nasal dryness	1	1
Nasal obstruction		2
Nasal odour	1	3
Nasal oedema	1	3
Nasal pruritus		1
Nasopharyngitis	18	60
Natural killer T cell count increased		1
Nausea	288	1,176
Neck mass		3
Neck pain	57	196
Neoplasm	1	1
Neoplasm malignant		1
Neoplasm skin		1
Nephrotic syndrome	1	3
Nerve compression	2	2
Nerve degeneration		1
Nerve injury	1	3
Nervousness	7	27
Nervous system disorder	1	1
Neuralgia	15	36
Neurogenic shock		4
Neurological symptom	2	3
Neuropathy peripheral	2	9
Neutropenia	3	6
Neutrophil count decreased	1	3
Neutrophilia		1
Nightmare	1	11
Night sweats	13	39

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	2	3	4	15
			3	2	7
			1		
		1	1		
			1		1
			1	1	2
		1	1		2
			1		
		8	20	10	40
			1		
	6	111	336	177	840
			2		1
		15	61	42	135
				1	1
					1
				1	3
		2	2		
					1
		1	1		2
		3	6	4	21
		1	1		
		4	13	11	23
					4
				2	3
				2	9
				3	6
			1	1	2
					1
			2	1	9
		5	12	8	27

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nipple pain	1	1
Non-Hodgkin's lymphoma	1	1
Noninfective gingivitis		2
Noninfective sialoadenitis	1	1
Nystagmus	1	3
Occupational exposure to SARS-CoV-2		1
Ocular discomfort	2	3
Ocular hyperaemia	9	24
Odynophagia	1	1
Oedema		1
Oedema mouth	1	2
Oedema peripheral		5
Off label use	86	182
Oligomenorrhoea	1	1
Oliguria	1	1
Ophthalmic herpes zoster		1
Ophthalmological examination abnormal	1	1
Ophthalmoplegia	1	2
Optic neuritis		2
Oral allergy syndrome		1
Oral blood blister		1
Oral candidiasis		3
Oral discomfort		7
Oral disorder	1	3
Oral herpes	5	23
Oral lichen planus	2	2
Oral mucosal blistering		4
Oral mucosal discolouration		1
Oral mucosal eruption		1
Oral mucosal erythema		1
Oral mucosal exfoliation		1
Oral mucosal roughening		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
					2
				1	1
				1	3
			1		
			1	2	2
		5	9	4	15
				1	1
			1		
				1	2
			2		3
		82	173	4	9
				1	1
				1	1
					1
		1	1		
				1	2
					2
					1
					1
			2		1
					7
			1	1	2
		2	4	3	19
				2	2
			2		2
					1
					1
					1
					1
					1

\* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral pain	3	23
Oral pruritus	1	3
Oral purpura	1	1
Orbital oedema	1	1
Orchitis		1
Oropharyngeal blistering		3
Oropharyngeal discomfort	3	6
Oropharyngeal pain	29	170
Orthostatic hypotension	1	3
Osmophobia		1
Osteoarthritis	2	4
Osteochondritis	1	1
Overdose	1	6
Oversensing	2	3
Oxygen saturation	1	1
Oxygen saturation decreased		18
Pain	229	697
Painful respiration	2	7
Pain in extremity	332	1,057
Pain in jaw	12	27
Pain of skin	12	35
Palatal oedema		1
Palindromic rheumatism	1	1
Pallor	4	28
Palpitations	38	149
Pancreatic carcinoma	1	1
Pancreatitis necrotising		1
Panic attack	3	3
Panic disorder		2
Panic reaction		4
Papilloedema		1
Papule	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	1	19
				1	3
				1	1
				1	1
					1
					3
		2	4	1	2
1	1	12	46	17	124
		1	1		2
					1
		1	3	1	1
		1	1		
		1	5		1
		1	1	1	2
				1	1
			2		16
	2	84	254	145	443
			1	2	6
	5	121	342	211	715
		5	10	7	17
		3	7	9	28
					1
				1	1
		1	7	3	21
		10	36	28	113
				1	1
					1
				3	3
					2
			1		3
					1
				3	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia	72	242
Paraesthesia oral	28	128
Paralysis	1	8
Paranoia		1
Parkinsonism		1
Parkinson's disease		2
Parosmia	6	17
Parotid gland enlargement		2
Parotitis		2
Pelvic pain	2	8
Penile swelling		1
Periarthritis	2	5
Pericardial effusion	1	2
Perineal pain	1	1
Periorbital oedema		1
Periorbital swelling	4	14
Peripheral coldness	10	35
Peripheral sensory neuropathy	1	1
Peripheral swelling	75	214
Peritonitis		1
Peroneal nerve palsy		1
Persistent postural-perceptual dizziness		1
Petechiae	3	7
Petit mal epilepsy		1
Phantom limb syndrome		1
Pharyngeal hypoaesthesia		1
Pharyngeal oedema		2
Pharyngeal paraesthesia	3	9
Pharyngeal pustule	1	1
Pharyngeal swelling	2	14
Pharyngeal ulceration	1	2
Pharyngitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		25	86	47	156
		18	59	10	69
				1	8
					1
					1
					2
		1	5	5	12
			1		1
			1		1
			2	2	6
					1
				2	5
				1	2
		1	1		
					1
		1	4	3	10
	1	2	10	8	25
		1	1		
	1	16	53	59	161
					1
					1
			1		
		2	3	1	4
					1
					1
			1		
			1		1
		2	3	1	6
		1	1		
		2	3		11
			1	1	1
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngitis streptococcal		1
Phlebitis	4	5
Photophobia	11	26
Photopsia	1	7
Photosensitivity reaction	1	2
Physical deconditioning		1
Piloerection	1	3
Pityriasis rosea		1
Plantar fasciitis	1	1
Platelet anisocytosis		1
Platelet count decreased	8	10
Platelet count increased	1	1
Pleural effusion	1	1
Pleurisy		4
Pleuritic pain	1	4
Pneumonia	1	10
Pneumonia bacterial		1
Pneumonitis	1	3
Pneumothorax spontaneous		1
Pollakiuria	1	6
Polyarthrits		3
Polymerase chain reaction positive		1
Polymyalgia rheumatica		3
Polymyositis		1
Poor quality product administered		1
Poor quality sleep	6	24
Portal vein thrombosis	1	1
Post lumbar puncture syndrome		1
Postmenopausal haemorrhage	2	3
Postprandial hypoglycaemia		1
Post procedural complication		1
Post stroke seizure		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	3	1	2
		1	4	10	22
			3	1	4
		1	2		
					1
				1	3
			1		
				1	1
					1
		1	1	7	9
				1	1
				1	1
					4
				1	4
				1	10
					1
			1	1	2
					1
		1	2		4
					3
			1		
					3
			1		1
			2	6	22
				1	1
					1
				2	3
					1
					1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Postural orthostatic tachycardia syndrome	1	2
Post viral fatigue syndrome	4	6
Pouchitis		1
Premature menarche	1	1
Presyncope	5	34
Primary biliary cholangitis		1
Proctalgia	1	3
Proctitis	1	1
Proctitis ulcerative		1
Product administered at inappropriate site	1	8
Product dose omission issue		1
Productive cough	5	19
Product preparation error	1	2
Product use issue	5	90
Prostatic abscess	1	1
Prostatitis		1
Proteinuria	1	1
Prothrombin time prolonged	1	1
Pruritus	74	239
Pseudolymphoma		1
Psoriasis	4	7
Psoriatic arthropathy	1	5
Psychiatric symptom		1
Psychotic disorder		1
Pulmonary embolism	24	42
Pulmonary hypertension		2
Pulmonary infarction	1	4
Pulmonary pain	2	16
Pulmonary sarcoidosis		1
Pulmonary thrombosis		2
Pulse abnormal		1
Pulseless electrical activity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				4	6
					1
		1	1		
		1	12	4	22
					1
		1	2		1
		1	1		
					1
		1	7		1
					1
			5	5	14
		1	2		
		5	85		5
				1	1
					1
				1	1
				1	1
		27	92	47	147
					1
			3	4	4
				1	5
					1
					1
				24	42
					2
				1	4
		2	4		12
			1		
					2
					1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pupillary disorder		1
Pupils unequal	1	1
Purging	1	1
Purpura		2
Pustular psoriasis		1
Pyrexia	267	1,143
Q fever	1	4
Quality of life decreased		1
Radiculitis brachial		2
Radiculopathy	1	1
Radioisotope uptake increased		1
Rash	74	226
Rash erythematous	21	78
Rash macular	8	34
Rash maculo-papular		2
Rash morbilliform	1	2
Rash papular	7	25
Rash pruritic	24	67
Rash vesicular		5
Raynaud's phenomenon		5
Reaction to colouring	1	1
Rectal abscess	1	1
Rectal haemorrhage	3	6
Red blood cell sedimentation rate abnormal	1	1
Red blood cell sedimentation rate increased	1	2
Reflux gastritis		1
Renal disorder	1	1
Renal failure		1
Renal impairment	3	3
Renal pain	10	22
Respiration abnormal	1	5
Respiratory arrest		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	1
			1		1
					1
	7	108	338	159	805
				1	4
					1
			1		1
				1	1
					1
		28	87	46	139
		7	27	14	51
		8	20		14
			2		
				1	2
		2	10	5	15
		12	27	12	40
			2		3
					5
				1	1
				1	1
				3	6
				1	1
				1	2
			1		
				1	1
					1
				3	3
		4	8	6	14
		1	2		3
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory disorder	1	8
Respiratory distress	1	1
Respiratory failure		4
Respiratory rate decreased		1
Respiratory rate increased		8
Respiratory tract irritation		1
Respiratory tract oedema		1
Restless legs syndrome	2	5
Restlessness	5	15
Retching	2	15
Retinal haemorrhage		2
Retinal injury	1	1
Retinal migraine	1	2
Retinal tear	1	1
Retinal toxicity		1
Retinal vein occlusion	1	2
Retinal vein thrombosis	1	1
Retinopathy	1	1
Reversible airways obstruction		1
Rheumatoid arthritis	9	15
Rhinalgia	1	2
Rhinitis	1	6
Rhinitis allergic		2
Rhinorrhoea	11	45
Road traffic accident	1	2
Rotator cuff syndrome	1	2
Sacroiliitis	1	2
Salivary gland disorder		1
Salivary gland enlargement	1	2
Salivary gland pain	1	2
Salivary hypersecretion		6
Salt craving		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	7
				1	1
					4
					1
					8
			1		
					1
		1	2	1	3
		1	3	4	12
		1	7	1	8
					2
				1	1
				1	2
				1	1
					1
				1	2
				1	1
				1	1
					1
				9	15
		1	1		1
			3	1	3
					2
	3	1	14	10	31
				1	2
				1	2
				1	2
					1
				1	2
				1	2
			2		4
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sarcoidosis	2	4
SARS-CoV-2 antibody test		1
SARS-CoV-2 antibody test negative	1	2
SARS-CoV-2 test negative	1	1
SARS-CoV-2 test positive	4	8
Scab	1	1
Sciatica		2
Scleritis	1	1
Screaming	1	1
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain	1	2
Scrotal swelling		3
Seasonal allergy	1	3
Secretion discharge		1
Seizure	7	23
Semen discolouration	1	1
Sensation of foreign body	1	6
Sensitisation	1	2
Sensitive skin	3	11
Sensitivity to weather change	1	2
Sensory disturbance	3	12
Sensory loss	3	5
Sepsis	1	4
Septic pulmonary embolism		1
Septic shock	1	2
Serositis	1	1
Serum ferritin decreased	1	1
Serum ferritin increased		1
Shock	1	4
Shoulder injury related to vaccine administration		3
Sinus congestion	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
			1		
			1	1	1
				1	1
		2	3	2	5
		1	1		
					2
				1	1
				1	1
					1
					1
		1	1		1
					3
				1	3
					1
				7	23
				1	1
				1	6
				1	2
		2	4	1	7
				1	2
		1	7	2	5
		1	3	2	2
				1	4
					1
				1	2
				1	1
				1	1
					1
				1	4
					3
				1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus disorder		1
Sinus headache	11	24
Sinusitis	2	6
Sinus pain	6	17
Sinus tachycardia		4
Sitting disability	1	1
Sjogren's syndrome	1	4
Skin abrasion	1	1
Skin burning sensation	2	10
Skin depigmentation		1
Skin discolouration	5	11
Skin disorder	1	3
Skin erosion	1	2
Skin exfoliation	2	5
Skin haemorrhage	1	1
Skin induration		1
Skin infection	1	1
Skin irritation	5	9
Skin laceration		1
Skin lesion	1	6
Skin mass		1
Skin plaque	1	1
Skin reaction	2	4
Skin sensitisation	1	2
Skin swelling	2	10
Skin temperature	2	2
Skin tightness	1	5
Skin ulcer		1
Skin warm	2	15
Skin weeping	1	1
Sleep apnoea syndrome	1	1
Sleep attacks		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	5	9	6	15
				2	6
		1	6	5	11
			2		2
		1	1		
				1	4
		1	1		
	2			2	10
					1
		4	5	1	6
				1	3
				1	2
				2	5
		1	1		
			1		
				1	1
		3	4	2	5
					1
			3	1	3
					1
				1	1
			1	1	1
		1	3	1	7
		1	1	1	1
			1	1	4
					1
	1	1	5	1	10
				1	1
				1	1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep deficit		1
Sleep disorder	18	41
Sleep disorder due to a general medical condition	1	3
Sleep disorder due to general medical condition, insomnia type	5	12
Sleep terror	2	4
Sluggishness	1	2
Small intestinal haemorrhage		1
Small intestinal obstruction	1	1
Sneezing	5	21
Soft tissue swelling	1	1
Somnolence	21	96
Speech disorder	4	15
Spinal column injury		1
Spinal fracture	1	1
Spinal pain	1	6
Spinal stenosis	1	1
Spondylitis	1	1
Status epilepticus	5	5
Stiff tongue	1	1
Stoma site discharge		1
Stomatitis	1	5
Strabismus	1	1
Stress	4	8
Stress cardiomyopathy		1
Stupor	1	1
Subarachnoid haemorrhage		2
Submaxillary gland enlargement	1	2
Sudden death	2	3
Sudden hearing loss	1	3
Suffocation feeling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		9	23	9	18
		1	1		2
		1	3	4	9
				2	4
			1	1	1
					1
				1	1
	1	2	13	3	8
				1	1
	1	7	30	14	66
		1	2	3	13
					1
				1	1
			1	1	5
				1	1
				1	1
				5	5
		1	1		
					1
			1	1	4
		1	1		
		2	3	2	5
					1
				1	1
					2
		1	2		
				2	3
				1	3
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Suicidal ideation	2	3
Sunburn		1
Suprapubic pain		1
Supraventricular extrasystoles	1	1
Supraventricular tachycardia		3
Suspected COVID-19	15	62
Sweating fever	1	9
Swelling	63	163
Swelling face	22	79
Swelling of eyelid	7	15
Swollen tongue	6	56
Syncope	20	89
Synovial cyst	1	1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	4	6
Systemic lupus erythematosus rash	1	2
Tachycardia	8	64
Tachypnoea		4
Taste disorder	13	29
Tearfulness	2	7
Temperature intolerance	2	4
Temperature perception test increased		1
Temperature regulation disorder		3
Temporal lobe epilepsy		1
Temporomandibular joint syndrome	1	1
Tenderness	19	37
Tendon injury	1	2
Tendonitis	4	7
Tendon pain		1
Tenosynovitis stenosaurs	1	2
Tension		1
Tension headache	11	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					1
			1		
				1	1
			1		2
		9	25	6	37
				1	9
		24	61	39	102
		3	16	19	63
		4	7	3	8
		4	17	2	39
				20	89
				1	1
					1
				4	6
				1	2
		2	19	6	45
			2		2
		7	14	6	15
			1	2	6
				2	4
					1
			1		2
					1
	2	13	25	6	12
				1	2
			1	4	6
					1
				1	2
					1
	2	2	5	9	26

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Testicular pain		2
Testicular swelling		2
Tetany		1
Therapeutic response unexpected	3	6
Thermal burn	2	4
Thermal burns of eye		2
Thinking abnormal	1	3
Thirst	7	29
Throat clearing		1
Throat irritation	3	21
Throat tightness	3	25
Thrombocytopenia	14	16
Thrombocytosis		1
Thrombophlebitis	2	2
Thrombophlebitis superficial		1
Thrombosis	12	26
Thrombosis in device	1	1
Thyroiditis subacute		1
Thyroid pain		1
Tinnitus	44	94
Tongue blistering		3
Tongue coated		1
Tongue discolouration	1	2
Tongue discomfort	2	4
Tongue disorder		7
Tongue dry		3
Tongue eruption		2
Tongue erythema		1
Tongue oedema		4
Tongue pruritus	2	2
Tongue ulceration		2
Tonic clonic movements	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					2
			1		
		3	5		1
				2	4
					2
				1	3
		2	10	5	19
					1
		1	4	2	17
		3	9		16
				14	16
			1		
		1	1	1	1
					1
				12	26
				1	1
			1		
					1
		8	17	36	77
			1		2
	1				1
		1	2		
		2	2		2
					7
			1		2
					2
			1		
					4
				2	2
			1		1
				1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonsillar disorder		2
Tonsillar hypertrophy	1	4
Tonsillar inflammation		1
Tonsillitis	1	3
Tooth abscess		1
Toothache	7	13
Tooth extraction	1	1
Toxic skin eruption		1
Tracheitis		1
Transferrin decreased	1	1
Transient ischaemic attack	9	12
Treatment noncompliance		1
Tremor	26	142
Trigeminal neuralgia	2	6
Trigger finger		1
Tri-iodothyronine		1
Tri-iodothyronine decreased		1
Troponin increased	1	1
Tunnel vision	1	2
Tympanic membrane hyperaemia	1	1
Type 1 diabetes mellitus		2
Type 2 diabetes mellitus	1	2
Type IV hypersensitivity reaction	1	1
Ulnar neuritis	1	1
Underdose		2
Unresponsive to stimuli	1	3
Upper-airway cough syndrome	1	2
Upper airway obstruction		1
Upper respiratory tract congestion	1	2
Upper respiratory tract infection	1	3
Urinary incontinence	2	9
Urinary retention		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	2		2
			1		
			2	1	1
					1
		1	2	6	11
				1	1
					1
					1
		1	1		
				9	12
					1
		8	28	18	114
		1	2	1	4
					1
			1		
					1
				1	1
				1	2
				1	1
					2
				1	2
		1	1		
				1	1
			2		
				1	3
				1	2
					1
				1	2
			1	1	2
		1	2	1	7
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary tract infection	1	13
Urinary tract pain		1
Urine abnormality		1
Urine flow decreased	1	1
Urine odour abnormal		2
Urine output		1
Urine output decreased		1
Urosepsis		1
Urticaria	27	85
Urticaria papular	1	1
Uterine contractions abnormal		1
Uterine haemorrhage	1	1
Uterine pain		1
Uveitis		2
Vaccination complication	3	6
Vaccination failure		1
Vaccination site abscess	1	1
Vaccination site bruising	7	17
Vaccination site cellulitis		7
Vaccination site discolouration		1
Vaccination site discomfort	7	25
Vaccination site erythema	48	165
Vaccination site haematoma		1
Vaccination site haemorrhage	1	6
Vaccination site hyperaesthesia		2
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		3
Vaccination site induration	8	19
Vaccination site infection	1	4
Vaccination site inflammation	5	16
Vaccination site irritation		4
Vaccination site joint erythema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	12
					1
			1		
				1	1
			1		1
					1
					1
		16	27	11	58
		1	1		
					1
				1	1
					1
					2
		1	3	2	3
					1
		1	1		
		3	8	4	9
			2		5
			1		
		5	15	2	10
		36	92	12	73
					1
		1	2		4
			1		1
					1
			1		2
		5	12	3	7
				1	4
		3	10	2	6
			1		3
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site joint movement impairment		2
Vaccination site joint pain		1
Vaccination site joint warmth	1	1
Vaccination site lymphadenopathy		3
Vaccination site mass	16	50
Vaccination site movement impairment	7	23
Vaccination site oedema		4
Vaccination site pain	150	648
Vaccination site paraesthesia	2	8
Vaccination site pruritus	21	57
Vaccination site rash	1	16
Vaccination site reaction	1	11
Vaccination site scab		1
Vaccination site swelling	45	165
Vaccination site urticaria		2
Vaccination site vesicles	2	2
Vaccination site warmth	9	71
Vaginal disorder	1	1
Vaginal haemorrhage	5	7
Varicella		1
Varicose vein	1	3
Vascular headache		4
Vascular injury		1
Vasculitic rash		1
Vasculitis	2	3
Vasoconstriction		2
Vasodilatation	1	4
Vein disorder		2
Vena cava embolism		1
Vena cava thrombosis		1
Venous thrombosis	1	2
Ventricular extrasystoles	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
					1
		1	1		
			3		
		8	17	8	33
		2	9	5	14
			1		3
1	6	80	278	70	370
		1	2	1	6
		16	31	5	26
			5	1	11
		1	3		8
					1
		24	73	21	92
					2
		1	1	1	1
		5	33	4	38
				1	1
		1	1	4	6
					1
			2	1	1
			2		2
					1
				2	3
					2
				1	4
			1		1
					1
				1	2
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ventricular fibrillation		1
Ventricular hypertrophy	1	1
Ventricular tachycardia	1	1
Vertigo	34	83
Vertigo labyrinthine		1
Vertigo positional	4	9
Vestibular migraine	2	4
Vestibular neuronitis		2
Viral infection	2	4
Viral labyrinthitis	1	1
Viral pharyngitis		1
Viral rash		1
Viral upper respiratory tract infection		1
Vision blurred	20	67
Visual acuity reduced	1	1
Visual brightness		1
Visual field defect	1	3
Visual impairment	12	28
Vitamin D deficiency	1	2
Vlth nerve paralysis	1	4
Vitiligo	1	1
Vitreous detachment	4	5
Vitreous floaters	3	6
Vomiting	66	299
Vomiting projectile	2	9
Vulval abscess		1
Vulvovaginal candidiasis		3
Vulvovaginal pruritus		1
Weight bearing difficulty	2	3
Weight decreased	6	11
Weight increased		1
Wheezing	5	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	1
		5	12	29	71
					1
		1	2	3	7
			1	2	3
					2
			1	2	3
				1	1
					1
					1
		4	14	16	53
				1	1
			1		
				1	3
		3	6	9	22
				1	2
				1	4
				1	1
				4	5
			2	3	4
		18	74	48	225
		1	1	1	8
					1
					3
			1		
		1	2	1	1
		2	5	4	6
					1
		1	6	4	29

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count decreased	2	3					2	3
White blood cell count increased	3	7				1	3	6
Wound haemorrhage		1						1
Wound infection	1	1					1	1
Wrong product administered	1	1					1	1
Wrong technique in product usage process		1				1		
Yellow skin		2						2
	1	4			1	4		
	8,572	29,962	10	118	2932	8813	5640	21149

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	13	47		1	6	9	7	38
Abdominal distension	5	17			1	2	4	15
Abdominal pain	18	64		1	2	7	16	57
Abdominal pain lower	2	5					2	5
Abdominal pain upper	25	98			8	14	17	84
Abdominal symptom		1						1
Abdominal tenderness	1	1			1	1		
Abnormal dreams		6				3		3
Abnormal loss of weight		1						1
Abnormal sensation in eye		1				1		
Abnormal weight gain		2						2
Abscess oral		1						1
Acarodermatitis	1	1					1	1
Acne	2	3					2	3
Acoustic neuroma	1	1					1	1
Acquired haemophilia		1						1
Acrochordon		1						1
Activated partial thromboplastin time prolonged	2	2					2	2
Acute disseminated encephalomyelitis	1	1					1	1
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	2	5					2	5
Acute myocardial infarction	2	5					2	5
Acute respiratory distress syndrome		1						1
Adrenocortical insufficiency acute	2	3					2	3
Adverse drug reaction	1	4				2	1	2
Adverse reaction				1				
Affect lability	1	1					1	1
Ageusia	5	18		1		3	5	15
Aggression	1	2				1	1	1
Agitation	1	2					1	2
Alanine aminotransferase increased	1	4					1	4
Alcoholic hangover		1						1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergic reaction to excipient		2
Allergic sinusitis		1
Allergy to vaccine	1	6
Alopecia	1	3
Alopecia totalis	1	1
Altered state of consciousness	1	1
Amblyopia	1	1
Amegakaryocytic thrombocytopenia		1
Amenorrhoea	1	1
Amnesia	3	10
Anaemia	3	7
Anaemia megaloblastic	1	1
Anaemia vitamin B12 deficiency	1	1
Anal haemorrhage		1
Anal incontinence	1	4
Anaphylactic reaction	1	21
Anaphylactic shock	1	5
Aneurysm	1	1
Angina pectoris	5	11
Angioedema	1	10
Anisocytosis		1
Ankylosing spondylitis		1
Anosmia	2	8
Anxiety	8	26
Apathy		5
Aphasia	2	5
Aphonia	2	3
Aphthous ulcer	1	2
Appetite disorder		1
Arrhythmia	5	12
Arrhythmia supraventricular		2
Arterial occlusive disease	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
			2	1	4
			1	1	2
				1	1
				1	1
				1	1
				1	1
			2	3	8
				3	7
				1	1
		1	1		
					1
	1		1	1	3
				1	21
				1	5
				1	1
				5	11
				1	10
					1
					1
			2	2	6
		2	4	6	22
			2		3
		1	1	1	4
				2	3
				1	2
					1
				5	12
					2
				1	2

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arterial rupture		1
Arterial stenosis		1
Arthralgia	127	465
Arthritis	4	26
Arthritis reactive		2
Arthritis viral	1	1
Arthropathy	2	4
Ascites		1
Asthenia	38	174
Asthenopia	3	7
Asthma	3	19
Asthma late onset		1
Asymptomatic COVID-19	1	1
Ataxia		1
Atrial fibrillation	7	33
Atrial flutter	2	3
Atrial tachycardia		1
Atrioventricular block	1	1
Atrioventricular block complete	1	1
Attention deficit hyperactivity disorder	1	1
Auditory disorder	1	3
Aura	1	1
Auricular swelling		2
Autoimmune anaemia	1	1
Autoimmune disorder		3
Autoimmune haemolytic anaemia	1	1
Autoimmune neutropenia	1	1
Axillary mass	1	2
Axillary pain	5	20
Axonal neuropathy		1
Back pain	34	126
Bacterial infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
1	6	22	61	105	404
		1	1	3	25
					2
			1	2	3
					1
		8	35	30	139
				3	7
			1	3	18
					1
1	1			7	33
				2	3
					1
				1	1
				1	1
				1	3
				1	1
					2
				1	1
					3
				1	1
				1	1
			1	1	1
		1	5	4	15
					1
	1	2	11	32	115
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Balance disorder	17	47
B-cell lymphoma		1
Bed rest	1	1
Bedridden		2
Biliary colic		1
Bladder disorder		1
Bladder dysfunction		1
Bladder pain	1	2
Blindness	6	11
Blindness unilateral	2	4
Blister	6	20
Blister infected		1
Blood alkaline phosphatase increased		1
Blood blister	1	2
Blood cholesterol increased	2	3
Blood count abnormal	1	1
Blood glucose	1	2
Blood glucose decreased	1	6
Blood glucose fluctuation		2
Blood glucose increased	3	9
Blood iron increased	2	2
Blood lactate dehydrogenase increased		1
Blood pH	1	1
Blood pH increased	1	3
Blood pressure abnormal		2
Blood pressure decreased	2	5
Blood pressure diastolic increased		1
Blood pressure fluctuation		3
Blood pressure increased	6	34
Blood pressure systolic decreased	1	1
Blood thyroid stimulating hormone increased		1
Blood urine		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5	15	42
					1
				1	1
					2
					1
					1
				1	2
				6	11
				2	4
		1	2	5	18
			1		
					1
				1	2
				2	3
				1	1
				1	2
			2	1	4
			1		1
			3	3	6
		1	1	1	1
					1
				1	1
		1	1		2
			1		1
			1	2	4
					1
			1		2
			5	6	29
				1	1
					1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood urine present	1	2
Body temperature	1	1
Body temperature abnormal	1	7
Body temperature decreased	1	4
Body temperature fluctuation	1	2
Body temperature increased	7	21
Bone pain	3	16
Bone swelling		1
Bradycardia	1	5
Brain stem stroke		1
Breast cancer		2
Breast enlargement		1
Breast inflammation	1	1
Breast mass	1	2
Breast oedema	1	1
Breast pain	5	6
Breast swelling	1	3
Breast tenderness	1	1
Breath odour		1
Bronchiectasis	1	2
Bronchitis		1
Bundle branch block	1	1
Bundle branch block right		2
Burning sensation	10	21
Bursitis	2	3
Cardiac arrest	2	14
Cardiac disorder	1	1
Cardiac failure	3	9
Cardiac failure acute	1	1
Cardiac flutter	2	11
Cardiogenic shock	1	2
Cardiomegaly		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	1
			1	1	6
		1	2		2
				1	2
		1	3	6	18
2	3			3	16
			1		
				1	5
					1
					2
					1
				1	1
		1	1	4	5
			1	1	2
		1	1		
					1
				1	2
			1		
				1	1
			1		1
		2	4	8	17
				2	3
				2	14
				1	1
				3	9
				1	1
				2	11
				1	2
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Carotid artery occlusion	1	1
Carpal tunnel syndrome	2	2
Catarrh		1
Cavernous sinus thrombosis	1	1
Cells in urine	1	1
Cellulitis	2	12
Central nervous system vasculitis	1	1
Cerebellar stroke		1
Cerebral artery thrombosis	1	1
Cerebral disorder		1
Cerebral haemorrhage	5	6
Cerebral infarction	2	4
Cerebral thrombosis	4	5
Cerebral venous sinus thrombosis		1
Cerebrovascular accident	24	45
Cervicobrachial syndrome		2
Cheilitis		1
Chest discomfort	12	57
Chest pain	25	92
Chest X-ray abnormal		1
Chillblains	5	7
Chills	79	361
Choking		2
Cholangitis	1	1
Cholelithiasis		1
Chorea		1
Chromatopsia	1	1
Chromaturia	1	3
Chronic fatigue syndrome	6	8
Chronic kidney disease		1
Chronic obstructive pulmonary disease	1	6
Circulatory collapse	1	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	2
					1
				1	1
				1	1
				2	12
				1	1
					1
				1	1
			1		
				5	6
				2	4
				4	5
					1
				24	45
					2
			1		
		3	9	9	48
	1	1	6	24	86
			1		
		5	5		2
	4	12	40	67	321
					2
				1	1
					1
					1
		1	1		
		1	1		2
1	1			6	8
					1
				1	6
				1	11

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clumsiness	1	2
Cluster headache	1	3
Coagulopathy		1
Cognitive disorder		5
Cold sweat	6	25
Colitis		1
Colitis ulcerative	2	5
Coma	1	2
Communication disorder	1	2
Concussion		1
Condition aggravated	18	60
Confusional arousal		1
Confusional state	11	51
Conjunctival haemorrhage		1
Conjunctivitis	1	4
Conjunctivitis bacterial		1
Constipation	5	15
Contrast media reaction		1
Contusion	17	36
Coordination abnormal	1	4
Corneal abrasion		1
Costochondritis		1
Cough	26	98
COVID-19	13	60
COVID-19 pneumonia		5
Cranial nerve disorder		1
Cranial nerve palsies multiple	1	1
C-reactive protein increased	1	8
Creutzfeldt-Jakob disease		1
Crohn's disease	1	2
Crying	1	5
Cutaneous vasculitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	3
			1		
			1		4
			1	6	24
					1
1	1			2	5
				1	2
				1	2
			1		
1	1	3	13	15	47
					1
		1	12	10	39
					1
				1	4
					1
		2	3	3	12
					1
	2	4	10	13	26
				1	4
					1
		3	18	23	80
	1		1	13	59
					5
					1
				1	1
			2	1	6
					1
				1	2
				1	5
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cyanosis	1	2
Cystitis	2	4
Cystitis interstitial		1
Cystitis-like symptom		1
Deafness	9	15
Deafness bilateral	1	1
Deafness transitory	1	1
Deafness unilateral		1
Death	4	23
Decreased appetite	23	120
Decreased interest	1	1
Deep vein thrombosis	11	21
Defaecation urgency		2
Dehydration	2	10
Delirium	1	9
Dementia	1	2
Demyelination	2	2
Depressed level of consciousness	2	4
Depressed mood	2	8
Depression	2	21
Derealisation		1
Dermal cyst		1
Dermatitis	5	5
Dermatitis acneiform		1
Dermatitis allergic	2	10
Dermatitis bullous		2
Dermatitis contact	2	2
Dermatitis infected		1
Diabetes mellitus	2	3
Diabetes mellitus inadequate control		1
Diabetic ketoacidosis		1
Diaphragmalgia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
		1	1	1	3
					1
					1
				9	15
				1	1
				1	1
					1
				4	23
	1	4	23	19	97
		1	1		
				11	21
					2
			1	2	9
				1	9
				1	2
				2	2
				2	4
			1	2	7
			1	2	20
					1
					1
		1	1	4	4
					1
		1	2	1	8
					2
				2	2
			1		
				2	3
					1
					1
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diarrhoea	56	253
Diarrhoea haemorrhagic	2	3
Diplegia	1	1
Diplopia	9	15
Discoloured vomit	1	1
Discomfort	2	20
Disease progression	1	1
Disease recurrence	15	47
Disorientation	4	20
Dissociation		1
Disturbance in attention	9	27
Diverticulitis		2
Diverticulum intestinal	1	1
Dizziness	76	373
Dizziness exertional	1	3
Dizziness postural	10	34
Drooling	1	1
Drug eruption	1	1
Drug hypersensitivity		2
Drug-induced liver injury		1
Drug ineffective	10	59
Drug level fluctuating	1	1
Dry eye		6
Dry mouth	4	29
Dry skin	5	9
Dry throat	1	6
Duodenogastric reflux		1
Dysarthria	4	14
Dysgeusia	9	41
Dysgraphia		2
Dyskinesia	4	6
Dysmenorrhoea		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	13	33	43	220
				2	3
				1	1
		3	4	6	11
			10	2	10
				1	1
			5	15	42
		1	2	3	18
					1
		2	5	7	22
					2
				1	1
	3	17	57	59	316
				1	3
		1	5	9	29
				1	1
				1	1
					2
					1
				10	59
				1	1
			2		4
	1		4	4	25
		2	3	3	6
	1		2	1	4
					1
			1	4	13
		4	13	5	28
					2
		1	1	3	5
			1		

\* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspepsia	4	18
Dysphagia	11	16
Dysphonia	1	6
Dyspnoea	50	184
Dyspnoea exertional	1	9
Dysstasia	8	11
Dysuria	5	11
Ear discomfort	3	6
Ear disorder	1	2
Ear infection	3	3
Ear pain	10	30
Ear pruritus		3
Ear swelling	1	3
Eating disorder	2	8
Eczema	3	8
Eczema nummular		1
Electrocardiogram abnormal	1	2
Embolic stroke	1	2
Embolism	9	11
Emotional disorder	1	3
Emotional distress		2
Emphysema		1
Energy increased	1	1
Enlarged uvula	1	1
Epigastric discomfort		1
Epiglottitis	1	1
Epilepsy		9
Epistaxis	11	37
Erectile dysfunction		2
Eructation		3
Erythema	31	80
Erythema annulare	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	3	13
		1	3	10	13
				1	6
		8	21	42	163
			3	1	6
		2	2	6	9
		3	6	2	5
		1	1	2	5
			1	1	1
		1	1	2	2
			4	10	26
			1		2
				1	3
			2	2	6
	1		1	3	7
			1		
				1	2
				1	2
				9	11
				1	3
					2
					1
				1	1
		1	1		
					1
				1	1
		1	3	10	34
					2
					3
	1	16	29	15	51
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema multiforme	2	4
Erythema of eyelid		1
Essential hypertension		1
Exertional headache		2
Exfoliative rash		1
Exposure to extreme temperature	1	1
External ear inflammation		1
External ear pain		1
Extrasystoles	1	3
Extremity necrosis	1	1
Eye allergy	1	1
Eye complication associated with device		1
Eye contusion	1	4
Eye discharge		1
Eye disorder	1	2
Eye haemorrhage	1	2
Eye infection		3
Eye inflammation		1
Eye irritation	1	3
Eyelid disorder		2
Eyelid oedema		1
Eyelid pain		1
Eyelid ptosis	3	4
Eyelid rash	1	1
Eyelids pruritus		2
Eye movement disorder		1
Eye oedema		1
Eye pain	9	43
Eye pruritus	4	11
Eye swelling	3	8
Eye symptom	1	1
Face injury	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
					1
					1
					2
					1
				1	1
					1
			1		
				1	3
				1	1
		1	1		
					1
	1	1	2		2
					1
			1	1	1
				1	2
					3
			1		
			1	1	2
			1		1
			1		
		1	2	2	2
		1	1		
					2
			1		
					1
		2	5	7	38
	2	2	4	2	7
	2		1	3	7
				1	1
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Face oedema	2	5
Facial discomfort		2
Facial neuralgia		3
Facial pain	6	18
Facial paralysis	24	68
Facial paresis	1	8
Factitious disorder	1	1
Faeces discoloured		4
Faeces pale		1
Fall	11	34
Fatigue	205	910
Fear	1	4
Fear of falling	1	2
Feeding disorder	2	7
Feeling abnormal	29	96
Feeling cold	17	90
Feeling drunk	1	2
Feeling hot	10	59
Feeling jittery	2	3
Feeling of body temperature change	3	13
Feeling of despair		1
Femoral neck fracture		1
Fibrin D dimer increased	4	4
Fibromyalgia	1	5
Flank pain	1	4
Flashback		1
Flat affect	1	1
Flatulence	5	15
Fluid retention	1	4
Flushing	3	18
Folliculitis		1
Food intolerance	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	3
			1		1
					3
		1	5	5	13
	1			24	68
			2	1	6
				1	1
			1		3
					1
		2	6	9	28
3	25	42	143	163	767
			1	1	3
				1	2
		1	2	1	5
	1	7	26	22	70
1	2	2	20	15	70
				1	2
		3	17	7	42
		1	1	1	2
		1	1	2	12
					1
				4	4
			1	1	4
			1	1	3
					1
		1	1		
		1	3	4	12
				1	4
		1	3	2	15
			1		
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Food poisoning		1
Foreign body sensation in eyes		3
Formication	1	3
Fractured skull depressed		1
Freezing phenomenon		2
Frequent bowel movements		2
Full blood count increased		1
Functional gastrointestinal disorder	1	2
Furuncle		4
Gait disturbance	25	63
Gait inability	8	19
Gamma-glutamyltransferase increased		1
Gastric cancer		1
Gastric dilatation		2
Gastric disorder	1	3
Gastric haemorrhage		1
Gastritis		1
Gastroenteritis	2	5
Gastrointestinal disorder	2	2
Gastrointestinal haemorrhage	1	2
Gastrointestinal pain	1	11
Gastrointestinal sounds abnormal	1	2
Gastrooesophageal reflux disease		5
Generalised tonic-clonic seizure	1	4
Giant cell arteritis		2
Gingival discomfort	1	1
Gingival pain	1	4
Gingival swelling		1
Glossodynia	4	13
Glucose urine present		1
Goitre		1
Gout	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
				1	3
					1
					2
					2
					1
				1	2
					4
	1	2	11	23	52
	1		1	8	18
					1
					1
					2
			1	1	2
					1
		1	1	1	4
		1	1	1	1
				1	2
			1	1	10
				1	2
					5
				1	4
					2
				1	1
				1	4
					1
			4	4	9
					1
			1		
				2	8

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Grip strength decreased	1	3
Groin pain	3	10
Guillain-Barre syndrome	2	7
Guttate psoriasis	2	2
Habit cough	1	1
Haematemesis		1
Haematochezia		3
Haematoma	1	2
Haematuria	1	1
Haemoglobin decreased		2
Haemolysis	1	1
Haemoptysis	1	1
Haemorrhage	3	10
Haemorrhage subcutaneous	1	1
Haemorrhage urinary tract	1	3
Haemorrhoids		2
Hair texture abnormal	1	1
Hallucination	1	5
Hallucination, auditory		1
Halo vision		1
Hand-arm vibration syndrome		1
Hand fracture		1
Hangover		4
Haptoglobin decreased		1
Headache	217	932
Head discomfort	8	14
Head injury	3	8
Heart injury		2
Heart rate	2	4
Heart rate abnormal	2	5
Heart rate decreased	2	5
Heart rate increased	12	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
			1	3	9
				2	7
				2	2
				1	1
					1
					3
		1	2		
				1	1
			1		1
				1	1
				1	1
				3	10
				1	1
				1	3
					2
		1	1		
				1	5
					1
					1
					1
					4
					1
1	13	42	131	175	801
		1	2	7	12
				3	8
					2
			1	2	3
			1	2	4
				2	5
		2	6	10	41

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate irregular	3	11
Heat oedema		1
Heat stroke		1
Hemiparesis		2
Herpes ophthalmic		2
Herpes virus infection		1
Herpes zoster	25	92
Herpes zoster oticus		1
Herpes zoster reactivation	1	3
Hiccups		1
Hip fracture		1
Hordeolum		1
Hot flush	5	28
Hyperacusis	3	5
Hyperaesthesia	1	4
Hyperaesthesia teeth		1
Hyperchlorhydria		1
Hypercoagulation	1	1
Hyperglycaemia		3
Hyperhidrosis	18	90
Hyperkalaemia		1
Hypersensitivity	12	37
Hypersomnia	4	17
Hypertension	16	56
Hypertensive urgency	1	1
Hyperthermia		2
Hyperthyroidism	2	2
Hypertonic bladder		1
Hyperventilation		1
Hypervolaemia		1
Hypoacusis	5	10
Hypoaesthesia	23	65

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	2	9
					1
					1
					2
					2
					1
			14	25	78
					1
				1	3
					1
					1
			3	5	25
			1	3	4
			1	1	3
					1
				1	1
					3
	1	5	18	13	72
					1
		1	4	11	33
			3	4	14
		3	5	13	51
				1	1
					2
				2	2
			1		
			1		
					1
		1	2	4	8
	1	6	15	17	50

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia oral	3	14
Hypocalcaemia		1
Hypoglycaemia		5
Hypokalaemic syndrome		1
Hypokinesia	3	6
Hyponatraemia		3
Hypophagia	1	2
Hypopnoea	1	5
Hyporeflexia		1
Hypotension	4	14
Hypothermia		2
Hypothyroidism	1	3
Hypotonia	1	2
Hypovitaminosis	1	1
Hypovolaemia		1
Hypoxia		3
Illrd nerve disorder	1	1
Illrd nerve paralysis	1	2
Illness	29	98
Immobile		1
Immune system disorder	1	6
Immune thrombocytopenia	4	9
Immunisation	1	1
Impaired driving ability	1	3
Inability to crawl	1	1
Inadequate analgesia	1	1
Inappropriate schedule of product administration	40	46
Incoherent	1	4
Incontinence	1	2
Incorrect route of product administration	1	7
Increased tendency to bruise		1
Induration	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	2	10
					1
			1		4
					1
				3	6
					3
				1	2
			1	1	4
					1
			1	4	13
					2
				1	3
				1	2
				1	1
					1
					3
				1	1
				1	2
	1	3	11	26	87
					1
				1	6
				4	9
				1	1
				1	3
				1	1
				1	1
		37	43	3	3
			2	1	2
				1	2
		1	7		
					1
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infarction	2	2
Infection	4	8
Inflammation	8	15
Inflammatory marker increased		2
Influenza	11	77
Influenza like illness	26	141
Injection related reaction	1	6
Injection site muscle weakness	1	1
Injection site pain	1	5
Injection site pustule	1	1
Injection site warmth		1
Insomnia	22	82
International normalised ratio abnormal	1	1
International normalised ratio decreased	1	3
International normalised ratio increased	1	10
Interstitial lung disease	1	1
Intestinal haemorrhage	1	1
Intestinal ischaemia		2
Intestinal mass		1
Intestinal obstruction	1	1
Intracranial aneurysm	1	1
Intranasal paraesthesia	1	2
Intravascular haemolysis		1
Iridocyclitis		2
Iron deficiency	1	2
Irregular breathing		1
Irregular sleep wake rhythm disorder	1	1
Irritability	1	4
Irritable bowel syndrome		7
Ischaemia	1	1
Ischaemic stroke	4	7
Jaundice		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				4	8
		1	1	7	14
					2
		4	9	7	68
	1	2	15	24	126
				1	6
				1	1
			2	1	3
				1	1
					1
		4	19	18	63
				1	1
			1	1	2
			2	1	8
				1	1
				1	1
					2
					1
				1	1
				1	1
		1	2		
					1
					2
				1	2
					1
		1	1		
			2	1	2
					7
				1	1
				4	7
			1		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint effusion		3
Joint lock		1
Joint microhaemorrhage		1
Joint noise	1	1
Joint range of motion decreased	9	15
Joint stiffness	4	24
Joint swelling	17	51
Joint vibration		1
Joint warmth		1
Kidney infection		2
Labile blood pressure		1
Labyrinthitis	2	9
Lacrimation increased	3	14
Laryngitis		1
Lethargy	18	78
Ligament disorder	1	1
Ligamentitis	1	1
Limb crushing injury	1	1
Limb discomfort	14	48
Limb immobilisation	1	2
Limb injury	2	2
Limb mass	2	4
Lip blister		1
Lip dry	1	3
Lip pain	2	6
Lip swelling	6	35
Listless	1	4
Livedo reticularis		2
Liver function test abnormal		2
Liver function test increased		3
Liver injury		2
Localised oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					1
					1
				1	1
	1	2	3	7	12
		1	3	3	21
		2	6	15	45
					1
					1
					2
					1
				2	9
		1	4	2	10
					1
	2	3	11	15	67
				1	1
				1	1
1	2	5	14	9	34
			1	1	1
		1	1	1	1
				2	4
					1
				1	3
			1	2	5
	1	2	11	4	24
				1	4
					2
					2
					3
					2
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction	2	3
Loss of consciousness	11	43
Loss of control of legs	1	1
Loss of personal independence in daily activities	6	17
Lower respiratory tract infection	2	18
Lower respiratory tract infection viral		1
Lymphadenitis	1	2
Lymphadenopathy	35	131
Lymph node pain	6	19
Lymphocyte count decreased	1	1
Lymphocytosis	1	1
Lymphoedema	1	3
Lymphoma		1
Lymphopenia	1	1
Macular hole	1	1
Macular oedema	1	2
Malaise	83	374
Malignant hypertension	1	1
Mallory-Weiss syndrome		1
Mass	1	1
Mass excision		1
Mastitis		1
Maternal exposure during pregnancy		2
Medication error	1	2
Memory impairment	2	8
Meniere's disease	2	5
Menopausal symptoms	1	1
Menorrhagia	1	1
Mental fatigue	1	4
Mental impairment		3
Metamorphopsia	1	3
Metastatic neoplasm	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		1
				11	43
				1	1
		1	5	5	12
				2	18
					1
		1	1		1
		9	27	26	104
		1	4	5	15
				1	1
				1	1
				1	3
					1
				1	1
				1	1
				1	2
2	4	19	68	64	306
				1	1
					1
		1	1		
			1		
			2		
			1	1	1
			1	2	7
				2	5
				1	1
		1	1		
				1	4
	1				3
				1	3
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Microembolism	1	1
Microvascular coronary artery disease	1	1
Micturition disorder		1
Micturition urgency	1	3
Middle insomnia	2	5
Migraine	14	55
Migraine with aura	3	10
Miliaria		1
Moaning		1
Mobility decreased	4	20
Monoparesis	1	1
Monoplegia		2
Mood altered		1
Morning sickness		3
Morose		1
Motion sickness	1	4
Motor dysfunction		1
Mouth breathing		1
Mouth cyst	1	2
Mouth haemorrhage	1	1
Mouth swelling	2	3
Mouth ulceration	6	15
Movement disorder	2	10
Multiple allergies		1
Multiple organ dysfunction syndrome		2
Multiple sclerosis	1	2
Multiple sclerosis relapse		3
Muscle atrophy	1	1
Muscle contractions involuntary		1
Muscle fatigue	2	14
Muscle rigidity		2
Muscle rupture		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
			1		
				1	3
			2	2	3
		2	8	12	47
		1	3	2	7
			1		
					1
			2	4	18
				1	1
					2
					1
					3
					1
				1	4
					1
					1
			1	1	1
				1	1
			1	2	2
			1	6	14
			1	2	9
					1
					2
				1	2
					3
				1	1
					1
			1	2	13
					2
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle spasms	15	39
Muscle strain	2	3
Muscle swelling		1
Muscle tightness	1	12
Muscle tone disorder		1
Muscle twitching	1	6
Muscular weakness	16	62
Musculoskeletal chest pain	2	14
Musculoskeletal discomfort	2	10
Musculoskeletal pain	1	3
Musculoskeletal stiffness	27	82
Myalgia	106	414
Myasthenia gravis	1	1
Myasthenia gravis crisis		1
Myelitis transverse		2
Myelodysplastic syndrome		1
Myocardial infarction	10	26
Myocardial ischaemia		3
Myofascial pain syndrome		1
Myositis	3	5
Nail avulsion		1
Nail discolouration		1
Nail pigmentation	1	1
Nasal congestion	4	15
Nasal discomfort	1	5
Nasal injury		1
Nasal obstruction		1
Nasal pruritus		1
Nasopharyngitis	12	35
Nausea	102	510
Neck injury		1
Neck mass		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7	12	32
				2	3
					1
			3	1	9
					1
			1	1	5
		2	6	14	56
				2	14
				2	10
				1	3
	1	4	12	23	70
3	7	23	56	83	358
				1	1
					1
					2
					1
				10	26
					3
			1		
				3	5
			1		
			1		
				1	1
		1	3	3	12
			1	1	4
					1
			1		
	1	3	8	9	27
	3	16	72	86	438
					1
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck pain	17	80
Needle issue		1
Negative thoughts		1
Neoplasm		1
Nerve compression	1	1
Nerve injury	1	1
Nervousness	7	22
Nervous system disorder	1	3
Neuralgia	7	22
Neuritis		1
Neurological symptom		2
Neuromuscular pain	1	1
Neuromyopathy		1
Neuropathy peripheral	6	10
Neutropenia		3
Neutropenic sepsis		2
Neutrophil count abnormal	1	1
Nightmare	4	13
Night sweats	3	23
Nocturnal dyspnoea		1
Nodule	2	2
Non-cardiac chest pain		1
Nuchal rigidity		1
Obstructive pancreatitis	1	2
Occipital neuralgia		1
Ocular discomfort		2
Ocular hyperaemia	6	13
Ocular hypertension		1
Ocular myasthenia	1	1
Ocular vascular disorder	1	1
Odynophagia	1	2
Oedema	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	10	14	70
					1
			1		1
				1	1
		2	5	5	17
				1	3
			2	7	20
					1
					2
				1	1
					1
				6	10
					3
					2
				1	1
			2	4	11
	1		3	3	20
					1
		1	1	1	1
			1		
				1	2
					1
					2
		1	4	5	9
					1
				1	1
				1	1
			1	1	1
		1	1	2	2

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema peripheral	1	4
Oesophageal discomfort		1
Oesophageal pain		1
Oesophageal spasm		1
Oesophageal varices haemorrhage		1
Off label use	42	104
Oliguria		1
Ophthalmic herpes zoster	1	2
Ophthalmoplegic migraine	1	1
Optic ischaemic neuropathy	1	1
Oral blood blister		1
Oral candidiasis	1	3
Oral discharge		1
Oral discomfort	3	7
Oral disorder		1
Oral herpes	4	11
Oral mucosal blistering		1
Oral mucosal exfoliation	1	1
Oral mucosal roughening	1	1
Oral pain	2	7
Oral papule		1
Oropharyngeal discomfort		4
Oropharyngeal pain	19	76
Osteoarthritis	3	9
Overdose	2	6
Oxygen saturation decreased	2	8
Pain	78	293
Painful respiration		2
Pain in extremity	125	462
Pain in jaw	2	17
Pain of skin	4	17
Pallor	3	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		2
			1		
					1
					1
					1
		39	99	3	5
					1
				1	2
		1	1		
				1	1
					1
				1	3
			1		
			1	3	6
					1
		1	2	3	9
			1		
				1	1
				1	1
			1	2	6
					1
			1		3
	1	4	12	15	64
				3	9
		2	6		
				2	8
2	4	18	56	60	237
			1		1
1	18	30	98	95	364
			2	2	15
		2	5	2	12
		1	3	2	9

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations	20	81
Pancreatic carcinoma		1
Pancreatitis		1
Pancreatitis acute	1	1
Pancytopenia		1
Panic attack		1
Panic reaction		1
Papule		1
Paraesthesia	37	105
Paraesthesia oral	7	31
Paralysis	3	9
Paramnesia		1
Paranasal sinus discomfort	1	2
Paranasal sinus hypersecretion	1	1
Paranoia	1	2
Paraparesis		1
Parkinson's disease		1
Parosmia	3	11
Paroxysmal arrhythmia		1
Partial seizures		2
Patellofemoral pain syndrome	1	1
Paternal exposure before pregnancy	1	1
Pelvic pain	2	4
Pemphigoid		1
Periarthritis	1	4
Pericardial effusion		1
Pericardial haemorrhage	1	1
Pericarditis	1	4
Periorbital cellulitis		1
Periorbital haematoma		1
Periorbital oedema		4
Periorbital pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	8	18	73
					1
					1
				1	1
					1
			1		
					1
	1	9	18	28	87
	1	5	8	2	23
				3	9
					1
		1	1		1
				1	1
		1	1		1
					1
		1	2	2	9
					1
					2
				1	1
				1	1
			1	2	3
					1
				1	4
					1
				1	1
				1	4
					1
			1		3
				1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Periorbital swelling	1	8
Peripheral coldness	5	22
Peripheral embolism		1
Peripheral ischaemia	1	2
Peripheral sensory neuropathy		1
Peripheral swelling	41	98
Peripheral vein thrombus extension	1	1
Peroneal nerve palsy		1
Petechiae		3
Petit mal epilepsy		3
Pharyngeal enanthema		1
Pharyngeal inflammation		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		3
Pharyngeal swelling	2	15
Pharyngeal ulceration		1
Pharyngitis		1
Phlebitis	1	5
Photophobia	3	9
Photopsia	4	11
Photosensitivity reaction		3
pH urine		1
Physical disability		1
Pigmentation disorder	1	1
Pityriasis rosea		1
Plantar fasciitis		2
Plasma viscosity abnormal	1	1
Platelet count decreased	4	7
Platelet count increased		1
Platelet disorder	1	1
Pleurisy	1	2
Pleuritic pain	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	7
		2	6	3	16
					1
			1	1	2
			1		
		8	15	33	83
				1	1
			1		
			1		2
					3
					1
					1
			1		
					1
					3
			1	2	14
					1
					1
		1	1		4
				3	9
		1	2	3	9
			1		2
					1
					1
				1	1
			1		
					2
				1	1
		1	1	3	6
					1
				1	1
				1	2
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia	6	13
Pneumonia fungal		1
Pneumonitis	2	2
Pollakiuria	1	4
Polychromasia	1	2
Polymyalgia rheumatica	6	13
Polyuria		1
Poor peripheral circulation		1
Poor quality sleep	5	10
Post herpetic neuralgia	1	3
Post procedural constipation	1	1
Postural orthostatic tachycardia syndrome		1
Post viral fatigue syndrome	3	11
Pre-existing condition improved	1	3
Pregnancy		1
Presyncope	7	20
Primary gastrointestinal follicular lymphoma		1
Primary headache associated with sexual activity		1
Procedural dizziness		1
Procedural nausea		2
Proctalgia		1
Product administered at inappropriate site	2	2
Product complaint	1	2
Productive cough	4	10
Product preparation issue		2
Product quality issue		1
Product use issue	2	61
Prolapse	1	1
Prostatic disorder	1	1
Prostatomegaly	1	2
Pruritus	55	147

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	13
					1
				2	2
		1	1		3
				1	2
				6	13
					1
			1		
		1	1	4	9
			1	1	2
		1	1		
					1
1	1			3	11
			2	1	1
			1		
		1	3	6	17
					1
					1
					2
					1
		2	2		
				1	2
		1	3	3	7
			2		
			1		
		2	59		2
				1	1
		1	1		
			1	1	1
		21	42	34	105

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psoriasis	2	5
Psoriatic arthropathy	1	3
Psychogenic seizure		1
Pulmonary artery thrombosis		1
Pulmonary congestion	1	2
Pulmonary embolism	24	47
Pulmonary fibrosis	1	1
Pulmonary oedema	2	5
Pulmonary pain	2	5
Pulmonary thrombosis	2	2
Pulseless electrical activity		1
Purpura	1	2
Pyrexia	64	388
Quadrantanopia	1	2
Rash	54	133
Rash erythematous	16	64
Rash macular	6	19
Rash maculo-papular	1	2
Rash papular	4	10
Rash pruritic	11	55
Rash vesicular	1	6
Raynaud's phenomenon	1	3
Reaction to excipient		1
Reaction to preservatives		2
Reaction to previous exposure to any vaccine		1
Reading disorder		1
Rectal haemorrhage		3
Reflux gastritis	1	1
Renal cyst	2	2
Renal disorder	1	2
Renal failure	1	3
Renal pain	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
				1	3
					1
					1
				1	2
				24	47
				1	1
				2	5
			1	2	4
	1			2	2
					1
				1	2
1	2	12	42	52	346
				1	2
		15	37	39	96
1	2	5	19	11	45
		4	7	2	12
		1	1		1
		2	2	2	8
		2	12	9	43
			2	1	4
			2	1	1
			1		
					2
					1
					1
					3
				1	1
				2	2
				1	2
				1	3
			2	2	11

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Age Range

65 - 79 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Respiration abnormal	1	6
Respiratory acidosis		1
Respiratory arrest	1	4
Respiratory depression		1
Respiratory disorder		4
Respiratory distress		1
Respiratory failure		2
Respiratory muscle weakness		1
Respiratory rate increased		3
Respiratory symptom		1
Respiratory tract congestion		1
Respiratory tract infection	1	1
Respiratory tract irritation	1	1
Restless legs syndrome		1
Restlessness	3	7
Retching		9
Retinal artery occlusion	1	1
Retinal detachment	1	1
Retinal disorder	1	1
Retinal exudates	1	1
Retinal migraine		2
Retinal vasculitis	1	1
Retinal vein occlusion	3	4
Retroperitoneal haemorrhage		1
Reversible cerebral vasoconstriction syndrome		1
Rheumatoid arthritis	5	19
Rhinitis		1
Rhinorrhoea	10	36
Rotator cuff syndrome	1	1
Salivary duct obstruction		1
Salivary gland enlargement		1
Salivary gland pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
					1
				1	4
					1
			1		3
					1
					2
					1
					3
	1				1
					1
				1	1
				1	1
					1
			2	3	5
			1		8
				1	1
				1	1
		1	1		
			2		
				1	1
				3	4
					1
					1
				5	19
					1
		2	7	8	29
				1	1
					1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Salivary hypersecretion		2
Sarcoidosis		1
SARS-CoV-2 antibody test negative	1	2
SARS-CoV-2 antibody test positive		1
SARS-CoV-2 test		1
SARS-CoV-2 test positive	1	3
Scab	2	2
Scar pain	1	2
Sciatica	1	5
Scratch	1	2
Seasonal allergy		1
Seborrhoea	1	1
Secretion discharge		1
Seizure	5	29
Seizure cluster		2
Sensation of blood flow		2
Sensation of foreign body		3
Sensitive skin	2	5
Sensory disturbance	2	7
Sensory loss	3	7
Sepsis	4	9
Sepsis syndrome		1
Serum sickness		1
Serum sickness-like reaction		2
Severe acute respiratory syndrome	1	1
Shock		5
Sialoadenitis		1
Sight disability		1
Sinus congestion	2	4
Sinus disorder	2	3
Sinus headache	4	16
Sinusitis	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
					1
			1	1	1
			1		
					1
			1	1	2
				2	2
			1	1	1
			1	1	4
				1	2
			1		
				1	1
					1
				5	29
					2
					2
					3
			1	2	4
				2	7
		1	1	2	6
				4	9
					1
					1
					2
				1	1
					5
					1
					1
				2	4
				2	3
		1	1	3	15
				3	8

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus node dysfunction		1
Sinus pain	2	2
Sitting disability		1
Skin burning sensation	2	5
Skin discharge	1	1
Skin discolouration	4	5
Skin disorder	2	2
Skin erosion		1
Skin exfoliation	1	5
Skin fissures	2	2
Skin haemorrhage	3	3
Skin induration	1	1
Skin infection	2	3
Skin irritation	4	10
Skin laceration		1
Skin lesion	1	6
Skin mass		2
Skin reaction	2	3
Skin swelling	3	4
Skin temperature		1
Skin tightness		2
Skin ulcer	1	1
Skin warm		10
Skin weeping	1	1
Skin wrinkling	2	2
Skull fracture		1
Sleep apnoea syndrome		1
Sleep deficit		1
Sleep disorder	4	28
Sleep disorder due to a general medical condition		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	2
					1
			1	2	4
				1	1
				4	5
				2	2
					1
		1	2		3
				2	2
				3	3
				1	1
		1	2	1	1
		1	2	3	8
			1		
			1	1	5
			2		
				2	3
		1	2	2	2
					1
					2
				1	1
			1		9
				1	1
		1	1	1	1
					1
					1
			6	4	22
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep disorder due to general medical condition, insomnia type	1	2
Slow speech	1	1
Sluggishness	1	1
Small intestinal haemorrhage		1
Sneezing	4	17
Somatic symptom disorder		1
Somnolence	15	50
Speech disorder	5	13
Spinal disorder		1
Spinal osteoarthritis		1
Spinal pain		7
Splenic artery embolisation	1	1
Splenic rupture	2	2
Sputum abnormal		1
Sputum discoloured	1	1
Staring		1
Status epilepticus	1	2
Stevens-Johnson syndrome		2
Stomatitis	2	6
Stress	1	2
Stridor		1
Subarachnoid haemorrhage		2
Subdural haemorrhage	1	1
Sudden death		3
Sudden hearing loss	3	6
Suicidal behaviour	1	1
Suicide attempt	1	1
Suspected COVID-19	8	48
Sweating fever	1	3
Swelling	24	61
Swelling face	12	44

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	1
		1	1		
					1
			2	4	15
					1
		5	10	10	40
	1	1	3	4	10
					1
					1
			1		6
				1	1
				2	2
					1
				1	1
					1
				1	2
					2
	1	1	1	1	5
				1	2
					1
					2
				1	1
					3
				3	6
				1	1
				1	1
		1	10	7	38
				1	3
		8	14	16	47
	1	2	8	10	36

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling of eyelid	2	8
Swollen tongue	8	29
Syncope	23	62
Synovial cyst		2
Synovitis		1
Systemic immune activation		1
Systemic lupus erythematosus		
Systolic hypertension		1
Tachycardia	11	29
Tachypnoea		1
Tardive dyskinesia	1	1
Taste disorder	5	19
Tearfulness		1
Temperature intolerance	2	3
Tenderness	5	16
Tendon injury		2
Tendonitis	1	2
Tendon pain	1	2
Tension	2	2
Tension headache	4	18
Terminal insomnia	1	1
Testicular swelling	1	1
Testis discomfort		1
Tetany		1
Therapeutic response unexpected	3	6
Thermal burn	1	2
Thinking abnormal	2	5
Thirst	4	15
Throat clearing		1
Throat irritation	2	8
Throat tightness	2	12
Thrombocytopenia	6	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	6
		1	5	7	24
	1			23	62
					2
					1
					1
	1				
					1
1	1	2	2	9	27
					1
				1	1
			3	5	16
					1
				2	3
		5	12		4
					2
				1	2
		1	1		1
				2	2
		2	2	2	16
				1	1
		1	1		
					1
					1
		1	3	2	3
				1	2
		1	1	1	4
		1	2	3	13
					1
				2	8
			2	2	10
				6	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombophlebitis	1	3
Thrombophlebitis superficial	1	1
Thrombosis	13	28
Thrombosis in device		1
Thyroxine free increased	1	1
Tinnitus	32	70
Tongue blistering	2	3
Tongue coated		1
Tongue discomfort	2	3
Tongue disorder	2	7
Tongue dry		1
Tongue erythema	1	1
Tongue movement disturbance		1
Tongue oedema		2
Tongue ulceration	1	2
Tonic convulsion		3
Tonsillar cyst	1	1
Toothache	5	11
Tooth fracture	1	2
Tooth infection	1	1
Toxic epidermal necrolysis		1
Toxicity to various agents		
Tracheal inflammation		1
Tracheal pain		1
Transient global amnesia	1	3
Transient ischaemic attack	16	26
Traumatic haemorrhage		1
Tremor	25	111
Trigger finger	1	2
Tri-iodothyronine decreased		1
Type 1 diabetes mellitus	1	2
Type 2 diabetes mellitus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		2
		1	1		
				13	28
					1
				1	1
		2	5	30	65
				2	3
					1
				2	3
		1	1	1	6
					1
				1	1
			1		
					2
				1	2
					3
		1	1		
		2	2	3	9
				1	2
				1	1
					1
	1				
			1		
			1		
				1	3
				16	26
					1
	3	5	15	20	96
			1	1	1
					1
				1	2
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Type IV hypersensitivity reaction		1
Typical aura without headache		1
Ulcer	1	1
Ulcerative keratitis		1
Unresponsive to stimuli		10
Upper-airway cough syndrome		1
Upper respiratory tract congestion		2
Ureteric stenosis		1
Urethral stenosis		1
Urinary incontinence	1	5
Urinary retention	1	4
Urinary tract infection	4	13
Urine abnormality	1	1
Urine flow decreased	1	1
Urine odour abnormal		2
Urine output		1
Urine output decreased	1	1
Urine output increased		1
Urticaria	10	33
Urticaria chronic	1	1
Uveitis		2
Vaccination complication		2
Vaccination site bruising	2	11
Vaccination site calcification	1	1
Vaccination site coldness		1
Vaccination site discolouration		1
Vaccination site discomfort	3	8
Vaccination site erythema	13	48
Vaccination site haemorrhage		3
Vaccination site induration	3	7
Vaccination site infection	2	4
Vaccination site inflammation	3	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
					1
					10
					1
			1		1
					1
				1	5
				1	4
1	1	1	4	3	9
		1	1		
		1	1		
					2
					1
				1	1
			1		
		3	8	7	25
				1	1
					2
					2
		2	5		6
				1	1
					1
					1
		2	5	1	3
		4	13	9	35
					3
		3	4		3
		1	1	1	3
		2	2	1	4

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site irritation	1	1
Vaccination site joint erythema		1
Vaccination site joint pain		1
Vaccination site lymphadenopathy		1
Vaccination site mass	3	16
Vaccination site movement impairment	1	4
Vaccination site necrosis	1	1
Vaccination site oedema		2
Vaccination site pain	57	225
Vaccination site paraesthesia		3
Vaccination site pruritus	6	20
Vaccination site rash	2	10
Vaccination site reaction	3	9
Vaccination site swelling	17	55
Vaccination site vesicles		1
Vaccination site warmth	4	18
Vaccine breakthrough infection	1	1
Vaginal cyst	1	1
Varicella zoster virus infection		1
Varicose vein		2
Vascular headache		1
Vascular pain	1	2
Vascular stent thrombosis	1	1
Vasculitic rash	1	2
Vasculitis	3	8
Vasodilatation		1
Vein disorder	2	2
Venous haemorrhage		1
Venous thrombosis	1	1
Venous thrombosis limb	1	1
Ventricular fibrillation		1
Ventricular tachycardia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					1
			5	3	11
			2	1	2
				1	1
					2
		25	80	32	145
			1		2
		4	10	2	10
		1	4	1	6
		1	3	2	6
		11	24	6	31
					1
		3	6	1	12
				1	1
				1	1
					1
					2
					1
		1	2		
				1	1
		1	1		1
		1	1	2	7
					1
		1	1	1	1
					1
				1	1
				1	1
					1
				2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo	26	80
Vertigo labyrinthine	1	2
Vertigo positional	3	5
Vestibular migraine	1	1
Vestibular neuritis	2	3
Viral infection	1	2
Virologic failure		1
Vision blurred	12	35
Visual acuity reduced	1	2
Visual impairment	9	28
Vitreous detachment		2
Vitreous floaters		4
Vitreous haemorrhage	2	2
Vomiting	41	181
Vomiting projectile	2	5
Vomiting psychogenic		1
Vulvovaginal pain		1
Vulvovaginal rash		1
Water pollution	1	1
Weight bearing difficulty		3
Weight decreased	4	11
Weight increased		2
Wheezing	3	16
White blood cell count abnormal	1	1
White blood cell count decreased	3	3
White blood cell count increased		2
White blood cell disorder	1	1
Withdrawal syndrome	1	1
Wound	2	5
Wound secretion	1	2
Wrist fracture		1
Writer's cramp		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	10	22	70
				1	2
		1	1	2	4
				1	1
				2	3
				1	2
					1
		1	4	11	31
				1	2
		5	9	4	19
					2
			1		3
				2	2
		9	25	32	156
				2	5
			1		1
			1		
				1	1
			1		2
			1	4	10
					2
		1	2	2	14
				1	1
		1	1	2	2
					2
				1	1
		1	1		
			1	2	4
				1	2
					1
					1

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wrong product administered	1	1			1	1		
Wrong technique in product usage process	1	2						1
	4,297	15,765	26	156	857	2657	3440	13108

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions	1	2					1	2
Abdominal discomfort	2	11			2	4		7
Abdominal distension	8	10			3	4	5	6
Abdominal lymphadenopathy		1						1
Abdominal pain	8	29			1	6	7	23
Abdominal pain lower		4						4
Abdominal pain upper	4	23			1	9	3	14
Abdominal tenderness		1						1
Abnormal behaviour	1	1					1	1
Abnormal dreams	1	4			1	3		1
Abnormal weight gain		1						1
Accidental overdose		1				1		
Acidosis		2				1		1
Activated partial thromboplastin time prolonged	1	1					1	1
Activated partial thromboplastin time shortened	1	1					1	1
Acute abdomen	1	1					1	1
Acute cardiac event		2						2
Acute coronary syndrome	1	1					1	1
Acute kidney injury	2	15					2	15
Acute myocardial infarction		8						8
Acute pulmonary oedema		1						1
Acute respiratory failure		1						1
Adverse drug reaction		2				2		
Age-related macular degeneration		1						1
Ageusia	2	8				2	2	6
Aggression		2						2
Agitation	3	12			1	5	2	7
Alanine aminotransferase increased		1						1
Alexia		1				1		
Allergy to vaccine	1	5			1	4		1
Alopecia	1	1					1	1
Altered state of consciousness		1						1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alveolitis	1	1
Amnesia	6	14
Amylase increased	1	1
Anaemia	1	5
Anal incontinence		3
Anaphylactic reaction	2	15
Angina pectoris	3	7
Angioedema	2	9
Ankylosing spondylitis		1
Anosmia	1	5
Anticoagulation drug level below therapeutic	1	1
Anuria	1	3
Anxiety	2	10
Aortic aneurysm		1
Aortic aneurysm rupture		1
Aortic arteriosclerosis		1
Aortic dissection		1
Aortic embolus	1	1
Aortic stenosis		1
Apathy	1	3
Aphasia	4	9
Aphonia		3
Appendicitis		1
Aptyalism	1	1
Areflexia		1
Arrhythmia	1	3
Arterial thrombosis		1
Arteriosclerosis coronary artery		1
Arthralgia	33	153
Arthritis	3	13
Arthritis reactive		1
Arthropathy	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	3	4	11
		1	1		
			1	1	4
					3
				2	15
				3	7
				2	9
					1
			2	1	3
				1	1
				1	3
			1	2	9
					1
					1
					1
					1
				1	1
					1
				1	3
			1	4	8
					3
					1
		1	1		
					1
				1	3
					1
					1
	1	10	31	23	122
			2	3	11
					1
		1	1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropod sting	1	1
Ascites		1
Aspiration		4
Asthenia	15	99
Asthenopia		3
Asthma	1	4
Asymptomatic COVID-19	5	6
Ataxia	3	3
Atelectasis		1
Atrial fibrillation	6	30
Atrial flutter		1
Atrioventricular block	1	1
Atrioventricular block complete	1	1
Autoimmune disorder		1
Autoscopy	1	1
Axonal neuropathy		1
Back pain	14	58
Bacterial infection		1
Balance disorder	8	43
Bedridden	1	6
Bile duct stone		1
Biliary sepsis		1
Bite		1
Bladder pain		1
Blepharitis		1
Blindness	4	8
Blindness transient		1
Blindness unilateral	1	1
Blister	3	13
Blood alkaline phosphatase increased		1
Blood blister	2	2
Blood creatine phosphokinase increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					4
		5	26	10	73
			1		2
				1	4
				5	6
				3	3
					1
				6	30
					1
				1	1
				1	1
					1
				1	1
					1
		2	11	12	47
					1
	1	3	13	5	30
				1	6
					1
					1
					1
				4	8
					1
				1	1
		1	5	2	8
					1
				2	2
			1		1

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\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood creatinine increased		1						1
Blood electrolytes increased		1				1		
Blood fibrinogen decreased	1	1					1	1
Blood glucose decreased	1	1					1	1
Blood glucose fluctuation	1	1					1	1
Blood glucose increased	2	8				2	2	6
Blood lactic acid increased		2				1		1
Blood magnesium decreased		1				1		
Blood potassium increased	1	1			1	1		
Blood pressure abnormal		1				1		
Blood pressure decreased	1	4					1	4
Blood pressure diastolic increased		1						1
Blood pressure increased	7	18			2	6	5	12
Blood pressure orthostatic abnormal		1						1
Blood pressure systolic decreased		1						1
Blood pressure systolic increased		1						1
Blood sodium decreased	1	5			1	2		3
Blood thrombin	1	1					1	1
Blood urea increased		2				1		1
Blood urine present		1						1
Blood viscosity increased		1				1		
Bloody discharge	1	1					1	1
Body temperature	2	3			2	2		1
Body temperature abnormal	2	4			1	2	1	2
Body temperature decreased	1	3					1	3
Body temperature fluctuation		1				1		
Body temperature increased	4	7			3	4	1	3
Bone contusion		1				1		
Bone pain	2	8			1	2	1	6
Bradycardia	2	3					2	3
Bradyphrenia	1	1					1	1
Brain hypoxia		1						1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
				1	1
				1	1
			2	2	6
			1		1
			1		
		1	1		
			1		
				1	4
					1
		2	6	5	12
					1
					1
		1	2		3
				1	1
			1		1
					1
				1	1
		2	2		1
		1	2	1	2
				1	3
			1		
		3	4	1	3
			1		
		1	2	1	6
				2	3
				1	1
					1

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\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Brain injury		1						1
Brain oedema		1						1
Brain stem stroke	1	1					1	1
Breast cancer	1	1					1	1
Breast pain	1	2					1	2
Breath odour		1				1		
Burning sensation	2	9			2	3		6
Bursitis	1	2			1	1		1
Cachexia		1						1
Cardiac arrest		20						20
Cardiac disorder		2						2
Cardiac failure	1	5					1	5
Cardiac failure chronic	1	1					1	1
Cardiac failure congestive		4						4
Cardiac valve disease		1						1
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		1						1
Carotid artery disease	1	1					1	1
Carpal tunnel syndrome		1						1
Cellulitis	4	14					4	14
Central venous pressure abnormal	1	1			1	1		
Central vision loss		1						1
Cerebellar infarction		1						1
Cerebellar stroke		1						1
Cerebral artery thrombosis	1	1					1	1
Cerebral disorder		1						1
Cerebral haemorrhage		9						9
Cerebral infarction	4	10					4	10
Cerebral thrombosis	5	6					5	6
Cerebral venous sinus thrombosis	2	3					2	3
Cerebral venous thrombosis	1	1					1	1
Cerebrovascular accident	29	81					29	81

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Charles Bonnet syndrome		1
Chest discomfort	4	19
Chest injury		1
Chest pain	15	47
Chillblains	1	1
Chills	20	147
Choking sensation		1
Cholelithiasis	2	2
Chromaturia		4
Chronic kidney disease		2
Chronic obstructive pulmonary disease	1	2
Circulatory collapse	2	17
Circumoral swelling		1
Clostridium difficile infection		1
Clot retraction		1
Cluster headache	1	4
Coagulation time prolonged		1
Coagulopathy	1	2
Cognitive disorder	2	11
Cold sweat	2	8
Colitis	2	2
Colitis microscopic	1	1
Colitis ulcerative	1	2
Coma	1	1
Coma scale abnormal		2
Communication disorder		2
Condition aggravated	4	21
Confusional state	23	96
Conjunctival haemorrhage	1	4
Conjunctivitis		1
Conjunctivitis bacterial		1
Constipation	3	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	6	1	13
					1
	1	4	9	11	38
		1	1		
	2	8	34	12	113
					1
				2	2
			1		3
					2
				1	2
				2	17
			1		
					1
					1
		1	3		1
					1
				1	2
				2	11
		1	2	1	6
				2	2
				1	1
				1	2
				1	1
					2
			1		1
		2	4	2	17
		5	17	18	79
				1	4
					1
					1
			3	3	8

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Contusion	7	19
Coordination abnormal	1	6
Coronary artery disease		2
Coronary artery occlusion		1
Coronary artery stenosis		1
Cor pulmonale		1
Costochondritis		1
Cough	12	48
Cough decreased		1
COVID-19	24	94
COVID-19 immunisation	1	1
COVID-19 pneumonia	4	16
C-reactive protein increased	2	7
Crying		3
Crystal arthropathy		1
Culture negative		1
Cyanosis		1
Cystitis		1
Deafness		4
Deafness unilateral		3
Death	4	54
Decreased appetite	15	102
Decreased interest		2
Decubitus ulcer	1	1
Deep vein thrombosis	10	23
Dehydration	7	17
Delirium	7	22
Delusion	1	2
Dementia	1	7
Dementia Alzheimer's type	1	1
Demyelination	1	1
Depressed level of consciousness		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5	5	14
			1	1	5
					2
					1
					1
					1
		6	17	6	31
			1		
		4	9	20	85
				1	1
				4	16
			3	2	4
			1		2
					1
					1
					1
					4
					3
				4	54
	2	5	22	10	80
					2
				1	1
				10	23
		4	5	3	12
				7	22
			1	1	1
				1	7
				1	1
				1	1
					4

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depressed mood	1	4
Depression		2
Dermatitis		4
Dermatitis allergic		5
Dermatitis bullous		2
Dermatitis exfoliative		1
Device related infection	1	1
Diabetes mellitus	2	4
Diabetes mellitus inadequate control		1
Diabetic diet		1
Diabetic ketoacidosis		1
Diarrhoea	37	160
Diplegia		2
Diplopia	2	7
Discomfort	2	9
Disease recurrence	5	22
Disorganised speech		2
Disorientation	4	12
Disseminated intravascular coagulation	1	1
Disseminated varicella zoster virus infection		1
Dissociation	1	1
Disturbance in attention	1	4
Dizziness	48	175
Dizziness exertional		1
Dizziness postural	5	16
Drug hypersensitivity		2
Drug ineffective	28	100
Drug interaction		1
Dry eye		3
Dry mouth	5	9
Dry skin	3	6
Dry throat	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
					2
			2		2
			3		2
					2
					1
				1	1
				2	4
					1
					1
					1
1	2	17	39	20	121
					2
		2	3		4
		1	4	1	5
		1	2	4	20
					2
			1	4	11
				1	1
					1
		1	1		
		1	2		2
		22	52	26	123
					1
		1	2	4	14
			2		
				28	100
			1		
			3		
		2	3	3	6
		2	5	1	1
				1	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysarthria	6	21
Dysgeusia	4	13
Dyskinesia	2	4
Dyspepsia	5	10
Dysphagia	2	12
Dysphonia		3
Dyspnoea	35	130
Dyspnoea exertional		3
Dyssomnia	1	1
Dysstasia	4	13
Dysuria		2
Ear discomfort		2
Ear infection		1
Ear pain	1	5
Eating disorder	2	5
Eczema	2	3
Electrocardiogram abnormal		1
Electrocardiogram ST segment abnormal		1
Electrocardiogram ST segment elevation		2
Embolic cerebral infarction	1	1
Embolic stroke	1	2
Embolism	6	6
Emotional disorder		2
Emotional distress	1	4
Emphysema		1
Encephalitis	1	1
Encephalitis viral	1	1
Encephalopathy		1
Enteritis		1
Enuresis	1	3
Epiglottic oedema		1
Epilepsy	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	6	20
		1	5	3	8
				2	4
		1	1	4	9
			1	2	11
			1		2
		12	25	23	105
			2		1
		1	1		
		1	3	3	10
					2
					2
			1		
			1	1	4
			1	2	4
		1	1	1	2
					1
					1
					2
				1	1
				1	2
				6	6
					2
			1	1	3
					1
				1	1
				1	1
			1		
			2	1	1
					1
				1	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis	14	33
Eructation		2
Erythema	17	60
Essential hypertension		1
Expired product administered		1
Exposure keratitis		1
Extrasystoles		1
Eye allergy		1
Eye contusion	1	1
Eye disorder		2
Eye haemorrhage	1	1
Eye infection		1
Eye pain	2	10
Eye pruritus	1	4
Eye swelling	2	10
Face oedema		1
Facial discomfort		1
Facial nerve disorder		1
Facial neuralgia	1	1
Facial pain	1	6
Facial paralysis	9	28
Facial paresis	1	3
Faeces discoloured		4
Faeces hard	1	1
Faeces pale		1
Fall	16	67
Fatigue	83	385
Fear		3
Feeding disorder	1	10
Feeling abnormal	9	34
Feeling cold	12	49
Feeling drunk		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	9	8	24
					2
		12	35	5	25
					1
			1		
			1		
					1
					1
		1	1		
					2
				1	1
					1
		2	2		8
		1	2		2
		1	3	1	7
					1
					1
			1		
		1	1		
			1	1	5
				9	28
		1	2		1
			3		1
				1	1
					1
		5	16	11	51
3	12	29	106	54	279
					3
			4	1	6
	1	3	12	6	22
		5	17	7	32
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling hot	8	31
Feeling jittery	1	1
Feeling of body temperature change	1	6
Femoral neck fracture	1	1
Femur fracture		1
Fibrin D dimer increased	1	3
Fibromyalgia		3
Flank pain		2
Flatulence	1	5
Fluid intake reduced		1
Fluid retention		1
Flushing		6
Folliculitis		1
Food allergy		1
Food aversion		1
Food refusal	1	2
Foreign body sensation in eyes	1	1
Fracture		1
Frequent bowel movements		2
Functional gastrointestinal disorder	1	1
Fungal skin infection		1
Furuncle		1
Gait disturbance	7	32
Gait inability	1	16
Gastric haemorrhage		1
Gastritis		2
Gastroenteritis		2
Gastroenteritis rotavirus	1	1
Gastroenteritis viral		1
Gastrointestinal carcinoma	1	1
Gastrointestinal disorder		1
Gastrointestinal pain		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	15	4	16
		1	1		
		1	2		4
				1	1
					1
				1	3
					3
			1		1
		1	1		4
					1
					1
			2		4
					1
					1
		1	1		1
		1	1		
					1
					2
				1	1
					1
					1
		2	5	5	27
		1	4		12
					1
					2
			1		1
				1	1
					1
				1	1
			1		
					6

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Gastrointestinal surgery	1	1
Gastroesophageal reflux disease		2
Generalised tonic-clonic seizure	2	4
General physical health deterioration	2	8
Giant cell arteritis		1
Gingival pain		2
Glassy eyes		1
Glaucoma		1
Gliososis		1
Glomerulonephritis minimal lesion		1
Glossodynia	2	4
Gout	2	7
Gouty tophus	1	1
Grip strength decreased		2
Groin pain		1
Guillain-Barre syndrome	1	4
Haemarthrosis	1	1
Haematemesis	1	7
Haematochezia	1	3
Haematoma		3
Haematuria	2	2
Haemoglobin decreased	1	3
Haemoptysis		3
Haemorrhage	5	11
Haemorrhage intracranial	1	5
Haemorrhage subcutaneous	1	1
Haemorrhage urinary tract		1
Haemorrhagic stroke	1	3
Hair texture abnormal	1	1
Hallucination	3	24
Hallucination, auditory		1
Hallucination, visual	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		1
				2	4
			2	2	6
					1
			1		1
					1
					1
					1
		1	1	1	3
				2	7
				1	1
					2
			1		
				1	4
				1	1
				1	7
				1	3
			1		2
		1	1	1	1
			1	1	2
					3
	1			5	11
				1	5
				1	1
					1
				1	3
				1	1
				3	24
					1
				1	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hand-eye coordination impaired		1
Headache	67	281
Head discomfort	2	5
Head injury	2	7
Heart injury		2
Heart rate abnormal		1
Heart rate decreased		5
Heart rate increased	4	13
Heart rate irregular	1	3
Hemianopia homonymous	1	1
Hemiparesis	1	12
Hemiplegia		1
Hepatic artery embolism		1
Hepatic enzyme increased		1
Herpes simplex encephalitis		1
Herpes virus infection		1
Herpes zoster	10	61
Herpes zoster meningoencephalitis	1	1
Hot flush	3	8
Hyperacusis		3
Hyperglycaemia		4
Hyperhidrosis	5	32
Hyperpyrexia		1
Hypersensitivity	3	19
Hypersensitivity pneumonitis		1
Hypersomnia	2	12
Hypertension	11	25
Hypertensive crisis	1	1
Hypertensive heart disease		3
Hypertonia		2
Hyperventilation		2
Hypnagogic hallucination		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	3	32	77	35	204
			2	2	3
			1	2	6
					2
					1
					5
			2	4	11
				1	3
				1	1
				1	12
					1
					1
			1		
					1
					1
		1	23	9	38
				1	1
		2	4	1	4
					3
					4
		3	8	2	24
					1
		2	6	1	13
					1
			3	2	9
	1	2	3	9	22
				1	1
					3
					2
					2
					1

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Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoacusis	1	3
Hypoaesthesia	9	25
Hypoaesthesia oral		1
Hypoglycaemia		3
Hypokinesia	4	5
Hyponatraemia		2
Hypophagia	1	3
Hypopnoea	2	4
Hyporeflexia		2
Hypotension	6	33
Hypothermia	1	6
Hypotonia		1
Hypoxia	1	5
Illness	12	49
Illusion		1
Immobile		2
Immune-mediated hepatic disorder	1	1
Immune thrombocytopenia	3	7
Immunisation reaction	1	1
Impaired driving ability	1	1
Impaired gastric emptying	1	1
Impaired quality of life	1	1
Inappropriate schedule of product administration	44	54
Incoherent		1
Incomplete course of vaccination		1
Incontinence	2	7
Incorrect route of product administration	1	6
Increased tendency to bruise		2
Infarction	2	4
Infection	2	14
Inflammation	3	8
Inflammatory marker increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
		2	3	7	22
					1
			1		2
				4	5
					2
				1	3
				2	4
			1		1
		2	7	4	26
				1	6
					1
				1	5
		4	11	8	38
			1		
					2
				1	1
				3	7
				1	1
		1	1		
				1	1
				1	1
		44	54		
					1
			1		
				2	7
		1	6		
			2		
				2	4
		1	3	1	11
		1	3	2	5
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza	2	22
Influenza like illness	12	71
Infusion related reaction	1	1
Inguinal mass		1
Initial insomnia		1
Injection site cellulitis	1	1
Injection site erythema	3	3
Injection site rash		1
Injection site swelling	2	2
Insomnia	4	27
International normalised ratio abnormal		1
International normalised ratio decreased	2	5
International normalised ratio increased	1	20
Intestinal infarction	1	1
Intestinal obstruction	1	2
Intestinal perforation	1	2
Iron deficiency anaemia		1
Irregular breathing		1
Ischaemic stroke	3	12
Jaundice	1	1
Jaw clicking		1
Joint effusion		3
Joint lock		1
Joint range of motion decreased	1	4
Joint stiffness	1	5
Joint swelling	8	23
Jugular vein thrombosis		1
Labyrinthitis	1	2
Lacrimation increased	1	6
Lacunar infarction		1
Left ventricular dysfunction	2	3
Left ventricular failure		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		16
		7	18	5	53
				1	1
					1
				1	1
		2	2	1	1
					1
		1	1	1	1
		1	7	3	20
					1
		1	1	1	4
			5	1	15
				1	1
				1	2
				1	2
					1
					1
				3	12
				1	1
			1		
			1		2
					1
				1	4
		1	4	7	19
					1
				1	2
		1	2		4
					1
				2	3
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	10	45
Leukaemia		1
Limb discomfort	9	26
Limb immobilisation		1
Limb mass		1
Lip blister	1	1
Lip dry	1	1
Lip pain		3
Lip swelling	5	29
Listless	2	3
Livedo reticularis		1
Liver function test abnormal		2
Liver function test increased		1
Localised infection	1	2
Localised oedema		1
Local reaction		2
Logorrhoea		1
Loss of consciousness	5	39
Loss of control of legs	1	1
Loss of personal independence in daily activities	1	7
Lower limb fracture		2
Lower respiratory tract infection	5	19
Lung consolidation		1
Lung disorder		1
Lung neoplasm malignant	2	3
Lymphadenitis		1
Lymphadenopathy	6	20
Lymphatic disorder	1	1
Lymph node pain		4
Lymphocyte count increased		1
Lymphoedema	3	3
Lymphoma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	4	13	6	32
					1
	1	5	13	4	13
			1		
			1		
				1	1
		1	1		
			2		1
		3	12	2	17
				2	3
					1
			1		1
					1
				1	2
			1		
			1		1
					1
				5	39
				1	1
		1	3		4
					2
				5	19
					1
					1
				2	3
					1
		4	8	2	12
				1	1
			1		3
					1
		1	1	2	2
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphopenia		1
Macular degeneration	1	1
Malaise	40	222
Mallory-Weiss syndrome		1
Mastication disorder		1
Melaena		3
Memory impairment	2	15
Menorrhagia	1	2
Mental disorder	1	1
Mental fatigue		2
Mental impairment	3	4
Mental status changes		1
Metamorphopsia	1	1
Microvascular coronary artery disease		1
Micturition disorder		1
Middle insomnia		2
Migraine	4	9
Migraine with aura	1	3
Miliaria		1
Mini mental status examination abnormal		1
Mitral valve incompetence	1	1
Mobility decreased	7	34
Monoparesis		2
Monoplegia		1
Mood swings		2
Morton's neuralgia		1
Motion sickness		1
Mouth haemorrhage	1	1
Mouth injury		1
Mouth swelling	1	3
Mouth ulceration		3
Movement disorder	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
	1	11	55	29	167
					1
					1
					3
		1	3	1	12
				1	2
				1	1
			1		1
				3	4
					1
				1	1
					1
					1
					2
		1	3	3	6
				1	3
			1		
					1
				1	1
		2	12	5	22
					2
					1
					2
					1
			1		
		1	1		
					1
		1	2		1
					3
			2	1	8

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mucosal haemorrhage		1
Mucous stools		1
Multiple organ dysfunction syndrome		2
Muscle disorder		1
Muscle fatigue	2	6
Muscle injury		1
Muscle mass	1	1
Muscle rigidity		2
Muscle spasms		7
Muscle strain		1
Muscle twitching		3
Muscular weakness	15	63
Musculoskeletal chest pain	4	13
Musculoskeletal deformity		1
Musculoskeletal discomfort	1	5
Musculoskeletal disorder		2
Musculoskeletal pain	1	2
Musculoskeletal stiffness	6	25
Myalgia	32	138
Myasthenia gravis crisis	1	1
Myelitis		1
Myelitis transverse		1
Myocardial haemorrhage		1
Myocardial infarction	6	29
Myocardial ischaemia		6
Myocardial necrosis marker increased	1	1
Myoclonus	1	2
Myositis	1	1
Nail ridging	1	1
Narcolepsy		1
Nasal congestion		2
Nasal discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					2
					1
				2	6
			1		
				1	1
					2
			1		6
					1
			1		2
		6	16	9	47
		2	4	2	9
					1
		1	2		3
					2
				1	2
	1	3	9	3	16
	1	16	43	16	95
				1	1
					1
					1
				6	29
					6
				1	1
				1	2
		1	1		
				1	1
					1
					2
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasopharyngitis	3	11
Nausea	34	190
Neck pain	5	33
Necrotising fasciitis		1
Neoplasm malignant	1	1
Nephrolithiasis		1
Nephrotic syndrome		1
Nerve compression	1	2
Nerve injury		1
Nervousness	3	10
Nervous system disorder		1
Neuralgia	1	7
Neurogenic shock		1
Neurological symptom	1	1
Neurologic neglect syndrome		1
Neuropathy peripheral		1
Neuropsychiatric symptoms		1
Neutropenia		2
Nightmare		1
Night sweats	1	6
Nocturia		1
Nocturnal dyspnoea		1
Nodule	1	3
Noninfective gingivitis	1	1
Nystagmus	1	1
Obsessive-compulsive symptom		1
Ocular discomfort	1	1
Ocular hyperaemia	2	7
Odynophagia	1	1
Oedema	1	3
Oedema peripheral	4	8
Off label use	45	78

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	8
	3	19	55	15	135
		2	10	3	23
					1
				1	1
					1
				1	2
					1
		1	5	2	5
					1
		1	1		6
					1
				1	1
					1
			1		
					2
			1		
	1	1	3		3
			1		
					1
				1	3
				1	1
				1	1
					1
		1	1		
		2	2		5
				1	1
		1	1		2
		2	3	2	5
		45	78		

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Onychoclasia	1	1
Ophthalmic herpes zoster		3
Optic neuropathy		1
Oral candidiasis		2
Oral herpes		1
Oral mucosal blistering		1
Oral mucosal eruption	1	2
Oral mucosal exfoliation	1	1
Oral pain	2	4
Orchitis		1
Oropharyngeal pain	3	17
Orthopnoea		2
Orthostatic hypotension	1	4
Osteoarthritis		2
Osteoporosis		1
Otorrhoea		1
Ovarian cyst	1	1
Overdose	2	3
Overflow diarrhoea		1
Oversensing		1
Oxygen consumption decreased	1	1
Oxygen saturation decreased	2	12
Pain	37	123
Painful respiration	1	3
Pain in extremity	47	195
Pain in jaw		4
Pain of skin	1	2
Pallor	2	11
Palpitations	12	20
Pancreatitis acute		1
Pancytopenia	1	2
Panic attack	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					3
					1
					2
					1
			1		
			1	1	1
		1	1		
		2	2		2
					1
		2	5	1	12
			1		1
		1	1		3
					2
					1
			1		
		1	1		
		2	3		
			1		
					1
		1	1		
		1	2	1	10
		17	43	20	80
			1	1	2
	2	21	70	26	125
			1		3
			1	1	1
		2	3		8
		5	6	7	14
					1
				1	2
			1	1	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panic reaction		1
Paraesthesia	8	32
Paraesthesia oral		7
Paralysis	1	4
Paranoia		1
Parkinsonism		2
Parkinson's disease		2
Parosmia		1
Parotid gland enlargement	1	1
Parotitis		2
Pemphigoid		5
Pemphigus		1
Periarthritis	1	3
Pericardial haemorrhage		1
Pericarditis		4
Periorbital swelling		1
Peripheral circulatory failure		1
Peripheral coldness	5	10
Peripheral ischaemia		1
Peripheral swelling	22	65
Personality change		1
Petechiae	1	2
Petit mal epilepsy		2
Pharyngeal erythema		1
Pharyngeal inflammation		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngeal swelling	1	4
Pharyngeal ulceration		1
Pharyngitis streptococcal		1
Phlebitis		1
Photophobia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		4	15	4	17
			6		1
				1	4
					1
			1		1
					2
			1		
				1	1
					2
					5
					1
	1			1	3
					1
					4
			1		
					1
		1	1	4	9
					1
		7	23	15	42
					1
		1	1		1
					2
					1
					1
					1
			2	1	2
					1
					1
					1
			1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Photopsia	1	2
pH urine increased		1
Pigmentation disorder	1	1
Pityriasis rosea		1
Platelet count decreased	7	9
Pleural effusion		3
Pleuritic pain		1
Pneumonia	4	23
Pneumonia aspiration		7
Pneumonia staphylococcal		1
Pneumonitis		6
Pollakiuria	3	5
Polyarthrits	1	1
Polymyalgia rheumatica	4	9
Polyp	1	1
Polyuria		1
Poor quality sleep	2	6
Posterior reversible encephalopathy syndrome		1
Post herpetic neuralgia		2
Postoperative ileus		1
Post procedural complication		1
Posture abnormal		1
Post viral fatigue syndrome	1	2
Presyncope		8
Primary cough headache		1
Product administration error		1
Productive cough	1	6
Product preparation error	1	1
Product use issue	1	30
Prostatic specific antigen increased		1
Prostatomegaly		1
Pruritus	29	87

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
		1	1		
					1
		3	3	4	6
					3
					1
				4	23
					7
					1
					6
			1	3	4
				1	1
				4	9
				1	1
			1		
			1	2	5
					1
			1		1
					1
					1
				1	2
			3		5
					1
			1		
		1	1		5
		1	1		
		1	30		
			1		
			1		
		23	53	6	34

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Psoriasis	1	3
Psychiatric symptom		1
Psychomotor hyperactivity	1	1
Psychotic behaviour		1
Psychotic disorder		3
Psychotic symptom		2
Pulmonary congestion		2
Pulmonary embolism	14	25
Pulmonary function test	1	1
Pulmonary haemorrhage	1	1
Pulmonary oedema	4	10
Pulmonary thrombosis	2	4
Pulse abnormal	1	2
Pulseless electrical activity		1
Purpura	3	6
Pustule		1
Pyrexia	30	184
Q fever		1
Rash	31	103
Rash erythematous	12	31
Rash macular	9	26
Rash maculo-papular	1	5
Rash morbilliform		1
Rash papular		2
Rash pruritic	13	34
Rash pustular	1	1
Rash vesicular	1	4
Reaction to excipient		1
Rectal haemorrhage	3	10
Red blood cell sedimentation rate increased		2
Red man syndrome		1
Regurgitation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
					1
		1	1		
					1
			1		2
					2
					2
				14	25
				1	1
				1	1
				4	10
				2	4
				1	2
					1
		2	3	1	3
					1
		12	42	18	142
					1
		20	54	11	49
		7	18	5	13
		4	15	5	11
			2	1	3
			1		
			2		
		7	17	6	17
				1	1
				1	4
					1
				3	10
					2
					1
					1

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Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Renal cancer	1	2
Renal disorder		1
Renal failure		3
Renal haemorrhage		1
Renal impairment	1	3
Renal pain	1	3
Repetitive speech		1
Respiration abnormal		1
Respiratory arrest		2
Respiratory disorder	1	2
Respiratory distress		1
Respiratory failure		1
Respiratory rate increased	1	2
Respiratory tract oedema		1
Restless legs syndrome	1	1
Restlessness		3
Retching		10
Reticulocyte count decreased	1	1
Retinal artery occlusion		1
Retinal injury	1	1
Retinal vein occlusion	1	1
Rhabdomyolysis		2
Rheumatoid arthritis	2	4
Rhinitis		3
Rhinorrhoea	2	12
Rib fracture		1
Right ventricular enlargement		1
Road traffic accident	1	2
Rosacea		1
Salivary hypersecretion	1	2
Sarcoma		1
SARS-CoV-2 test positive	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
					3
					1
				1	3
		1	1		2
					1
					1
					2
				1	2
					1
					1
				1	2
					1
				1	1
					3
			4		6
				1	1
					1
				1	1
				1	1
					2
				2	4
			1		2
		2	3		9
					1
			1		
		1	1		1
					1
				1	2
					1
				1	8

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Scab		2				2		
Sciatica		4						4
Sciatic nerve neuropathy		1						1
Screaming		1				1		
Seasonal allergy		1						1
Secretion discharge	1	2			1	1		1
Seizure	3	24					3	24
Senile dementia		1						1
Sensitive skin	1	1			1	1		
Sensory disturbance		2				1		1
Sensory loss	1	1					1	1
Sepsis	2	11					2	11
Shock	1	1					1	1
Sinonasal obstruction	1	1			1	1		
Sinus arrest	2	2					2	2
Sinus congestion		1						1
Sinus headache	2	3					2	3
Sinusitis		2						2
Sinus tachycardia		1						1
Skin abrasion		2						2
Skin burning sensation	1	4					1	4
Skin cancer		1						1
Skin discolouration	3	14			2	5	1	9
Skin disorder		1						1
Skin erosion		2				1		1
Skin exfoliation		5				1		4
Skin hypertrophy		1				1		
Skin induration		1				1		
Skin infection	1	1			1	1		
Skin injury		1				1		
Skin irritation	3	7			1	1	2	6
Skin laceration		1						1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					4
			1		
					1
			1		
		1	1		1
				3	24
					1
		1	1		
			1		1
				1	1
				2	11
				1	1
		1	1		
				2	2
					1
				2	3
					2
					1
					2
				1	4
					1
		2	5	1	9
					1
			1		1
			1		4
			1		
			1		
		1	1		
			1		
		1	1	2	6
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin mass		2
Skin reaction	2	4
Skin tightness		1
Skin ulcer	1	2
Skin warm	1	4
Skin weeping		2
Sleep apnoea syndrome		1
Sleep attacks		1
Sleep disorder	6	20
Small intestinal obstruction		1
Sneezing	4	10
Snoring		1
Social avoidant behaviour		1
Social fear		1
Soft tissue infection		1
Somnolence	9	38
Speech disorder	3	11
Spinal cord disorder		1
Splenomegaly		1
Sputum discoloured		1
Sputum increased		1
Staphylococcal infection	1	1
Staphylococcal sepsis	1	1
Stereotypy		1
Stevens-Johnson syndrome		1
Stoma site extravasation		1
Stoma site haemorrhage		1
Stomatitis		1
Streptococcal abscess	1	1
Stress		1
Stress cardiomyopathy	1	1
Stridor		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		2	4		
					1
				1	2
		1	4		
					2
					1
					1
		4	10	2	10
					1
		4	5		5
			1		
					1
					1
					1
		3	11	6	27
		1	3	2	8
					1
					1
					1
				1	1
				1	1
					1
			1		
					1
					1
			1	1	1
			1		
				1	1
					1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Subacute inflammatory demyelinating polyneuropathy	1	1
Subarachnoid haemorrhage	1	2
Subdural haematoma		1
Sudden death	1	14
Sudden hearing loss		1
Suicide attempt		1
Superior sagittal sinus thrombosis		1
Supraventricular tachycardia	1	3
Suspected COVID-19	7	23
Sweating fever		4
Swelling	10	21
Swelling face	6	27
Swelling of eyelid	1	2
Swollen tongue	2	17
Syncope	12	48
Synovitis		3
Systemic lupus erythematosus rash	1	1
Systolic hypertension		1
Tachycardia	1	5
Tachypnoea		2
Taste disorder		5
Temperature regulation disorder		1
Tenderness	2	6
Tendonitis		1
Tenosynovitis		1
Tension headache	1	4
Testicular pain		1
Testicular swelling	1	2
Therapeutic procedure	1	1
Therapeutic product ineffective		1
Therapeutic response unexpected	5	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
					1
				1	14
					1
					1
					1
				1	3
		3	6	4	17
					4
		6	14	4	7
		3	7	3	20
				1	2
			5	2	12
				12	48
					3
				1	1
					1
			1	1	4
					2
			1		4
					1
		1	3	1	3
					1
					1
				1	4
			1		
		1	2		
		1	1		
					1
		5	7		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thermal burn	1	1
Thirst		5
Throat irritation	1	2
Throat tightness	1	5
Thrombocytopenia	5	12
Thrombocytosis		1
Thrombophlebitis	1	2
Thrombophlebitis superficial	1	1
Thrombosis	8	17
Thrombotic thrombocytopenic purpura	2	2
Tinnitus	4	12
Tongue coated		1
Tongue disorder		1
Toothache		1
Toxic epidermal necrolysis		1
Tracheitis	1	1
Transient ischaemic attack	10	24
Traumatic intracranial haemorrhage		1
Tremor	8	72
Trigeminal nerve disorder		1
Troponin increased	1	3
Tubulointerstitial nephritis		1
Tunnel vision		2
Type IV hypersensitivity reaction		1
Ulcer		3
Underdose		2
Underweight	2	2
Unresponsive to stimuli		11
Upper gastrointestinal haemorrhage		2
Upper limb fracture	1	5
Upper respiratory tract infection	1	1
Urinary incontinence	5	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		3
			1	1	1
				1	5
				5	12
					1
				1	2
		1	1		
				8	17
				2	2
		1	2	3	10
			1		
					1
			1		
					1
				1	1
				10	24
					1
		4	13	4	59
			1		
				1	3
					1
					2
					1
			1		2
			2		
				2	2
					11
					2
				1	5
		1	1		
		2	3	3	10

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary retention		7
Urinary tract disorder		1
Urinary tract infection	4	15
Urinary tract infection bacterial		1
Urine analysis abnormal		1
Urosepsis		1
Urticaria	12	36
Urticaria chronic	1	1
Urticaria papular		1
Uveitis		1
Vaccination failure		3
Vaccination site bruising	2	5
Vaccination site cellulitis		3
Vaccination site discolouration		1
Vaccination site discomfort	1	6
Vaccination site erythema	12	45
Vaccination site haematoma		1
Vaccination site haemorrhage		2
Vaccination site hypersensitivity	1	1
Vaccination site induration	2	4
Vaccination site infection	1	2
Vaccination site inflammation	1	3
Vaccination site joint movement impairment		1
Vaccination site joint pain	1	2
Vaccination site joint swelling		1
Vaccination site mass	1	8
Vaccination site movement impairment	1	3
Vaccination site oedema		1
Vaccination site pain	18	117
Vaccination site pruritus	3	13
Vaccination site pustule	1	1
Vaccination site rash	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					7
					1
		1	3	3	12
			1		1
					1
		10	22	2	14
				1	1
					1
					3
				2	5
			2		1
					1
		1	3		3
		9	30	3	15
					1
			1		1
		1	1		
		2	3		1
				1	2
		1	1		2
			1		
		1	2		
					1
			3	1	5
			1	1	2
					1
		12	52	6	65
		3	11		2
				1	1
		1	8	1	4

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site swelling	10	35
Vaccination site ulcer		1
Vaccination site urticaria	1	1
Vaccination site vesicles		2
Vaccination site warmth	2	18
Vaccine breakthrough infection	11	11
Vaginal haemorrhage	1	1
Varicella	1	2
Vascular dementia	1	4
Vascular injury	2	2
Vasculitic rash		3
Vasculitis	1	7
Vasodilatation	1	1
Venous thrombosis	1	1
Ventricular extrasystoles		1
Ventricular fibrillation		2
Vertebral artery stenosis	1	1
Vertigo	12	33
Vertigo positional		2
Viral infection		2
Viral labyrinthitis		1
Vision blurred	7	26
Visual acuity reduced		1
Visual impairment	4	14
Visual perseveration	1	1
Vitreous floaters		1
Vomiting	27	124
Vomiting projectile	1	1
Vulval haemorrhage		1
Walking aid user	1	1
Weight decreased	2	6
Weight loss diet		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	22	1	13
					1
		1	1		
					2
		2	8		10
				11	11
				1	1
		1	2		
				1	4
				2	2
			1		2
			1	1	6
		1	1		
				1	1
					1
					2
				1	1
	1	3	8	9	25
					2
			1		1
			1		
		4	12	3	14
			1		
		1	3	3	11
				1	1
					1
	2	9	33	18	91
		1	1		
					1
		1	1		
			1	2	5
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wheezing	5	12			3	6	2	6
White blood cell count increased	1	2					1	2
White blood cell disorder	1	1					1	1
		1				1		
	2,134	8,543	4	42	790	2274	1344	6269

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	5	17			3	6	2	11
Abdominal distension	1	9				4	1	5
Abdominal pain	5	31				14	5	17
Abdominal pain lower	1	1			1	1		
Abdominal pain upper	15	50			5	16	10	34
Abnormal behaviour	2	3				1	2	2
Abnormal dreams	2	4			2	3		1
Abnormal faeces	1	4			1	4		
Abnormal sensation in eye	1	1			1	1		
Abortion spontaneous	4	7					4	7
Abscess		2						2
Abscess drainage		1						1
Accidental overdose		16				16		
Acne		1				1		
Acoustic neuroma		1						1
Acute coronary syndrome	1	1					1	1
Acute kidney injury	2	3					2	3
Acute respiratory failure		1						1
Adjustment disorder with depressed mood	1	1					1	1
Adnexa uteri pain		2						2
Adverse drug reaction	1	5				3	1	2
Adverse event	1	1			1	1		
Ageusia	4	12				4	4	8
Agitation	3	4			2	2	1	2
Alanine aminotransferase increased	1	1					1	1
Allergic oedema	1	1					1	1
Allergy to vaccine		3				2		1
Alopecia	1	1					1	1
Amenorrhoea	1	2					1	2
Amnesia	2	5				2	2	3
Anaemia		2						2
Anal haemorrhage		1						1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactic reaction	6	34
Anaphylactic shock	1	4
Anaphylactoid reaction		1
Anaphylactoid shock		1
Anger		1
Angina pectoris	1	4
Angioedema	1	8
Ankylosing spondylitis		1
Anosmia	3	7
Anticoagulation drug level increased		1
Anxiety	7	22
Apathy		1
Aphasia		1
Aphonia		1
Aphthous ulcer	2	2
Appendicitis		1
Appetite disorder		1
Arrhythmia		1
Arrhythmia supraventricular	1	2
Arterial thrombosis	1	1
Arthralgia	107	272
Arthritis	3	6
Arthritis reactive	2	4
Arthritis viral		1
Arthropathy		1
Arthropod bite	1	1
Aspartate aminotransferase increased		1
Asthenia	21	74
Asthenopia	1	6
Asthma	3	13
Asymptomatic COVID-19		7
Atrial fibrillation	4	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	34
				1	4
					1
					1
				1	4
				1	8
					1
			1	3	6
					1
		4	8	3	14
					1
			1		
					1
		1	1	1	1
					1
			1		
					1
		1	1		
					1
		25	87	82	185
			1	3	5
				2	4
			1		
					1
		1	1		
					1
		6	30	15	44
			2	1	4
		1	4	2	9
					7
				4	11

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atrioventricular block	1	1
Aura	1	1
Autoimmune disorder	1	1
Autoimmune haemolytic anaemia	1	1
Autoimmune uveitis		1
Autoscopy	1	1
Axillary mass	1	4
Axillary pain	28	54
Back injury	1	1
Back pain	19	64
Balance disorder	12	21
Bedridden	1	1
Bladder neoplasm	1	1
Bladder pain		1
Blepharospasm	1	3
Blindness	1	5
Blindness transient		1
Blindness unilateral	1	1
Blister	1	7
Blister rupture		1
Blood glucose abnormal		1
Blood glucose decreased	1	3
Blood glucose increased	2	5
Blood growth hormone abnormal	1	2
Blood immunoglobulin G increased		1
Blood immunoglobulin M increased		1
Blood lactic acid increased	1	1
Blood luteinising hormone abnormal		1
Blood potassium decreased		2
Blood pressure abnormal	2	2
Blood pressure decreased	2	3
Blood pressure fluctuation	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				1	1
				1	1
					1
				1	1
			2	1	2
		5	16	23	38
				1	1
		7	25	12	39
		2	3	10	18
				1	1
				1	1
					1
				1	3
				1	5
					1
				1	1
		1	3		4
			1		
					1
			1	1	2
				2	5
		1	2		
			1		
			1		
		1	1		
			1		
					2
		2	2		
		1	1	1	2
				1	2

\* I=Interval, C=Cumulative

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure increased	4	19
Blood pressure systolic increased		1
Blood test abnormal	1	1
Blood urine		1
Blood urine present	1	2
Body temperature	2	2
Body temperature abnormal	2	3
Body temperature decreased	2	3
Body temperature fluctuation	2	3
Body temperature increased	6	20
Bone neoplasm	1	1
Bone pain	5	14
Bradycardia	1	2
Bradykinesia		1
Brain stem syndrome		1
Breast cancer	1	2
Breast cellulitis	1	1
Breast inflammation	1	1
Breast mass	1	2
Breast pain	3	8
Breast swelling	2	4
Breast tenderness	1	1
Bulimia nervosa		1
Bundle branch block right		1
Burning sensation	7	18
Bursitis	1	2
Butterfly rash	1	2
Candida infection	1	1
Cardiac arrest	1	5
Cardiac disorder		2
Cardiac failure	1	1
Cardiac flutter	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8	3	11
			1		
				1	1
					1
		1	2		
		2	2		
		1	2	1	1
			1	2	2
		1	1	1	2
		4	10	2	10
		1	1		
		1	6	4	8
				1	2
					1
					1
				1	2
				1	1
				1	2
				3	8
		1	2	1	2
				1	1
					1
		4	7	3	11
				1	2
				1	2
				1	1
				1	5
					2
				1	1
				2	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac murmur	2	3
Catarrh		1
Cellulitis	4	8
Central vision loss	1	1
Cerebellar stroke		1
Cerebral artery embolism	1	1
Cerebral infarction		1
Cerebral thrombosis		1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	9	16
Chest discomfort	17	48
Chest pain	22	55
Chillblains	3	5
Chills	94	301
Choking		1
Choking sensation	1	1
Chorioretinopathy	1	1
Choroidal neovascularisation		1
Chromaturia	1	1
Chronic fatigue syndrome	2	3
Circulatory collapse		5
Circumstance or information capable of leading to medication error		5
Cluster headache	1	5
Coagulopathy	1	1
Cognitive disorder	1	3
Cold-stimulus headache	1	1
Cold sweat	8	18
Colitis		1
Colitis ulcerative	1	1
Communication disorder	1	2
Condition aggravated	8	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
			1		
				4	8
				1	1
					1
				1	1
					1
				1	1
				9	16
		8	15	9	33
		5	17	17	38
		3	4		1
		27	117	67	184
					1
				1	1
				1	1
					1
		1	1		
				2	3
					5
			5		
			1	1	4
				1	1
				1	3
				1	1
		4	9	4	9
					1
				1	1
			1	1	1
		2	5	6	20

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Confusional state	7	19
Congenital multiplex arthrogryposis	1	1
Conjunctival haemorrhage		1
Conjunctival hyperaemia	1	1
Conjunctival oedema	1	1
Conjunctivitis	1	3
Consciousness fluctuating		1
Constipation	2	6
Contraindicated product administered		1
Contraindicated product prescribed	1	1
Contusion	13	18
Coordination abnormal	2	2
Coronary artery disease	1	2
Coronavirus infection		1
Cortisol decreased		1
Costochondritis		1
Cough	22	69
COVID-19	28	145
COVID-19 immunisation		1
COVID-19 pneumonia		2
C-reactive protein increased		1
Crohn's disease		1
Crying	2	3
CT hypotension complex		2
Cyanosis		1
Cystitis	2	2
Deafness	1	3
Deafness neurosensory		1
Deafness unilateral	1	2
Death	4	13
Decreased appetite	15	36
Decreased embryo viability	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	6	16
				1	1
					1
				1	1
				1	1
		1	1		2
					1
		1	1	1	5
			1		
		1	1		
		6	7	7	11
				2	2
				1	2
					1
					1
		8	31	14	38
		8	25	20	120
			1		
					2
					1
					1
		1	1	1	2
					2
					1
				2	2
				1	3
					1
				1	2
				4	13
		7	14	8	22
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deep vein thrombosis	4	7
Dehydration	3	6
Delirium	1	2
Delusion	1	1
Depressed level of consciousness	2	3
Depressed mood	4	8
Depression	4	9
Dermatitis	2	6
Dermatitis allergic		1
Dermatitis atopic		3
Dermatitis exfoliative generalised	1	1
Dermatitis infected		1
Diabetes mellitus		1
Diabetic ketoacidosis		1
Diaphragmatic disorder	1	1
Diarrhoea	41	117
Diastolic hypertension		1
Diplopia	4	6
Discomfort	5	12
Disease recurrence	6	11
Disorientation	5	8
Disturbance in attention	12	16
Diverticulitis	1	2
Diverticulum		1
Dizziness	88	273
Dizziness exertional		1
Dizziness postural	9	18
Drug eruption		2
Drug ineffective	21	133
Drug interaction	1	2
Dry eye	3	6
Dry mouth	4	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	7
		1	1	2	5
				1	2
		1	1		
				2	3
		1	1	3	7
		1	1	3	8
			1	2	5
			1		
					3
				1	1
					1
					1
				1	1
		15	43	26	74
					1
		1	1	3	5
		3	6	2	6
			1	6	10
		2	3	3	5
		3	5	9	11
				1	2
			1		
		32	108	56	165
					1
		3	5	6	13
					2
				21	133
			1	1	1
			1	3	5
		1	5	3	6

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry skin	3	3
Dry throat		2
Dupuytren's contracture	1	1
Dysarthria	2	4
Dysdiadochokinesis	1	1
Dysfunctional uterine bleeding		1
Dysgeusia	7	28
Dyskinesia	3	3
Dysmenorrhoea	1	2
Dyspepsia	4	7
Dysphagia	4	10
Dysphonia	2	3
Dyspnoea	41	117
Dyspnoea at rest		1
Dyspnoea exertional	1	5
Dysstasia	2	6
Dysuria	3	5
Ear discomfort	3	5
Ear haemorrhage	1	2
Ear infection		1
Ear pain	8	23
Eating disorder		1
Eczema	1	3
Electric shock		1
Embolism	5	5
Eosinophil count increased		1
Epicondylitis	1	1
Epididymitis		1
Epigastric discomfort		1
Epilepsy	3	9
Epistaxis	12	23
Erectile dysfunction	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	1	1
					2
				1	1
			2	2	2
				1	1
					1
		3	16	4	12
		1	1	2	2
				1	2
		1	1	3	6
		2	4	2	6
		1	1	1	2
		8	26	33	91
					1
			1	1	4
		1	3	1	3
			1	3	4
		1	3	2	2
				1	2
					1
		2	6	6	17
			1		
		1	2		1
			1		
				5	5
					1
				1	1
					1
			1		
				3	9
		4	9	8	14
				1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erection increased		1
Erythema	18	59
Erythema multiforme	1	2
Euphoric mood		1
Excessive granulation tissue		1
Exercise tolerance decreased	1	2
Exfoliative rash		1
Expired product administered	1	3
Exposure during pregnancy	1	1
Exposure via breast milk	23	64
External ear pain	1	1
Extrasystoles	1	3
Eye abscess		1
Eye disorder		1
Eye inflammation		1
Eye irritation	2	5
Eyelid irritation		1
Eyelid oedema	1	1
Eyelid ptosis	2	4
Eye pain	7	19
Eye pruritus		2
Eye swelling	2	9
Facial discomfort		2
Facial pain	2	10
Facial paralysis	17	38
Facial paresis	1	1
Facial spasm		1
Faeces soft		1
Fall	7	11
Fatigue	219	580
Fear		1
Fear of injection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		12	35	6	24
				1	2
					1
					1
				1	2
					1
		1	3		
		1	1		
		15	52	8	12
		1	1		
				1	3
					1
			1		
					1
		1	1	1	4
			1		
				1	1
		1	2	1	2
		1	7	6	12
			1		1
			5	2	4
					2
			4	2	6
				17	38
		1	1		
					1
					1
		2	6	5	5
		81	218	138	362
			1		
			1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeding disorder	1	4
Feeling abnormal	20	76
Feeling cold	22	53
Feeling drunk	1	4
Feeling hot	17	46
Feeling jittery	1	3
Feeling of body temperature change	6	11
Feeling of despair	1	1
Feeling of relaxation	1	1
Fibrin D dimer increased		1
Fibromyalgia	1	1
Fine motor skill dysfunction		1
Flank pain		2
Flatulence	2	5
Fluid retention	1	2
Flushing	7	20
Foetal exposure during pregnancy	2	2
Foetal malformation	1	1
Food aversion	2	2
Food intolerance	1	1
Food poisoning	1	1
Foreign body in gastrointestinal tract	1	1
Foreign body in mouth	1	1
Formication		3
Frequent bowel movements	1	1
Gait disturbance	6	19
Gait inability	2	7
Gastric antral vascular ectasia		1
Gastric disorder		1
Gastritis	1	2
Gastroenteritis		3
Gastroenteritis viral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	2
		6	25	14	51
		6	17	16	36
		1	4		
		9	26	8	20
				1	3
		3	5	3	6
				1	1
				1	1
					1
				1	1
					1
			1		1
			1	2	4
				1	2
		4	9	3	11
		1	1	1	1
				1	1
				2	2
				1	1
				1	1
				1	1
			1		2
				1	1
		1	3	5	16
		1	2	1	5
					1
			1		
				1	2
					3
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal haemorrhage	1	1
Gastrointestinal pain	3	8
Gastrointestinal sounds abnormal		2
Gastrooesophageal reflux disease		1
Generalised tonic-clonic seizure	1	5
General physical health deterioration		2
Genital haemorrhage		1
Giant cell arteritis	1	1
Gingival bleeding	1	1
Gingival pain	1	5
Glossitis		1
Glossodynia	3	6
Glycopenia	1	1
Gonorrhoea		1
Gout	2	2
Groin pain	2	3
Guillain-Barre syndrome	2	3
Haemarthrosis	1	1
Haematemesis	1	3
Haematochezia		1
Haematoma	1	2
Haematuria	2	2
Haemolysis		1
Haemophilia		1
Haemoptysis		2
Haemorrhage	3	7
Haemorrhage in pregnancy	1	1
Haemorrhage subcutaneous	1	2
Haemorrhage urinary tract	1	2
Hair colour changes		1
Hair disorder	1	1
Hallucination	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1	2	7
					2
					1
				1	5
					2
					1
				1	1
		1	1		
			1	1	4
					1
		2	4	1	2
		1	1		
					1
				2	2
				2	3
				2	3
				1	1
				1	3
					1
				1	2
				2	2
					1
					1
					2
			1	3	6
				1	1
				1	2
			1	1	1
			1		
		1	1		
				4	4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hallucination, visual		1
Hangover	1	2
Headache	285	749
Head discomfort	3	9
Head injury		2
Heart disease congenital		1
Heart rate abnormal	1	3
Heart rate decreased		2
Heart rate increased	13	37
Heart rate irregular	3	8
Hemiplegia		1
Hepatic pain	2	2
Herpes simplex reactivation		1
Herpes zoster	2	20
Herpes zoster oticus	1	1
Hot flush	10	26
Hunger		1
Hyperacusis		2
Hyperaesthesia	2	5
Hyperaesthesia teeth	1	1
Hyperglycaemia	6	8
Hyperhidrosis	33	66
Hypersensitivity	4	28
Hypersomnia	4	5
Hypertension	13	34
Hyperthyroidism	1	2
Hyperventilation	1	2
Hypoacusis	2	3
Hypoaesthesia	25	62
Hypoaesthesia oral	2	16
Hypocalcaemia	1	1
Hypogeusia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
		115	326	170	423
		2	5	1	4
			1		1
			1	1	2
					2
		5	13	8	24
			1	3	7
					1
		1	1	1	1
					1
			12	2	8
				1	1
		4	10	6	16
					1
			1		1
			2	2	3
		1	1		
		1	1	5	7
		11	22	22	44
		1	12	3	16
		1	2	3	3
		3	10	10	24
				1	2
		1	1		1
		1	1	1	2
		8	21	17	41
		1	7	1	9
				1	1
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoglycaemia	1	3
Hypokalaemic syndrome		1
Hypokinesia	5	6
Hypophagia	1	1
Hypopnoea	1	1
Hyporesponsive to stimuli		1
Hypotension	2	10
Hypothermia		1
Hypotonia		1
Hypoxia	2	3
IgA nephropathy	1	1
Illness	16	51
Immobile		1
Immune thrombocytopenia	2	2
Immunisation		1
Impaired healing		1
Inappropriate affect	1	1
Inappropriate schedule of product administration	34	50
Incontinence	1	2
Incorrect dose administered		2
Incorrect route of product administration	2	5
Increased insulin requirement		1
Increased upper airway secretion		1
Increased viscosity of upper respiratory secretion	1	1
Indifference		1
Induration		2
Infection	4	7
Inflammation	3	12
Inflammatory marker increased		2
Inflammatory pain	1	1
Influenza	20	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
		1	1	4	5
				1	1
				1	1
					1
			2	2	8
					1
					1
				2	3
				1	1
		5	12	11	39
					1
				2	2
					1
					1
				1	1
		33	49	1	1
			1	1	1
			2		
		2	5		
					1
			1		
				1	1
			1		1
		1	3	3	4
			2	3	10
					2
		1	1		
		4	13	16	34

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	26	87
Infusion related reaction		1
Injection related reaction		3
Injection site erythema	2	2
Injection site pain	5	8
Injection site warmth	1	1
Injury associated with device		1
Insomnia	9	41
Intentional product misuse		1
Intentional product use issue		1
International normalised ratio decreased	1	2
International normalised ratio increased	1	2
Intervertebral disc protrusion	1	1
Intrusive thoughts	1	1
Iritis	1	2
Iron deficiency anaemia		1
Irritability	2	4
Irritable bowel syndrome		1
Ischaemic stroke		2
Itching scar		1
IVth nerve paralysis		1
Joint injury	1	1
Joint noise		1
Joint prosthesis user		1
Joint range of motion decreased	2	6
Joint stiffness	2	2
Joint swelling	6	16
Jugular vein thrombosis	1	1
Keratitis		2
Kidney infection	1	1
Kidney transplant rejection	1	1
Labyrinthitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	38	19	49
					1
			1		2
		1	1	1	1
		2	3	3	5
				1	1
			1		
		5	19	4	22
			1		
			1		
				1	2
			1	1	1
		1	1		
		1	1		
				1	2
					1
				2	4
					1
					2
			1		
					1
					1
		2	3		3
				2	2
		1	4	5	12
		1	1		
			2		
				1	1
				1	1
					2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lacrimation increased	1	6
Lacunar stroke		1
Laryngeal pain		1
Laryngitis		1
Lethargy	24	70
Libido decreased		1
Libido increased		1
Limb discomfort	21	43
Limb injury	2	2
Limb mass		3
Lip dry	1	1
Lip erythema		1
Lip pain		2
Lip swelling	5	20
Liquid product physical issue		2
Liver function test abnormal		1
Localised infection		2
Localised oedema	1	3
Loss of consciousness	6	24
Loss of control of legs		1
Loss of libido	1	2
Loss of personal independence in daily activities	4	6
Lower respiratory tract infection	1	3
Lung consolidation	1	1
Lung disorder	1	2
Lung infiltration	2	2
Lymphadenitis	3	4
Lymphadenopathy	94	207
Lymphangitis	1	1
Lymph gland infection		1
Lymph node pain	16	34
Lymph node palpable		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
					1
			1		
					1
		11	40	13	30
					1
			1		
		9	18	12	25
				2	2
			2		1
				1	1
					1
					2
		3	10	2	10
			2		
					1
			1		1
		1	1		2
				6	24
					1
				1	2
		1	1	3	5
				1	3
				1	1
				1	2
		1	1	1	1
			1	3	3
		30	73	64	134
				1	1
			1		
		2	10	14	24
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphocyte count decreased	1	1
Lymphoedema		2
Lymphoma		1
Magnetic resonance imaging brain abnormal	1	1
Major depression	3	3
Malaise	72	220
Mass	2	4
Mast cell activation syndrome		1
Maternal exposure during pregnancy	4	9
Maternal exposure timing unspecified	1	1
Mean cell volume decreased		1
Medication error		1
Memory impairment	3	6
Meniere's disease	1	1
Menorrhagia	2	4
Menstrual disorder		1
Menstruation delayed	2	6
Menstruation irregular	4	4
Mental disorder	1	1
Mental fatigue		5
Mental impairment		1
Metastases to lymph nodes		3
Metrorrhagia	3	5
Micturition urgency	1	1
Middle insomnia	1	5
Migraine	28	68
Migraine with aura	3	4
Miliaria		3
Mobility decreased	6	13
Monoparesis	1	2
Monoplegia	1	6
Mood swings		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		1
					1
				1	1
				3	3
		32	96	40	124
				2	4
					1
		2	5	2	4
		1	1		
					1
			1		
		2	4	1	2
				1	1
		1	2	1	2
					1
			1	2	5
		2	2	2	2
		1	1		
					5
					1
					3
		1	1	2	4
				1	1
		1	3		2
1	1	5	21	23	47
		1	1	2	3
			1		2
		1	4	5	9
				1	2
				1	6
					2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Morning sickness		1
Motion sickness	1	3
Mouth swelling	1	3
Mouth ulceration	4	8
Movement disorder	2	4
Multiple organ dysfunction syndrome	1	1
Multiple sclerosis		1
Multiple sclerosis relapse	1	1
Muscle atrophy	2	3
Muscle spasms	11	30
Muscle spasticity		1
Muscle twitching	1	7
Muscular weakness	11	33
Musculoskeletal chest pain	4	9
Musculoskeletal discomfort	1	5
Musculoskeletal disorder	1	6
Musculoskeletal pain		1
Musculoskeletal stiffness	10	31
Myalgia	114	315
Myasthenia gravis	2	2
Myelitis transverse	1	2
Myelosuppression		1
Myocardial infarction	4	8
Myocarditis		1
Myoclonus		1
Nasal congestion	4	11
Nasal discomfort		1
Nasal disorder	1	1
Nasal dryness	2	3
Nasopharyngitis	8	19
Nausea	133	376
Neck mass		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	3
			1	1	2
		3	5	1	3
		2	2		2
				1	1
					1
				1	1
				2	3
		2	9	9	21
					1
			2	1	5
		2	4	9	29
		1	3	3	6
			2	1	3
				1	6
			1		
		3	10	7	21
		43	145	71	170
				2	2
				1	2
					1
				4	8
					1
					1
		1	6	3	5
					1
				1	1
				2	3
		3	9	5	10
		52	149	81	227
			1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck pain	26	62
Needle issue		1
Nerve compression	1	1
Nerve injury	2	5
Nervousness	4	11
Nervous system disorder	1	1
Neuralgia	9	13
Neurogenic bladder		1
Neurogenic shock		4
Neurological symptom	1	2
Neuropathy peripheral	2	7
Neutropenia	1	2
Nightmare	2	3
Night sweats	4	16
No adverse event	3	8
Nodule		1
Occipital neuralgia	1	1
Occupational exposure to product		1
Ocular discomfort	1	1
Ocular hyperaemia	2	5
Oedema peripheral	1	4
Oesophageal pain	1	1
Off label use	36	72
Optic neuritis	1	1
Oral blood blister	1	1
Oral candidiasis	1	1
Oral discomfort	1	2
Oral dysaesthesia		1
Oral herpes	3	6
Oral mucosal blistering	1	1
Oral pain	1	5
Oral pruritus	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	21	17	41
			1		
				1	1
		1	3	1	2
		3	3	1	8
				1	1
		2	4	7	9
					1
					4
				1	2
				2	7
				1	2
			1	2	2
		1	6	3	10
		3	8		
			1		
				1	1
			1		
		1	1		
		1	1	1	4
			1	1	3
				1	1
		36	72		
				1	1
		1	1		
				1	1
		1	1		1
					1
		1	3	2	3
		1	1		
			1	1	4
			2	1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oropharyngeal discomfort		2
Oropharyngeal pain	23	59
Orthopnoea		2
Osteitis	1	1
Osteoarthritis	1	2
Osteonecrosis of jaw	1	1
Overdose		3
Oxygen saturation decreased		4
Pain	92	237
Painful respiration		1
Pain in extremity	130	348
Pain in jaw	9	17
Pain of skin	3	9
Pallor	4	13
Palmar erythema	1	3
Palpitations	22	57
Pancreatic carcinoma	1	1
Panic attack	2	3
Panic reaction	1	2
Papule		2
Paraesthesia	40	110
Paraesthesia oral	12	49
Paralysis	2	4
Parkinsonism	1	1
Parkinson's disease	2	2
Parophthalmia	1	1
Parosmia	3	5
Parotitis		1
Partial seizures		1
Peau d'orange		1
Pelvic discomfort		1
Pelvic pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		9	23	14	36
					2
				1	1
				1	2
				1	1
			3		
					4
		34	98	58	139
					1
		57	151	73	197
		2	3	7	14
			2	3	7
		3	8	1	5
			1	1	2
		9	20	13	37
				1	1
				2	3
		1	2		
			1		1
		20	46	20	64
		8	31	4	18
				2	4
				1	1
				2	2
				1	1
		2	2	1	3
			1		
					1
			1		
					1
		1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pemphigoid	1	1
Peptic ulcer haemorrhage		1
Periarthritis	3	6
Pericardial effusion		1
Pericarditis	1	1
Periorbital swelling	3	6
Peripheral coldness	3	13
Peripheral swelling	32	81
Peroneal nerve palsy	1	3
Persistent postural-perceptual dizziness		1
Petechiae	1	2
Petit mal epilepsy		2
Pharyngeal disorder		1
Pharyngeal hypoaesthesia		1
Pharyngeal paraesthesia	3	3
Pharyngeal swelling	5	13
Pharyngitis		1
Phlebitis	1	1
Photophobia	6	13
Photopsia		1
Photosensitivity reaction	1	1
Pityriasis	1	1
Pityriasis rosea	1	1
Plasma cell myeloma		1
Platelet count abnormal	1	1
Pleural effusion	3	3
Pleurisy		1
Pleuritic pain		1
Pneumonia	1	2
Pollakiuria		2
Polyarthrits	1	1
Polymenorrhoea		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1	3	5
					1
				1	1
		1	2	2	4
		1	8	2	5
		9	31	23	50
		1	1		2
					1
		1	2		
					2
					1
			1		
		3	3		
		2	5	3	8
			1		
				1	1
		3	6	3	7
					1
				1	1
		1	1		
		1	1		
					1
		1	1		
				3	3
					1
					1
				1	2
					2
				1	1
			1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Polymyalgia rheumatica	2	2
Poor quality product administered	5	88
Poor quality sleep	4	11
Postmenopausal haemorrhage		1
Post viral fatigue syndrome	3	4
Pregnancy test positive	1	1
Premature baby		2
Presyncope	2	24
Product administered at inappropriate site	2	6
Product complaint		1
Product contamination		1
Product contamination physical	1	1
Productive cough	4	10
Product label confusion		1
Product packaging quantity issue		4
Product preparation error		5
Product preparation issue		1
Product quality issue		1
Product storage error	1	8
Product supply issue		1
Product temperature excursion issue	3	71
Product use issue	4	28
Prostatic pain	1	1
Prostatitis	1	1
Pruritus	27	98
Pseudofolliculitis		1
Psoriasis	1	3
Psoriatic arthropathy		1
Psychiatric symptom	1	1
Pulmonary embolism	9	15
Pulmonary fibrosis	1	1
Pulmonary pain	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		5	88		
		3	8	1	3
					1
				3	4
		1	1		
					2
		1	12	1	12
		2	5		1
			1		
			1		
		1	1		
			3	4	7
			1		
			4		
			5		
			1		
			1		
		1	8		
			1		
		3	71		
		4	28		
				1	1
				1	1
		15	47	12	51
					1
				1	3
					1
		1	1		
				9	15
				1	1
			1	2	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary thrombosis	1	3
Pulmonary tuberculosis	1	1
Puncture site discharge		1
Purpura	1	1
Pyrexia	147	444
Q fever		1
Rash	36	101
Rash erythematous	9	26
Rash macular	5	9
Rash papular	3	5
Rash pruritic	8	26
Rash vesicular		1
Raynaud's phenomenon	3	4
Reaction to excipient		1
Rectal haemorrhage	2	2
Reflux gastritis		1
Renal failure	2	3
Renal haemorrhage	1	1
Renal impairment	1	1
Renal pain	4	10
Renal vasculitis		1
Respiratory arrest		1
Respiratory disorder		3
Respiratory rate decreased	1	1
Respiratory rate increased		1
Respiratory tract infection	1	2
Restless legs syndrome	1	2
Restlessness	2	2
Retching		2
Retinal artery thrombosis		1
Retinal exudates	1	1
Reversed hot-cold sensation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	1
					1
		1	1		
		58	213	89	231
					1
		20	56	16	45
		1	8	8	18
		3	5	2	4
		1	1	2	4
		1	10	7	16
					1
		2	2	1	2
					1
				2	2
			1		
				2	3
				1	1
				1	1
			2	4	8
					1
					1
			2		1
				1	1
					1
			1	1	1
				2	2
			1		1
				1	1
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rheumatic disorder	1	1
Rheumatoid arthritis	5	10
Rheumatoid factor increased		1
Rhinitis	1	1
Rhinorrhoea	10	23
Rotator cuff syndrome	1	2
Salivary gland pain	1	1
Salivary hypersecretion		1
SARS-CoV-2 antibody test negative		7
SARS-CoV-2 test positive	3	11
Scar	1	1
Scarlet fever	1	1
Sciatica	1	2
Scratch		1
Seasonal allergy	2	2
Second primary malignancy		1
Sedation complication	1	1
Seizure	8	14
Sensation of foreign body	1	1
Sensitive skin	1	2
Sensory disturbance	2	3
Sensory loss	2	2
Sepsis	1	1
Serotonin syndrome		1
Shock		1
Shock symptom	1	1
Sialoadenitis	1	1
Sigmoidoscopy abnormal	1	1
Sinus disorder		1
Sinus headache	1	10
Sinusitis	1	3
Sinus pain	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				5	10
					1
				1	1
		2	7	8	16
				1	2
				1	1
			1		
			7		
		1	3	2	8
		1	1		
				1	1
		1	1		1
					1
		1	1	1	1
					1
				1	1
				8	14
				1	1
				1	2
		1	1	1	2
		1	1	1	1
				1	1
					1
				1	1
				1	1
					1
			3	1	7
			1	1	2
			1	2	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus tachycardia		1
Skin abrasion	1	2
Skin burning sensation		2
Skin discolouration		1
Skin disorder	1	2
Skin exfoliation	2	3
Skin irritation	1	5
Skin lesion	2	3
Skin odour abnormal		1
Skin reaction	1	3
Skin sensitisation	1	1
Skin swelling		2
Skin temperature	1	1
Skin tightness	1	2
Skin warm	1	4
Sleep apnoea syndrome	1	1
Sleep disorder	8	17
Sluggishness	1	3
Sneezing	1	8
Soft tissue swelling	1	1
Somnolence	4	27
Speech disorder	2	4
Spinal fracture	1	1
Spinal pain	2	3
Status epilepticus		2
Stomatitis	3	6
Stress		1
Stridor		2
Sudden death	1	1
Suicide attempt	1	1
Sunburn		1
Supraventricular tachycardia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		
			1		1
				1	2
		2	2		1
			1	1	4
		2	3		
			1		
		1	3		
		1	1		
					2
				1	1
		1	2		
				1	4
				1	1
		4	9	4	8
				1	3
			4	1	4
				1	1
			5	4	22
		1	1	1	3
				1	1
				2	3
					2
			2	3	4
			1		
					2
				1	1
				1	1
					1
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Suspected COVID-19	5	33
Sweating fever	3	5
Swelling	22	53
Swelling face	10	30
Swelling of eyelid	2	3
Swollen tongue	6	19
Syncope	15	71
Synovial cyst	1	1
Synovial rupture		1
Tachycardia	7	33
Tachypnoea	1	4
Taste disorder	4	9
Teething		1
Temperature difference of extremities	1	1
Temperature regulation disorder	2	3
TEMPI syndrome		1
Tenderness	7	14
Tension		1
Tension headache	5	17
Testicular pain	2	2
Therapeutic response unexpected	1	2
Thinking abnormal	1	1
Thirst	3	7
Throat clearing		1
Throat irritation		8
Throat tightness	2	11
Thrombocytopenia	3	5
Thrombophlebitis superficial		1
Thrombosis	7	9
Thrombotic stroke	1	1
Tinnitus	16	28
Tongue blistering	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	17	2	16
				3	5
		7	23	15	30
		6	16	4	14
			1	2	2
		2	6	4	13
				15	71
				1	1
			1		
		4	15	3	18
		1	1		3
		2	5	2	4
			1		
				1	1
		1	2	1	1
					1
		3	10	4	4
			1		
		1	8	4	9
				2	2
			1	1	1
				1	1
		1	2	2	5
					1
			6		2
		1	3	1	8
				3	5
					1
				7	9
				1	1
		2	5	14	23
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue discolouration	1	1
Tongue discomfort		1
Tongue disorder		2
Tongue eruption		1
Tongue erythema		1
Tongue haemorrhage	1	1
Tongue pruritus		1
Tongue ulceration	1	1
Tonic clonic movements		1
Tonsillar hypertrophy	2	4
Tonsillitis	1	2
Toothache	1	3
Tooth disorder		1
Tooth erosion	1	1
Toxicity to various agents	1	1
Transient global amnesia	1	1
Transient ischaemic attack	5	9
Tremor	19	60
Triple negative breast cancer	1	1
Trismus	1	2
Type I hypersensitivity		1
Ulcerative keratitis		1
Ulnar nerve injury		2
Underdose	1	6
Unresponsive to stimuli	1	5
Upper-airway cough syndrome		1
Upper respiratory tract infection	1	1
Urinary bladder haemorrhage	1	1
Urinary incontinence	1	5
Urinary retention	1	4
Urinary tract infection	5	15
Urine odour abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			2		
					1
					1
		1	1		
					1
				1	1
					1
		1	2	1	2
				1	2
				1	3
			1		
		1	1		
				1	1
				1	1
				5	9
		8	20	11	40
				1	1
				1	2
					1
					1
					2
		1	6		
				1	5
			1		
				1	1
				1	1
			1	1	4
				1	4
				5	15
			1		

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\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urticaria	9	27
Urticaria chronic		1
Uveitis	1	1
Vaccination error		1
Vaccination failure	1	2
Vaccination site bruising	2	7
Vaccination site cellulitis		3
Vaccination site coldness	1	1
Vaccination site cyst		1
Vaccination site discomfort		4
Vaccination site dryness		1
Vaccination site erythema	12	43
Vaccination site haemorrhage		3
Vaccination site hypoaesthesia	1	2
Vaccination site induration	1	3
Vaccination site infection		1
Vaccination site inflammation	3	5
Vaccination site joint discomfort		1
Vaccination site joint movement impairment		3
Vaccination site lymphadenopathy		1
Vaccination site mass	5	21
Vaccination site movement impairment	4	7
Vaccination site nodule		1
Vaccination site oedema		1
Vaccination site pain	73	214
Vaccination site paraesthesia		4
Vaccination site pruritus	5	19
Vaccination site rash	5	15
Vaccination site reaction	1	3
Vaccination site scab		2
Vaccination site swelling	16	56
Vaccination site urticaria		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	16	1	11
					1
				1	1
			1		
		1	1		1
		2	5		2
			1		2
				1	1
					1
			2		2
			1		
		6	28	6	15
					3
			1	1	1
		1	3		
			1		
		2	4	1	1
			1		
			1		2
					1
		2	12	3	9
		3	4	1	3
					1
					1
		39	135	34	79
			3		1
		3	11	2	8
		3	7	2	8
		1	3		
					2
		10	35	6	21
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site vesicles		1
Vaccination site warmth	7	23
Vaccine breakthrough infection	5	5
Vaginal haemorrhage	2	5
Vasculitis	4	5
Vasodilatation	1	1
Vertigo	18	36
Vertigo positional	3	4
Vestibular disorder		1
Vestibular neuronitis		2
Viral infection		1
Viral rash	1	2
Viral tonsillitis		1
Vision blurred	13	34
Visual acuity reduced	2	3
Visual field defect	1	1
Visual impairment	7	11
Vitamin D deficiency		1
Vitreous detachment	1	2
Vomiting	35	88
Vomiting projectile	1	2
Vulval haemorrhage	1	1
Vulvovaginal candidiasis		1
Vulvovaginal pain		1
Vulvovaginal ulceration		1
Weight decreased	1	1
Weight loss poor	1	1
Wheezing	2	14
White blood cell count decreased		1
Wrong product administered		1
Wrong technique in product usage process		3
	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		5	13	2	10
				5	5
		1	2	1	3
		3	3	1	2
				1	1
		5	9	13	27
				3	4
					1
					2
			1		
				1	2
					1
		3	12	10	22
		1	1	1	2
				1	1
		2	4	5	7
					1
				1	2
		11	31	24	57
				1	2
					1
					1
				1	1
				1	1
			4	2	10
					1
			1		
			3		
		1	7		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	3,985	11,119	1	1	1401	4366	2584	6753

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**UNITED STATES**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Allergy to vaccine		1		1			
Anaphylactic reaction	2	3		1	2	2	
Anaphylactic shock	1	1			1	1	
Aphasia	2	2	1	1	1	1	
Arthralgia	1	1	1	1			
Asthenia	1	1			1	1	
Asthma	1	1	1	1			
Autism spectrum disorder	1	1			1	1	
Back pain	1	1	1	1			
Balance disorder	1	1	1	1			
Basal ganglia infarction	1	1			1	1	
Blood glucose increased		1		1			
Blood lactic acid increased	1	1			1	1	
Body temperature increased	2	2	2	2			
Burning sensation	2	2	2	2			
Cerebral palsy	1	1			1	1	
Cerebrovascular accident	1	1			1	1	
Chest discomfort	1	1	1	1			
Chills	8	10	8	10			
Circumstance or information capable of leading to medication error		1		1			
Cough	1	1			1	1	
COVID-19	4	4	2	2	2	2	
Death	2	2			2	2	
Diarrhoea	2	2	1	1	1	1	
Disorientation	1	1	1	1			
Dizziness	4	8	2	5	2	3	
Drug ineffective	2	2			2	2	
Dry mouth		1		1			
Ductus arteriosus premature closure		1					1
Dyskinesia	1	1	1	1			
Dysphagia	1	1	1	1			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysstasia	1	1			1	1
Erythema	1	1			1	1
Exposure during pregnancy		1		1		
Exposure to SARS-CoV-2	1	1	1	1		
Exposure via breast milk	5	43	3	40	2	3
Eye irritation	1	1	1	1		
Eye pain	1	2	1	2		
Eye swelling		1		1		
Facial paralysis	2	2			2	2
Facial spasm	1	1			1	1
Fatigue	6	10	6	10		
Feeling abnormal	2	2	2	2		
Fever neonatal	2	2			2	2
Gastrointestinal tract irritation	1	1	1	1		
Headache	7	12	6	9	1	3
Heart rate increased	1	2	1	2		
Hyperglycaemia	1	1			1	1
Hyperhidrosis	1	2	1	1		1
Hypersensitivity	2	2			2	2
Hyperventilation	1	1	1	1		
Hypotension	1	1			1	1
Hypotonia	1	1	1	1		
Illness	1	2	1	1		1
Incoherent	1	1			1	1
Increased appetite		1		1		
Infantile vomiting		2		2		
Infant irritability	1	4		3	1	1
Influenza like illness	1	1	1	1		
Injection site pain		1		1		
Injury	1	1	1	1		
Insomnia	2	3	2	3		
Irritability	1	1	1	1		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic cerebral infarction	1	1			1	1
Kidney infection	1	1			1	1
Lethargy		2		2		
Ligament rupture	1	1			1	1
Limb discomfort	1	1	1	1		
Loss of consciousness	4	7			4	7
Lymphadenitis	1	1	1	1		
Malaise	2	3	2	2		1
Maternal exposure during pregnancy		1				1
Migraine	1	1	1	1		
Mobility decreased	1	1			1	1
Motor dysfunction	1	1			1	1
Muscle contractions involuntary	1	1	1	1		
Muscle twitching	3	3	3	3		
Musculoskeletal discomfort	1	1	1	1		
Myalgia	3	3	3	3		
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	3	5	3	3		2
Neutropenia neonatal		1				1
Ocular hyperaemia	1	1	1	1		
Off label use	4	8	4	8		
Oropharyngeal pain	4	4	4	4		
Oxygen saturation abnormal	1	1	1	1		
Pain	2	7	2	6		1
Pain in extremity	3	4	3	4		
Pallor		1				1
Paraesthesia	2	2	1	1	1	1
Paranasal sinus discomfort	1	1	1	1		
Periorbital swelling		1		1		
Piloerection	1	1	1	1		
Poor feeding infant		1		1		

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\* AE=Adverse Event

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	1	1	1	1		
Product administered to patient of inappropriate age	8	18	8	18		
Productive cough	1	1	1	1		
Product use issue	1	2	1	2		
Pulmonary arterial pressure abnormal		1				1
Pyrexia	10	18	9	16	1	2
Rash	2	4	2	4		
Rash neonatal	1	1	1	1		
Rhinorrhoea	2	2	2	2		
Seizure	2	5			2	5
Sensitive skin	1	1	1	1		
Sneezing	1	1	1	1		
Somnolence	2	3	1	2	1	1
Syncope	2	2			2	2
Tinnitus	1	1			1	1
Tonsillar inflammation	1	1	1	1		
Tremor	4	4	4	4		
Trismus	1	1			1	1
Urinary tract infection	1	1			1	1
Urticaria	3	3	1	1	2	2
Vaccination site pain	1	1	1	1		
Ventricular hypertrophy		1				1
Vision blurred	1	2			1	2
Vomiting	4	5	2	2	2	3
Wheezing	1	1			1	1
White blood cell count increased	1	1			1	1
Wrong product administered		1		1		
	192	318	130	231	62	87

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	3	17			3	17		
Abdominal distension		3				2		1
Abdominal pain	5	30			3	25	2	5
Abdominal pain lower		1				1		
Abdominal pain upper	6	32			5	30	1	2
Abdominal rigidity		1				1		
Abnormal behaviour		1						1
Abnormal dreams		1				1		
Abortion missed		1						1
Abortion spontaneous	1	7					1	7
Accident	1	1					1	1
Accidental exposure to product		1				1		
Accidental overdose		2				1		1
Acne		1						1
Acoustic neuritis		1				1		
Administration site reaction		1				1		
Ageusia	6	19			6	16		3
Agitation		1				1		
Alanine aminotransferase increased		2				2		
Albumin globulin ratio decreased		1				1		
Allergy to vaccine	1	7			1	6		1
Alopecia		3				3		
Alopecia areata		1				1		
Altered state of consciousness		1						1
Amnesia		1						1
Anaphylactic reaction	5	32					5	32
Anaphylactic shock	2	3					2	3
Anaphylactoid reaction		1						1
Anger		1						1
Angina pectoris		1						1
Angioedema		6						6
Anosmia	5	19			5	17		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Antibody test negative		1
Anxiety	5	17
Aphasia	1	3
Aphonia	1	1
Aphthous ulcer		1
Appendicitis	4	5
Arrhythmia		7
Arthralgia	9	143
Arthritis		4
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased		2
Asthenia	19	103
Asthenopia	1	2
Asthma	5	6
Asymptomatic COVID-19	1	2
Ataxia	1	1
Atelectasis		1
Atrial fibrillation	1	1
Autoimmune disorder	1	1
Autoscopy		1
Axillary mass	1	2
Axillary pain	3	20
Back pain	5	50
Balance disorder	1	5
Basedow's disease	1	1
Bladder pain		1
Blepharospasm		2
Blindness	3	4
Blindness transient		1
Blister	3	5
Blood bilirubin increased		1
Blood creatine increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		5	15		2
			1	1	2
		1	1		
			1		
				4	5
					7
1	1	8	139	1	4
			4		
			1		
			2		
		16	89	3	14
		1	2		
		3	3	2	3
				1	2
				1	1
					1
				1	1
			1		
		1	2		
		3	20		
		5	46		4
		1	4		1
				1	1
			1		
			2		
				3	4
					1
		1	2	2	3
			1		
			1		

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood creatine phosphokinase increased		1
Blood glucose decreased	1	1
Blood glucose increased		1
Blood lactic acid increased		1
Blood potassium decreased		1
Blood potassium increased		1
Blood pressure abnormal		2
Blood pressure decreased	1	6
Blood pressure fluctuation		1
Blood pressure increased	4	16
Blood pressure systolic increased		1
Blood sodium decreased	1	2
Blood urine present	1	1
Body temperature abnormal		2
Body temperature decreased	2	3
Body temperature fluctuation	1	2
Body temperature increased		8
Bone pain	5	8
Brain death		1
Breast mass	1	2
Breast pain	1	2
Breast swelling	1	1
Bronchitis		1
Bronchospasm		2
Burning sensation	3	10
Cardiac disorder	1	4
Cardiac flutter	2	3
Cardiac murmur		1
Cardiomyopathy		1
Cardiovascular disorder	1	1
Carotid artery occlusion	1	1
Cerebral venous sinus thrombosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		
			1		
			1		
			1		
			2		
			5	1	1
					1
		3	9	1	7
					1
			1	1	1
			1		1
			2	3	
		1	2		
			8		
		5	8		
					1
		1	2		
		1	2		
		1	1		
			1		
					2
		3	9		1
		1	2		2
				2	3
					1
					1
		1	1		
				1	1
				1	1

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrovascular accident		3
Cerumen impaction	1	1
Chest discomfort	6	39
Chest pain	13	56
Chills	59	495
Choking sensation		1
Cholelithiasis	1	1
Chromaturia		3
Circulatory collapse		1
Circumstance or information capable of leading to medication error	2	3
Clonus	1	1
Coagulation time prolonged		1
Cognitive disorder		1
Cold sweat	1	17
Cold urticaria		1
Colitis	1	1
Communication disorder		1
Concussion		2
Condition aggravated	4	21
Confusional state	2	10
Conjunctivitis		1
Constipation		4
Contusion	1	6
Coombs negative haemolytic anaemia		1
Costochondritis		1
Costovertebral angle tenderness		1
Cough	10	58
COVID-19	44	100
C-reactive protein increased		1
Crying		2
Cyanosis	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	1		
		2	19	4	20
		8	41	5	15
		55	479	4	16
					1
				1	1
			3		
					1
		2	3		
		1	1		
			1		
					1
		1	15		2
			1		
		1	1		
					1
					2
		4	19		2
			6	2	4
			1		
			3		1
		1	5		1
					1
			1		
			1		
		6	43	4	15
		19	39	25	61
					1
			1		1
		1	2	1	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deafness	2	3
Deafness neurosensory	1	1
Deafness transitory		1
Deafness unilateral	1	1
Death	1	4
Decreased appetite	4	26
Deep vein thrombosis	4	6
Defaecation urgency		1
Dehydration	5	18
Delirium	1	3
Demyelinating polyneuropathy		1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness		1
Depressed mood	1	3
Depression		1
Device breakage		1
Diabetes mellitus		1
Diaphragmatic paralysis		1
Diarrhoea	7	78
Diplegia	1	1
Discomfort	3	18
Disease recurrence	1	5
Disorientation	2	8
Disturbance in attention	1	5
Disturbance in social behaviour		1
Dizziness	39	240
Dizziness postural	2	6
Drug hypersensitivity	1	3
Drug ineffective	17	74
Dry eye		1
Dry mouth	2	11
Dry skin		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
				1	1
					1
				1	1
				1	4
		4	23		3
				4	6
			1		
		1	11	4	7
				1	3
					1
			1		
					1
		1	3		
					1
					1
					1
		7	73		5
				1	1
		3	14		4
			3	1	2
		1	7	1	1
		1	5		
			1		
		31	200	8	40
		2	4		2
		1	2		1
				17	74
			1		
		2	11		
			2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry throat	2	11
Dysaesthesia	1	1
Dysarthria		2
Dysgeusia	4	14
Dyskinesia		1
Dysmenorrhoea	3	3
Dyspepsia	1	4
Dysphagia	3	19
Dysphemia		3
Dysphonia		10
Dyspnoea	28	119
Dysstasia	1	5
Dystonia	4	4
Dysuria		2
Ear congestion	1	1
Ear discomfort	4	10
Ear disorder		1
Ear infection	1	2
Ear pain	3	8
Ear swelling		3
Eating disorder		1
Ejection fraction abnormal		1
Electrocardiogram abnormal		1
Electrocardiogram QT prolonged		2
Electrocardiogram T wave peaked		1
Emotional disorder		1
Enlarged uvula		1
Eosinophil count increased		1
Epistaxis	1	5
Eructation		1
Erythema	11	40
Euphoric mood	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	9		2
		1	1		
			1		1
		4	12		2
					1
		3	3		
		1	4		
		2	9	1	10
			3		
			5		5
		16	71	12	48
			2	1	3
		1	1	3	3
			2		
		1	1		
		3	9	1	1
			1		
		1	1		1
		3	8		
			2		1
			1		
			1		
					1
					2
			1		
			1		
					1
		1	4		1
			1		
		8	34	3	6
		1	1		

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\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Expired product administered	1	1
Exposure during pregnancy	1	8
Exposure to SARS-CoV-2	2	7
Extraocular muscle paresis	1	1
Eye discharge	1	2
Eye disorder	2	4
Eye infection		1
Eye irritation		1
Eyelid disorder	1	1
Eyelid ptosis	1	2
Eye movement disorder		1
Eye pain		9
Eye pruritus		4
Eye swelling	5	15
Face injury	1	3
Face oedema		2
Facial neuralgia		1
Facial pain		6
Facial paralysis	7	22
Facial paresis	1	3
Facial spasm		2
Factor V Leiden mutation	1	1
Faeces discoloured		1
Faeces soft		1
Fall	5	9
Fatigue	70	458
Fear		2
Fear of injection	1	1
Feeding disorder	1	3
Feeling abnormal	17	53
Feeling cold	3	19
Feeling drunk		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	7		1
		2	6		1
				1	1
		1	2		
		2	4		
			1		
			1		
				1	1
				1	2
			1		
			8		1
			3		1
		2	11	3	4
			1	1	2
			1		1
					1
			5		1
				7	22
		1	1		2
			1		1
				1	1
			1		
		3	5	2	4
		65	445	5	13
			1		1
		1	1		
			2	1	1
		12	42	5	11
		3	17		2
			2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling hot	8	43
Feeling jittery		2
Feeling of body temperature change	1	4
Fibrin D dimer increased		1
Flank pain		1
Flatulence		1
Fluid imbalance		1
Flushing	1	29
Foaming at mouth	1	1
Foetal death		1
Foetal hypokinesia	1	1
Foreign body in throat	1	1
Foreign body sensation in eyes		1
Formication		1
Full blood count abnormal		2
Gait disturbance		5
Gait inability		3
Gastroenteritis viral	1	2
Gastrointestinal disorder	2	3
Gastrointestinal inflammation		1
Gastrointestinal injury	1	1
Gastroesophageal reflux disease		2
Generalised anxiety disorder		1
Generalised tonic-clonic seizure	1	3
Genital herpes	1	1
Gingival blister		1
Gingival discolouration		1
Gingival discomfort		1
Gingival pain		2
Gingival ulceration		1
Glassy eyes		1
Grunting		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	34	3	9
			2		
		1	4		
			1		
			1		
					1
		1	20		9
		1	1		
					1
				1	1
				1	1
			1		
			1		
			2		
			4		1
			2		1
		1	2		
		2	3		
			1		
		1	1		
			2		
			1		
				1	3
				1	1
			1		
					1
					1
					2
			1		
			1		
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematemesis	3	3
Haematochezia	5	7
Haemoglobin decreased		1
Haemoptysis	1	1
Haemorrhage	2	4
Haemorrhagic stroke		1
Hallucination	1	3
Hallucination, auditory	1	1
Hallucination, visual		1
Hangover		2
Headache	81	587
Head discomfort	3	5
Head injury	3	7
Heart injury	1	1
Heart rate decreased		1
Heart rate increased	5	70
Heart rate irregular	1	3
Hemiparesis	2	3
Hepatic enzyme increased	3	3
Herpes simplex	1	2
Herpes zoster	1	8
Hot flush	2	20
Hunger		1
Hyperacusis		2
Hyperaemia		1
Hyperaesthesia		3
Hyperglycaemia		1
Hyperhidrosis	11	69
Hyperpyrexia		3
Hypersensitivity	16	28
Hypersomnia	1	7
Hypertension		13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
				5	7
					1
		1	1		
			1	2	3
					1
				1	3
				1	1
					1
			2		
		71	560	10	27
		3	5		
		1	1	2	6
				1	1
			1		
		2	52	3	18
		1	2		1
		1	1	1	2
		1	1	2	2
		1	2		
		1	6		2
		2	18		2
			1		
			2		
			1		
			3		
			1		
		9	62	2	7
					3
		10	19	6	9
		1	7		
			8		5

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperthermia		1
Hyperthyroidism	1	1
Hyperventilation		5
Hypoacusis	2	2
Hypoaesthesia	11	81
Hypoaesthesia oral	4	13
Hypoglycaemia	1	4
Hypokalaemia		1
Hypopnoea		2
Hyporesponsive to stimuli		1
Hypotension	2	16
Hypothermia		1
Illness	7	25
Immune thrombocytopenia		3
Immunisation	1	1
Immunisation reaction	1	1
Impaired work ability		1
Inappropriate schedule of product administration	5	70
Incoherent	1	1
Incorrect dose administered	1	2
Incorrect route of product administration	2	5
Induration		1
Infection	2	2
Infectious mononucleosis	1	1
Inflammation	2	9
Influenza		5
Influenza like illness	8	30
Injected limb mobility decreased		1
Injection site erythema	1	6
Injection site pain	1	10
Injection site pruritus	1	2
Injection site rash		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			3		2
		2	2		
		6	60	5	21
		2	9	2	4
			2	1	2
					1
			2		
			1		
		2	8		8
					1
		6	18	1	7
					3
		1	1		
				1	1
			1		
		5	70		
		1	1		
		1	2		
		2	4		1
			1		
		1	1	1	1
				1	1
		2	7		2
			4		1
		5	26	3	4
			1		
		1	6		
		1	10		
		1	2		
			2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site reaction		1
Injection site swelling	1	3
Injection site urticaria		1
Injury		1
Insomnia	4	24
Inspiratory capacity decreased		1
Intracranial aneurysm		2
Intracranial pressure increased	1	1
Intranasal paraesthesia		1
Iron deficiency	1	1
Irritability	1	2
Irritable bowel syndrome	1	2
Jaundice	1	2
Joint dislocation		1
Joint injury	2	2
Joint instability		1
Joint range of motion decreased	1	11
Joint stiffness	1	4
Joint swelling		2
Keratitis		1
Kidney infection	1	2
Lack of spontaneous speech	1	1
Lacrimal disorder		1
Lacrimation decreased		1
Lacrimation increased		1
Lactic acidosis		1
Laryngeal oedema		1
Lethargy	4	17
Ligament injury		1
Limb discomfort	1	8
Limb injury	1	1
Limb mass	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	3		
			1		
					1
		3	21	1	3
			1		
					2
				1	1
			1		
		1	1		
		1	2		
		1	2		
				1	2
					1
		1	1	1	1
					1
			8	1	3
		1	4		
			1		1
			1		
				1	2
				1	1
			1		
			1		
					1
					1
		1	14	3	3
			1		
		1	7		1
		1	1		
		2	3		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lipase decreased		1
Lipase increased	1	1
Lip blister		1
Lip disorder	1	1
Lip dry		1
Lip erythema		1
Lip oedema		2
Lip swelling	3	17
Lip ulceration		1
Liver function test abnormal		1
Localised infection		1
Localised oedema	1	1
Loss of consciousness	22	49
Loss of personal independence in daily activities	4	10
Lower respiratory tract infection		1
Lung disorder		1
Lymphadenitis		1
Lymphadenopathy	16	149
Lymph node pain	3	27
Lymph node palpable		2
Lymphocyte count decreased		1
Macule		1
Malaise	18	104
Mass	1	5
Maternal exposure during pregnancy	6	21
Medication error	1	1
Melaena	1	1
Meniere's disease	1	1
Meningism		1
Meningitis noninfective		1
Menorrhagia	4	4
Menstrual disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			1		
		1	1		
			1		
			1		
			1		1
		1	11	2	6
			1		
					1
			1		
		1	1		
			1	22	48
		2	7	2	3
					1
			1		
			1		
		12	138	4	11
		2	26	1	1
			2		
			1		
			1		
		15	97	3	7
		1	5		
		6	21		
		1	1		
				1	1
				1	1
			1		
					1
		4	4		
		1	3		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Menstruation irregular		1
Mental impairment		6
Metabolic encephalopathy		1
Metabolic function test abnormal		1
Metamorphopsia		1
Metrorrhagia		1
Micturition disorder		1
Micturition urgency		1
Middle insomnia	1	3
Migraine	9	51
Migraine with aura		1
Mobility decreased	3	8
Monoplegia		2
Mood swings	1	2
Motion sickness		2
Motor dysfunction		1
Mouth swelling		3
Mouth ulceration		2
Movement disorder		3
Mucosal disorder		1
Muscle contractions involuntary	1	1
Muscle discomfort		1
Muscle disorder		2
Muscle fatigue	1	3
Muscle spasms	7	20
Muscle swelling		1
Muscle tightness	1	8
Muscle twitching	2	6
Muscular weakness	6	26
Musculoskeletal chest pain	1	5
Musculoskeletal discomfort	1	4
Musculoskeletal disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					6
			1		1
					1
			1		1
			1		1
		1	3		
		7	46	2	5
			1		
		2	6	1	2
					2
		1	1		1
			2		
			1		
			3		
			2		
			3		
			1		
		1	1		
			1		
			2		
		1	3		
		6	17	1	3
			1		
			7	1	1
		2	6		
		5	20	1	6
			4	1	1
			3	1	1
			2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal pain	1	3
Musculoskeletal stiffness	2	19
Myalgia	18	227
Mydriasis	1	1
Myocardial infarction	1	2
Myocardial necrosis marker increased	1	2
Myocardial strain	1	1
Myocarditis	2	5
Myoclonus		1
Narcolepsy		1
Nasal congestion	8	34
Nasal discomfort		2
Nasal dryness		2
Nasal injury		2
Nasal oedema		3
Nasal pruritus		1
Nasopharyngitis	6	18
Nausea	46	367
Near death experience		1
Neck mass		1
Neck pain	4	34
Neoplasm		1
Nephropathy		1
Nerve injury	1	2
Nervousness	2	8
Neuralgia	1	7
Neuralgic amyotrophy		1
Neurological symptom	1	2
Neuropathy peripheral		1
Neutrophil count increased		1
Nightmare		2
Night sweats	1	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
		2	18		1
		16	218	2	9
		1	1		
		1	1		1
				1	2
				1	1
				2	5
					1
					1
		6	30	2	4
			2		
			2		
			2		
			1		2
			1		
		6	18		
		39	344	7	23
					1
			1		
		3	27	1	7
			1		
			1		
				1	2
		1	7	1	1
			6	1	1
					1
				1	2
					1
			2		
		1	14		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nipple pain		1
Nodule	3	3
Noninfective encephalitis		1
Occipital neuralgia		1
Ocular discomfort	1	3
Ocular hyperaemia	1	5
Odynophagia	1	2
Oedema mouth		1
Oedema peripheral		1
Oesophagitis	1	1
Off label use	6	46
Optic neuritis	1	1
Oral discomfort	1	3
Oral disorder	1	3
Oral herpes	1	3
Oral mucosal eruption		1
Oral pain	1	3
Oral pruritus		2
Orbital oedema	1	1
Oropharyngeal discomfort	2	6
Oropharyngeal pain	7	48
Orthostatic intolerance	1	1
Otitis media	1	1
Overdose	3	11
Oxygen saturation decreased		1
Pain	54	401
Painful respiration	1	2
Pain in extremity	45	225
Pain in jaw	1	5
Pain of skin		2
Palatal swelling		1
Pallor	6	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1	2	2
					1
			1		
		1	2		1
			3	1	2
		1	1		1
					1
			1		
		1	1		
		6	44		2
				1	1
		1	3		
		1	3		
		1	3		
			1		
		1	2		1
			1		1
				1	1
		2	5		1
		7	42		6
		1	1		
		1	1		
		3	11		
					1
		47	376	7	25
		1	2		
1	1	43	218	2	7
		1	5		
			2		
			1		
		4	6	2	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations	6	45
Pancreatitis	1	1
Panic attack		2
Panic disorder	1	1
Panic reaction		1
Paraesthesia	10	80
Paraesthesia oral	1	11
Paralysis		2
Paranasal sinus discomfort	2	6
Paranoia	1	1
Parosmia		1
Periarthritis		1
Pericardial effusion		1
Pericarditis	1	3
Periorbital swelling	1	3
Peripheral coldness		4
Peripheral swelling	9	29
Peripheral venous disease	1	1
Petechiae		2
Pharyngeal enanthema		1
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia	1	3
Pharyngeal oedema	1	2
Pharyngeal paraesthesia		4
Pharyngeal swelling	3	21
Pharyngeal ulceration		1
Phlebitis superficial	1	1
Photophobia		3
Photopsia		1
Photosensitivity reaction		3
Phrenic nerve injury		1
Piloerection		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	33	2	12
				1	1
			2		
		1	1		
			1		
		7	62	3	18
			9	1	2
					2
		2	6		
		1	1		
			1		
					1
					1
				1	3
			2	1	1
			3		1
		7	26	2	3
				1	1
			1		1
			1		
			2	1	1
		1	1		1
			4		
			11	3	10
			1		
		1	1		
			3		
			1		
			3		
					1
			3		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pityriasis		1
Pityriasis rosea		1
Platelet count decreased	2	4
Platelet count increased		2
Platelet disorder	1	1
Pleural effusion		1
Pleurisy		1
Pleuritic pain		1
Pneumonia	3	4
Pneumonitis		2
Pollakiuria		3
Polyserositis		1
Polyuria		1
Poor quality product administered	4	6
Poor quality sleep	1	3
Postictal state		1
Postural orthostatic tachycardia syndrome		
Premature delivery		1
Premature labour		1
Premature rupture of membranes		1
Presyncope	5	21
Procedural pain		1
Product administered at inappropriate site	2	9
Product administration error		2
Product formulation issue		1
Productive cough	1	2
Product preparation error		5
Product preparation issue	1	2
Product prescribing error		1
Product temperature excursion issue	4	5
Product use issue	3	35
Protein urine present	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	2	1	2
					2
				1	1
			1		
			1		1
				3	4
					2
			3		
					1
			1		
		4	6		
		1	3		
			1		
1	1				
					1
					1
					1
		4	18	1	3
					1
		2	8		1
			1		1
					1
			1	1	1
			5		
		1	1		1
			1		
		4	5		
		3	33		2
		1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pruritus	15	76
Psychotic disorder	1	1
Pulmonary embolism	4	6
Pulmonary infarction		1
Pulmonary pain	1	5
Pulmonary thrombosis	2	2
Pulse absent		1
Pupil fixed	1	1
Purpura	1	1
Pyrexia	69	527
Rash	19	98
Rash erythematous	2	13
Rash macular	2	8
Rash maculo-papular		2
Rash morbilliform	1	3
Rash papular	1	6
Rash pruritic	4	17
Reaction to excipient		1
Renal pain		1
Respiration abnormal		1
Respiratory disorder		4
Respiratory distress		6
Respiratory symptom		1
Respiratory tract congestion	2	4
Respiratory tract irritation		1
Restless legs syndrome	1	1
Restlessness	2	7
Retching		4
Retinal vein occlusion	1	1
Rhabdomyolysis	1	1
Rheumatoid arthritis	1	1
Rhinalgia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		11	61	4	15
				1	1
				4	6
					1
		1	5		
				2	2
					1
				1	1
		1	1		
		59	495	10	32
		14	79	5	19
		2	10		3
		1	6	1	2
			2		
		1	1		2
		1	6		
		3	15	1	2
			1		
			1		
			1		
			1		3
					6
			1		
		1	3	1	1
			1		
		1	1		
		2	6		1
			4		
				1	1
				1	1
				1	1
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinitis allergic	1	1
Rhinorrhoea	6	22
Road traffic accident	2	2
Ruptured cerebral aneurysm		1
Salivary hypersecretion	1	1
SARS-CoV-2 antibody test negative		2
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive		27
Scar		1
Schizophrenia	1	1
Sciatica		1
Seasonal allergy	1	2
Secretion discharge	1	1
Seizure	13	22
Seizure like phenomena	1	1
Sensation of blood flow		1
Sensation of foreign body		5
Sensitive skin	1	3
Sensory disturbance	1	1
Shock		2
Shock symptom		1
Shoulder injury related to vaccine administration		1
Sinus congestion	1	5
Sinus headache	1	2
Sinusitis	4	6
Sinus rhythm		1
Sinus tachycardia		3
Skin burning sensation		4
Skin discolouration	1	3
Skin discomfort		1
Skin disorder		5
Skin exfoliation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		6	21		1
				2	2
					1
		1	1		
			2		
			1		
			4		23
			1		
				1	1
					1
		1	2		
		1	1		
				13	22
				1	1
					1
			2		3
		1	3		
		1	1		
					2
					1
			1		
			5		
		1	2		
		3	5	1	1
			1		
			1		2
			4		
		1	2		1
			1		
			5		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin irritation		1
Skin lesion		1
Skin swelling	1	1
Skin tightness	1	2
Sleep disorder	1	7
Slow response to stimuli		1
Slow speech		1
Sluggishness	3	3
Sneezing	2	6
Snoring		1
Somnolence	2	12
Speech disorder	1	13
Spinal pain		4
Sputum increased	1	1
Stomatitis		4
Strabismus		1
Stress		2
Subarachnoid haemorrhage		2
Subcutaneous abscess		1
Sudden visual loss	1	1
Suicidal ideation	1	1
Suicide attempt		1
Suspected COVID-19	1	2
Suture related complication		1
Swelling	10	30
Swelling face	5	20
Swelling of eyelid	2	5
Swollen tongue	4	10
Syncope	23	71
Systemic lupus erythematosus	1	1
Tachycardia	6	52
Tachypnoea		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	1		
			1	1	1
		1	7		
			1		
			1		
		2	2	1	1
		2	6		
					1
		2	12		
		1	9		4
			3		1
		1	1		
			4		
					1
			1		1
					2
			1		
				1	1
				1	1
					1
		1	1		1
					1
		8	27	2	3
		2	14	3	6
		1	3	1	2
		2	6	2	4
		1	3	22	68
				1	1
		3	31	3	21
			2		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tardive dyskinesia	1	1
Taste disorder		3
Temperature intolerance		1
Temperature regulation disorder		2
Temporomandibular joint syndrome		1
Tenderness	1	5
Tendonitis		1
Tension headache	1	4
Therapeutic product effect delayed	1	1
Thirst		5
Throat irritation	4	21
Throat tightness	7	31
Thrombocytopenia		3
Thrombophlebitis superficial	1	1
Thrombosis	6	8
Thunderclap headache		1
Thyrotoxic crisis	2	2
Tinea pedis	1	1
Tinnitus	9	15
Tongue discomfort		3
Tongue disorder		1
Tongue pruritus		1
Tonsillar hypertrophy		2
Tonsillar ulcer		1
Tonsillitis		1
Tonsillolith		1
Toothache		1
Torsade de pointes		1
Transaminases increased		1
Tremor	12	41
Trigeminal neuralgia		4
Trismus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			3		
			1		
			2		
					1
		1	5		
			1		
		1	4		
		1	1		
			5		
		1	13	3	8
		2	7	5	24
					3
				1	1
				6	8
					1
				2	2
		1	1		
		7	11	2	4
			3		
					1
			1		
			2		
			1		
			1		
			1		
					1
					1
		9	35	3	6
			1		3
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Troponin increased	2	3
Tuberculin test positive		1
Tunnel vision	2	5
Underdose	2	7
Unresponsive to stimuli	1	1
Upper-airway cough syndrome	1	4
Upper respiratory tract congestion	1	3
Urethral disorder		1
Urinary tract infection	2	3
Urine abnormality		1
Urine analysis abnormal		1
Urine odour abnormal		1
Urticaria	13	76
Use of accessory respiratory muscles		1
Uterine haemorrhage		1
Uterine pain	1	1
Vaccination failure	6	10
Vaccination site bruising	1	4
Vaccination site cellulitis		1
Vaccination site discolouration	2	2
Vaccination site discomfort		3
Vaccination site erythema	4	56
Vaccination site haemorrhage	1	5
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia	1	5
Vaccination site induration	1	10
Vaccination site infection		1
Vaccination site inflammation		4
Vaccination site injury		1
Vaccination site joint movement impairment		1
Vaccination site lymphadenopathy	1	5
Vaccination site macule		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
			1		
				2	5
		2	7		
				1	1
		1	4		
		1	3		
			1		
		1	2	1	1
			1		
			1		
		9	59	4	17
			1		
					1
				1	1
				6	10
		1	4		
					1
		2	2		
			3		
		4	55		1
		1	5		
			1		
			4	1	1
		1	10		
			1		
			3		1
			1		
					1
		1	5		
			1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site mass		7
Vaccination site movement impairment		4
Vaccination site nodule		1
Vaccination site oedema		1
Vaccination site pain	22	297
Vaccination site papule		2
Vaccination site paraesthesia		6
Vaccination site pruritus	2	20
Vaccination site rash	1	16
Vaccination site reaction	1	3
Vaccination site scab		1
Vaccination site swelling	2	61
Vaccination site urticaria		3
Vaccination site vesicles		2
Vaccination site warmth	1	18
Vaginal haemorrhage	2	4
Vaginal lesion		1
Vascular pain	1	1
Ventricular tachycardia		1
Vertigo	3	13
Viral rash		1
Vision blurred	5	11
Visual acuity reduced	1	1
Visual field defect	1	3
Visual impairment		4
Vomiting	26	131
Vulval disorder		1
Vulvovaginal pain	1	1
Weight decreased	1	1
Weight increased	1	1
Wheezing	3	8
White blood cell count decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			7		
			4		
			1		
			1		
		21	295	1	2
			2		
			6		
		2	19		1
		1	15		1
			2	1	1
			1		
		2	58		3
			3		
			2		
		1	18		
		1	2	1	2
			1		
				1	1
					1
		3	11		2
			1		
		3	6	2	5
		1	1		
			2	1	1
			3		1
		20	115	6	16
			1		
				1	1
				1	1
		1	1		
		1	2	2	6
		1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
White blood cell count increased		4				1			3
Wound	1	1			1	1			
Wrong product administered		1				1			
Wrong technique in product usage process	1	3			1	2			1
Yellow skin		1				1			
	1,628	9,093	3	3	1127	7457	501		1636

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	11	50			11	46		4
Abdominal distension	2	9			1	8	1	1
Abdominal infection	1	1					1	1
Abdominal pain	10	62			5	50	5	12
Abdominal pain lower		7				5		2
Abdominal pain upper	22	69			17	60	5	9
Abdominal rigidity		1				1		
Abnormal behaviour	2	3					2	3
Abnormal dreams	1	11				10	1	1
Abnormal faeces	1	2					1	2
Abnormal sensation in eye	1	3			1	3		
Abnormal withdrawal bleeding		1				1		
Abortion	1	1					1	1
Abortion induced		1						1
Abortion spontaneous	7	21					7	21
Accident		1				1		
Accidental exposure to product		3				3		
Accidental overdose		10				8		2
Accidental underdose		1				1		
Acetonaemia		1				1		
Acne	1	7			1	7		
Acute coronary syndrome	1	2					1	2
Acute disseminated encephalomyelitis		2						2
Acute febrile neutrophilic dermatosis	1	1					1	1
Acute myocardial infarction	2	3					2	3
Adenoma benign		1				1		
Administration site erythema		1				1		
Adrenocortical insufficiency acute		1						1
Adverse drug reaction		1				1		
Affect lability	1	1					1	1
Ageusia	10	57			10	53		4
Aggression	2	2			1	1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Agitation	2	7
Alanine aminotransferase decreased		1
Alanine aminotransferase increased		1
Allergic respiratory disease		1
Allergic sinusitis		1
Allergy test positive		1
Allergy to vaccine	2	22
Alopecia	2	5
Alopecia areata		1
Altered state of consciousness	1	1
Amnesia	3	9
Amniotic cavity infection	1	1
Anaemia		1
Anaesthesia		1
Anal incontinence		2
Anal pruritus	1	1
Anaphylactic reaction	17	93
Anaphylactic shock	4	10
Anaphylactoid reaction		3
Aneurysm ruptured		1
Angina pectoris	1	1
Angioedema	6	23
Angiopathy	1	3
Anion gap decreased		1
Anion gap increased		1
Anomalous pulmonary venous connection		1
Anosmia	8	56
Anxiety	14	84
Anxiety disorder		1
Aortic disorder	1	1
Aortitis		1
Apathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7		
					1
					1
			1		
			1		
			1		
			11	2	11
		2	5		
			1		
				1	1
		2	6	1	3
				1	1
			1		
			1		
			2		
		1	1		
		1	1	16	92
				4	10
					3
					1
				1	1
				6	23
			2	1	1
			1		
			1		
					1
		8	50		6
		12	74	2	10
					1
				1	1
					1
			1		

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aphasia	4	7
Aphonia	2	6
Aphthous ulcer	1	1
Appendicitis	4	15
Appendicitis perforated	1	1
Application site haemorrhage		1
Areflexia	1	1
Arrhythmia	6	15
Arteriosclerosis		1
Arteriospasm coronary	1	3
Arthralgia	67	496
Arthritis	1	7
Arthritis reactive	1	1
Arthropathy		3
Arthropod bite		1
Aspartate aminotransferase increased		1
Asthenia	43	240
Asthenopia	2	9
Asthma	5	26
Asymptomatic COVID-19	4	12
Atrial fibrillation	4	10
Atrioventricular block	1	1
Aura	1	2
Autoimmune disorder	3	8
Autoimmune thyroiditis		1
Autonomic nervous system imbalance		3
Axillary mass	3	13
Axillary pain	8	59
Back disorder	2	2
Back pain	34	145
Bacteraemia		1
Bacterial infection	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	4	6
		2	3		3
		1	1		
				4	15
				1	1
					1
		1	1		
				6	15
					1
				1	3
		56	462	11	34
		1	7		
				1	1
			2		1
			1		
			1		
		33	197	10	43
		2	8		1
		4	19	1	7
		1	3	3	9
				4	10
				1	1
			1	1	1
				3	8
					1
			2		1
		3	10		3
		7	56	1	3
		2	2		
		27	118	7	27
					1
		1	1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bacterial vaginosis	1	1
Bacteriuria		1
Balance disorder	11	37
Basedow's disease	1	1
Bedridden		2
Behaviour disorder		1
Bilirubin urine present		1
Binocular eye movement disorder	1	1
Blepharospasm		3
Blindness	2	6
Blindness transient	1	2
Blindness unilateral		1
Blister	6	17
Blood albumin decreased		1
Blood bilirubin increased		1
Blood calcium increased		1
Blood chloride decreased		1
Blood chloride increased		1
Blood cholesterol abnormal	2	2
Blood cholesterol increased		1
Blood chromium increased	1	1
Blood count abnormal		1
Blood creatine phosphokinase increased		1
Blood creatinine decreased		1
Blood creatinine increased		1
Blood electrolytes decreased	1	1
Blood follicle stimulating hormone increased	1	1
Blood glucose abnormal		1
Blood glucose decreased	1	7
Blood glucose increased	2	8
Blood iron decreased		2
Blood ketone body increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		7	28	4	9
				1	1
			2		
					1
			1		
				1	1
			3		
				2	6
				1	2
					1
		5	16	1	1
			1		
			1		
			1		1
		2	2		
			1		
				1	1
			1		
			1		
					1
				1	1
				1	1
			1		
			5	1	2
		1	5	1	3
			2		
					1

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Blood phosphorus decreased	1	1
Blood potassium decreased	1	4
Blood pressure abnormal	1	7
Blood pressure decreased	8	20
Blood pressure diastolic decreased		2
Blood pressure diastolic increased		2
Blood pressure fluctuation	1	3
Blood pressure increased	11	98
Blood pressure systolic increased		3
Blood test abnormal	2	2
Blood thyroid stimulating hormone increased		1
Blood urine present	1	5
Body temperature abnormal		7
Body temperature decreased	1	6
Body temperature fluctuation		2
Body temperature increased	4	30
Bone pain	8	35
Bone swelling		2
Booster dose missed		2
Bowel movement irregularity		1
Brachial plexopathy		2
Bradycardia	1	1
Bradykinesia		1
Bradyphrenia	1	2
Brain cancer metastatic	1	1
Brain injury		2
Brain stem syndrome		1
Breast discharge		1
Breast discomfort		1
Breast disorder	2	3
Breast mass	1	2
Breast pain	4	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		3
		1	5		2
		7	15	1	5
			2		
			2		
		1	3		
		5	62	6	36
			1		2
		2	2		
			1		
		1	5		
			6		1
			5	1	1
			2		
		4	28		2
		7	27	1	8
			1		1
			2		
			1		1
				1	1
			1		
		1	2		
				1	1
					2
					1
			1		
			1		
		2	3		
		1	2		
		4	15		

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast swelling	1	4
Breast tenderness	1	5
Breathing-related sleep disorder	1	1
Breath odour		2
Bronchial disorder	1	1
Bronchitis	1	3
Bronchospasm	3	12
Bruxism		1
Burning sensation	20	89
Bursitis	1	3
Butterfly rash		1
Candida infection		1
Capillary nail refill test abnormal		1
Carbon dioxide increased		1
Cardiac arrest	2	8
Cardiac discomfort	1	1
Cardiac disorder	1	4
Cardiac failure		1
Cardiac flutter	5	12
Cardiac neoplasm unspecified		1
Cardiac valve sclerosis		1
Cardiac valve vegetation		1
Cardiogenic shock		2
Cardiomyopathy		1
Cardio-respiratory arrest		2
Cardiovascular disorder		2
Carpal tunnel syndrome	1	1
Cellulitis	3	8
Cellulitis gangrenous		1
Central nervous system lesion		1
Cerebellar ataxia		1
Cerebellar stroke	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
		1	4		1
		1	1		
			2		
		1	1		
		1	3		
		1	8	2	4
			1		
		16	72	4	17
			1	1	2
			1		
			1		
			1		
				2	8
		1	1		
		1	2		2
					1
				5	12
					1
					1
					2
					1
					2
			1		1
				1	1
				3	8
					1
			1		
			1		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral disorder	2	2
Cerebral haemorrhage		2
Cerebral thrombosis	1	1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	11	26
Cervical radiculopathy	1	1
Cheilitis	1	4
Chest discomfort	27	150
Chest injury	1	2
Chest pain	28	150
Chillblains		3
Chills	156	1,183
Choking	1	4
Choking sensation		1
Cholecystitis	1	1
Cholestasis	1	2
Chromaturia		4
Chronic fatigue syndrome	1	1
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Ciliary muscle spasm		1
Circadian rhythm sleep disorder	1	1
Circulatory collapse		2
Circumstance or information capable of leading to medication error	5	15
Claustrophobia		1
Clumsiness	1	2
Cluster headache		1
Coagulopathy	1	2
Coccidioidomycosis		1
Coccydynia	1	1
Cognitive disorder		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
					2
				1	1
				1	1
				11	26
				1	1
		1	3		1
		23	111	4	39
				1	2
		13	101	15	49
			2		1
		142	1117	14	66
				1	4
					1
				1	1
				1	2
			4		
		1	1		
					1
			1		
		1	1		
					2
		5	15		
			1		
			1	1	1
			1		
				1	2
					1
		1	1		
			4		4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cold sweat	6	38
Colitis ulcerative	2	3
Coma		1
Concussion	2	3
Condition aggravated	19	71
Conductive deafness		1
Confusional state	13	37
Congestive cardiomyopathy		1
Conjunctival haemorrhage	1	1
Conjunctival irritation		1
Conjunctival oedema		1
Conjunctivitis		4
Constipation		12
Contusion	3	19
Coordination abnormal		1
Corneal oedema		1
Corneal reflex decreased		2
Costochondritis	1	1
Cough	41	184
COVID-19	105	303
COVID-19 pneumonia	1	5
Cranial nerve disorder		1
Cranial nerve paralysis		1
C-reactive protein increased		2
Crohn's disease		1
Crying	2	14
Cutaneous lupus erythematosus		1
Cyanosis	1	5
Cyst		2
Cystitis		1
Cyst rupture		1
Deafness	10	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	33	2	5
				2	3
					1
		1	2	1	1
		9	45	10	26
					1
		9	26	4	11
					1
				1	1
			1		
			1		
			4		
			12		
		1	17	2	2
					1
			1		
			1		1
				1	1
		37	147	4	37
		37	75	68	228
				1	5
					1
					1
			2		
			1		
		2	13		1
					1
			2	1	3
			2		
			1		
			1		
		1	1	9	22

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deafness bilateral	1	1
Deafness neurosensory		4
Deafness transitory	2	2
Deafness unilateral	2	6
Death	6	9
Decreased appetite	8	81
Decreased embryo viability	1	1
Decreased interest		1
Deep vein thrombosis	14	17
Defaecation urgency		1
Dehydration	3	21
Delirium	2	6
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		1
Dental paraesthesia		1
Depressed level of consciousness	1	7
Depressed mood	2	4
Depression	2	7
Dermatitis	1	4
Dermatitis acneiform		1
Dermatitis allergic		3
Dermatitis contact	1	1
Dermatitis exfoliative		1
Diabetes mellitus		2
Diabetic ketoacidosis		1
Diaphragmatic disorder		1
Diarrhoea	45	260
Diarrhoea haemorrhagic	2	4
Diffuse alopecia	1	1
Dilatation ventricular		1
Diplopia	2	5
Disability		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					4
				2	2
				2	6
				6	9
		7	78	1	3
		1	1		
			1		
				14	17
			1		
		1	16	2	5
				2	6
					1
					1
			1		
				1	7
		2	3		1
		2	5		2
			3	1	1
			1		
			2		1
		1	1		
					1
					2
					1
			1		
		39	243	6	17
				2	4
				1	1
					1
		2	4		1
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discomfort	9	44
Disease recurrence	4	27
Disorganised speech	1	1
Disorientation	9	20
Dissociation		1
Disturbance in attention	4	22
Diverticulitis	1	1
Dizziness	137	664
Dizziness exertional		2
Dizziness postural		7
Drooling	2	3
Dropped head syndrome		1
Drug eruption		1
Drug hypersensitivity		6
Drug ineffective	42	228
Drug interaction		7
Drug screen positive	1	1
Dry eye	1	5
Dry mouth	4	33
Dry skin		3
Dry throat	1	13
Duodenogastric reflux	1	2
Dysaesthesia		3
Dysarthria	2	12
Dyschromatopsia		1
Dysgeusia	11	90
Dyskinesia	3	8
Dysmenorrhoea	1	6
Dyspepsia	4	15
Dysphagia	11	54
Dysphemia		1
Dysphonia	4	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	42		2
		3	20	1	7
				1	1
		5	10	4	10
			1		
		3	18	1	4
				1	1
		102	549	35	115
			2		
			7		
		2	3		
					1
			1		
			6		
				42	228
			6		1
		1	1		
		1	5		
		2	25	2	8
			3		
		1	10		3
		1	2		
			2		1
		2	7		5
			1		
		10	86	1	4
		1	5	2	3
		1	6		
		3	13	1	2
		6	31	5	23
					1
		1	17	3	15

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea	87	342
Dyspnoea at rest	1	1
Dyspnoea exertional		13
Dysstasia	3	11
Dystonia	2	2
Dysuria		3
Ear congestion	1	2
Ear discomfort	7	26
Ear disorder	3	6
Ear infection	3	3
Ear pain	14	53
Ear pruritus	5	6
Ear swelling	1	5
Eating disorder	3	7
Eczema		2
Ejection fraction decreased	1	1
Electrocardiogram abnormal	2	7
Electrocardiogram PR shortened	1	1
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment depression	1	1
Electrocardiogram ST segment elevation	1	1
Embolism		1
Emotional disorder	1	3
Emotional distress		1
Enanthema		1
Encephalitis	1	2
Encephalopathy		1
Endocarditis		1
Endocrine ophthalmopathy	1	1
Enlarged uvula	2	5
Epicondylitis		2
Epinephrine increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		48	202	39	140
				1	1
			10		3
		2	6	1	5
				2	2
			3		
				1	2
		7	25		1
		3	6		
		2	2	1	1
		12	48	2	5
		4	5	1	1
			3	1	2
		2	5	1	2
			2		
				1	1
		2	7		
				1	1
					1
				1	1
				1	1
					1
		1	2		1
			1		
			1		
				1	2
					1
					1
				1	1
		1	3	1	2
			2		
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis	7	22
Epstein-Barr virus infection reactivation		1
Erectile dysfunction	2	6
Eructation	1	2
Erythema	10	115
Erythema marginatum		1
Erythema multiforme	1	4
Erythema of eyelid		4
Escherichia bacteraemia	1	1
Euphoric mood	1	3
Eustachian tube dysfunction	1	1
Exaggerated startle response	1	1
Excessive ocular convergence	1	1
Exercise electrocardiogram abnormal	1	1
Exercise lack of		1
Exercise tolerance decreased		1
Exposure during pregnancy	7	21
Exposure to SARS-CoV-2	7	16
Exposure via breast milk	1	1
Exposure via skin contact		2
Extensive swelling of vaccinated limb		1
Extraocular muscle paresis	1	1
Extrasystoles	2	4
Extremity contracture		1
Eye contusion	1	3
Eye discharge		2
Eye disorder	2	11
Eye haemorrhage	8	12
Eye infection		1
Eye inflammation		3
Eye irritation		16
Eyelid disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	19	2	3
					1
				2	6
			1	1	1
		7	84	3	31
			1		
				1	4
			3		1
				1	1
		1	2		1
		1	1		
		1	1		
				1	1
				1	1
			1		
			1		
		5	17	2	4
		7	13		3
		1	1		
			2		
			1		
				1	1
		2	4		
			1		
		1	3		
			2		
		1	9	1	2
				8	12
			1		
			2		1
			16		
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid irritation	1	2
Eyelid pain		4
Eyelid ptosis	1	4
Eyelid sensory disorder		1
Eyelids pruritus		3
Eye movement disorder	2	5
Eye oedema	1	4
Eye pain	7	49
Eye paraesthesia		1
Eye pruritus	5	21
Eye swelling	7	49
Face injury	1	2
Face oedema	1	2
Facet joint syndrome		1
Facial bones fracture	1	1
Facial discomfort	2	4
Facial nerve disorder		2
Facial neuralgia		1
Facial pain	6	25
Facial paralysis	35	117
Facial paresis	3	8
Faeces discoloured		1
Fall	11	31
False negative investigation result	1	1
Fasciitis		1
Fatigue	216	1,283
Fear	2	4
Fear of death	1	1
Febrile convulsion		1
Feeding disorder	3	7
Feeling abnormal	44	226
Feeling cold	13	64

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
			3		1
		1	2		2
			1		
			3		
		2	4		1
		1	4		
		7	44		5
					1
		4	17	1	4
		5	39	2	10
				1	2
			1	1	1
			1		
				1	1
		2	4		
			1		1
			1		
		4	19	2	6
			1	35	116
		3	6		2
			1		
		5	19	6	12
				1	1
					1
		196	1216	20	67
		1	3	1	1
				1	1
					1
		2	5	1	2
		38	202	6	24
		10	59	3	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling drunk	2	5
Feeling hot	30	170
Feeling jittery	2	11
Feeling of body temperature change	6	20
Fibrin D dimer increased	1	4
Fibromyalgia	1	2
Fine motor skill dysfunction		4
Fistula		1
Flank pain	1	8
Flatulence	1	6
Fluid retention	1	1
Flushing	13	116
Foetal death	2	2
Folliculitis		2
Food intolerance	1	1
Formication		5
Frequent bowel movements		1
Frustration tolerance decreased	1	1
Fungal infection		2
Gait disturbance	16	54
Gait inability	2	14
Gallbladder disorder		1
Gallbladder oedema	1	1
Gallbladder polyp		1
Gastric dilatation	1	1
Gastric disorder		1
Gastric pH decreased		1
Gastritis		4
Gastroenteritis viral		1
Gastrointestinal disorder	3	13
Gastrointestinal infection		1
Gastrointestinal pain	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3		2
		26	144	4	26
		2	9		2
		5	17	1	3
			2	1	2
		1	2		
			3		1
			1		
		1	7		1
		1	6		
		1	1		
		10	89	3	27
				2	2
			2		
		1	1		
			4		1
			1		
		1	1		
			1		1
		8	39	8	15
			6	2	8
					1
				1	1
		1	1		
			1		
			3		1
			1		
		2	12	1	1
			1		
		2	6	2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gastrointestinal sounds abnormal		3				3		
Gastrointestinal tract irritation	1	1			1	1		
Gastrointestinal viral infection		1				1		
Gastrooesophageal reflux disease	1	6			1	5		1
Generalised tonic-clonic seizure	1	2					1	2
Genital herpes		2				2		
Genital herpes simplex		2				2		
Genital lesion		1				1		
Genital ulceration		1				1		
Gingival bleeding		2				1		1
Gingival erythema		1				1		
Gingival pain		2				2		
Gingival swelling		3				3		
Glassy eyes		1				1		
Glossitis		1				1		
Glossodynia	1	9			1	8		1
Glycosylated haemoglobin increased		1						1
Gout	1	5				4	1	1
Granuloma skin		1						1
Grip strength decreased	1	3			1	3		
Groin pain		3				3		
Grunting	1	3			1	2		1
Guillain-Barre syndrome	1	10					1	10
Haematemesis	1	1					1	1
Haematochezia	4	10					4	10
Haematocrit decreased		1				1		
Haematoma	1	2			1	2		
Haematuria		1				1		
Haemoglobin decreased		4				2		2
Haemoglobin increased		1				1		
Haemolytic anaemia	1	4					1	4
Haemoptysis	2	5			1	2	1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhage	9	16
Haemorrhage subcutaneous		1
Hallucination	3	8
Hallucination, auditory		2
Hallucination, visual		2
Hand-eye coordination impaired		1
Hangover	1	5
Headache	227	1,639
Head discomfort	13	46
Head injury	4	4
Heart rate abnormal	3	9
Heart rate decreased	3	10
Heart rate increased	43	224
Heart rate irregular	5	14
Heat illness	1	1
Hemiparesis		1
Hemiplegia		3
Hepatic enzyme abnormal		1
Hepatic enzyme increased	1	2
Hepatic pain		1
Hepatomegaly		2
Herpes simplex		3
Herpes simplex reactivation		1
Herpes virus infection		3
Herpes zoster	15	46
Herpes zoster oticus	1	1
Heterophoria	1	1
Hiccups		1
Hidradenitis		1
Histamine level increased		1
HIV test false positive	1	2
HIV test negative	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				9	16
					1
				3	8
					2
					2
					1
		1	5		
		199	1523	28	116
		10	40	3	6
		1	1	3	3
		2	7	1	2
		1	5	2	5
		28	165	15	59
		4	10	1	4
		1	1		
					1
					3
					1
		1	2		
			1		
			1		1
			3		
			1		
			3		
		12	36	3	10
				1	1
				1	1
			1		
			1		
					1
		1	2		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hordeolum	1	3
Hormone level abnormal		2
Hot flush	9	62
Hunger		3
Huntington's disease	1	1
Hydrophobia		1
Hyperacusis	3	8
Hyperaesthesia	2	13
Hyperaesthesia teeth		2
Hyperbilirubinaemia	1	1
Hyperhidrosis	47	204
Hyperparathyroidism		1
Hyperpyrexia	4	4
Hypersensitivity	16	88
Hypersomnia	2	15
Hypertension	8	72
Hypertensive crisis		3
Hypertensive emergency		1
Hypertensive heart disease		1
Hypertrichosis		1
Hyperventilation		8
Hypervigilance	1	2
Hypoacusis	8	14
Hypoaesthesia	58	314
Hypoaesthesia eye	1	2
Hypoaesthesia oral	15	93
Hypocalcaemia		1
Hypogeusia		1
Hypoglycaemia		3
Hypokalaemia	1	2
Hypokinesia	3	7
Hypomagnesaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
			1		1
		7	52	2	10
			3		
		1	1		
			1		
		2	6	1	2
		2	12		1
			2		
				1	1
		40	177	7	27
			1		
				4	4
		11	50	5	38
		2	15		
		4	44	4	28
					3
					1
					1
			1		
			4		4
		1	2		
		7	13	1	1
		34	244	24	70
		1	2		
		13	70	2	23
					1
			1		
			3		
				1	2
		2	6	1	1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypopnoea		1
Hyporeflexia		1
Hyposmia		2
Hypotension	5	19
Hypothermia		1
Hypothyroidism		1
Hypotonia		1
Hypoxia	1	2
Idiopathic intracranial hypertension	1	1
Ill-defined disorder	1	1
Illness	20	59
Immune-mediated arthritis		1
Immune system disorder	4	8
Immune thrombocytopenia		6
Immunodeficiency		1
Impaired driving ability		5
Impaired gastric emptying	1	1
Impaired healing	1	1
Impaired work ability		3
Impetigo		1
Impulsive behaviour		1
Inappropriate schedule of product administration	23	170
Incoherent	1	2
Incomplete course of vaccination		3
Incorrect dose administered		5
Incorrect route of product administration	7	37
Increased appetite		1
Increased tendency to bruise		1
Increased upper airway secretion		3
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			2		
		2	11	3	8
					1
					1
			1		
				1	2
				1	1
		1	1		
		16	53	4	6
					1
		2	3	2	5
					6
					1
			4		1
				1	1
		1	1		
			2		1
			1		
			1		
		23	170		
			1	1	1
			3		
			5		
		6	36	1	1
			1		
			1		
			3		
					1
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Induration		3				3		
Infection	1	4				1	1	3
Infertility female	1	1					1	1
Inflammation	7	21			6	19	1	2
Inflammatory bowel disease		1						1
Influenza	3	17			3	16		1
Influenza like illness	20	95			18	86	2	9
Inhibitory drug interaction		1				1		
Initial insomnia		3				3		
Injected limb mobility decreased	1	3			1	3		
Injection site bruising		1				1		
Injection site erythema		7				7		
Injection site extravasation		2				2		
Injection site indentation		1				1		
Injection site mass		1				1		
Injection site pain	1	31			1	31		
Injection site pruritus	1	4			1	4		
Injection site rash		2				2		
Injection site swelling	1	7			1	7		
Injection site warmth		3				3		
Injury	2	3			2	2		1
Insomnia	19	101			16	89	3	12
Insulin resistance	1	1			1	1		
International normalised ratio decreased		1				1		
Intracardiac thrombus	1	2					1	2
Intracranial aneurysm	1	1					1	1
Intracranial pressure increased	1	2					1	2
Intranasal hypoaesthesia		1				1		
Intraocular pressure increased	1	1			1	1		
Iridocyclitis	1	1					1	1
Iritis		1				1		
Irregular breathing		1				1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Irritability	4	12
Jaundice	2	3
Jaw clicking		1
Jaw disorder		1
Joint dislocation		2
Joint effusion		1
Joint injury		1
Joint instability		1
Joint lock	1	2
Joint noise		1
Joint range of motion decreased	3	22
Joint stiffness	2	14
Joint swelling	4	21
Labyrinthitis		1
Lack of spontaneous speech		1
Lacrimation increased	4	15
Large intestinal obstruction		1
Large intestine perforation	1	1
Laryngeal discomfort		1
Laryngeal oedema		1
Laryngitis	1	3
Laryngospasm		3
Laziness		1
Lethargy	13	69
Ligament disorder		1
Ligament injury		1
Ligament sprain	2	3
Limb deformity		1
Limb discomfort	9	61
Limb injury		5
Limb mass	1	2
Lip blister	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	11		1
			1	2	2
			1		
			1		
			1		1
			1		
			1		
		1	2		
			1		
		3	20		2
		2	13		1
		2	18	2	3
					1
					1
		3	12	1	3
					1
				1	1
			1		
					1
		1	3		
					3
			1		
			1		
		2	3		
			1		
		5	48	4	13
			5		
		1	2		
		1	2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip disorder	2	5
Lip erythema		1
Lip exfoliation		1
Lip infection		1
Lip injury	1	2
Lip oedema		1
Lip pain	1	2
Lip pruritus		6
Lip swelling	13	54
Livedo reticularis		4
Liver disorder		2
Liver function test abnormal		1
Liver injury		1
Liver tenderness		1
Local anaesthesia		1
Local reaction		1
Loose body in joint	1	1
Loss of consciousness	43	89
Loss of personal independence in daily activities	7	28
Loss of proprioception		1
Lower respiratory tract infection	1	3
Lung disorder	1	3
Lung hyperinflation		1
Lung infiltration		1
Lupus myositis	1	1
Lymphadenitis		8
Lymphadenopathy	54	414
Lymphangitis		1
Lymph gland infection		2
Lymph node pain	10	86
Lymphoedema		5
Lymphoma	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		
			1		
			1		
			1		
		1	2		
			1		
		1	2		
			4		2
		10	35	3	19
			2		2
			1		1
			1		
					1
			1		
			1		
			1		
				1	1
		2	2	41	87
		5	22	2	6
					1
				1	3
		1	2		1
			1		
					1
				1	1
			8		
		52	393	2	21
					1
			2		
		10	83		3
			5		
				1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Macroglossia		1
Major depression		2
Malaise	49	309
Malignant hypertension		1
Malnutrition		1
Mania	1	3
Mass		5
Mast cell degranulation present		1
Mastication disorder		1
Mastitis	3	6
Mastoid disorder		1
Maternal exposure during pregnancy	7	48
Maternal exposure timing unspecified		3
Measles	1	1
Melanoma recurrent	2	2
Memory impairment	3	17
Meningeal disorder		1
Meningitis		1
Menopausal symptoms		1
Menorrhagia	15	23
Menstrual disorder	8	16
Menstruation delayed	2	4
Menstruation irregular	8	17
Mental disorder	2	6
Mental fatigue		1
Mental impairment	3	19
Mesenteric vein thrombosis	1	1
Metabolic function test abnormal		1
Metrorrhagia	3	10
Microangiopathic haemolytic anaemia	1	1
Middle ear effusion		1
Middle insomnia	2	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
		47	294	2	15
					1
			1		
		1	2		1
			4		1
			1		
			1		
				3	6
					1
		7	46		2
			3		
				1	1
				2	2
		3	13		4
					1
					1
			1		
		13	20	2	3
		6	14	2	2
		2	3		1
		8	17		
		1	5	1	1
			1		
				3	19
				1	1
			1		
		2	9	1	1
				1	1
			1		
		2	16		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine	25	118
Migraine with aura	3	5
Miliaria		2
Miosis		1
Mobility decreased	4	26
Mononeuropathy		1
Monoplegia	1	2
Mood altered	1	1
Motion sickness	1	3
Motor dysfunction	1	4
Mouth swelling	1	11
Mouth ulceration	2	5
Movement disorder	7	24
Mucosal disorder		1
Multiple sclerosis	2	4
Multiple sclerosis relapse	1	1
Muscle atrophy		1
Muscle contractions involuntary		2
Muscle discomfort	1	4
Muscle disorder	1	2
Muscle fatigue		8
Muscle rigidity		1
Muscle spasms	15	74
Muscle strain		3
Muscle swelling	1	3
Muscle tightness	8	27
Muscle twitching	1	17
Muscular weakness	12	88
Musculoskeletal chest pain	1	13
Musculoskeletal discomfort	3	14
Musculoskeletal disorder		3
Musculoskeletal pain		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		20	104	5	14
		2	4	1	1
			2		
			1		
		3	21	1	5
					1
				1	2
		1	1		
			2	1	1
			1	1	3
		1	6		5
		2	4		1
		5	20	2	4
			1		
				2	4
				1	1
			1		
			1		1
		1	4		
		1	2		
			8		
					1
		10	57	5	17
			3		
		1	3		
		6	23	2	4
		1	13		4
		8	61	4	27
		1	13		
		3	14		
			1		2
			4		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal stiffness	20	72
Mutism		1
Myalgia	66	604
Myelitis transverse	5	6
Myocardial infarction	10	16
Myocardial necrosis marker increased		1
Myocarditis	6	10
Myoclonus		1
Myopia		1
Myositis		3
Nail discolouration		1
Nasal congestion	14	90
Nasal discharge discolouration		1
Nasal discomfort	1	3
Nasal disorder	1	3
Nasal dryness		1
Nasal oedema	1	6
Nasal pruritus	1	1
Nasopharyngitis	14	45
Nausea	140	813
Near death experience	2	5
Neck injury		1
Neck mass	1	2
Neck pain	25	158
Needle issue		3
Neoplasm	1	1
Neoplasm progression	1	1
Neoplasm skin		2
Nephrolithiasis	1	1
Nerve compression		5
Nerve injury	3	5
Nervousness	6	27

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		18	66	2	6
			1		
		60	566	6	38
				5	6
				10	16
					1
				6	10
					1
			1		
					3
					1
		14	84		6
			1		
		1	2		1
		1	3		
					1
		1	5		1
				1	1
		13	42	1	3
		110	720	30	93
				2	5
			1		
		1	2		
		19	139	6	19
			3		
		1	1		
				1	1
			2		
				1	1
			5		
		2	3	1	2
		6	25		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervous system disorder		3
Neuralgia	6	31
Neuralgic amyotrophy		2
Neurological symptom	1	4
Neuropathy peripheral	12	29
Neutrophil count decreased		1
Neutrophil count increased		1
Nightmare		9
Night sweats	3	47
Nipple exudate bloody		1
Nipple infection	1	1
Nipple pain	1	3
Nipple swelling		1
No adverse event	1	3
Nocturia		1
Nocturnal dyspnoea	1	1
Nodule		1
Noninfective encephalitis		3
Noninfective gingivitis		1
Nuchal rigidity		2
Nystagmus		2
Obstructive airways disorder		4
Occupational exposure to SARS-CoV-2		2
Ocular discomfort	4	14
Ocular hyperaemia	2	18
Ocular vascular disorder	1	1
Odynophagia	1	7
Oedema		5
Oedema peripheral		7
Off label use	24	164
Ophthalmic herpes simplex		1
Optic neuritis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
		2	23	4	8
			1		1
			2	1	2
				12	29
					1
			1		
			8		1
		2	43	1	4
			1		
		1	1		
		1	3		
			1		
		1	3		
					1
		1	1		
			1		
					3
			1		
			1		1
			1		1
			1		3
			2		
		4	11		3
		2	16		2
		1	1		
		1	5		2
			4		1
			5		2
		22	159	2	5
					1
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral blood blister		1
Oral candidiasis	1	2
Oral discomfort	3	13
Oral disorder		3
Oral herpes	3	12
Oral mucosal blistering		3
Oral mucosal eruption		3
Oral pain	2	7
Oral pruritus	3	10
Orchitis		1
Oropharyngeal blistering	1	2
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	3	17
Oropharyngeal pain	24	178
Oropharyngeal spasm		1
Oropharyngeal swelling		1
Orthopnoea		1
Orthostatic hypotension		1
Osteochondritis		1
Osteomyelitis		1
Otorrhoea		1
Ovarian cyst	1	1
Ovarian disorder	1	1
Ovarian enlargement	1	1
Overdose	3	14
Overweight		1
Oxygen saturation abnormal		1
Oxygen saturation decreased	4	10
Pain	140	1,014
Painful respiration		4
Pain in extremity	152	736
Pain in jaw	8	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		
		2	11	1	2
			3		
		2	11	1	1
			3		
			2		1
		1	6	1	1
		3	8		2
					1
				1	2
			1		
		3	13		4
		20	164	4	14
					1
					1
					1
			1		
					1
			1		
				1	1
				1	1
		1	1		
		3	13		1
			1		
				1	1
				1	1
			1		
			1		
		3	6	1	4
		126	958	14	56
			4		
	1	140	702	12	34
		7	25	1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain of skin	2	17
Palatal swelling		3
Pallor	3	27
Palmar erythema		3
Palpitations	27	164
Pancreatitis		3
Pancreatitis acute	1	3
Pancytopenia		1
Panic attack	5	14
Panic disorder		2
Panic reaction		7
Paraesthesia	65	358
Paraesthesia ear		1
Paraesthesia mucosal		1
Paraesthesia oral	9	111
Paralysis	4	10
Paranasal sinus discomfort	1	14
Paranoia	1	2
Paraplegia	1	1
Parosmia	2	15
Parotid duct obstruction		1
Pelvic mass	2	2
Pelvic pain	2	5
Periarthritis		2
Pericardial disease		1
Pericardial effusion		1
Pericarditis	1	7
Periorbital pain		1
Periorbital swelling		8
Peripheral coldness	7	38
Peripheral nerve injury		2
Peripheral swelling	14	107

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	17		
			3		
		3	21		6
			2		1
		18	116	9	48
					3
				1	3
					1
		4	10	1	4
			2		
			6		1
		46	293	19	65
			1		
			1		
		7	84	2	27
				4	10
		1	14		
			1	1	1
				1	1
		1	13	1	2
					1
				2	2
		1	4	1	1
			2		
					1
					1
				1	7
			1		
			7		1
		5	33	2	5
					2
		12	100	2	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral vascular disorder		1
Peripheral venous disease		1
Peroneal nerve palsy		1
Personality change	2	2
Petechiae	2	13
Pharyngeal disorder	1	3
Pharyngeal erythema		5
Pharyngeal haemorrhage	1	1
Pharyngeal hypoaesthesia	1	8
Pharyngeal mass		3
Pharyngeal oedema	2	4
Pharyngeal paraesthesia	1	13
Pharyngeal swelling	11	63
Pharyngitis		3
Pharyngitis streptococcal		1
Phlebitis	1	1
Photophobia	4	16
Photopsia	1	2
Photosensitivity reaction	1	8
Physical examination abnormal		1
Pigmentation disorder		1
Piloerection		2
Pityriasis rosea	1	1
Plantar fasciitis	1	1
Platelet count decreased	3	7
Platelet count increased	1	2
Platelet disorder	1	1
Pleural effusion	1	4
Pleurisy	1	1
Pleuritic pain		3
Pneumocystis jirovecii pneumonia		1
Pneumonia	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
		1	1	1	1
		1	10	1	3
			2	1	1
			4		1
				1	1
		1	5		3
			2		1
		2	2		2
		1	10		3
		4	28	7	35
			2		1
			1		
		1	1		
		3	14	1	2
		1	2		
			6	1	2
					1
					1
			1		1
		1	1		
		1	1	2	6
		1	2		
		1	1		
		1	1		3
		1	1		
			3		
					1
				4	10

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
PO2 decreased		1
Poisoning	1	1
Pollakiuria	1	7
Polyarthritis		1
Polymenorrhoea	1	2
Polyneuropathy		1
Polyuria		2
Poor peripheral circulation	1	4
Poor quality product administered	3	7
Poor quality sleep	2	11
Poor venous access	1	1
Porphyria acute		1
Portal vein thrombosis	4	4
Postmenopausal haemorrhage	1	2
Postoperative wound infection		1
Post-traumatic neck syndrome		1
Post-traumatic stress disorder		1
Postural orthostatic tachycardia syndrome	2	6
Post viral fatigue syndrome	1	1
Pre-existing condition improved	1	1
Premature labour	1	1
Premenstrual syndrome	1	4
Pressure of speech		2
Presyncope	13	61
Procedural site reaction		1
Product administered at inappropriate site	3	18
Product administration error		2
Product complaint		1
Product confusion		1
Product dose omission issue	3	3
Productive cough	4	13
Product leakage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
		1	7		
					1
		1	2		
			1		1
		1	3		1
		3	7		
		2	11		
		1	1		
					1
				4	4
				1	2
					1
			1		
		1	1	1	5
		1	1		
		1	1		
				1	1
		1	4		
			1		1
		9	47	4	14
					1
		2	16	1	2
			2		
			1		
			1		
		3	3		
		4	12		1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Product preparation error		10
Product preparation issue	2	7
Product quality issue	1	1
Product storage error		1
Product supply issue		1
Product temperature excursion issue	2	2
Product use issue	5	129
Protein total decreased		1
Prothrombin time prolonged	1	2
Pruritus	39	252
Psoriasis		1
Psoriatic arthropathy		1
Psychomotor hyperactivity	1	2
Pulmonary artery occlusion	1	1
Pulmonary congestion	1	4
Pulmonary embolism	17	17
Pulmonary infarction	1	1
Pulmonary mass		1
Pulmonary oedema	2	2
Pulmonary pain	1	7
Pulmonary thrombosis	4	5
Pulse abnormal		4
Pupils unequal	1	1
Purpura		2
Pustule	1	1
Pyrexia	171	1,188
Radiculitis brachial		2
Rash	52	273
Rash erythematous	8	46
Rash macular	3	30
Rash maculo-papular		6
Rash papular	1	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			8		2
		2	7		
		1	1		
			1		
			1		
		2	2		
		4	125	1	4
			1		
		1	1		1
		33	218	6	34
			1		
					1
			1	1	1
				1	1
				1	4
				17	17
				1	1
					1
				2	2
		1	5		2
				4	5
			2		2
				1	1
			2		
				1	1
		151	1097	20	91
					2
		42	215	10	58
		8	36		10
		1	23	2	7
			6		
		1	12		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash pruritic	4	37
Rash pustular		1
Rash vesicular	2	6
Raynaud's phenomenon		3
Reaction to excipient		1
Rectal haemorrhage	1	3
Red blood cell count decreased		2
Red blood cells urine positive		1
Red ear syndrome		1
Reduced facial expression		1
Renal disorder		1
Renal failure	1	1
Renal pain	1	7
Respiratory arrest	1	1
Respiratory disorder	3	5
Respiratory distress	3	13
Respiratory failure		4
Respiratory rate decreased	1	2
Respiratory rate increased		9
Respiratory tract congestion		8
Respiratory tract oedema		3
Restless legs syndrome	1	3
Restlessness	3	15
Restrictive pulmonary disease		1
Retching		4
Retinal artery occlusion	1	1
Retinal vein occlusion	2	2
Rhabdomyolysis	1	1
Rheumatic disorder		1
Rheumatoid arthritis	4	7
Rhinalgia		3
Rhinitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	32		5
			1		
		1	3	1	3
			2		1
			1		
				1	3
			1		1
			1		
			1		
				1	1
			6	1	1
				1	1
		2	4	1	1
				3	13
					4
		1	2		
			5		4
			8		
					3
			2	1	1
		2	13	1	2
					1
			4		
				1	1
				2	2
				1	1
			1		
				4	7
			3		
			2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinitis allergic		1
Rhinorrhoea	15	85
Rhinovirus infection		1
Right ventricular dysfunction		1
Road traffic accident	1	2
Rosacea		1
Salivary gland enlargement		1
Salivary hypersecretion		2
SARS-CoV-1 test positive	1	1
SARS-CoV-2 antibody test negative	2	7
SARS-CoV-2 antibody test positive		3
SARS-CoV-2 test positive	6	58
Scab		1
Scar	2	2
Sciatica		1
Scleritis		2
Scleroderma	1	1
Scratch		3
Screaming		2
Seasonal allergy	1	1
Secretion discharge		2
Sedation		2
Seizure	17	31
Seizure like phenomena		1
Self-injurious ideation	1	1
Sensation of foreign body	1	16
Sensitisation		1
Sensitive skin	1	7
Sensitivity to weather change		1
Sensorimotor disorder		1
Sensory disturbance		6
Sensory loss	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		15	76		9
			1		
					1
		1	1		1
			1		
			1		
			2		
		1	1		
		2	6		1
			3		
		1	12	5	46
			1		
		1	1	1	1
			1		
					2
				1	1
			3		
			1		1
		1	1		
			1		1
			2		
		1	1	16	30
					1
		1	1		
		1	9		7
			1		
		1	7		
			1		
					1
			5		1
			2	2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sepsis	1	4
Serum ferritin decreased		1
Serum sickness		1
Shock		2
Shock symptom		1
Sialoadenitis		1
Sinus congestion	1	5
Sinus disorder	2	8
Sinus headache	1	5
Sinusitis	8	19
Sinus pain		5
Sinus tachycardia		5
Sitting disability		2
Sjogren's syndrome	1	3
Skin burning sensation	3	12
Skin depigmentation		1
Skin discolouration	3	18
Skin discomfort		1
Skin disorder	2	8
Skin exfoliation	1	7
Skin hyperpigmentation		1
Skin indentation		1
Skin injury		2
Skin irritation		4
Skin laceration	1	3
Skin lesion	1	5
Skin mass	2	3
Skin odour abnormal		1
Skin oedema		1
Skin reaction		3
Skin sensitisation		1
Skin swelling	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
					1
					1
					2
					1
					1
		1	5		
		2	8		
		1	5		
		7	18	1	1
			5		
			2		3
			2		
				1	3
		3	10		2
			1		
		1	13	2	5
			1		
		1	6	1	2
		1	6		1
			1		
			1		
			2		
			4		
		1	3		
		1	5		
		2	3		
			1		
			1		
			2		1
			1		
			2	1	1

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\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin tightness		2
Skin ulcer		3
Skin warm	1	3
Sleep apnoea syndrome	1	1
Sleep deficit	1	1
Sleep disorder	7	18
Sleep disorder due to a general medical condition		2
Sleep disorder due to general medical condition, insomnia type		2
Sleep paralysis		2
Sleep talking	1	1
Sluggishness	1	6
Small fibre neuropathy		1
Sneezing	2	16
Snoring		1
Soft tissue disorder		1
Somnolence	9	67
Speech disorder	9	29
Speech sound disorder	1	1
Spinal cord disorder		1
Spinal disorder	1	3
Spinal pain	1	12
Splenomegaly		2
Spondylitis		1
Sputum discoloured	2	3
Staphylococcal infection	2	3
Staring		2
Stevens-Johnson syndrome		2
Sticky skin	1	1
Still's disease	1	1
Stomatitis	3	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			3		
		1	3		
				1	1
		1	1		
		6	17	1	1
			2		
			2		
			2		
		1	1		
		1	6		
					1
		1	15	1	1
			1		
			1		
		6	60	3	7
		4	14	5	15
		1	1		
					1
			1	1	2
		1	11		1
			1		1
					1
		1	1	1	2
				2	3
			1		1
					2
		1	1		
				1	1
		3	8		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Strabismus		1
Strawberry tongue		1
Streptococcal infection		2
Stress	2	9
Stress urinary incontinence	1	1
Stridor		2
Substance abuse		1
Sudden cardiac death		1
Sudden death	1	1
Sudden hearing loss	3	4
Suffocation feeling		1
Suicidal ideation	1	3
Sunburn		1
Superficial vein prominence	1	1
Supraventricular extrasystoles	1	2
Supraventricular tachycardia		1
Suspected COVID-19	2	16
Swelling	19	101
Swelling face	18	89
Swelling of eyelid	2	13
Swollen tongue	13	64
Syncope	46	98
Synovial cyst		1
Syringe issue	1	2
Systemic immune activation		1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	2	3
Systemic scleroderma		1
Tachycardia	8	139
Tachyphrenia		3
Tachypnoea		6
Taste disorder	6	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		1
		2	9		
		1	1		
					2
					1
					1
				1	1
				3	4
			1		
				1	3
					1
				1	1
		1	2		
					1
			3	2	13
		15	88	4	13
		15	65	3	24
		2	13		
		5	30	8	34
				46	98
			1		
		1	2		
					1
					1
				2	3
					1
		3	89	5	50
			3		
			3		3
		5	23	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temperature intolerance		5
Temperature regulation disorder		1
Tenderness	4	19
Tendonitis		2
Tendon pain		1
Tension		2
Tension headache	1	5
Terminal insomnia		2
Testicular swelling	1	2
Tetany		2
Therapeutic response unexpected	1	4
Thinking abnormal	3	6
Thirst	3	15
Throat clearing	2	8
Throat irritation	13	87
Throat tightness	17	90
Thrombocytopenia	6	10
Thrombophlebitis	2	2
Thrombophlebitis superficial	3	4
Thrombosis	26	32
Thrombotic microangiopathy	1	1
Thrombotic stroke	1	1
Thyroid disorder	1	2
Thyroidectomy	1	1
Thyroid function test abnormal	1	1
Thyroiditis	1	2
Thyroiditis subacute	1	2
Thyroid mass	2	2
Thyroid pain	1	2
Thyrotoxic crisis	1	1
Tic		1
Tinnitus	38	93

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		2
			1		
		4	17		2
			2		
			1		
			2		
		1	5		
			2		
		1	1		1
					2
		1	4		
		2	5	1	1
		3	14		1
		1	4	1	4
		8	66	5	21
		13	49	4	41
				6	10
		2	2		
		3	3		1
				26	32
				1	1
				1	1
		1	2		
		1	1		
		1	1		
		1	2		
			1	1	1
		1	1	1	1
		1	2		
			1		
				1	1
		23	64	15	29

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue blistering	1	2
Tongue discolouration		2
Tongue discomfort	3	9
Tongue disorder	2	11
Tongue dry		1
Tongue eruption	1	3
Tongue erythema		1
Tongue haemorrhage		1
Tongue movement disturbance		1
Tongue pruritus	2	6
Tongue ulceration	1	2
Tonsillar disorder		1
Tonsillar hypertrophy		1
Tonsillitis		1
Toothache	2	11
Tooth disorder		1
Tooth fracture	1	1
Tooth injury	1	1
Transient ischaemic attack	5	6
Transverse sinus stenosis	1	1
Tremor	24	115
Tricuspid valve incompetence	1	1
Trigeminal neuralgia		5
Trigeminal neuritis		1
Trigger finger	2	2
Trismus	2	5
Troponin increased	4	8
Tryptase decreased		1
Tryptase increased		1
Tunnel vision	1	6
Type IV hypersensitivity reaction		2
Ulcer		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		1
		2	6	1	3
		1	7	1	4
			1		
		1	1		2
			1		
			1		
					1
		1	4	1	2
		1	2		
					1
			1		
			1		
		2	11		
					1
		1	1		
		1	1		
				5	6
				1	1
		19	89	5	26
				1	1
			4		1
			1		
		2	2		
		1	3	1	2
				4	8
			1		
			1		
				1	6
			2		
			1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Underdose	3	19
Undifferentiated connective tissue disease		1
Unresponsive to stimuli		2
Upper-airway cough syndrome	3	7
Upper gastrointestinal haemorrhage	1	1
Upper respiratory tract congestion	2	7
Upper respiratory tract infection		2
Urinary incontinence	4	9
Urinary tract disorder		1
Urinary tract infection	3	5
Urine output decreased	1	1
Urine output increased		1
Urticaria	28	206
Urticaria chronic	1	1
Use of accessory respiratory muscles		1
Uterine contractions during pregnancy		2
Uterine haemorrhage	1	1
Uveitis		1
Uvulitis		1
Vaccination failure	34	45
Vaccination site bruising	4	20
Vaccination site cellulitis	1	6
Vaccination site coldness		3
Vaccination site discolouration		7
Vaccination site discomfort	4	12
Vaccination site erythema	11	145
Vaccination site extravasation	1	1
Vaccination site haemorrhage	1	6
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity		2
Vaccination site hypoaesthesia	2	9
Vaccination site induration		16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	19		
					1
					2
		3	6		1
				1	1
			4	2	3
			2		
		2	5	2	4
			1		
		1	3	2	2
		1	1		
			1		
		18	157	10	49
		1	1		
			1		
			1		1
				1	1
					1
			1		
				34	45
		4	20		
			1	1	5
			3		
			7		
		4	11		1
		10	140	1	5
		1	1		
		1	6		
			1		
			2		
		2	9		
			16		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site infection		1
Vaccination site inflammation	1	4
Vaccination site irritation	1	2
Vaccination site joint erythema		2
Vaccination site joint movement impairment		5
Vaccination site joint pain		5
Vaccination site joint swelling	1	2
Vaccination site lymphadenopathy	2	9
Vaccination site mass	4	21
Vaccination site movement impairment	2	17
Vaccination site nodule		5
Vaccination site oedema	1	2
Vaccination site pain	73	758
Vaccination site paraesthesia	1	9
Vaccination site pruritus	8	71
Vaccination site pustule		1
Vaccination site rash	6	35
Vaccination site reaction		7
Vaccination site scab		1
Vaccination site scar	1	1
Vaccination site swelling	15	143
Vaccination site thrombosis	1	1
Vaccination site ulcer		1
Vaccination site urticaria	2	23
Vaccination site vesicles		6
Vaccination site warmth	5	71
Vaginal haemorrhage	4	10
Vaginal infection		1
Varicocele	1	1
Vascular rupture	1	1
Vein discolouration		2
Ventricular arrhythmia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	4		
		1	2		
			1		1
			4		1
			3		2
		1	1		1
		2	8		1
		4	21		
		2	17		
			5		
		1	2		
		70	736	3	22
		1	8		1
		8	69		2
			1		
		6	33		2
			7		
			1		
		1	1		
		14	138	1	5
				1	1
			1		
		2	21		2
			6		
		5	70		1
		2	7	2	3
			1		
		1	1		
		1	1		
			2		
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ventricular extrasystoles	1	8
Ventricular fibrillation		2
Ventricular tachycardia		1
Vertebral artery dissection	1	1
Vertigo	20	71
Vertigo positional	1	4
Vestibular neuritis	1	1
VIIIth nerve lesion		1
Viral infection		1
Viral upper respiratory tract infection		1
Vision blurred	17	50
Visual acuity reduced		1
Visual field defect	1	1
Visual impairment	7	28
Vitamin B12 decreased		1
Vitamin D decreased		1
Vitamin D deficiency	1	1
Vitreous detachment		1
Vitreous floaters	1	1
Vocal cord disorder		1
Vocal cord paralysis		1
Vomiting	54	248
Vomiting projectile	4	7
Vulvovaginal mycotic infection		2
Vulvovaginal swelling		1
Walking disability		1
Weight decreased	3	8
Weight fluctuation	1	1
Weight increased		2
Wheezing	11	30
White blood cell count abnormal	1	1
White blood cell count decreased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	7		1
					2
					1
				1	1
		14	52	6	19
		1	3		1
				1	1
					1
			1		
					1
		9	34	8	16
			1		
		1	1		
		6	20	1	8
					1
			1		
				1	1
					1
				1	1
					1
		38	205	16	43
		4	7		
			2		
			1		
					1
		2	5	1	3
		1	1		
			2		
		7	24	4	6
		1	1		
			1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased	2	9			2	6		3
White blood cells urine		1				1		
Winged scapula		1				1		
Withdrawal bleed		1				1		
Wound	2	2			1	1	1	1
Wound closure		1				1		
Wound haemorrhage		1				1		
Wrong product administered	1	5			1	5		
Wrong technique in product usage process	1	9			1	8		1
Xanthopsia		1				1		
Yellow skin	1	1					1	1
	1	2			1	2		
	5,066	27,148		1	3528	21884	1538	5264

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	17	53			16	50	1	3
Abdominal distension	8	18			8	17		1
Abdominal pain	17	63			13	51	4	12
Abdominal pain lower	3	9			2	7	1	2
Abdominal pain upper	26	70			21	59	5	11
Abdominal rigidity		2				1		1
Abnormal behaviour	2	2			2	2		
Abnormal clotting factor	1	1					1	1
Abnormal dreams	2	6			2	6		
Abnormal faeces		2				2		
Abnormal sensation in eye	1	2			1	2		
Accidental exposure to product		2				2		
Accidental overdose		4				4		
Acne	4	5			4	5		
Acute kidney injury		1						1
Acute myocardial infarction		1						1
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		1						1
Acute respiratory failure	1	1					1	1
Adrenal disorder	1	2			1	1		1
Adrenergic syndrome		1				1		
Adverse event	1	1			1	1		
Affect lability	1	1					1	1
Ageusia	5	45			4	42	1	3
Aggression		2				2		
Agitation	1	8			1	8		
Allergy to chemicals	1	1			1	1		
Allergy to vaccine	4	15			1	7	3	8
Alopecia	5	9			4	6	1	3
Alopecia universalis		1				1		
Amaurosis fugax		1						1
Amnesia	5	12			3	9	2	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaemia	1	1
Anal haemorrhage	1	1
Anal incontinence	3	3
Anal skin tags		1
Anaphylactic reaction	26	67
Anaphylactic shock	2	4
Anger		3
Angina pectoris	5	8
Angioedema	5	14
Anion gap abnormal		1
Ankle fracture	2	2
Anosmia	7	38
Anterior chamber cell		1
Antibody test abnormal		1
Anti Kell antibody test positive	1	1
Antinuclear antibody positive		1
Anxiety	15	53
Anxiety disorder	1	1
Apathy	1	2
Aphasia	2	6
Aphonia	2	5
Aphthous ulcer	1	4
Appendicitis	6	11
Appendicitis perforated	4	4
Appendix disorder	1	1
Aptyalism		1
Arrhythmia	1	5
Arthralgia	106	414
Arthritis	3	9
Arthropathy	4	9
Arthropod sting	1	1
Asthenia	62	227

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		2	2	1	1
			1		
				26	67
				2	4
			3		
				5	8
		1	1	4	13
			1		
				2	2
		4	32	3	6
					1
			1		
		1	1		
			1		
		11	47	4	6
		1	1		
		1	2		
		1	3	1	3
		1	2	1	3
		1	4		
				6	11
				4	4
				1	1
			1		
				1	5
		93	384	13	30
		2	6	1	3
		4	9		
		1	1		
		54	206	8	21

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenopia	4	7
Asthma	3	11
Asthma exercise induced		1
Asymptomatic COVID-19	2	8
Ataxia		2
Atelectasis		1
Atrial fibrillation	12	21
Atrial flutter	3	3
Auricular swelling	1	2
Autoimmune disorder	1	4
Autoimmune thyroid disorder	1	1
Autoimmune thyroiditis	2	2
Autoscopy	1	1
Axillary mass	1	3
Axillary pain	12	35
Back disorder		1
Back injury		1
Back pain	41	139
Bacterial pyelonephritis	1	1
Balance disorder	8	28
Basal ganglia haemorrhage		2
Basal ganglia stroke		1
Basophil count increased		1
Bed rest	2	2
Bedridden	3	6
Biliary tract disorder	1	1
Bladder discomfort	1	2
Bladder disorder		1
Bladder spasm		1
Blepharitis		1
Blepharochalasis		1
Blepharospasm		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6	1	1
		3	9		2
			1		
		1	4	1	4
			1		1
				12	21
		1	1	2	2
			1	1	1
				1	4
				1	1
				2	2
		1	1		
		1	3		
		10	33	2	2
			1		
			1		
		28	120	13	19
				1	1
		5	21	3	7
					2
					1
			1		
		2	2		
		2	5	1	1
				1	1
			1	1	1
			1		
			1		
			1		
			1		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blindness	2	5
Blindness transient	1	3
Blindness unilateral	3	5
Blister	4	13
Blood bilirubin abnormal	1	1
Blood bilirubin increased		1
Blood blister	1	1
Blood copper increased		1
Blood creatine increased		1
Blood creatine phosphokinase abnormal	1	1
Blood creatine phosphokinase increased	1	2
Blood creatinine abnormal	1	1
Blood creatinine increased	1	1
Blood disorder	1	1
Blood glucose decreased	2	5
Blood glucose fluctuation		1
Blood glucose increased	6	19
Blood iron decreased		1
Blood lactic acid increased		1
Blood potassium decreased	1	6
Blood pressure abnormal	3	5
Blood pressure decreased	6	13
Blood pressure diastolic decreased		1
Blood pressure diastolic increased		1
Blood pressure fluctuation		4
Blood pressure increased	18	65
Blood pressure systolic increased		4
Blood sodium decreased		1
Blood test abnormal	1	1
Blood thyroid stimulating hormone decreased		1
Blood thyroid stimulating hormone increased	1	4
Blood triglycerides abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
				1	3
				3	5
		3	9	1	4
				1	1
					1
				1	1
			1		
			1		
		1	1		
			1	1	1
				1	1
		1	1		
		1	1		
		1	2	1	3
			1		
		5	16	1	3
					1
					1
			5	1	1
		2	3	1	2
		2	3	4	10
			1		
					1
			3		1
		9	35	9	30
			1		3
			1		
				1	1
					1
		1	3		1
		1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood triglycerides increased	1	2
Blood urine present	5	8
Blue toe syndrome	2	2
Body temperature abnormal		3
Body temperature decreased	3	6
Body temperature fluctuation	1	1
Body temperature increased	7	26
Bone disorder		2
Bone pain	8	20
Bone swelling		1
Brachial plexopathy		1
Bradycardia	2	2
Bradykinesia	2	2
Bradyphrenia		3
Brain oedema	1	2
Brain stem haemorrhage		1
Brain stem infarction	1	1
Brain stem syndrome		1
Breast discharge		2
Breast discomfort		2
Breast pain	9	13
Breast swelling	1	1
Breast tenderness	1	3
Breath sounds abnormal	2	2
Bronchial oedema	1	1
Bronchitis		2
Bronchospasm		6
Burning sensation	14	51
Burn oesophageal	1	1
Bursitis	1	1
Caffeine consumption	1	1
Candida infection	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		3	5	2	3
				2	2
			2		1
		2	5	1	1
		1	1		
		7	26		
			2		
		7	19	1	1
			1		
					1
				2	2
		2	2		
					3
				1	2
					1
				1	1
					1
			2		
			1		1
		8	11	1	2
		1	1		
		1	3		
		2	2		
				1	1
			2		
			4		2
		9	38	5	13
		1	1		
		1	1		
		1	2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Capillary fragility	1	1
Cardiac arrest	3	4
Cardiac disorder	7	11
Cardiac failure	1	1
Cardiac failure congestive	1	1
Cardiac fibrillation		1
Cardiac flutter	6	9
Cardio-respiratory arrest	1	1
Cardiospasm	3	3
Cardiovascular disorder	1	2
Carpal tunnel syndrome		1
Cartilage injury		1
Cell marker decreased	1	1
Cellulitis	1	5
Cerebellar stroke	1	1
Cerebral artery occlusion	1	1
Cerebral disorder		3
Cerebral haemorrhage	3	5
Cerebral palsy	1	1
Cerebral thrombosis	3	4
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	20	30
Cervical radiculopathy		1
Change in sustained attention	1	1
Chest discomfort	33	101
Chest pain	31	81
Chest X-ray abnormal		1
Chillblains	1	1
Chills	173	832
Choking	6	6
Choking sensation	1	3
Cholecystitis infective	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				3	4
		4	8	3	3
				1	1
				1	1
					1
				6	9
				1	1
		2	2	1	1
		1	2		
			1		
			1		
				1	1
				1	5
				1	1
				1	1
			3		
				3	5
				1	1
				3	4
				1	1
				20	30
			1		
		1	1		
		28	74	5	27
		21	61	10	20
					1
		1	1		
		161	778	12	54
				6	6
		1	2		1
				1	1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cholestasis		2
Chromaturia	1	1
Chronic inflammatory demyelinating polyradiculoneuropathy	1	1
Chronic kidney disease		3
Chronic obstructive pulmonary disease	2	2
Circadian rhythm sleep disorder	1	1
Circulatory collapse		1
Circumoral swelling	1	2
Circumstance or information capable of leading to medication error	7	23
Clostridium difficile colitis	1	1
Clostridium difficile infection	1	1
Coagulopathy	2	2
Coccydynia	1	1
Cognitive disorder	2	8
Cold sweat	7	19
Colitis	1	2
Colitis ischaemic	2	2
Colitis ulcerative	1	1
Coma		1
Communication disorder		1
Complex regional pain syndrome		1
Complicated appendicitis	1	1
Complication associated with device		1
Concussion	2	5
Condition aggravated	19	63
Confusional state	13	26
Conjunctival haemorrhage	2	3
Conjunctivitis	2	3
Conjunctivitis viral		1
Consciousness fluctuating	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
				1	1
					3
				2	2
		1	1		
					1
		1	2		
		7	23		
				1	1
				1	1
		2	2		
		1	1		
		2	6		2
		6	16	1	3
		1	1		1
				2	2
				1	1
					1
			1		
			1		
				1	1
					1
			1	2	4
		14	48	5	15
		9	20	4	6
				2	3
		2	3		
			1		
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Constipation	9	12
Contusion	15	33
Coordination abnormal	1	3
Corneal disorder		1
Corneal graft rejection		1
Corneal infection		1
Corneal infiltrates		1
Costochondritis		2
Cough	45	156
COVID-19	125	294
COVID-19 pneumonia	1	7
C-reactive protein increased		3
Crohn's disease		1
Crying	1	6
Crystal urine		1
Cutaneous vasculitis	1	1
Cyanosis	3	6
Cyst		1
Cystitis		1
Cystitis bacterial	1	1
Cystitis escherichia	1	1
Daydreaming		1
Deafness	9	24
Deafness neurosensory	1	3
Deafness unilateral	6	11
Death	1	7
Decreased appetite	25	88
Deep vein thrombosis	10	17
Defaecation urgency	1	1
Dehydration	11	24
Delirium	5	7
Delirium febrile	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	9	3	3
		13	31	2	2
			1	1	2
					1
					1
					1
			1		1
		39	131	6	25
2	2	37	97	88	197
				1	7
			3		
					1
			5	1	1
			1		
		1	1		
		3	6		
			1		
					1
		1	1		
				1	1
			1		
			1	9	23
				1	3
				6	11
				1	7
		23	81	2	7
				10	17
		1	1		
		8	15	3	9
				5	7
				1	1

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dementia Alzheimer's type	1	1
Dental discomfort	1	1
Depersonalisation/derealisation disorder	1	2
Depressed level of consciousness		1
Depressed mood	1	5
Depression	3	10
Dermatitis	1	3
Dermatitis allergic		1
Dermatitis atopic	1	1
Dermatitis contact		1
Dermatomyositis		1
Diabetes mellitus	1	3
Diabetes mellitus inadequate control		2
Diabetic coma	1	1
Diarrhoea	66	215
Diarrhoea haemorrhagic	1	4
Diplopia	7	14
Discharge		1
Discomfort	11	37
Discouragement	1	1
Disease progression		1
Disease recurrence	6	27
Disorientation	9	12
Disseminated intravascular coagulation	1	1
Disseminated varicella zoster virus infection	1	1
Dissociation		2
Disturbance in attention	4	23
Diverticulitis	4	4
Dizziness	127	454
Dizziness postural	2	7
Drug hypersensitivity	1	12
Drug ineffective	74	192

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
		1	2		
					1
		1	5		
		2	8	1	2
		1	3		
			1		
		1	1		
			1		
					1
				1	3
					2
				1	1
		56	195	10	20
				1	4
		5	9	2	5
			1		
		10	33	1	4
		1	1		
			1		
		3	19	3	8
		4	7	5	5
				1	1
				1	1
			1		1
		3	18	1	5
				4	4
1	1	104	384	23	70
		2	7		
		1	11		1
2	2			74	192

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug interaction	2	4
Dry eye	2	8
Dry mouth	9	29
Dry skin	3	6
Dry throat	1	4
Dysaesthesia		2
Dysarthria	7	10
Dysentery	1	1
Dysgeusia	21	75
Dysgraphia	1	1
Dyskinesia	3	6
Dyslexia		1
Dysmenorrhoea	2	3
Dyspareunia		1
Dyspepsia	9	25
Dysphagia	16	39
Dysphemia		1
Dysphonia	12	28
Dyspnoea	90	235
Dyspnoea exertional		3
Dysstasia	7	14
Dystonia		2
Dysuria	2	5
Ear congestion	1	4
Ear discomfort	10	19
Ear disorder		3
Ear infection		2
Ear injury	1	1
Ear pain	10	42
Ear pruritus	1	5
Ear swelling	1	4
Eating disorder	6	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
		2	7		1
		6	24	3	5
		3	5		1
		1	4		
			2		
		2	5	5	5
				1	1
		19	70	2	5
				1	1
		2	4	1	2
			1		
		1	2	1	1
			1		
		8	24	1	1
1	1	11	28	5	11
					1
		10	22	2	6
1	1	56	144	34	91
			1		2
		6	12	1	2
					2
			3	2	2
		1	3		1
		7	15	3	4
			2		1
			1		1
		1	1		
		8	39	2	3
		1	5		
		1	4		
		6	10		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema	2	3
Electrocardiogram abnormal	1	3
Emotional disorder	1	5
Emotional distress	3	4
Encephalopathy		1
Energy increased	3	9
Enlarged uvula		1
Enteritis		1
Eosinophilia		1
Episcleritis		2
Epistaxis	8	20
Erectile dysfunction	2	2
Eructation	3	4
Erythema	46	132
Erythema multiforme		1
Erythema nodosum	1	1
Erythema of eyelid	1	3
Escherichia urinary tract infection	1	1
Euphoric mood	3	3
Exercise tolerance decreased		1
Exophthalmos	2	2
Expired product administered		1
Exposure to SARS-CoV-2	2	13
Exposure via skin contact		2
External ear disorder		1
External ear pain	1	2
Extra dose administered		1
Extrasystoles	2	2
Eye allergy		1
Eye contusion		2
Eye discharge	1	4
Eye disorder	10	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3		
		1	2		1
		1	5		
		2	2	1	2
					1
		3	9		
					1
					1
			1		
			2		
		7	18	1	2
				2	2
		3	4		
		39	114	7	18
					1
		1	1		
			1	1	2
				1	1
		3	3		
			1		
				2	2
			1		
		1	2		
			1		
		2	2		
			1		
			2		
		1	4		
		9	13	1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye haemorrhage	8	13
Eye inflammation	1	4
Eye irritation	3	16
Eyelid disorder	1	3
Eyelid function disorder		1
Eyelid irritation		1
Eyelid pain		1
Eyelid ptosis	1	3
Eyelid sensory disorder	1	1
Eyelids pruritus	1	2
Eye movement disorder	1	2
Eye oedema		1
Eye pain	5	25
Eye paraesthesia		1
Eye pruritus	1	12
Eye swelling	10	34
Eye ulcer		1
Face injury		2
Face oedema		1
Facial bones fracture	1	1
Facial discomfort	1	5
Facial nerve disorder	1	3
Facial pain	2	15
Facial paralysis	44	76
Facial paresis	1	3
Faeces discoloured	4	6
Faeces soft	2	3
Fall	12	27
False positive investigation result		1
Fatigue	232	919
Fear	3	9
Fear of death	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				8	13
		1	3		1
		3	12		4
		1	3		
			1		
			1		
		1	3		
		1	1		
				1	2
		1	2		
			1		
		4	24	1	1
			1		
		1	9		3
		7	24	3	10
			1		
			2		
			1		
				1	1
		1	5		
			1	1	2
		2	15		
		1	1	43	75
		1	3		
		4	5		1
		1	1	1	2
		6	15	6	12
			1		
1	1	219	870	13	49
		3	9		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Febrile convulsion		1
Feeding disorder	4	11
Feeling abnormal	94	236
Feeling cold	16	61
Feeling drunk	1	5
Feeling hot	27	95
Feeling jittery	1	6
Feeling of body temperature change	5	13
Feeling of relaxation	1	1
Fibrin D dimer increased	2	4
Fibromyalgia	2	3
Fine motor skill dysfunction		1
Finger deformity		1
Flank pain		4
Flatulence	5	10
Fluid intake reduced		1
Fluid retention	1	2
Flushing	10	72
Folliculitis	1	1
Food aversion		1
Food poisoning	1	1
Foot deformity		1
Foreign body aspiration		1
Foreign body in eye		1
Foreign body in throat	1	1
Foreign body sensation in eyes		1
Formication	2	2
Freezing phenomenon	1	2
Frequent bowel movements		2
Frostbite		1
Frustration tolerance decreased		2
Functional gastrointestinal disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	9	1	2
		86	215	8	21
		14	54	2	7
		1	5		
		20	78	7	17
		1	4		2
		5	13		
		1	1		
		1	3	1	1
		2	3		
			1		
			1		
			4		
		5	10		
			1		
		1	2		
		7	55	3	17
		1	1		
			1		
		1	1		
			1		
					1
			1		
				1	1
			1		
		2	2		
		1	2		
			2		
			1		
			2		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fungal infection		1
Fungal skin infection	1	1
Furuncle		1
Gait disturbance	21	66
Gait inability	4	19
Gallbladder disorder	1	3
Gastric disorder	3	6
Gastric infection		1
Gastroenteritis	1	2
Gastroenteritis viral	3	4
Gastrointestinal disorder	1	10
Gastrointestinal haemorrhage	1	2
Gastrointestinal hypomotility	1	1
Gastrointestinal oedema		1
Gastrointestinal pain	1	4
Gastrooesophageal reflux disease	3	7
Generalised tonic-clonic seizure	1	1
General physical health deterioration	1	1
Genital herpes	1	1
Genital swelling	1	1
Gingival bleeding	1	5
Gingival blister		1
Gingival disorder		1
Gingival erythema		2
Gingival pain		5
Gingival recession		1
Gingival swelling	1	4
Glassy eyes		1
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	1	1
Glossitis		2
Glossodynia	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			1		
		18	53	3	13
		1	13	3	6
			2	1	1
		2	5	1	1
					1
		1	1		1
		3	4		
		1	9		1
				1	2
		1	1		
					1
		1	4		
		3	7		
				1	1
		1	1		
		1	1		
		1	5		
					1
			1		
			2		
			5		
			1		
		1	4		
			1		
			1		
		1	1		
			2		
		1	9		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glycosylated haemoglobin increased	1	1
Goitre		3
Good syndrome		1
Gout	2	2
Grip strength decreased	4	7
Groin pain	1	3
Grunting		2
Guillain-Barre syndrome	1	4
Haematochezia	6	8
Haematocrit increased		1
Haematology test abnormal		1
Haematoma	2	2
Haematuria		2
Haemoglobin decreased	2	3
Haemolysis	1	1
Haemolytic anaemia	1	1
Haemophagocytic lymphohistiocytosis		1
Haemoptysis	1	2
Haemorrhage	2	11
Haemorrhage intracranial		1
Haemorrhage urinary tract		1
Haemorrhagic stroke		1
Haemorrhoids	2	3
Hair injury		1
Hallucination	3	7
Hallucination, auditory	1	2
Hallucination, visual	2	2
Hand fracture		2
Hangover	2	5
Headache	271	1,133
Head discomfort	16	48
Head injury	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		1
					1
		2	2		
		3	6	1	1
		1	2		1
			2		
			1	1	3
				6	8
			1		
			1		
		2	2		
			1		1
			1	2	2
				1	1
				1	1
					1
		1	2		
				2	11
					1
					1
					1
		1	2	1	1
			1		
				3	7
				1	2
				2	2
					2
		2	4		1
		245	1046	26	87
		12	38	4	10
		2	5		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head titubation		1
Heart injury	1	1
Heart rate abnormal	7	7
Heart rate decreased	4	7
Heart rate increased	33	135
Heart rate irregular	5	12
Heart valve incompetence	1	1
Helicobacter infection		1
Hemiparesis		1
Hepatic enzyme abnormal	1	1
Hepatic enzyme increased	2	3
Hepatic necrosis		1
Hepatitis	1	2
Hepatitis acute		1
Herpes simplex	1	2
Herpes virus infection		1
Herpes zoster	16	43
Hidradenitis		1
Histamine level increased		2
Hordeolum		3
Hot flush	7	34
Hunger	1	4
Hydronephrosis		1
Hyperacusis	1	4
Hyperaesthesia		5
Hyperaesthesia teeth		1
Hypercholesterolaemia		1
Hyperglycaemia		2
Hyperhidrosis	39	126
Hypermetropia		1
Hypersensitivity	23	69
Hypersomnia	6	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
		5	5	2	2
		3	5	1	2
		25	106	8	29
		3	10	2	2
		1	1		
					1
					1
				1	1
		1	2	1	1
					1
				1	2
					1
		1	2		
			1		
		14	35	2	8
			1		
			2		
			3		
		7	33		1
		1	4		
					1
		1	4		
			5		
			1		
			1		
			1		1
		31	108	8	18
			1		
		18	50	5	19
		4	21	2	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertension	23	61
Hypertensive emergency		2
Hypertonia		1
Hyperventilation	5	8
Hypoacusis	2	14
Hypoaesthesia	50	165
Hypoaesthesia eye		3
Hypoaesthesia oral	14	58
Hypoaesthesia teeth		1
Hypogeusia		4
Hypoglycaemia		2
Hypokalaemic syndrome	1	1
Hypokinesia	1	6
Hyponatraemic syndrome	1	1
Hypophagia		2
Hypopnoea	1	2
Hyposmia		2
Hypotension	7	12
Hypothermia		1
Hypothyroidism	1	3
Hypoxia		2
Hysterectomy	1	1
Idiosyncratic drug reaction		1
Iliad nerve paralysis		1
Iliotibial band syndrome		1
Illness	46	98
Illness anxiety disorder		1
Immobile	1	2
Immune system disorder	3	7
Immune thrombocytopenia	1	3
Immunisation		1
Immunodeficiency	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	26	16	35
					2
			1		
		5	8		
		1	11	1	3
		40	131	10	34
			3		
		11	44	3	14
			1		
			4		
					2
		1	1		
		1	6		
		1	1		
			2		
		1	2		
			2		
		3	7	4	5
					1
			1	1	2
					2
				1	1
			1		
					1
		41	90	5	8
			1		
				1	2
		2	6	1	1
				1	3
			1		
				1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Immunosuppression		1
Impaired driving ability	2	5
Impaired healing		1
Impaired quality of life		1
Impaired work ability	1	9
Inappropriate schedule of product administration	28	108
Incoherent		1
Incorrect dosage administered		1
Incorrect dose administered	2	6
Incorrect route of product administration	6	15
Increased tendency to bruise		1
Increased upper airway secretion	1	3
Infection	3	4
Inflammation	5	14
Inflammatory pain		1
Influenza	3	16
Influenza B virus test positive		1
Influenza like illness	26	93
Initial insomnia		1
Injection site bruising	2	3
Injection site erythema	3	4
Injection site inflammation		1
Injection site pain	3	22
Injection site rash		1
Injection site swelling	1	4
Injury	1	2
Inner ear disorder		1
Insomnia	33	89
Insulin resistant diabetes	1	1
Internal haemorrhage	1	1
International normalised ratio decreased	1	1
International normalised ratio increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3	1	2
					1
					1
		1	9		
		28	108		
					1
			1		
		2	5		1
		5	13	1	2
			1		
			1	1	2
		3	4		
		4	11	1	3
			1		
		2	15	1	1
			1		
		24	87	2	6
			1		
		2	3		
		3	4		
			1		
		3	21		1
			1		
		1	4		
		1	1		1
					1
		28	83	5	6
				1	1
				1	1
				1	1
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intervertebral disc protrusion		3
Intestinal haemorrhage	1	1
Intestinal obstruction		1
Intracranial pressure increased	1	1
Intraocular pressure increased	1	1
Intrusive thoughts		1
Iritis	1	1
Irregular sleep wake rhythm disorder		2
Irritability	2	7
Irritable bowel syndrome	2	2
Ischaemic stroke	1	1
Jaundice	1	2
Jaw clicking		1
Jaw cyst		1
Jaw disorder	1	3
Job dissatisfaction	1	1
Joint dislocation		4
Joint effusion		1
Joint injury	2	3
Joint instability		1
Joint lock	1	1
Joint range of motion decreased	5	11
Joint stiffness	4	10
Joint swelling	16	36
Joint warmth		1
Keratic precipitates		2
Keratitis		1
Kidney infection	1	1
Labile hypertension		1
Laboratory test abnormal		1
Labyrinthitis		1
Lack of spontaneous speech	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
				1	1
					1
				1	1
		1	1		
			1		
		1	1		
			2		
		2	7		
		2	2		
				1	1
			1	1	1
			1		
			1		
1	1	1	2		1
		1	1		
					4
			1		
		2	3		
					1
		1	1		
		2	8	3	3
		4	9		1
		14	31	2	5
			1		
					2
					1
				1	1
			1		
			1		
					1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lacrimation increased	1	16
Large intestine infection	1	1
Laryngeal oedema		1
Laryngitis		2
Latent autoimmune diabetes in adults		1
Laziness		1
Lethargy	12	44
Leukocytosis		1
Ligament sprain	1	2
Limb discomfort	15	49
Limb injury	1	5
Limb mass	1	3
Lip blister	1	4
Lip erythema		2
Lipids increased		1
Lip injury	1	2
Lip oedema		1
Lip pain		1
Lip pruritus		7
Lip swelling	11	49
Liquid product physical issue		4
Livedo reticularis		2
Liver disorder	1	1
Liver function test abnormal		1
Liver function test increased		1
Liver injury		1
Localised infection	1	2
Localised oedema		2
Loss of consciousness	37	64
Loss of personal independence in daily activities	8	21
Lower limb fracture	1	1
Lower respiratory tract congestion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	14		2
				1	1
			2		1
			1		1
		12	44		
					1
		1	2		
		14	45	1	4
		1	5		
		1	3		
			1	1	3
			1		1
			1		
		1	1		1
					1
			1		
			3		4
		7	35	4	14
			4		
			1		1
				1	1
					1
			1		
			2		
			2		
				37	64
		5	17	3	4
				1	1
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lower respiratory tract infection	1	2
Lung carcinoma cell type unspecified stage I		1
Lung disorder	1	1
Lymphadenitis		4
Lymphadenopathy	46	182
Lymph node pain	14	48
Lymphocyte count abnormal		2
Lymphoedema		3
Lymphoma		1
Macroglossia	1	1
Macular hole		1
Maculopathy	1	1
Madarosis		1
Malaise	75	298
Mammogram abnormal	1	1
Mass	2	10
Mastication disorder	1	2
Mastoid disorder	1	1
Mean cell volume increased		1
Mean platelet volume decreased		1
Measles	1	1
Memory impairment	7	15
Meniere's disease	2	3
Meningitis	1	1
Meningitis viral		1
Menorrhagia	3	5
Menstrual disorder		1
Menstruation irregular		1
Mental disorder	1	3
Mental fatigue		1
Mental impairment	1	5
Mental status changes	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
				1	1
			2		2
1	1	43	162	3	20
		13	42	1	6
			1		1
			3		
					1
				1	1
					1
			1		
		70	283	5	15
		1	1		
		2	9		1
		1	2		
		1	1		
			1		
			1		
				1	1
		6	9	1	6
				2	3
				1	1
					1
		3	4		1
			1		
			1		
		1	2		1
			1		
				1	5
		1	1		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meralgia paraesthetica		1
Mesenteric artery aneurysm	1	1
Mesenteric panniculitis		1
Metastases to meninges		1
Methylenetetrahydrofolate reductase gene mutation	1	1
Micturition urgency	1	2
Middle insomnia	2	9
Migraine	16	55
Migraine with aura	1	3
Miosis	1	1
Mitral valve prolapse		1
Mobility decreased	10	20
Monoplegia		2
Mood swings		1
Morning sickness	1	1
Motion sickness		4
Motor dysfunction	1	3
Mouth haemorrhage		1
Mouth swelling		4
Mouth ulceration	1	2
Movement disorder	5	22
Mucosal disorder		2
Mucosa vesicle		1
Mucous stools		1
Multi-organ disorder	1	1
Multiple fractures		1
Multiple organ dysfunction syndrome		1
Multiple sclerosis		1
Multiple sclerosis relapse	3	3
Muscle atrophy		1
Muscle contractions involuntary	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
					1
		1	1		
			1	1	1
		2	8		1
		14	49	2	6
		1	3		
		1	1		
					1
		9	17	1	3
					2
			1		
				1	1
			4		
		1	2		1
			1		
			2		2
		1	2		
		4	18	1	4
			1		1
					1
			1		
				1	1
					1
					1
				3	3
			1		
		1	3		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle contracture	1	2
Muscle discomfort		3
Muscle disorder	2	5
Muscle fatigue	4	4
Muscle mass		1
Muscle rigidity	1	1
Muscle rupture		1
Muscle spasms	20	64
Muscle spasticity	1	2
Muscle strain	1	2
Muscle swelling	2	3
Muscle tightness	2	17
Muscle twitching	8	16
Muscular weakness	19	55
Musculoskeletal chest pain	2	11
Musculoskeletal discomfort	5	20
Musculoskeletal disorder	1	1
Musculoskeletal pain	3	4
Musculoskeletal stiffness	9	42
Myalgia	79	369
Myasthenia gravis		2
Mydriasis	2	3
Myelitis transverse	1	1
Myelopathy		1
Myocardial infarction	5	14
Myocardial necrosis marker increased		2
Myocarditis		2
Myoclonus		2
Nail discolouration	1	1
Narcolepsy	1	1
Nasal congestion	15	59
Nasal discomfort		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			3		
		2	5		
		3	3	1	1
			1		
		1	1		
					1
		14	52	6	12
		1	2		
			1	1	1
		1	1	1	2
		2	15		2
		5	12	3	4
		11	41	8	14
		2	10		1
		4	17	1	3
				1	1
		2	2	1	2
		9	41		1
		68	340	11	29
					2
		2	3		
				1	1
					1
				5	14
					2
					2
					2
		1	1		
				1	1
		15	54		5
			2		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal disorder	1	1
Nasal oedema	1	4
Nasal pruritus	1	1
Nasopharyngitis	21	54
Nausea	141	583
Near death experience	5	7
Neck mass		5
Neck pain	27	98
Necrotising retinitis	1	1
Needle issue		1
Neoplasm malignant	1	1
Nephrolithiasis	5	9
Nerve compression	2	5
Nerve injury		2
Nervousness	7	26
Nervous system disorder	2	3
Neuralgia	8	20
Neuritis		2
Neurological symptom	1	2
Neuropathy peripheral	6	14
Neutropenia		1
Neutrophil count abnormal		1
Nightmare	4	9
Night sweats	6	21
Nipple pain		1
No adverse event	2	4
Nodule	4	7
Noninfective encephalitis		1
Non-pitting oedema	1	1
Nuchal rigidity		1
Nystagmus	1	1
Obstructive airways disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2		2
		1	1		
		20	52	1	2
		120	520	21	63
		1	1	4	6
			5		
		20	89	7	9
				1	1
					1
				1	1
				5	9
		1	4	1	1
			1		1
		7	26		
				2	3
		5	15	3	5
			2		
			1	1	1
		1	2	5	12
					1
					1
		4	8		1
		6	19		2
			1		
		2	4		
		4	7		
					1
				1	1
			1		
		1	1		
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Occipital neuralgia	1	2
Occupational exposure to SARS-CoV-2		2
Ocular discomfort	6	9
Ocular hyperaemia	3	21
Ocular vascular disorder	1	1
Odynophagia	1	5
Oedema		3
Oedema peripheral	2	4
Oesophageal disorder		1
Off label use	17	59
Oligomenorrhoea		1
Onychalgia		1
Onychoclasia	1	1
Optic nerve disorder	1	1
Optic neuritis	1	1
Oral blood blister	1	1
Oral candidiasis		2
Oral discomfort	1	6
Oral disorder		2
Oral herpes	1	9
Oral mucosal blistering		2
Oral mucosal eruption		2
Oral mucosal erythema		4
Oral mucosal exfoliation		1
Oral mucosal roughening	1	1
Oral pain	1	9
Oral pruritus	1	4
Oral viral infection		1
Orbital oedema		1
Organising pneumonia		1
Oropharyngeal blistering		1
Oropharyngeal discomfort	4	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
			2		
		6	9		
		2	18	1	3
				1	1
		1	4		1
			3		
		1	3	1	1
					1
		17	59		
			1		
			1		
		1	1		
				1	1
				1	1
				1	1
			2		
		1	5		1
			1		1
		1	8		1
			2		
			2		
			3		1
			1		
		1	1		
		1	8		1
		1	2		2
			1		
					1
					1
		3	10	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oropharyngeal pain	28	91
Oropharyngeal spasm		1
Orthostatic heart rate response increased		1
Orthostatic hypotension	1	2
Osteoarthritis		1
Osteomyelitis		1
Osteopenia		1
Otitis media	1	1
Overdose	2	13
Overweight		2
Oxygen saturation decreased	3	15
Pain	163	707
Painful respiration		2
Pain in extremity	202	655
Pain in jaw	7	28
Pain of skin	3	8
Palatal disorder		1
Palatal swelling	1	4
Pallor	3	14
Palmar erythema		1
Palpitations	25	98
Pancreatic disorder	1	1
Pancreatitis	1	2
Pancreatitis acute	1	2
Panic attack	1	4
Panic disorder	2	2
Panic reaction		1
Papule		1
Paraesthesia	41	179
Paraesthesia oral	10	57
Paralysis	1	3
Paranasal sinus discomfort		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		26	84	2	7
					1
			1		
			1	1	1
			1		
					1
			1		
		1	1		
		2	12		1
			2		
		2	9	1	6
		146	658	17	49
			1		1
1	1	178	611	24	44
1	1	7	25		3
		2	6	1	2
			1		
		1	2		2
			11	3	3
			1		
		21	81	4	17
				1	1
				1	2
				1	2
			3	1	1
		2	2		
			1		
			1		
		36	148	5	31
		9	46	1	11
				1	3
			4		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paranasal sinus hypersecretion		3
Paranasal sinus hyopsecretion		1
Paranoia		1
Parkinson's disease		1
Parosmia	6	14
Pelvic inflammatory disease		1
Pelvic pain	1	3
Pemphigoid		1
Pericardial effusion	2	2
Pericarditis	2	2
Periorbital cellulitis		1
Periorbital discomfort		1
Periorbital disorder		2
Periorbital oedema		2
Periorbital pain		1
Periorbital swelling	2	9
Peripheral artery thrombosis	1	1
Peripheral coldness	8	17
Peripheral ischaemia		1
Peripheral paralysis	1	1
Peripheral sensory neuropathy		1
Peripheral swelling	38	109
Peroneal nerve palsy	1	3
Personality change		1
Pertussis		1
Petechiae	2	7
Pharyngeal erythema	1	2
Pharyngeal haemorrhage	1	1
Pharyngeal hypoesthesia	2	3
Pharyngeal inflammation		1
Pharyngeal mass	1	3
Pharyngeal oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			1		
			1		
					1
		4	12	2	2
					1
		1	3		
					1
				2	2
				2	2
					1
			1		
			2		
			1		1
					1
		2	7		2
		1	1		
		6	14	2	3
					1
				1	1
			1		
1	1	33	97	5	12
		1	3		
			1		
					1
			3	2	4
		1	2		
				1	1
		2	2		1
			1		
		1	3		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal paraesthesia	1	6
Pharyngeal swelling	15	36
Pharyngitis streptococcal	1	3
Photophobia	2	14
Photopsia	1	2
Photosensitivity reaction	3	5
Physical deconditioning		1
Piloerection		1
Platelet count decreased	4	10
Pleural effusion	2	3
Pneumonia	8	16
Pneumonia aspiration	1	1
Pneumonia viral		1
Pneumonitis	1	2
PO2 decreased		1
Pollakiuria	2	7
Polymyalgia rheumatica		1
Polymyositis		1
Polyneuropathy	1	1
Polyuria	2	4
Poor peripheral circulation		1
Poor quality product administered	7	14
Poor quality sleep	1	8
Portal vein thrombosis	2	2
Postmenopausal haemorrhage	5	6
Post-traumatic neck syndrome		2
Postural orthostatic tachycardia syndrome		2
Posture abnormal		1
Posturing		1
Potentiating drug interaction	1	3
Pre-existing condition improved		2
Premenstrual syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		3
		7	19	8	17
			2	1	1
		2	14		
			1	1	1
		2	4	1	1
			1		
			1		
		1	4	3	6
				2	3
				8	16
				1	1
					1
			1	1	1
					1
		2	7		
					1
					1
				1	1
		1	3	1	1
					1
		7	14		
		1	8		
				2	2
				5	6
					2
			1		1
			1		
					1
		1	3		
			2		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prescribed overdose		1
Presyncope	15	31
Prinzmetal angina	1	2
Procedural pain		1
Proctalgia		1
Product administered at inappropriate site	5	11
Product administration error		3
Product complaint	1	1
Product dispensing issue	1	1
Product dose omission in error	1	1
Product dose omission issue	2	4
Productive cough	4	14
Product odour abnormal		1
Product preparation error	1	6
Product preparation issue	1	8
Product quality issue	1	3
Product storage error	3	3
Product supply issue	2	3
Product temperature excursion issue	3	4
Product use issue	1	36
Prostate infection		1
Protein total decreased	1	1
Pruritus	64	227
Pruritus genital		1
Pseudomonas infection	1	1
Psoriasis	1	1
Psoriatic arthropathy	1	2
Psychiatric symptom		1
Psychomotor hyperactivity		2
Psychotic disorder	1	1
Pulmonary congestion	2	5
Pulmonary embolism	10	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		9	21	6	10
			1	1	2
			1		
		5	11		
			3		
		1	1		
		1	1		
		1	1		
		2	4		
		4	13		1
			1		
		1	6		
		1	6		2
		1	3		
		3	3		
		2	3		
		3	4		
		1	36		
					1
		1	1		
		51	189	13	38
					1
				1	1
		1	1		
				1	2
			1		
			1		1
		1	1		
				2	5
				10	18

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary oedema	1	5
Pulmonary pain	3	6
Pulmonary thrombosis	4	7
Pulse abnormal		3
Pulse absent	1	1
Pupillary disorder	1	2
Pustule		2
Pyrexia	185	810
Quality of life decreased		1
Radial nerve palsy	1	1
Rash	62	202
Rash erythematous	9	35
Rash macular	7	28
Rash maculo-papular	1	5
Rash morbilliform	3	3
Rash papular	3	11
Rash pruritic	9	33
Rash vesicular	1	6
Raynaud's phenomenon	3	4
Reaction to excipient		1
Rectal haemorrhage	2	3
Rectal tenesmus		1
Red blood cell sedimentation rate increased		1
Red cell distribution width decreased		1
Reduced facial expression	1	1
Renal cyst		1
Renal disorder	1	1
Renal failure		1
Renal impairment	1	1
Renal pain	2	8
Respiration abnormal	3	5
Respiratory arrest		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
		1	3	2	3
				4	7
			3		
				1	1
		1	2		
			1		1
		168	746	17	64
			1		
		1	1		
		49	166	13	36
		8	31	1	4
		7	26		2
		1	5		
		3	3		
		3	11		
		7	29	2	4
		1	6		
		3	4		
					1
				2	3
			1		
			1		
			1		
				1	1
					1
				1	1
		2	8		
		3	5		
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory disorder	1	5
Respiratory distress	2	13
Respiratory failure		1
Respiratory rate decreased	1	2
Respiratory rate increased	2	6
Respiratory symptom		1
Respiratory tract congestion		4
Respiratory tract infection	2	2
Respiratory tract oedema		1
Restless legs syndrome		3
Restlessness	5	9
Retching	1	6
Retinal detachment	2	2
Retinal tear	2	3
Retinal vascular thrombosis	1	1
Retinitis		1
Rheumatoid arthritis	7	12
Rhinalgia	2	4
Rhinorrhoea	15	58
Rib fracture		1
Road traffic accident	1	1
Root canal infection	1	1
Rosacea		1
Salivary gland disorder	1	1
Salivary gland pain		1
Salivary hypersecretion	3	4
Sarcoidosis	1	1
SARS-CoV-2 antibody test negative	3	11
SARS-CoV-2 antibody test positive		4
SARS-CoV-2 test		1
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	11	41

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	2
				2	13
					1
		1	1		1
			3	2	3
					1
			4		
				2	2
					1
			3		
		4	7	1	2
		1	5		1
				2	2
				2	3
				1	1
					1
2	2		1	7	11
		1	3	1	1
		12	54	3	4
			1		
				1	1
			1		
			1		
		1	2	2	2
				1	1
		3	10		1
			3		1
					1
			1		
		6	16	5	25

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scab	1	3
Scar		1
Sciatica	1	2
Scleral haemorrhage	1	1
Scleritis	1	1
Scleroderma	1	1
Scratch	3	5
Screaming	1	2
Scrotal infection		1
Seborrhoea		1
Secretion discharge	4	4
Seizure	14	20
Seizure like phenomena	1	1
Sensation of foreign body	1	7
Sensitisation		1
Sensitive skin		2
Sensitivity to weather change		1
Sensory disturbance	1	2
Sensory level abnormal	1	1
Sensory loss	4	10
Sepsis	2	3
Serotonin syndrome		1
Serum ferritin decreased		1
Shock	1	3
Shoulder injury related to vaccine administration	1	1
Sialoadenitis		1
Sickle cell anaemia with crisis	2	2
Sinus congestion	1	13
Sinus disorder	4	13
Sinus headache	4	8
Sinusitis	2	12
Sinus pain	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
					1
		1	2		
				1	1
				1	1
				1	1
		3	4		1
			1	1	1
					1
			1		
		3	3	1	1
				14	20
				1	1
		1	6		1
			1		
			2		
			1		
		1	2		
		1	1		
		4	8		2
				2	3
					1
					1
		1	1		2
		1	1		
					1
				2	2
		1	12		1
		4	13		
		4	8		
		2	12		
		2	6		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus tarsi syndrome		1
Skeletal injury		1
Skin burning sensation	5	12
Skin discolouration	6	13
Skin disorder	2	9
Skin erosion	1	1
Skin exfoliation	4	6
Skin fissures	1	1
Skin haemorrhage	2	3
Skin irritation	1	3
Skin lesion	2	3
Skin lesion removal		1
Skin mass	1	2
Skin reaction		1
Skin sensitisation	1	1
Skin swelling		1
Skin tightness	2	2
Skin ulcer		1
Skin warm	1	1
Skin wrinkling	1	1
Sleep attacks	1	1
Sleep deficit	2	2
Sleep disorder	8	23
Sleep disorder due to a general medical condition		2
Sleep talking		1
Sleep terror		1
Slow speech	1	1
Sluggishness	3	9
Small intestinal obstruction	1	2
Sneezing	6	25
Snoring		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		5	12		
		4	10	2	3
		2	7		2
		1	1		
		3	5	1	1
		1	1		
		2	3		
		1	3		
		2	3		
			1		
		1	2		
			1		
		1	1		
			1		
		2	2		
			1		
		1	1		
		1	1		
		2	2		
		8	22		1
			2		
			1		
			1		
		1	1		
		2	8	1	1
				1	2
		5	24	1	1
			1		

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\* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Soft tissue injury		1
Somnolence	17	66
Speech disorder	5	22
Spinal disorder		1
Spinal pain	1	5
Splenomegaly		1
Splinter	1	1
Spondylitis	1	1
Sputum discoloured	1	2
Staphylococcal skin infection		1
Status asthmaticus		1
Stiff tongue		1
Stomatitis	2	10
Streptococcal infection		1
Stress	3	10
Stridor	1	6
Subcutaneous abscess	1	2
Subdural haemorrhage		1
Sudden hearing loss	1	1
Sudden visual loss	1	1
Suicidal ideation	2	6
Sunburn		1
Supraventricular extrasystoles		2
Supraventricular tachycardia		2
Suspected COVID-19	9	22
Sweating fever	1	1
Swelling	26	81
Swelling face	27	78
Swelling of eyelid	4	10
Swollen tongue	13	38
Syncope	21	41
Systemic lupus erythematosus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		17	63		3
		3	14	2	8
			1		
		1	4		1
					1
		1	1		
				1	1
			1	1	1
					1
					1
		1	8	1	2
			1		
		3	10		
		1	3		3
				1	2
					1
				1	1
				1	1
				2	6
			1		
			1		1
					2
		5	8	4	14
				1	1
		24	64	2	17
		22	58	5	20
		2	8	2	2
1	1	6	20	7	18
			1	21	40
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tachycardia	8	46
Tachyphrenia		3
Tachypnoea		8
Taste disorder	9	20
Tearfulness	1	2
Temperature intolerance		1
Temporomandibular joint syndrome	1	1
Tenderness	6	14
Tendonitis		1
Tendon pain		1
Tenosynovitis		1
Tension		1
Tension headache	1	3
Testicular pain	1	3
Therapeutic product effect prolonged		1
Therapeutic response unexpected	6	15
Thinking abnormal	3	13
Thirst	5	15
Thirst decreased		1
Thoracic outlet syndrome		1
Throat irritation	9	33
Throat tightness	18	54
Thrombocytopenia	4	5
Thrombophlebitis superficial	1	3
Thrombosis	28	37
Thyroid disorder		1
Thyroid function test abnormal		1
Thyroiditis acute		1
Thyroiditis subacute		1
Thyroid mass		1
Thyroid pain	1	2
Thyroxine decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	28	6	18
			3		
			7		1
		6	17	3	3
		1	2		
			1		
				1	1
		5	12	1	2
					1
			1		
			1		
		1	3		
			2	1	1
			1		
			1		
		1	3		
			2		
			1		
		6	15		
		3	13		
		5	14		1
			1		
			1		
		8	24	1	9
		12	29	6	25
				4	5
		1	2		1
				28	37
			1		
			1		
					1
			1		
			1		
		1	2		
			1		

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 \* AE=Adverse Event  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tinnitus	43	94
Tongue blistering	1	2
Tongue coated		1
Tongue discolouration	1	3
Tongue discomfort	1	7
Tongue disorder	2	6
Tongue dry		3
Tongue erythema		1
Tongue injury		1
Tongue oedema		1
Tongue paralysis	1	2
Tongue pruritus		4
Tongue ulceration		3
Tooth abscess		1
Toothache	2	11
Tooth disorder	1	2
Tooth fracture	2	2
Tooth infection	2	3
Tooth loss		1
Torticollis		1
Tracheal obstruction	1	1
Tracheitis		1
Tracheomalacia		1
Transient ischaemic attack	6	8
Tremor	37	105
Trigeminal nerve disorder		1
Trigeminal neuralgia		1
Trigger finger	2	2
Tri-iodothyronine decreased		1
Trismus		1
Troponin	1	1
Troponin increased	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		28	63	15	31
			1	1	1
			1		
			2	1	1
			6	1	1
		2	6		
			3		
			1		
			1		
					1
				1	2
			3		1
			2		1
					1
		1	8	1	3
		1	2		
		2	2		
		2	3		
					1
			1		
				1	1
			1		
					1
				6	8
		31	83	6	22
					1
					1
		2	2		
			1		
			1		
				1	1
		1	3	1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tunnel vision	3	5
Type 1 diabetes mellitus	1	1
Type 2 diabetes mellitus		1
Type III immune complex mediated reaction		1
Ulcer		1
Underdose	1	12
Unresponsive to stimuli		3
Upper-airway cough syndrome	1	7
Upper airway obstruction	1	2
Upper limb fracture	1	2
Upper respiratory tract congestion		14
Upper respiratory tract infection	1	2
Urge incontinence		1
Urinary incontinence	2	5
Urinary retention	1	1
Urinary tract infection	5	10
Urinary tract infection bacterial		1
Urine analysis abnormal	1	3
Urine output decreased	1	1
Urticaria	35	128
Use of accessory respiratory muscles		3
Uterine disorder		1
Uterine inflammation		1
Uveitis		3
Vaccination complication	1	1
Vaccination failure	10	17
Vaccination site bruising		12
Vaccination site cellulitis		4
Vaccination site coldness	1	1
Vaccination site discolouration	1	2
Vaccination site discomfort		4
Vaccination site erythema	15	85

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	5
				1	1
					1
			1		
		1	11		1
					3
		1	7		
				1	2
		1	1		1
			14		
		1	2		
			1		
		2	5		
				1	1
		4	6	1	4
					1
		1	3		
		1	1		
		24	89	11	39
			2		1
			1		
					1
					3
		1	1		
				10	17
			12		
			2		2
		1	1		
		1	2		
			4		
		15	78		7

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site exfoliation	1	1
Vaccination site haemorrhage	2	7
Vaccination site hypoaesthesia	2	4
Vaccination site induration	1	7
Vaccination site infection		3
Vaccination site inflammation		3
Vaccination site injury		1
Vaccination site irritation	1	3
Vaccination site joint movement impairment	2	6
Vaccination site joint pain	1	2
Vaccination site lymphadenopathy	1	2
Vaccination site macule		2
Vaccination site mass	7	24
Vaccination site movement impairment	1	17
Vaccination site nodule		2
Vaccination site oedema		2
Vaccination site pain	101	540
Vaccination site pallor		1
Vaccination site paraesthesia	1	4
Vaccination site pruritus	13	45
Vaccination site pustule	1	1
Vaccination site rash	5	15
Vaccination site reaction	1	4
Vaccination site swelling	24	96
Vaccination site urticaria	1	6
Vaccination site vesicles	1	2
Vaccination site warmth	6	43
Vaginal discharge		1
Vaginal disorder		1
Vaginal haemorrhage	4	7
Vaginal infection		1
Varicella zoster virus infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	6		1
		2	4		
		1	7		
			3		
			3		
			1		
		1	3		
		2	5		1
		1	2		
		1	2		
			2		
		7	24		
		1	16		1
			2		
					2
1	1	97	525	4	15
			1		
		1	4		
		12	43	1	2
		1	1		
		4	12	1	3
		1	4		
		23	93	1	3
		1	6		
		1	2		
		6	41		2
			1		
			1		
		4	6		1
			1		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Varicose vein	1	1
Vascular occlusion	1	1
Vasculitic rash		1
Vasculitis		1
Vein rupture	1	1
Ventricular extrasystoles	2	9
Vertigo	23	70
Vertigo positional	1	2
Vestibular migraine	1	1
Viral infection	1	1
Vision blurred	16	56
Visual acuity reduced	2	4
Visual field defect	1	2
Visual impairment	12	23
Vitamin D decreased	1	2
Vitamin D deficiency		2
Vlth nerve paralysis	1	2
Vitreous detachment	1	1
Vitreous floaters	1	1
Vocal cord disorder		1
Vomiting	59	169
Vulvovaginal burning sensation	1	1
Vulvovaginal mycotic infection	1	1
Vulvovaginal pain	1	1
Vulvovaginal pruritus		1
Vulvovaginal rash		1
Vulvovaginal swelling		1
Walking aid user	1	1
Weight bearing difficulty	1	2
Weight decreased	7	22
Weight fluctuation	2	3
Weight increased	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
			1		
			1		
				1	1
		2	5		4
		15	60	8	10
				1	2
		1	1		
		1	1		
		10	39	6	17
		2	3		1
		1	2		
		7	17	5	6
		1	2		
			2		
				1	2
				1	1
				1	1
					1
		41	126	18	43
		1	1		
		1	1		
		1	1		
					1
					1
					1
				1	1
		1	1		1
		4	15	3	7
		2	3		
		2	2	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wheezing	14	37			10	25	4	12
White blood cell count decreased	1	2			1	1		1
White blood cell count increased	2	8			1	7	1	1
Wound		2				2		
Wound haemorrhage	1	3			1	2		1
Wound infection	1	1					1	1
Wrong product administered	2	4			2	4		
Wrong technique in product usage process	2	10			2	10		
	6,002	20,192	17	17	4413	16265	1589	3927

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal discomfort	15	65			13	61	2	4
Abdominal distension	3	18			3	17		1
Abdominal infection	1	1					1	1
Abdominal pain	12	46			9	37	3	9
Abdominal pain lower	1	3			1	1		2
Abdominal pain upper	28	83			26	76	2	7
Abdominal rigidity	1	1			1	1		
Abdominal symptom		1				1		
Abdominal tenderness	1	1			1	1		
Abdominal wall haematoma		1						1
Abdominal wall haemorrhage		1						1
Abnormal behaviour	1	3			1	3		
Abnormal clotting factor		1						1
Abnormal dreams	3	10			2	8	1	2
Abnormal faeces		1				1		
Abnormal sensation in eye		1				1		
Abscess	1	1					1	1
Acarodermatitis		1						1
Accident		1						1
Accidental exposure to product		4				4		
Accidental overdose		3				3		
Accidental underdose		1				1		
Acidosis	1	1					1	1
Acne	1	5			1	5		
Acoustic neuritis		1						1
Activated partial thromboplastin time prolonged		2				1		1
Acute febrile neutrophilic dermatosis		1						1
Acute hepatic failure		1						1
Acute kidney injury		4						4
Acute myeloid leukaemia		1						1
Acute myocardial infarction		2						2

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute respiratory distress syndrome		1
Acute respiratory failure		1
Adhesion		1
Administration site irritation	1	1
Adnexa uteri pain		1
Adrenal insufficiency		2
Adrenocortical insufficiency acute		1
Adverse event	2	3
Affective disorder	1	1
Ageusia	11	33
Agitation	2	4
Alanine aminotransferase abnormal		1
Alanine aminotransferase increased	1	3
Allergic reaction to excipient		1
Allergy to arthropod sting	1	2
Allergy to vaccine	2	13
Allodynia		1
Alopecia	5	10
Altered state of consciousness		2
Altered visual depth perception	1	1
Ammonia increased		1
Amnesia	7	11
Anaemia		3
Anaemia vitamin B12 deficiency	1	1
Anal haemorrhage	1	1
Anal incontinence	2	3
Anal infection		1
Anaphylactic reaction	8	29
Anaphylactic shock	1	2
Anaphylactoid reaction		1
Aneurysm		1
Anger	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
		1	1		
			1		
					2
					1
		2	3		
		1	1		
		9	29	2	4
		2	4		
			1		
		1	3		
			1		
		1	2		
		1	12	1	1
			1		
		5	8		2
					2
		1	1		
					1
		5	7	2	4
			1		2
		1	1		
		1	1		
		2	3		
			1		
				8	29
				1	2
					1
					1
		1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angina pectoris	7	16
Angina unstable		1
Angioedema	2	12
Angiokeratoma	1	1
Angiopathy		1
Angle closure glaucoma	1	1
Angular cheilitis		1
Ankle fracture	1	1
Anorectal discomfort	1	2
Anosmia	10	25
Antibody test abnormal	1	1
Antibody test negative		2
Anxiety	19	48
Apathy	2	2
Aphasia	3	10
Aphonia	3	6
Apnoea		1
Appendicitis	4	8
Appendicitis perforated	1	2
Appetite disorder		3
Aptyalism		1
Arachnoid cyst		1
Areflexia		1
Arrhythmia	10	17
Arrhythmia supraventricular		1
Arterial occlusive disease	1	1
Arterial thrombosis		1
Arthralgia	127	442
Arthritis	7	24
Arthritis allergic		1
Arthropathy	2	5
Arthropod bite		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	16
					1
				2	12
		1	1		
			1		
				1	1
			1		
				1	1
		1	2		
		8	21	2	4
		1	1		
			2		
		17	42	2	6
		1	1	1	1
		1	4	2	6
		2	4	1	2
					1
				4	8
				1	2
			3		
			1		
					1
					1
				10	17
					1
				1	1
					1
		119	407	8	35
		7	22		2
			1		
		2	5		
			3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropod infestation		1
Arthropod sting	2	3
Aspartate aminotransferase increased	1	2
Aspiration	1	1
Asthenia	113	341
Asthenopia	1	4
Asthma	10	21
Asymptomatic COVID-19	3	8
Ataxia		2
Atelectasis	2	2
Atrial fibrillation	11	51
Atrial flutter	2	3
Atrioventricular block complete	1	1
Autoimmune disorder	3	6
Autoimmune haemolytic anaemia		1
Autoimmune thyroiditis		2
Autonomic nervous system imbalance	1	1
Autoscopy		2
Avulsion fracture	1	1
Axillary mass		2
Axillary pain	3	17
Back disorder	1	4
Back injury	2	4
Back pain	49	135
Bacterial infection	1	1
Bacterial test positive		1
Balance disorder	18	47
Band neutrophil count increased		1
Basal ganglia haemorrhage		1
Basophil count abnormal		1
Bedridden	3	11
Biliary tract disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	3		
		1	2		
				1	1
		89	285	24	56
		1	4		
		5	15	5	6
			1	3	7
			1		1
		1	1	1	1
			1	11	50
		1	1	1	2
				1	1
				3	6
					1
					2
		1	1		
			1		1
		1	1		
			2		
		3	17		
		1	4		
		2	4		
		41	113	8	22
		1	1		
			1		
		12	39	6	8
					1
			1		1
		2	9	1	2
		1	1		

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Biopsy	1	1
Bipolar disorder	1	1
Bladder discomfort		1
Bladder disorder	1	2
Bladder pain		1
Blast cell count increased		1
Blepharospasm	1	2
Blindness	3	10
Blindness transient	1	5
Blindness unilateral	2	5
Blister	6	19
Blood bilirubin decreased		1
Blood bilirubin increased	1	2
Blood calcium increased		1
Blood chloride decreased		1
Blood cholesterol	1	1
Blood cholesterol increased	1	4
Blood copper increased	1	1
Blood count abnormal		1
Blood creatine phosphokinase increased	1	2
Blood creatinine increased	1	5
Blood disorder	1	3
Blood fibrinogen decreased		1
Blood folate decreased		1
Blood folate increased	1	1
Blood glucose abnormal		3
Blood glucose decreased	4	11
Blood glucose increased	3	30
Blood immunoglobulin E increased		1
Blood immunoglobulin G decreased		2
Blood insulin increased	1	1
Blood iron decreased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
			1		
		1	2		
			1		
					1
		1	2		
				3	10
				1	5
				2	5
		6	15		4
			1		
		1	2		
			1		
			1		
		1	1		
		1	4		
		1	1		
			1		
				1	2
		1	4		1
		1	3		
					1
			1		
		1	1		
			2		1
		3	5	1	6
		1	21	2	9
					1
			2		
		1	1		
			1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood magnesium decreased		1
Blood potassium decreased		1
Blood potassium increased	1	1
Blood pressure abnormal		6
Blood pressure decreased	7	20
Blood pressure fluctuation	5	18
Blood pressure increased	18	74
Blood pressure measurement	1	1
Blood pressure orthostatic increased	1	1
Blood pressure systolic increased	1	1
Blood sodium decreased		1
Blood test abnormal	4	4
Blood triglycerides increased		1
Blood uric acid increased		1
Blood urine present	1	9
Body height decreased	5	15
Body temperature		2
Body temperature abnormal		6
Body temperature decreased	4	7
Body temperature fluctuation	1	2
Body temperature increased	8	41
Body tinea		1
Bone disorder	2	4
Bone pain	9	28
Bone swelling		3
Bowel movement irregularity	4	9
Bradycardia	1	2
Bradykinesia		1
Bradyphrenia		2
Brain death		1
Brain injury		1
Brain oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
			3		3
		2	11	5	9
		4	12	1	6
		11	44	7	30
		1	1		
		1	1		
		1	1		
					1
		3	3	1	1
					1
					1
		1	7		2
		5	14		1
			2		
			6		
		4	7		
		1	2		
		8	39		2
			1		
		1	3	1	1
		9	27		1
			2		1
		4	9		
				1	2
			1		
			2		
					1
					1
					1

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast cancer		1
Breast discomfort		1
Breast disorder		1
Breast mass	2	3
Breast pain	6	23
Breast swelling	2	4
Bronchitis	7	13
Bronchospasm	1	3
Burning mouth syndrome		1
Burning sensation	16	50
Burn oral cavity		1
Bursitis	2	2
Butterfly rash		1
Candida infection		1
Capillary disorder	1	1
Capillary nail refill test abnormal	1	1
Carbohydrate antigen 125 increased		1
Cardiac arrest	5	13
Cardiac discomfort		3
Cardiac disorder	2	14
Cardiac failure		1
Cardiac failure chronic		1
Cardiac failure congestive		4
Cardiac flutter	1	4
Cardiomyopathy	1	2
Cardio-respiratory arrest		1
Carpal tunnel syndrome	1	1
Cataract	1	3
Cataract nuclear		1
Cellulitis	5	12
Cerebellar stroke		1
Cerebral disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		
		1	2	1	1
		5	22	1	1
		2	4		
		4	9	3	4
		1	2		1
			1		
		16	46		4
					1
		1	1	1	1
					1
		1	1		
		1	1		
			1		
				5	13
			3		
		1	7	1	7
					1
					1
					4
				1	4
				1	2
					1
		1	1		
			1	1	2
					1
				5	12
					1
			2		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral haemorrhage	2	5
Cerebral infarction		2
Cerebral palsy	1	1
Cerebral thrombosis	1	1
Cerebral venous sinus thrombosis	1	1
Cerebrospinal fluid leakage	1	1
Cerebrovascular accident	24	67
Chalazion		1
Chapped lips	2	3
Chest discomfort	32	81
Chest pain	29	94
Chillblains	2	3
Chills	189	772
Choking	1	8
Choking sensation	1	3
Chondritis		1
Chromatopsia		3
Chromaturia	1	4
Chronic kidney disease	1	1
Chronic obstructive pulmonary disease		4
Circadian rhythm sleep disorder		1
Circulatory collapse	1	2
Circumstance or information capable of leading to device use error		1
Circumstance or information capable of leading to medication error	14	80
Cluster headache	1	2
Coagulopathy	1	3
Cognitive disorder	1	6
Cold sweat	10	24
Colitis	3	5
Colitis ischaemic	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
					2
				1	1
				1	1
				1	1
				24	67
			1		
		2	3		
		25	64	7	17
		17	59	12	35
		2	3		
		169	700	20	72
1	1			1	8
		1	3		
			1		
			3		
		1	4		
				1	1
1	1		2		2
			1		
			1		
		14	80		
		1	2		
			1	1	2
		1	3		3
		8	21	2	3
		2	4	1	1
				1	1

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Colitis ulcerative	1	1
Communication disorder		1
Condition aggravated	40	110
Confusional state	7	33
Conjunctival haemorrhage	3	6
Conjunctival hyperaemia		1
Conjunctivitis		2
Conjunctivitis allergic		2
Constipation	8	20
Contraindication to medical treatment		1
Contrast media allergy		1
Contusion	9	39
Conversion disorder	1	1
Coordination abnormal	1	2
Coronary artery disease		1
Coronavirus infection		1
Cough	42	164
COVID-19	105	267
COVID-19 immunisation		1
COVID-19 pneumonia	4	13
C-reactive protein increased	1	7
Crying	2	4
CSF protein increased		1
Cyanosis	1	3
Cystitis	4	8
Cytokine storm		1
Daydreaming		1
Deafness	6	12
Deafness bilateral		1
Deafness neurosensory	1	4
Deafness transitory		1
Deafness unilateral	3	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		29	88	11	22
		4	20	3	13
				3	6
					1
			2		
			2		
		8	19		1
			1		
			1		
		7	33	2	6
		1	1		
			1	1	1
					1
			1		
1	1	37	153	5	11
	1	23	75	82	192
			1		
				4	13
			4	1	3
		1	3	1	1
					1
			1		
				6	12
					1
				1	4
					1
				3	15

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Death	8	24
Decreased activity		1
Decreased appetite	37	119
Deep vein thrombosis	11	20
Defaecation disorder	1	1
Dehydration	8	35
Delirium	3	8
Delusion	1	3
Dementia	1	6
Demyelinating polyneuropathy		1
Dental caries	1	1
Dental paraesthesia	1	2
Dental restoration failure		1
Depressed level of consciousness	2	3
Depressed mood	4	11
Depression	3	7
Dermatitis	2	7
Dermatitis allergic		1
Dermatitis contact		1
Dermatomyositis	1	2
Dermatophytosis of nail	1	1
Dermoid cyst		1
Device leakage	1	1
Diabetes mellitus	1	5
Diabetic wound		1
Diaphragmalgia		1
Diaphragmatic disorder	1	1
Diarrhoea	81	302
Diarrhoea haemorrhagic	1	4
Differential white blood cell count abnormal		1
Diplegia		1
Diplopia	6	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			8	24
			1		
		29	98	8	21
		1	1	10	19
		1	1		
		1	16	7	19
				3	8
			1	1	2
				1	6
					1
		1	1		
		1	2		
			1		
				2	3
	1	4	10		1
		2	6	1	1
		1	6	1	1
					1
			1		
				1	2
		1	1		
					1
		1	1		
				1	5
					1
			1		
		1	1		
		68	267	13	35
				1	4
					1
					1
		5	9	1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discomfort	10	29
Disease progression		1
Disease recurrence	10	40
Disorientation	3	20
Disseminated intravascular coagulation		1
Disturbance in attention	4	14
Disturbance in social behaviour		1
Diverticulitis	3	7
Diverticulum intestinal		1
Dizziness	126	510
Dizziness postural	2	12
Drainage		1
Drooling		3
Drowning	1	1
Drug effective for unapproved indication	1	1
Drug eruption	1	2
Drug hypersensitivity	5	11
Drug ineffective	68	177
Drug interaction	2	8
Dry eye		6
Dry mouth	11	33
Dry skin	3	11
Dry throat	4	6
Dumping syndrome	1	1
Dupuytren's contracture		1
Dysarthria	4	10
Dysentery		1
Dysgeusia	6	41
Dysgraphia	1	1
Dyskinesia	3	7
Dyslipidaemia		1
Dyspepsia	6	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	29		
			1		
		2	14	8	26
		1	14	2	6
					1
		2	12	2	2
			1		
				3	7
					1
		103	446	23	64
		1	10	1	2
			1		
			3		
				1	1
		1	1		
			1	1	1
		4	9	1	2
	1		1	68	176
		1	5	1	3
			6		
		9	31	2	2
		3	9		2
		4	6		
		1	1		
					1
		4	7		3
					1
		6	39		2
		1	1		
		3	7		
			1		
		5	18	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysphagia	10	33
Dysphemia		2
Dysphonia	11	34
Dyspnoea	71	218
Dyspnoea at rest	1	2
Dyspnoea exertional	3	6
Dysstasia	11	29
Dysuria	1	4
Ear discomfort	2	20
Ear disorder	1	4
Ear infection	1	5
Ear infection viral	1	1
Ear pain	10	29
Ear pruritus	1	5
Ear swelling	1	5
Eating disorder	3	18
Ebola disease		1
Ecchymosis		1
Eczema	2	4
Ejection fraction decreased		2
Electrocardiogram T wave abnormal	1	1
Embolic stroke		1
Embolism		1
Emotional disorder		4
Emphysema	2	2
Encephalitis		2
Encephalopathy	1	1
Endocarditis		1
Endometriosis	1	1
Energy increased	1	2
Enlarged uvula	1	3
Eosinophil count increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	26	2	7
			2		
		7	24	4	10
1	1	43	142	28	76
				1	2
		2	5	1	1
		6	18	5	11
		1	4		
		2	18		2
		1	4		
		1	5		
		1	1		
		7	24	3	5
		1	5		
		1	5		
		2	16	1	2
					1
			1		
		2	3		1
					2
		1	1		
					1
					1
			4		
		1	1	1	1
					2
				1	1
					1
				1	1
		1	2		
		1	3		
					1

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis	9	27
Eructation		3
Erythema	35	150
Erythema multiforme	1	1
Erythema nodosum		1
Erythema of eyelid		2
Essential hypertension	1	1
Eustachian tube disorder		1
Eustachian tube dysfunction		1
Excessive cerumen production	2	4
Exercise tolerance decreased		1
Exophthalmos		1
Expired product administered	2	2
Exposure to SARS-CoV-2	9	15
Exposure via skin contact		4
Extraocular muscle disorder	1	1
Extraocular muscle paresis		1
Extrasystoles		2
Eye contusion	1	4
Eye discharge		3
Eye disorder	4	12
Eye haemorrhage		6
Eye infection		1
Eye inflammation		1
Eye irritation	1	10
Eyelid disorder		1
Eyelid function disorder	2	3
Eyelid oedema		2
Eyelid pain	2	4
Eyelid ptosis	1	4
Eyelids pruritus	2	2
Eye movement disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	19	4	8
			3		
		32	134	3	16
				1	1
			1		
			2		
		1	1		
			1		
					1
		2	4		
			1		
					1
		2	2		
		9	14		1
			4		
		1	1		
					1
			2		
		1	4		
			3		
		3	9	1	3
					6
			1		
					1
		1	10		
			1		
			1	2	2
			2		
		2	4		
			2	1	2
		2	2		
				1	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye oedema		2
Eye pain	10	30
Eye pruritus	2	19
Eye swelling	6	22
Face injury	1	1
Facial bones fracture		1
Facial discomfort		2
Facial neuralgia	1	1
Facial pain	4	15
Facial paralysis	17	77
Facial paresis		2
Faecaloma	1	1
Faeces discoloured	5	7
Faeces soft		1
Fall	25	74
Fatigue	262	904
Fear	1	13
Fear of falling		1
Feeding disorder	3	14
Feeling abnormal	71	274
Feeling cold	13	70
Feeling drunk	1	6
Feeling hot	19	108
Feeling jittery	1	7
Feeling of body temperature change	6	22
Fibrin D dimer increased	1	3
Fibromyalgia	1	4
Flank pain		1
Flatulence	5	19
Fluid intake reduced		3
Fluid overload		1
Fluid retention	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		8	24	2	6
		2	18		1
		4	13	2	9
		1	1		
					1
			2		
		1	1		
		3	13	1	2
				17	77
					2
				1	1
		4	6	1	1
			1		
		15	44	10	30
1	2	238	835	24	69
		1	12		1
			1		
		2	10	1	4
		63	253	8	21
		10	58	3	12
			5	1	1
		17	98	2	10
		1	6		1
		5	21	1	1
			1	1	2
		1	3		1
			1		
		5	18		1
			2		1
					1
		1	2	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flushing	11	52
Foaming at mouth	1	1
Food aversion		1
Food poisoning		2
Foot deformity		1
Foot fracture	3	3
Foreign body in throat		2
Foreign body sensation in eyes	2	2
Formication	2	2
Fracture		1
Frequent bowel movements	2	4
Frustration tolerance decreased	1	3
Full blood count abnormal		1
Functional gastrointestinal disorder	2	2
Fungal infection	1	3
Gait disturbance	26	96
Gait inability	9	25
Gallbladder disorder		2
Gangrene	1	1
Gastric disorder	4	12
Gastric ulcer		1
Gastritis	1	1
Gastritis bacterial		1
Gastroenteritis viral		3
Gastrointestinal disorder	3	10
Gastrointestinal haemorrhage	2	5
Gastrointestinal hypomotility		1
Gastrointestinal motility disorder		1
Gastrointestinal pain	5	10
Gastrointestinal sounds abnormal		1
Gastrointestinal stoma complication		1
Gastrooesophageal reflux disease	5	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	46	1	6
		1	1		
			1		
			2		
			1		
		1	1	2	2
					2
		2	2		
		2	2		
					1
		1	3	1	1
		1	3		
					1
		2	2		
		1	3		
		13	64	13	32
		5	13	4	12
			1		1
				1	1
		4	12		
					1
		1	1		
					1
			1		2
		3	9		1
				2	5
					1
			1		
		5	10		
			1		
			1		
		5	17		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Generalised anxiety disorder	1	1
Generalised tonic-clonic seizure	1	2
Gingival bleeding	1	1
Gingival discomfort	1	1
Gingival erythema		1
Gingival pain		2
Gingival swelling		1
Gingivitis		1
Glare		1
Glassy eyes		1
Glaucoma		2
Glomerular filtration rate decreased	2	2
Glomerulonephritis minimal lesion	1	1
Glossitis		2
Glossodynia	4	10
Glycosylated haemoglobin increased	1	2
Goitre	1	1
Gout		2
Grip strength decreased	1	1
Groin pain	2	3
Guillain-Barre syndrome	3	7
Haematemesis	1	6
Haematochezia	2	14
Haematoma	2	4
Haematuria		4
Haemoglobin abnormal		1
Haemoglobin decreased		2
Haemoptysis	2	8
Haemorrhage	6	17
Haemorrhage urinary tract	1	3
Haemorrhagic stroke		3
Haemorrhagic urticaria	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	2
				1	1
		1	1		
			1		
			2		
			1		
			1		
			1		
			1		
					2
				2	2
				1	1
			2		
		4	9		1
		1	1		1
		1	1		
			2		
		1	1		
		1	1	1	2
				3	7
				1	6
		1	1	1	13
		2	4		
			1		3
					1
					2
			4	2	4
			1	6	16
				1	3
					3
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhoids	1	5
Hallucination	6	14
Hallucination, auditory		2
Hallucination, visual		3
Hand fracture		2
Hangover		1
Haptoglobin increased	1	1
Headache	289	1,061
Head deformity	1	1
Head discomfort	4	28
Head injury	3	12
Heart injury	1	3
Heart rate abnormal	1	7
Heart rate decreased		7
Heart rate increased	18	106
Heart rate irregular	3	15
Heart valve incompetence	1	1
Hemiparesis	3	6
Hemiplegia		3
Henoch-Schonlein purpura	1	2
Heparin-induced thrombocytopenia		1
Hepatic cyst		1
Hepatic enzyme increased	4	4
Hepatic function abnormal	1	1
Hepatic pain	1	2
Hepatitis	1	3
Hepatitis acute		1
Hepatomegaly	1	1
Hereditary haemorrhagic telangiectasia		1
Herpes simplex		6
Herpes simplex reactivation		1
Herpes virus infection	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		1
				6	14
					2
					3
					2
					1
		1	1		
		263	976	26	85
				1	1
		3	25	1	3
		3	6		6
				1	3
		1	5		2
			4		3
		12	83	6	23
		1	12	2	3
				1	1
				3	6
					3
				1	2
					1
			1		
		4	4		
				1	1
				1	2
				1	3
					1
		1	1		
			1		
			5		1
			1		
		1	1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster	19	64
Herpes zoster oticus	1	1
Hiatus hernia		1
Hiccups		4
Hip fracture	2	4
Hordeolum		1
Hot flush	4	19
Hyperactive pharyngeal reflex		1
Hyperacusis	2	5
Hyperaesthesia	1	4
Hyperaesthesia teeth		1
Hyperchlorhydria		1
Hyperglycaemia	1	2
Hyperhidrosis	26	101
Hyperlipidaemia		1
Hyperpyrexia	2	2
Hyperreflexia		1
Hypersensitivity	22	67
Hypersensitivity vasculitis	2	4
Hypersomnia	11	35
Hypertension	20	84
Hypertensive crisis	1	2
Hypertensive emergency		1
Hyperthermia		1
Hypertonia		1
Hyperventilation	1	4
Hypoacusis	2	15
Hypoesthesia	34	127
Hypoesthesia eye	1	2
Hypoesthesia oral	3	27
Hypoesthesia teeth		1
Hypogeusia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	54	5	10
				1	1
			1		
			4		
				2	4
					1
		3	18	1	1
			1		
		2	4		1
		1	4		
			1		
					1
				1	2
		21	87	5	14
					1
				2	2
			1		
		20	49	2	18
				2	4
		10	32	1	3
1	1	9	46	11	38
				1	2
					1
			1		
					1
		1	4		
		2	12		3
		27	100	7	27
		1	2		
		3	25		2
			1		
			3	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoglycaemia		4
Hypokalaemia		1
Hypokinesia	4	9
Hypophagia		3
Hypopnoea	4	7
Hyporesponsive to stimuli		1
Hyposmia		1
Hypotension	5	26
Hypothermia	1	3
Hypothyroidism		1
Hypovolaemic shock	1	2
Hypoxia	3	6
Illrd nerve paralysis	1	1
Ileus		1
Ill-defined disorder		2
Illness	48	127
Immobile	2	2
Immune system disorder	1	4
Immune thrombocytopenia	1	2
Impaired driving ability	1	4
Impaired healing		2
Impaired self-care	1	1
Impaired work ability	2	3
Inappropriate affect	1	1
Inappropriate schedule of product administration	29	134
Incision site haemorrhage		1
Incoherent	1	3
Incomplete course of vaccination	1	3
Incontinence		2
Incorrect dosage administered	1	2
Incorrect dose administered		5
Incorrect dose administered by device	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		2
					1
		3	6	1	3
			1		2
		2	3	2	4
					1
			1		
		2	10	3	16
				1	3
					1
				1	2
				3	6
				1	1
					1
			2		
1	1	45	117	3	10
				2	2
		1	3		1
				1	2
		1	3		1
			2		
				1	1
			1	2	2
		1	1		
		28	133	1	1
					1
			1	1	2
		1	3		
			1		1
		1	2		
			4		1
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect route of product administration	3	18
Increased appetite	1	1
Increased bronchial secretion		1
Increased upper airway secretion		2
Increased viscosity of upper respiratory secretion		1
Induration		1
Infection	5	10
Inflammation	7	17
Inflammatory pain		1
Influenza	9	29
Influenza like illness	29	102
Initial insomnia	1	3
Injected limb mobility decreased	1	4
Injection site bruising		2
Injection site discolouration		2
Injection site discomfort		2
Injection site erythema	2	16
Injection site haematoma		1
Injection site haemorrhage	1	4
Injection site induration		1
Injection site mass		2
Injection site nodule		1
Injection site oedema		1
Injection site pain	7	71
Injection site papule		1
Injection site pruritus		2
Injection site rash		7
Injection site reaction	1	2
Injection site swelling	5	15
Injection site urticaria		1
Injection site warmth		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	17		1
		1	1		
			1		
			1		1
					1
			1		
		2	4	3	6
		6	15	1	2
			1		
		7	25	2	4
		27	94	2	8
		1	3		
		1	4		
			2		
			2		
			2		
		2	16		
					1
		1	4		
			1		
			2		
			1		
			1		
		7	70		1
			1		
			2		
			7		
		1	2		
		5	15		
			1		
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inner ear disorder	1	1
Insomnia	32	106
Intentional product misuse		1
Internal haemorrhage	1	1
International normalised ratio decreased		2
International normalised ratio increased		3
Intervertebral disc protrusion		1
Intestinal haemorrhage	1	1
Intestinal obstruction		1
Intra-abdominal haematoma		1
Intracranial mass	1	1
Intranasal paraesthesia		2
Intraocular pressure increased		2
Intraocular pressure test abnormal		1
Iridocyclitis	1	2
Irritability	1	4
Irritability postvaccinal		1
Irritable bowel syndrome	1	5
Ischaemic stroke	2	8
IVth nerve paralysis		2
Jaundice	1	3
Jaw clicking	1	1
Jaw disorder	1	1
Joint injury	1	3
Joint instability		1
Joint lock	1	2
Joint noise	1	1
Joint range of motion decreased	3	10
Joint stiffness	2	7
Joint swelling	11	38
Joint warmth	1	1
Kidney infection	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		28	96	4	10
			1		
				1	1
			2		
			1		2
			1		
				1	1
					1
				1	1
			2		
			1		1
			1		
				1	2
		1	4		
			1		
			3	1	2
				2	8
					2
		1	2		1
		1	1		
		1	1		
		1	2		1
			1		
		1	2		
		1	1		
		3	10		
		2	6		1
		10	34	1	4
		1	1		
				1	6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laboratory test abnormal	1	1
Labyrinthitis		1
Lacrimation increased	4	16
Lacunar infarction		1
Large intestine polyp		1
Laryngeal oedema		1
Laryngeal pain		1
Laryngitis	2	3
Laziness		1
Lethargy	13	50
Leukaemia		5
Leukocytosis		3
Lichenoid keratosis		1
Ligament sprain	1	3
Limb discomfort	14	45
Limb injury	2	7
Limb mass		2
Lipase increased		1
Lip blister		1
Lip discolouration		1
Lip disorder		5
Lip erythema	1	2
Lip haemorrhage	1	1
Lipids increased		1
Lip injury	2	2
Lip oedema		3
Lipoma	1	1
Lip pain		2
Lip swelling	7	37
Liquid product physical issue		1
Listless	1	2
Liver disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		3	15	1	1
					1
			1		
					1
			1		
		1	1	1	2
			1		
		11	44	2	6
			1		4
			1		2
					1
		1	3		
		11	42	3	3
		2	7		
			2		
			1		
			1		
					1
			5		
		1	2		
				1	1
			1		
		2	2		
			2		1
				1	1
			2		
		7	30		7
			1		
		1	2		
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver function test increased	1	1
Liver injury	2	2
Localised infection	1	4
Loss of consciousness	19	72
Loss of personal independence in daily activities	10	29
Low density lipoprotein increased	1	1
Lower gastrointestinal haemorrhage		1
Lower respiratory tract congestion		1
Lower respiratory tract infection	1	1
Lumbar puncture abnormal		1
Lumbar radiculopathy		1
Lung disorder	3	6
Lung hyperinflation	1	1
Lung infiltration	1	1
Lung neoplasm malignant	1	1
Lung opacity	1	1
Lymphadenitis		1
Lymphadenopathy	42	115
Lymph node pain	5	19
Lymph node palpable	1	1
Lymphocyte count decreased		1
Lymphocytosis		1
Lymphoedema		2
Lymphoma		1
Lymphopenia		1
Macular oedema		1
Macule		1
Major depression	1	1
Malaise	97	404
Mass	6	11
Mastication disorder		5
May-Thurner syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	2
		1	4		
				19	72
		6	22	4	7
		1	1		
					1
			1		
				1	1
					1
			1		
	1	3	6		
		1	1		
				1	1
				1	1
		1	1		
					1
		41	110	1	5
		4	17	1	2
		1	1		
			1		
			1		
			2		
					1
					1
					1
			1		
				1	1
		88	369	9	35
		5	10	1	1
			3		2
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mechanical urticaria		1
Medication error		1
Melaena		1
Memory impairment	9	19
Meniere's disease		1
Meningitis	1	2
Meningitis aseptic		2
Meningitis viral		2
Mental disorder	1	4
Mental impairment	5	11
Mental status changes	1	3
Metabolic acidosis		1
Metamyelocyte count increased		1
Microembolism		1
Micturition disorder		1
Micturition urgency	1	1
Middle insomnia		6
Migraine	10	33
Migraine with aura	1	4
Migraine without aura	1	1
Miliaria		1
Mitral valve disease	1	1
Mitral valve incompetence		1
Mixed connective tissue disease		1
Moaning		1
Mobility decreased	5	19
Monocyte count abnormal		1
Monocyte count increased		3
Monoplegia		2
Mood altered		1
Mood swings		1
Motor dysfunction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
		9	18		1
					1
				1	2
					2
					2
		1	3		1
				5	11
		1	2		1
			1		
					1
					1
			1		
		1	1		
			6		
		7	25	3	8
		1	4		
		1	1		
			1		
				1	1
					1
					1
			1		
		4	16	1	3
			1		
			2		1
					2
			1		
					1
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mouth haemorrhage	1	3
Mouth injury		1
Mouth swelling	4	15
Mouth ulceration	1	5
Movement disorder	7	28
Mucosal disorder		1
Mucosal inflammation		1
Mucous stools	1	1
Multi-organ disorder	1	1
Multiple organ dysfunction syndrome		2
Multiple sclerosis	1	3
Multiple sclerosis relapse		2
Muscle contractions involuntary		2
Muscle discomfort	2	7
Muscle disorder		3
Muscle fatigue	1	3
Muscle injury	1	1
Muscle rigidity		2
Muscle spasms	21	75
Muscle spasticity		1
Muscle strain	1	6
Muscle swelling		2
Muscle tightness	3	26
Muscle twitching	3	14
Muscular weakness	18	63
Musculoskeletal chest pain	2	12
Musculoskeletal discomfort	7	20
Musculoskeletal disorder	1	5
Musculoskeletal pain	3	7
Musculoskeletal stiffness	26	88
Myalgia	98	378
Myasthenia gravis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
			1		
		3	11	1	4
		1	5		
		5	24	2	4
			1		
			1		
		1	1		
		1	1		
					2
				1	3
					2
			1		1
		2	7		
			1		2
		1	3		
		1	1		
			1		1
		17	65	4	10
					1
		1	5		1
			2		
		3	22		4
		2	11	1	3
		11	46	7	17
		2	10		2
		7	18		2
		1	3		2
		2	6	1	1
		25	78	1	10
1	1	90	353	8	25
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myelitis transverse		4
Myelocyte count increased		1
Myocardial infarction	12	39
Myocarditis	1	2
Myoclonus		1
Myositis		1
Nasal congestion	15	60
Nasal crusting		1
Nasal discomfort	1	4
Nasal disorder		1
Nasal dryness	1	2
Nasal injury	1	1
Nasal oedema	2	4
Nasal pruritus		1
Nasopharyngitis	22	76
Nausea	152	586
Near death experience		5
Neck injury		1
Neck mass		3
Neck pain	23	92
Necrosis	1	1
Needle issue	1	1
Neoplasm	3	3
Neoplasm malignant	3	4
Neoplasm progression		2
Neoplasm skin	1	1
Nephrolithiasis	1	8
Nephropathy	3	3
Nephrotic syndrome	1	1
Nerve compression	3	7
Nerve injury	2	3
Nervousness	8	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
				12	39
				1	2
			1		
			1		
		14	57	1	3
			1		
		1	4		
			1		
		1	2		
		1	1		
		2	4		
			1		
		21	75	1	1
1	1	136	532	16	54
					5
			1		
			3		
		20	82	3	10
				1	1
		1	1		
		3	3		
				3	4
			1		1
		1	1		
				1	8
				3	3
				1	1
		2	6	1	1
		2	3		
		7	30	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervous system disorder	3	8
Neuralgia	7	17
Neuritis		1
Neurological symptom		2
Neuromyelitis optica spectrum disorder	1	1
Neuropathy peripheral	7	21
Neutropenia		1
Neutrophil count abnormal		1
Neutrophil count decreased		1
Neutrophil count increased		1
Nightmare		10
Night sweats	7	19
Nipple pain		2
Nipple swelling		2
Nitrite urine present		1
No adverse event	8	19
Nocturia	1	1
Nodal rhythm		1
Nodule		4
Non-Hodgkin's lymphoma		2
Normocytic anaemia		1
Nystagmus		1
Obesity		1
Obstructive airways disorder		1
Occipital neuralgia		1
Ocular discomfort	2	8
Ocular hyperaemia	3	14
Ocular icterus		1
Oculofacial paralysis	1	1
Odynophagia		4
Oedema		3
Oedema peripheral	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6		2
		6	16	1	1
			1		
			2		
				1	1
			1	7	20
					1
					1
					1
			1		
			9		1
		5	16	2	3
			2		
			2		
			1		
		8	19		
		1	1		
			1		
			4		
					2
			1		
			1		
			1		
					1
		2	8		
		3	12		2
			1		
				1	1
			4		
			2		1
		2	2		

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oesophageal pain		2
Off label use	23	119
Oligodipsia		1
Omphalitis	1	1
Optic ischaemic neuropathy	3	3
Optic neuritis		3
Oral candidiasis	1	2
Oral discomfort	1	8
Oral disorder		3
Oral fungal infection	1	2
Oral herpes	5	13
Oral lichen planus	1	1
Oral mucosal blistering	2	2
Oral pain	3	4
Oral pruritus		5
Orchitis		1
Orchitis noninfective		1
Oromandibular dystonia		1
Oropharyngeal discomfort	6	14
Oropharyngeal pain	23	87
Orthostatic hypotension		2
Osteoarthritis		3
Osteomyelitis		1
Osteoporosis		1
Ovarian cancer		1
Overdose	1	18
Overweight		1
Oxygen saturation abnormal		4
Oxygen saturation decreased	6	20
Pain	194	624
Painful respiration	2	3
Pain in extremity	205	766

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		23	118		1
					1
				1	1
				3	3
					3
		1	2		
		1	8		
			2		1
		1	2		
		4	12	1	1
		1	1		
		1	1	1	1
		3	4		
			4		1
			1		
			1		
			1		
		4	10	2	4
		22	82	1	5
			1		1
			3		
					1
		1	18		
					1
			4		
		1	7	5	13
1	1	175	568	19	56
				2	3
		187	716	18	50

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain in jaw	4	22
Pain of skin	4	9
Palatal disorder		1
Pallor		4
Palmar erythema		2
Palpitations	19	93
Pancreatic disorder	1	1
Pancreatitis		3
Pancreatitis acute		1
Pancytopenia		2
Panic attack	3	6
Panic disorder		1
Panic reaction	3	4
Paraesthesia	24	111
Paraesthesia oral	8	48
Paralysis	3	18
Paranasal sinus discomfort		4
Paranasal sinus hypersecretion		1
Paranoia		2
Paraplegia	1	1
Parkinsonism	1	1
Parkinson's disease		1
Parosmia	2	14
Patient elopement		1
Pelvic fracture		1
Pemphigoid		1
Penile haemorrhage		1
Pericardial effusion		4
Pericarditis	1	8
Periorbital oedema		1
Periorbital swelling	1	9
Peripheral coldness	2	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	17		5
		4	9		
					1
			2		2
			2		
		13	77	6	16
		1	1		
					3
					1
					2
		2	5	1	1
			1		
		3	4		
		24	98		13
		6	41	2	7
				3	18
			4		
			1		
			2		
				1	1
		1	1		
					1
		2	14		
			1		
					1
					1
					4
				1	8
			1		
		1	8		1
		2	14		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral sensory neuropathy		2
Peripheral swelling	41	134
Peroneal nerve palsy		2
Petechiae		3
Pharyngeal erythema	3	5
Pharyngeal inflammation	1	1
Pharyngeal paraesthesia	1	1
Pharyngeal swelling	8	36
Pharyngitis	3	4
Pharyngitis streptococcal		3
Phlebitis		2
Photophobia	3	11
Photopsia		5
Photosensitivity reaction	1	2
Pigmentation disorder		1
Pituitary tumour benign		1
Plantar erythema		1
Plantar fasciitis		1
Platelet count decreased	4	15
Platelet count increased		2
Platelet disorder		1
Pleural effusion		1
Pleuritic pain		2
Plicated tongue		1
Pneumonia	6	28
Pneumonia aspiration	1	1
Pneumonia bacterial		1
Pneumonia staphylococcal	1	1
Pneumonia viral	1	2
Pneumonitis	1	1
Pneumothorax	2	3
Poisoning		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		33	112	8	22
					2
			1		2
		3	5		
		1	1		
		1	1		
		6	22	2	14
		2	3	1	1
			3		
			2		
		2	10	1	1
			3		2
			1	1	1
			1		
					1
			1		
			1		
			3	4	12
			2		
					1
					1
			1		1
			1		
				6	28
				1	1
					1
				1	1
				1	2
				1	1
				2	3
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pollakiuria	4	14
Polychondritis		1
Polycythaemia		1
Polydipsia		1
Polymyalgia rheumatica	2	4
Polyuria	2	2
Poor quality product administered	3	14
Poor quality sleep	2	13
Postictal state		1
Post procedural complication		1
Post procedural haemorrhage		1
Post procedural infection		1
Post procedural oedema		1
Post-traumatic neuralgia		1
Post-traumatic stress disorder		1
Posture abnormal		1
Potentiating drug interaction	1	2
Pre-existing condition improved	1	2
Presyncope	5	28
Procedural haemorrhage		1
Proctalgia		1
Product administered at inappropriate site	8	19
Product administration error		4
Product colour issue	1	1
Product communication issue		1
Product dose omission issue	6	13
Productive cough	4	11
Product leakage		1
Product preparation error		10
Product preparation issue		6
Product quality issue		1
Product storage error		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	14		
					1
			1		
			1		
				2	4
		2	2		
		3	14		
		2	13		
					1
	1				
					1
					1
			1		
			1		
			1		
			1		
		1	2		
		1	2		
		4	21	1	7
					1
			1		
		7	18	1	1
			3		1
		1	1		
			1		
		6	13		
		4	11		
			1		
			10		
			6		
			1		
			3		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product supply issue	3	5
Product temperature excursion issue	2	3
Product use in unapproved indication	1	1
Product use issue	3	49
Prostate cancer	1	2
Prostatic specific antigen increased		1
Proteinuria	1	2
Prothrombin level increased		1
Prothrombin time prolonged		1
Pruritus	58	242
Pseudofolliculitis		1
Psoriasis	3	6
Psoriatic arthropathy	1	1
Psychiatric symptom		1
Psychomotor hyperactivity	1	2
Pulmonary artery thrombosis		1
Pulmonary congestion	4	7
Pulmonary embolism	10	24
Pulmonary fibrosis	1	3
Pulmonary hypertension		1
Pulmonary mass	1	2
Pulmonary oedema	3	6
Pulmonary pain		3
Pulmonary thrombosis	14	18
Pulmonary venous thrombosis	1	1
Pulse abnormal	1	4
Pulse absent	1	1
Pulseless electrical activity	1	1
Pulse pressure increased		1
Pulse volume decreased	1	1
Pustule		3
Pyrexia	193	671

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5		
		2	3		
		1	1		
		3	48		1
				1	2
			1		
		1	1		1
					1
			1		
		53	214	5	28
			1		
		1	4	2	2
				1	1
			1		
		1	2		
					1
				4	7
				10	24
				1	3
					1
		1	2		
				3	6
					3
				14	18
				1	1
				1	4
				1	1
				1	1
			1		
		1	1		
			2		1
		169	603	24	68

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Quality of life decreased	1	1
Rash	78	243
Rash erythematous	6	37
Rash macular	8	28
Rash maculo-papular		2
Rash morbilliform	1	3
Rash papular	3	19
Rash pruritic	7	39
Rash pustular		1
Rash vesicular	1	5
Reaction to excipient	1	3
Reaction to preservatives	1	1
Reading disorder		1
Rectal discharge		1
Rectal haemorrhage		5
Red blood cell count abnormal		1
Red blood cell count decreased	2	2
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased		4
Red cell distribution width increased		1
Reduced facial expression		1
Regurgitation		1
Renal atrophy	1	1
Renal cyst		1
Renal disorder		5
Renal failure	1	4
Renal impairment	2	4
Renal pain	1	6
Renal tubular disorder	1	1
Renal tubular injury		1
Respiration abnormal		1
Respiratory arrest	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		69	208	9	35
		4	28	2	9
		7	25	1	3
			2		
			1	1	2
		1	16	2	3
		5	33	2	6
			1		
		1	5		
		1	1		2
		1	1		
					1
			1		
					5
			1		
		1	1	1	1
			1		
			2		2
					1
					1
			1		
			3		2
				1	4
				2	4
		1	5		1
				1	1
					1
					1
				3	7

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory disorder	1	10
Respiratory distress	3	11
Respiratory failure		2
Respiratory rate decreased	2	2
Respiratory rate increased	1	4
Respiratory symptom	1	1
Respiratory tract congestion	7	14
Respiratory tract infection		4
Respiratory tract inflammation	1	1
Respiratory tract irritation	2	2
Respiratory tract oedema	1	1
Restless legs syndrome	2	2
Restlessness	2	8
Retching	4	22
Retinal artery occlusion		2
Retinal detachment		1
Retinal disorder		1
Retinal vascular thrombosis	1	1
Retinal vein occlusion	1	3
Retinitis pigmentosa		1
Retinopathy hypertensive		1
Rhabdomyolysis		1
Rheumatic disorder	1	1
Rheumatoid arthritis	6	14
Rhinalgia		1
Rhinitis		3
Rhinitis allergic		1
Rhinorrhoea	23	77
Rib fracture	1	2
Rotator cuff syndrome		1
Salivary gland disorder	1	1
Salivary gland enlargement		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	7		3
				3	11
					2
		1	1	1	1
				1	4
				1	1
		4	11	3	3
					4
		1	1		
		1	1	1	1
				1	1
		2	2		
		2	7		1
1	1	2	18	2	4
					2
					1
			1		
		1	1		
				1	3
					1
					1
		1	1		
				6	14
			1		
			2		1
			1		
		22	73	1	4
				1	2
			1		
				1	1
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Salivary hypersecretion	2	5
SARS-CoV-2 antibody test negative	5	15
SARS-CoV-2 antibody test positive		4
SARS-CoV-2 test negative		1
SARS-CoV-2 test positive	5	31
Scab	1	3
Scar	2	4
Sciatica	4	11
Scleral discolouration		1
Scratch		2
Screaming	1	1
Scrotal disorder		1
Scrotal erythema		1
Scrotal inflammation		1
Scrotal pain	1	2
Seasonal allergy	1	2
Secretion discharge	1	4
Sedation		1
Seizure	10	32
Seizure like phenomena		1
Sensation of blood flow		1
Sensation of foreign body	1	8
Sensitive skin	1	4
Sensitivity to weather change		1
Sensory disturbance		7
Sensory level abnormal		1
Sensory loss	2	3
Sepsis		4
Serum sickness	1	1
Shock	1	5
Shock symptom		1
Sialoadenitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	1	1
		4	13	1	2
			4		
			1		
			10	5	21
		1	3		
		2	2		2
		4	7		4
			1		
			2		
		1	1		
			1		
			1		
		1	2		
		1	2		
		1	4		
			1		
				10	32
					1
					1
		1	8		
		1	4		
			1		
			7		
			1		
		1	2	1	1
					4
		1	1		
				1	5
					1
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus bradycardia		2
Sinus congestion	3	8
Sinus disorder	5	12
Sinus headache	3	8
Sinusitis	6	12
Sinusitis bacterial		2
Sinus pain	1	3
Sinus tachycardia		1
Sitting disability		1
Skin abrasion		2
Skin bacterial infection	1	1
Skin burning sensation		11
Skin discolouration	10	26
Skin disorder	4	17
Skin exfoliation	3	8
Skin fissures		1
Skin haemorrhage	3	3
Skin indentation	1	1
Skin infection	1	1
Skin irritation	3	4
Skin laceration	2	9
Skin laxity		1
Skin lesion	2	7
Skin mass	2	3
Skin reaction		1
Skin swelling	1	5
Skin turgor decreased	1	1
Skin warm		3
Sleep deficit		1
Sleep disorder	6	25
Sleep disorder due to a general medical condition		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		2	7	1	1
		4	9	1	3
		3	8		
		6	12		
					2
		1	3		
			1		
			1		
			2		
				1	1
			11		
		8	22	2	4
		4	16		1
		3	8		
					1
		2	2	1	1
		1	1		
				1	1
		3	4		
		1	3	1	6
			1		
		2	6		1
		2	2		1
			1		
		1	4		1
				1	1
			3		
			1		
		6	23		2
			3		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep disorder due to general medical condition, insomnia type		1
Slow speech		1
Sluggishness	3	9
Small intestinal haemorrhage	1	1
Small intestinal obstruction		1
Sneezing	8	26
Soft tissue swelling	1	1
Solar lentigo		1
Somatic symptom disorder	1	2
Somnolence	23	98
Speech disorder	7	30
Spinal cord disorder		1
Spinal fusion surgery		1
Spinal osteoarthritis		2
Spinal pain	1	5
Spleen disorder	1	1
Splenic infarction	1	1
Splenic vein thrombosis		1
Splinter haemorrhages		1
Staphylococcal infection	1	2
Staring	1	2
Stenosis		1
Stevens-Johnson syndrome	1	1
Stoma site pruritus		1
Stomatitis		4
Strabismus	1	3
Streptococcus test positive		1
Stress	3	10
Subarachnoid haemorrhage		3
Sudden cardiac death		1
Sudden death	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		3	9		
				1	1
					1
		7	25	1	1
		1	1		
					1
		1	2		
		22	94	1	4
		5	24	2	6
					1
					1
			2		
		1	5		
				1	1
				1	1
					1
			1		
				1	2
				1	2
					1
				1	1
			1		
			3		1
			1	1	2
			1		
		2	9	1	1
					3
					1
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden hearing loss	1	3
Suffocation feeling		1
Suicidal ideation		1
Sunburn	1	3
Superficial vein prominence		1
Superior sagittal sinus thrombosis	1	1
Supraventricular extrasystoles		1
Supraventricular tachycardia		1
Suspected COVID-19	8	24
Swelling	15	68
Swelling face	18	74
Swelling of eyelid	2	9
Swollen tongue	8	33
Syncope	15	47
Synovitis		1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	1	3
Tachycardia	4	18
Tachypnoea	2	6
Taste disorder	7	25
Temperature intolerance	1	3
Temperature regulation disorder		1
Tenderness	6	14
Tendon discomfort		1
Tendonitis		1
Tendon pain	1	2
Tenosynovitis		1
Tension		1
Tension headache	1	4
Terminal insomnia		1
Testicular pain		1
Testicular swelling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
			1		
					1
		1	3		
			1		
				1	1
					1
					1
		3	7	5	17
		13	56	2	12
		14	55	4	19
		2	8		1
		4	22	4	11
			1	15	46
			1		
					1
				1	3
		2	8	2	10
		1	3	1	3
		7	23		2
		1	3		
			1		
		6	14		
			1		
			1		
			1	1	1
			1		
			1		
			2	1	2
			1		
			1		
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tetanus	1	1
Thalamic infarction		1
Therapeutic response unexpected	8	23
Thermal burn		2
Thinking abnormal	2	13
Thirst	4	13
Throat clearing		1
Throat irritation	6	32
Throat tightness	7	27
Thrombocytopenia	2	6
Thrombophlebitis superficial	2	4
Thrombosis	29	48
Thrombotic stroke	1	1
Thyroid disorder	1	2
Thyroiditis		1
Tic		1
Tinnitus	24	58
Tongue blistering		1
Tongue coated		2
Tongue discolouration	1	2
Tongue discomfort	3	9
Tongue disorder	2	9
Tongue eruption	1	1
Tongue erythema	1	4
Tongue haematoma		1
Tongue movement disturbance	2	2
Tongue oedema		1
Tongue pruritus		3
Tonsillar hypertrophy		1
Tooth abscess	1	1
Toothache	6	17
Tooth discolouration	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		8	23		
			1		1
		2	12		1
		3	11	1	2
			1		
		6	28		4
		5	17	2	10
				2	6
			1	2	3
			1	29	47
				1	1
		1	2		
			1		
			1		
		20	50	4	8
			1		
			2		
		1	2		
		3	9		
		2	9		
		1	1		
		1	4		
			1		
		2	2		
			1		
			3		
			1		
		1	1		
		6	15		2
		1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tooth disorder	1	4
Tooth infection	2	4
Tooth injury		1
Total lung capacity decreased	1	1
Tourette's disorder	1	1
Toxicity to various agents		1
Transaminases decreased	1	1
Transaminases increased		1
Transient global amnesia		1
Transient ischaemic attack	3	10
Transplant failure		1
Tremor	27	98
Trigeminal nerve disorder	1	3
Trigeminal neuralgia	1	1
Trigger finger	2	2
Troponin I increased	1	1
Troponin increased	1	4
Tumour marker abnormal		1
Tunnel vision		1
Type 1 diabetes mellitus		1
Type V hyperlipidaemia	1	1
Ulcer		1
Underdose	3	21
Unresponsive to stimuli	2	11
Upper-airway cough syndrome	1	5
Upper limb fracture	1	2
Upper respiratory tract congestion	3	8
Upper respiratory tract infection	1	3
Ureteric stenosis		1
Urinary incontinence	2	9
Urinary retention	1	2
Urinary tract infection	5	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
		1	3	1	1
					1
		1	1		
				1	1
					1
			1		
			1		
				3	10
					1
	1	24	81	3	17
		1	2		1
		1	1		
		2	2		
		1	1		
		1	1		3
					1
					1
					1
				1	1
			1		
		3	21		
				2	11
		1	4		1
				1	2
		3	8		
		1	3		
					1
		1	6	1	3
				1	2
		4	16	1	6

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\* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary tract infection bacterial		1
Urine abnormality		1
Urine analysis abnormal	2	2
Urine leukocyte esterase positive	1	2
Urine output decreased	1	1
Urine output increased		1
Urobilinogen urine increased		1
Urticaria	27	108
Urticaria thermal		1
Vaccination complication	1	2
Vaccination failure	12	20
Vaccination site bruising	1	16
Vaccination site cellulitis	1	5
Vaccination site coldness		4
Vaccination site discolouration	2	5
Vaccination site discomfort	2	14
Vaccination site erythema	23	98
Vaccination site extravasation		1
Vaccination site haematoma		1
Vaccination site haemorrhage	4	16
Vaccination site hypoaesthesia	1	3
Vaccination site induration	1	4
Vaccination site infection		3
Vaccination site inflammation	1	4
Vaccination site irritation	1	1
Vaccination site joint movement impairment		2
Vaccination site joint pain		2
Vaccination site lymphadenopathy		1
Vaccination site macule		2
Vaccination site mass	6	31
Vaccination site movement impairment	2	9
Vaccination site nodule	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		2	2		
		1	2		
		1	1		
			1		
			1		
		24	94	3	14
			1		
1	1		1	1	1
				12	20
		1	13		3
			1	1	4
			4		
		2	5		
		2	14		
		23	92		6
			1		
					1
		4	16		
		1	3		
		1	4		
			3		
		1	3		1
		1	1		
			2		
			2		
			1		
			2		
		5	28	1	3
		2	9		
		1	3		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site oedema		1
Vaccination site pain	113	489
Vaccination site papule		1
Vaccination site paraesthesia	1	5
Vaccination site pruritus	18	69
Vaccination site rash	9	25
Vaccination site reaction	2	8
Vaccination site streaking	1	1
Vaccination site swelling	17	88
Vaccination site urticaria	3	11
Vaccination site vesicles		1
Vaccination site warmth	8	42
Vaginal discharge		1
Vaginal haemorrhage	1	2
Varicella	1	1
Varicose vein	1	3
Vascular pain		1
Vein discolouration		1
Vein disorder	2	5
Venous thrombosis limb	1	2
Ventricular arrhythmia		1
Ventricular extrasystoles	1	3
Ventricular fibrillation		2
Ventricular tachycardia		2
Vertigo	18	62
Vertigo positional	2	2
Vestibular disorder	2	3
Viral test positive	1	1
Viral upper respiratory tract infection		1
Vision blurred	16	59
Visual acuity reduced	1	1
Visual field defect	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
1	1	111	475	2	14
			1		
		1	5		
		18	64		5
		8	24	1	1
		2	7		1
		1	1		
		17	82		6
		2	9	1	2
			1		
		8	37		5
			1		
				1	2
		1	1		
		1	3		
			1		
			1		
		1	4	1	1
				1	2
					1
				1	3
					2
					2
		12	53	6	9
		2	2		
		1	2	1	1
		1	1		
			1		
		14	50	2	9
		1	1		
		1	3		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment	9	34			5	26	4	8
Vitamin B12 increased	1	1			1	1		
Vitamin D decreased	2	3			2	3		
Vitamin D deficiency	1	1			1	1		
Vlth nerve paralysis		3						3
Vitreous degeneration		1						1
Vitreous floaters	1	4			1	2		2
Vocal cord disorder	1	1					1	1
Vomiting	53	205	1	1	37	169	16	36
Vomiting projectile	1	4			1	4		
Vulvovaginal burning sensation		1				1		
Walking aid user	2	3			2	3		
Walking disability	1	1			1	1		
Weight decreased	17	43			11	35	6	8
Weight fluctuation		1				1		
Weight increased	6	13			6	13		
Wheezing	9	21			7	15	2	6
White blood cell count decreased		3				3		
White blood cell count increased	1	11			1	7		4
White blood cells urine positive	1	2			1	2		
White matter lesion		1						1
Wound	1	3				1	1	2
Wound haemorrhage	1	1			1	1		
Wrist fracture		1						1
Wrong product administered	2	6			2	6		
Wrong schedule		1				1		
Wrong technique in device usage process		1				1		
Wrong technique in product usage process	1	7			1	7		
	1	2			1	2		
	6,022	21,566	15	22	4575	17169	1447	4397

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	7	18			7	17		1
Abdominal distension	2	4			2	4		
Abdominal pain	2	11			2	8		3
Abdominal pain lower		2				2		
Abdominal pain upper	9	33			8	29	1	4
Abnormal behaviour		2				2		
Abnormal dreams	1	2			1	1		1
Abnormal faeces		2				2		
Acarodermatitis		1				1		
Accidental exposure to product		2				2		
Accidental overdose		1				1		
Achlorhydria	1	1			1	1		
Acne		1				1		
Acute hepatic failure		1						1
Acute kidney injury	1	4					1	4
Acute myeloid leukaemia		2						2
Acute myocardial infarction	1	1					1	1
Adrenal disorder		1				1		
Ageusia		8				8		
Aggression		2				1		1
Agitation	1	2			1	1		1
Allergy to vaccine		4				3		1
Alopecia		1				1		
Altered state of consciousness	1	2					1	2
Amnesia		4				3		1
Amyloidosis		1						1
Anaemia	1	3				1	1	2
Anal haemorrhage		1				1		
Anal incontinence		1				1		
Anaphylactic reaction	1	4					1	4
Anger		3				1		2
Angina pectoris		2						2

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angioedema	1	1
Anorectal discomfort		1
Anosmia		2
Antibody test abnormal		1
Anxiety	3	14
Aortic arteriosclerosis	1	1
Aortic valve disease		1
Apathy		1
Aphasia	3	4
Aphonia		1
Apnoea	1	1
Appetite disorder		1
Application site erythema	1	1
Application site swelling	1	1
Arrhythmia	1	8
Arteriosclerosis		1
Arteriosclerosis coronary artery	1	1
Arthralgia	28	99
Arthritis	3	10
Arthropathy	1	5
Asthenia	31	126
Asthenopia		2
Asthma	1	2
Asymptomatic COVID-19	1	4
Atelectasis		1
Atrial fibrillation	5	23
Autoimmune haemolytic anaemia	1	1
Autoimmune thyroiditis		1
Axillary pain		1
Back disorder		2
Back injury		1
Back pain	6	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
			2		
			1		
		3	10		4
		1	1		
					1
			1		
		2	3	1	1
			1		
				1	1
			1		
		1	1		
		1	1		
				1	8
					1
		1	1		
		26	92	2	7
		3	10		
		1	5		
		24	103	7	23
			2		
				1	2
			1	1	3
					1
				5	23
				1	1
					1
			1		
			2		
					1
		5	25	1	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bacterial infection		1				1		
Balance disorder	5	20			2	14	3	6
Barrett's oesophagus	1	1					1	1
Basal ganglia stroke		1						1
Bedridden	2	6			2	4		2
Belligerence		1						1
Bladder disorder		1				1		
Bladder dysfunction		1				1		
Blast cell crisis		1						1
Blindness	1	4					1	4
Blister	1	7				5	1	2
Blood albumin decreased		1				1		
Blood blister		2						2
Blood calcium decreased		1				1		
Blood calcium increased		1						1
Blood chloride decreased		1				1		
Blood chloride increased		2				2		
Blood cholesterol increased		1				1		
Blood count abnormal		2				1		1
Blood creatine increased		1						1
Blood creatinine increased		1				1		
Blood glucose abnormal	1	2				1	1	1
Blood glucose decreased	1	3			1	3		
Blood glucose fluctuation		1				1		
Blood glucose increased	2	10			1	7	1	3
Blood iron decreased		1						1
Blood iron increased		1				1		
Blood lactic acid increased	1	1					1	1
Blood potassium decreased	3	4			1	2	2	2
Blood potassium increased		1						1
Blood pressure abnormal	1	2			1	2		
Blood pressure decreased	1	2					1	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood pressure fluctuation		3				3		
Blood pressure increased	8	33			6	22	2	11
Blood pressure systolic increased	1	3				1	1	2
Blood sodium decreased	1	1			1	1		
Blood test abnormal		1				1		
Blood urea increased		1				1		
Blood urine present	1	2			1	2		
Body height decreased		14				14		
Body temperature	1	1			1	1		
Body temperature abnormal	1	1			1	1		
Body temperature increased	2	14			1	13	1	1
Bone density abnormal	1	1			1	1		
Bone neoplasm		1				1		
Bone pain	2	6			1	5	1	1
Bowel movement irregularity	1	5			1	5		
Bradycardia		1						1
Bradykinesia		1				1		
Brain injury		1						1
Brain stem stroke	1	1					1	1
Breast cancer		1						1
Breast pain	1	2			1	2		
Breast swelling	1	1			1	1		
Breath sounds abnormal	1	1			1	1		
Bronchitis	2	3			2	3		
Bronchospasm		1				1		
Bundle branch block left	1	1					1	1
Burning sensation	5	16			5	14		2
Bursitis		2				2		
Cardiac arrest	3	8					3	8
Cardiac disorder	5	8			3	4	2	4
Cardiac failure		2						2
Cardiac failure congestive		3						3

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiac flutter		2						2
Cardiac pacemaker insertion		1				1		
Cardiac valve disease		1				1		
Cardiogenic shock		1						1
Cardiomyopathy		1						1
Cataract	1	2					1	2
Catatonia		1				1		
Cellulitis	1	4					1	4
Central nervous system lesion		1						1
Cerebral artery embolism	1	1					1	1
Cerebral haemorrhage	1	2					1	2
Cerebral infarction		1						1
Cerebral thrombosis	1	2					1	2
Cerebrovascular accident	9	25					9	25
Chest discomfort	2	9			1	5	1	4
Chest injury		1						1
Chest pain	3	20			2	14	1	6
Chills	38	146			35	132	3	14
Choking		1						1
Choking sensation	3	3			2	2	1	1
Cholecystitis		1						1
Chorea		1						1
Chromaturia	1	3			1	3		
Chronic myeloid leukaemia recurrent		1						1
Chronic obstructive pulmonary disease	1	1					1	1
Circumstance or information capable of leading to device use error		2				2		
Circumstance or information capable of leading to medication error	5	31			5	31		
Clostridium difficile infection		1						1
Coagulopathy	1	1					1	1
Coccidioidomycosis		1						1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		
			1		
					1
					1
				1	2
			1		
				1	4
					1
				1	1
				1	2
				9	25
		1	5	1	4
					1
		2	14	1	6
		35	132	3	14
					1
		2	2	1	1
					1
					1
		1	3		
					1
				1	1
			2		
		5	31		
					1
				1	1
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Cognitive disorder	1	4
Cold sweat		2
Colitis	1	1
Colitis microscopic		1
Colitis ulcerative		1
Colon cancer		1
Coma		2
Communication disorder		2
Concussion	1	1
Condition aggravated	6	34
Confusional state	6	26
Constipation	2	6
Contraindicated product administered		1
Contraindication to vaccination		1
Contusion	2	13
Coronary artery occlusion		1
Cor pulmonale acute	1	1
Cough	12	44
COVID-19	32	103
COVID-19 pneumonia	2	11
C-reactive protein increased		3
Crying		3
Culture urine positive		1
Cyanosis		1
Cystitis	1	3
Deafness	3	11
Deafness unilateral		2
Death	7	31
Decreased appetite	13	49
Deep vein thrombosis	4	5
Degenerative bone disease		1
Dehydration	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		2
			2		
				1	1
					1
					1
					2
			1		1
				1	1
		4	25	2	9
		5	17	1	9
		2	6		
			1		
			1		
		2	12		1
					1
				1	1
		10	37	2	7
1	2	9	24	23	79
				2	11
			1		2
			2		1
			1		
					1
				1	3
				3	11
					2
				7	31
		9	41	4	8
				4	5
			1		
		1	6	1	6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Delirium		6
Delusion	1	1
Delusional perception	1	3
Dementia	2	7
Dental discomfort		1
Depressed level of consciousness		1
Depressed mood		1
Depression	1	1
Dermatitis	2	4
Dermatitis allergic	1	1
Dermatitis contact		1
Dermatitis diaper		1
Diabetes mellitus		1
Diabetes mellitus inadequate control	1	3
Diarrhoea	18	88
Diarrhoea haemorrhagic	1	2
Diet refusal		1
Diplopia	2	3
Discomfort		12
Disease recurrence	4	10
Disorganised speech	1	1
Disorientation	3	14
Disturbance in attention	1	2
Diverticulitis	1	2
Dizziness	31	154
Dreamy state	1	1
Drooling		1
Drug hypersensitivity	2	5
Drug ineffective	19	74
Drug interaction		2
Dry eye		1
Dry mouth	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					6
				1	1
		1	2		1
				2	7
			1		
					1
			1		
		1	1		
		1	3	1	1
		1	1		
			1		
					1
					1
				1	3
		16	77	2	11
				1	2
					1
		2	3		
			11		1
		1	3	3	7
				1	1
		1	6	2	8
				1	2
				1	2
		26	134	5	20
		1	1		
					1
		2	5		
	1			19	74
			1		1
			1		
		1	5		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry skin		3
Dry throat		2
Dysarthria	2	7
Dysentery		2
Dysgeusia	2	5
Dysgraphia		1
Dyskinesia	1	7
Dyspepsia	1	3
Dysphagia	2	14
Dysphemia		1
Dysphonia	3	8
Dyspnoea	18	71
Dyspnoea exertional		2
Dysstasia	4	16
Dysuria	3	6
Ear discomfort	1	2
Ear disorder	1	3
Ear haemorrhage		1
Ear infection	1	2
Ear pain	3	9
Ear swelling		1
Eating disorder	3	9
Electrolyte imbalance		1
Embolic stroke		1
Emotional disorder		2
Emotional distress	1	1
Energy increased		1
Eosinophil count decreased		1
Eosinophil count increased		2
Epistaxis	3	15
Eructation		2
Erythema	8	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			2		
		2	4		3
					2
		2	4		1
			1		
			5	1	2
		1	3		
		2	11		3
					1
		3	8		
		9	43	9	28
			2		
		2	9	2	7
		2	4	1	2
		1	2		
		1	1		2
			1		
		1	2		
		3	8		1
			1		
		3	6		3
					1
					1
			2		
		1	1		
			1		
					1
			1		1
		2	8	1	7
			2		
		8	36		4

\* I=Interval, C=Cumulative

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema multiforme		1
Erythema of eyelid		1
Euphoric mood		1
Excessive cerumen production	1	1
Exposure to SARS-CoV-2		3
Exposure via skin contact		2
Extra dose administered		1
Extrasystoles		4
Eye discharge	1	1
Eye disorder		1
Eye haemorrhage		1
Eye infection		1
Eye inflammation		1
Eyelid haematoma		1
Eye movement disorder		1
Eye pain		8
Eye pruritus		3
Eye swelling		5
Face injury		1
Face oedema		1
Facial pain	1	4
Facial paralysis	4	11
Faeces discoloured		1
Faeces soft		1
Fall	10	40
Fatigue	58	219
Fear	1	3
Feeding disorder	3	7
Feeling abnormal	23	82
Feeling cold	2	15
Feeling drunk		1
Feeling hot	8	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		
		1	1		
			3		
			2		
			1		
			3		1
		1	1		
					1
					1
			1		
			1		
			1		
					1
			8		
			2		1
			4		1
			1		
					1
		1	4		
			1	4	10
			1		
					1
		5	19	5	21
		52	196	6	23
		1	3		
		3	7		
		21	77	2	5
		2	15		
			1		
		8	26		

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\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling of body temperature change		3
Femur fracture		1
Fibromyalgia		1
Flank pain		1
Flatulence		3
Fluid retention		2
Flushing		5
Food allergy	2	2
Food aversion	1	1
Foot deformity	1	1
Frequent bowel movements		3
Frustration tolerance decreased		2
Functional gastrointestinal disorder		1
Fungal peritonitis	1	1
Gait disturbance	17	49
Gait inability	3	16
Gallbladder disorder	1	2
Gastric disorder	1	2
Gastric ulcer		1
Gastroenteritis viral	1	1
Gastrointestinal disorder		3
Gastrointestinal haemorrhage	1	2
Gastrointestinal motility disorder		1
Gastrointestinal pain	1	1
Gastrointestinal sounds abnormal	1	2
Gastrooesophageal reflux disease		3
General physical health deterioration	2	6
Genital herpes		1
Gingival bleeding		1
Gingival swelling		1
Glassy eyes	1	2
Glaucoma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
					1
			1		
					1
			2		1
					2
			4		1
		2	2		
		1	1		
		1	1		
			3		
			1		1
			1		
				1	1
		12	35	5	14
		2	8	1	8
				1	2
		1	2		
					1
				1	1
					3
				1	2
			1		
		1	1		
		1	2		
			2		1
		1	1	1	5
			1		
			1		
			1		
			1	1	1
					1

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 \* AE=Adverse Event  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glomerular filtration rate decreased		2
Glossitis		1
Glossodynia		1
Gout	1	3
Grip strength decreased	1	1
Groin pain		3
Grunting	1	1
Guillain-Barre syndrome	1	2
Haematochezia		3
Haematocrit decreased		3
Haematoma	1	4
Haemoglobin decreased		8
Haemoptysis	1	5
Haemorrhage	1	6
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		1
Haemorrhagic varicella syndrome		1
Hair growth abnormal	1	1
Hallucination	1	9
Hallucination, auditory		2
Hallucination, visual		3
Hangover		1
Headache	37	164
Head discomfort	1	7
Head injury	2	5
Hearing disability		1
Heart injury	1	1
Heart rate abnormal		4
Heart rate decreased		1
Heart rate increased	3	24
Heart rate irregular		4
Hepatic enzyme increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
			1		
		1	2		1
		1	1		
			2		1
		1	1		
				1	2
					3
			2		1
		1	3		1
			5		3
			3	1	2
				1	6
					1
					1
		1	1		
				1	9
					2
					3
			1		
		34	146	3	18
		1	5		2
		1	2	1	3
			1		
				1	1
			4		
					1
		2	20	1	4
			3		1
				1	1

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\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster	8	18
Hip fracture	1	4
Hot flush	2	7
Hunger		1
Hyperaesthesia		1
Hyperhidrosis	5	21
Hyperpyrexia		1
Hypersensitivity	5	16
Hypersensitivity vasculitis	1	1
Hypersomnia	1	12
Hypertension	6	26
Hyperventilation		1
Hypoacusis	5	17
Hypoaesthesia	4	15
Hypoaesthesia oral	1	4
Hypokalaemia		1
Hypokinesia	2	3
Hypophagia		1
Hypopnoea		1
Hypotension		3
Illrd nerve paralysis		1
Illness	11	35
Immobile		1
Immune system disorder		1
Immune thrombocytopenia	1	3
Immunisation		1
Immunodeficiency		2
Impaired driving ability		1
Inappropriate schedule of product administration	10	39
Incoherent		3
Incomplete course of vaccination	1	1
Incontinence		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	16	1	2
				1	4
		2	6		1
			1		
			1		
		4	20	1	1
					1
		5	13		3
				1	1
			10	1	2
		2	13	4	13
			1		
		2	13	3	4
		4	12		3
		1	4		
					1
			1	2	2
					1
					1
			1		2
					1
		8	30	3	5
					1
					1
				1	3
			1		
					2
			1		
		9	38	1	1
			1		2
		1	1		
			1		1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect dose administered	1	5
Increased viscosity of bronchial secretion		1
Infection		3
Inflammation	3	9
Inflammatory marker increased		1
Influenza	4	5
Influenza like illness	2	13
Injection site discomfort		2
Injection site erythema	3	8
Injection site haemorrhage		2
Injection site induration		1
Injection site pain	4	11
Injection site pruritus		5
Injection site swelling		5
Injection site warmth	1	5
Inner ear disorder		1
Insomnia	7	40
Instillation site pain		1
Internal haemorrhage		1
International normalised ratio decreased		1
International normalised ratio increased		2
Intestinal ischaemia		1
Intestinal perforation		1
Irritability		1
Ischaemic stroke		2
Jaundice		1
Jaw disorder		2
Joint effusion	1	1
Joint injury		1
Joint range of motion decreased	2	5
Joint stiffness		3
Joint swelling	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		
			1		
			3		
		3	9		
			1		
		4	5		
		2	13		
			2		
		3	8		
			2		
			1		
		4	11		
			5		
			5		
		1	5		
			1		
		6	33	1	7
			1		
					1
					1
			1		1
					1
					2
					1
			2		
				1	1
			1		
		2	5		
			3		
		1	11	1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Kidney infection		1
Lacrimation increased	1	4
Large intestinal haemorrhage		1
Laryngeal oedema		1
Laziness		1
Lethargy	5	17
Leukocytosis		1
Ligament rupture		1
Ligament sprain		1
Limb discomfort	4	15
Limb injury		5
Limb mass	1	1
Lip dry		1
Lip swelling	4	15
Localised infection	1	2
Localised oedema		1
Loss of consciousness	7	22
Loss of control of legs		3
Loss of personal independence in daily activities	3	10
Lung disorder	1	1
Lung infiltration		2
Lung opacity		1
Lymphadenopathy	5	15
Lymph node pain		5
Lymphocyte count decreased		2
Lymphoedema		2
Macular degeneration		3
Macule		1
Malaise	24	105
Mass	1	5
Mastication disorder	2	3
Memory impairment	3	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	4		
					1
			1		
		5	12		5
			1		
			1		
		4	13		2
			5		
		1	1		
			1		
		4	12		3
			1	1	1
					1
				7	22
					3
		3	9		1
		1	1		
			1		1
					1
		5	15		
			5		
			2		
			2		
					3
			1		
		19	90	5	15
		1	4		1
		2	3		
		3	7		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meniere's disease	1	1
Meningitis viral		1
Mental disorder		3
Mental impairment	1	4
Mental status changes		1
Micturition disorder		1
Micturition urgency		1
Middle insomnia		1
Migraine	1	2
Migraine with aura		1
Moaning	1	1
Mobility decreased		7
Monoclonal gammopathy	1	1
Monocyte count increased		1
Monoparesis		1
Motor dysfunction	1	1
Mouth haemorrhage		1
Mouth swelling		1
Movement disorder		4
Mucosal disorder		1
Mucous stools		1
Muscle discomfort		3
Muscle disorder	3	4
Muscle rigidity		1
Muscle spasms	4	15
Muscle strain	1	1
Muscle swelling	1	1
Muscle tightness	1	5
Muscle twitching		1
Muscular weakness	10	21
Musculoskeletal chest pain	2	5
Musculoskeletal discomfort	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			2		1
				1	4
			1		
					1
			1		
			1		
		1	2		
					1
		1	1		
			5		2
		1	1		
			1		
					1
		1	1		
			1		
			1		
			4		
			1		
			1		
			3		
		3	3		1
					1
		2	11	2	4
		1	1		
		1	1		
			3	1	2
					1
		7	14	3	7
		1	3	1	2
		2	5		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal disorder		3
Musculoskeletal stiffness	7	27
Mutism		1
Myalgia	19	63
Myasthenia gravis		1
Myocardial infarction	3	15
Nasal congestion	5	14
Nasal discomfort	2	3
Nasal mucosal disorder		1
Nasal oedema	1	1
Nasal pruritus		1
Nasopharyngitis	3	12
Nausea	25	129
Near death experience	2	4
Neck mass	1	1
Neck pain	5	27
Neoplasm	2	2
Neoplasm malignant		1
Nerve injury	1	3
Nervousness	4	10
Nervous system disorder		1
Neuralgia	1	2
Neurological symptom	1	1
Neuropathy peripheral	2	6
Neutrophil count decreased		1
Nightmare	1	3
Night sweats	1	6
Nipple pain	1	2
Nipple swelling	1	1
No adverse event	3	3
Nocturia		1
Nystagmus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		6	23	1	4
					1
		18	60	1	3
					1
				3	15
		3	11	2	3
		2	3		
			1		
				1	1
			1		
		2	11	1	1
		22	115	3	14
				2	4
		1	1		
		4	24	1	3
		1	1	1	1
					1
		1	3		
		3	8	1	2
			1		
		1	2		
		1	1		
				2	6
			1		
		1	3		
		1	6		
		1	2		
		1	1		
		3	3		
			1		
					1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Obsessive thoughts		1						1
Obstructive airways disorder	1	1					1	1
Ocular discomfort		2				2		
Ocular hyperaemia		3				3		
Ocular vascular disorder	1	1			1	1		
Oedema	1	2			1	2		
Oedema peripheral		2				1		1
Oesophageal achalasia	1	1			1	1		
Oesophageal stenosis	1	1					1	1
Off label use	1	21				20	1	1
Oliguria		1				1		
Oral discomfort		1				1		
Oral herpes	1	6			1	6		
Oral mucosal blistering		1				1		
Oral pain	2	5			2	5		
Oropharyngeal discomfort	1	5			1	5		
Oropharyngeal pain	5	15			4	13	1	2
Osteoarthritis		1				1		
Overdose	1	8			1	8		
Oxygen consumption decreased		1						1
Oxygen saturation abnormal		1				1		
Oxygen saturation decreased	2	13				4	2	9
Pain	36	146			33	132	3	14
Painful respiration		2						2
Pain in extremity	53	196			51	178	2	18
Pain in jaw		1				1		
Pain of skin		2				1		1
Pallor	1	4			1	1		3
Palpable purpura		1				1		
Palpitations	1	13			1	9		4
Pancreatitis acute	1	1					1	1
Panic reaction	1	2			1	2		

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			2		
			3		
		1	1		
		1	2		
			1		1
		1	1		
				1	1
			20	1	1
			1		
			1		
		1	6		
			1		
		2	5		
		1	5		
		4	13	1	2
			1		
		1	8		
					1
			1		
			4	2	9
		33	132	3	14
					2
		51	178	2	18
			1		
			1		1
		1	1		3
			1		
		1	9		4
				1	1
		1	2		

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Paraesthesia	5	19
Paraesthesia oral		5
Paranasal sinus discomfort		1
Paranasal sinus hypersecretion		1
Paranoia		1
Parkinsonism	1	1
Parkinson's disease		1
Parosmia	2	3
Pemphigus		2
Periorbital swelling		2
Peripheral coldness	3	6
Peripheral swelling	11	40
Peripheral venous disease	2	2
Perivascular dermatitis		1
Personality change		1
Petechiae	1	4
Pharyngeal disorder		1
Pharyngeal enanthema		1
Pharyngeal erythema		1
Pharyngeal hypoaesthesia		1
Pharyngeal swelling	1	3
Phlebitis superficial	1	1
Photopsia		1
Plasma cell myeloma		1
Platelet count decreased	2	7
Pleurisy		2
Pneumonia	2	20
Pneumonia aspiration		1
Pneumothorax	1	1
Pollakiuria	1	2
Polydipsia		1
Polymyalgia rheumatica		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	16		3
			3		2
			1		
			1		
			1		
				1	1
					1
		1	2	1	1
					2
			1		1
		3	6		
		10	34	1	6
		2	2		
			1		
					1
		1	2		2
			1		
			1		
			1		
		1	3		
		1	1		
					1
					1
		1	3	1	4
			1		1
				2	20
					1
				1	1
		1	2		
			1		
					2

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Age Range

**Greater than or equal to 80 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Polyuria		1
Poor peripheral circulation	1	2
Poor quality product administered	1	4
Poor quality sleep	1	6
Post herpetic neuralgia		1
Potentiating drug interaction		1
Presyncope	1	7
Product administered at inappropriate site	2	2
Product administration error		1
Product dose omission issue	3	4
Productive cough		2
Product leakage		1
Product preparation error		3
Product preparation issue		5
Product quality issue	1	1
Product storage error		1
Product use issue		9
Pruritus	24	82
Psoriasis		2
Psychomotor hyperactivity	1	1
Psychotic disorder	1	1
Pulmonary congestion		1
Pulmonary embolism	3	6
Pulmonary fibrosis	1	2
Pulmonary oedema		3
Pulmonary pain		1
Pulse abnormal		1
Pulse absent	1	1
Pulse pressure decreased	1	1
Purpura		1
Pustule		1
Pyrexia	30	131

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2		
		1	4		
		1	6		
			1		
			1		
		1	5		2
		2	2		
			1		
		3	4		
			2		
			1		
			3		
			5		
		1	1		
			1		
			9		
		23	72	1	10
			2		
		1	1		
				1	1
					1
				3	6
				1	2
					3
			1		
			1		
				1	1
				1	1
					1
					1
		28	112	2	19

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Rash	20	73
Rash erythematous	2	11
Rash macular	6	14
Rash maculo-papular		1
Rash morbilliform		1
Rash papular	2	5
Rash pruritic	2	14
Rash vesicular		1
Reaction to excipient		2
Red blood cell count decreased		2
Red blood cell sedimentation rate increased		2
Renal atrophy		1
Renal disorder		2
Renal failure	1	4
Renal impairment		4
Renal infarct	1	1
Renal injury	1	1
Respiratory arrest		2
Respiratory disorder	2	3
Respiratory distress		3
Respiratory failure		2
Respiratory rate decreased		1
Respiratory rate increased	1	2
Respiratory tract congestion		1
Restless legs syndrome	1	1
Restlessness	1	4
Retching	1	7
Rheumatoid arthritis		1
Rhinitis allergic		1
Rhinorrhoea	3	17
Rosacea		1
Rotator cuff syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		19	68	1	5
		2	11		
		4	12	2	2
			1		
					1
		1	3	1	2
		2	13		1
			1		
			2		
			2		
					2
					1
			1		1
				1	4
					4
				1	1
				1	1
					2
		1	1	1	2
					3
					2
			1		
		1	1		
		1	4		
		1	4		3
					1
			1		
		3	16		1
			1		
					1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Salivary gland disorder		1
SARS-CoV-2 antibody test negative		4
SARS-CoV-2 test false positive	1	1
SARS-CoV-2 test positive	1	10
Scab		1
Sciatica		3
Scratch	1	4
Secretion discharge	2	2
Sedation		1
Seizure		7
Sensation of foreign body		3
Sensitive skin		2
Sensory disturbance		2
Sensory loss		1
Sepsis	2	5
Seronegative arthritis		2
Shock	1	2
Sinus bradycardia		1
Sinus disorder	2	6
Sinus headache		2
Sinusitis	3	5
Sitting disability		1
Sjogren's syndrome		1
Skin burning sensation		1
Skin depigmentation	1	2
Skin discolouration	3	7
Skin disorder		2
Skin exfoliation		1
Skin fissures	1	1
Skin haemorrhage	1	1
Skin injury		1
Skin irritation		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			4		
				1	1
		1	3		7
			1		
			2		1
		1	3		1
		2	2		
					1
					7
			3		
			2		
			2		
					1
				2	5
					2
				1	2
			1		
		2	5		1
			2		
		2	4	1	1
					1
					1
			1		
		1	2		
		3	7		
			1		1
			1		
		1	1		
		1	1		
			1		
			2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin laxity		1				1		
Skin lesion	1	4			1	4		
Skin reaction		4				3		1
Skin swelling		2				2		
Sleep disorder	3	13			3	13		
Small intestinal haemorrhage		1						1
Sneezing	1	14			1	13		1
Somnolence	10	29			9	22	1	7
Speech disorder	2	9			1	4	1	5
Spinal pain		1				1		
Spinal stenosis		1				1		
Stoma site haemorrhage		1						1
Stomatitis	1	2			1	2		
Stress		1				1		
Subdural haematoma	1	1					1	1
Sudden hearing loss	1	1					1	1
Sunburn		1				1		
Superficial injury of eye		1				1		
Supraventricular tachycardia		1						1
Suspected COVID-19	3	8			1	3	2	5
Swelling	5	22			5	19		3
Swelling face	7	25			7	22		3
Swelling of eyelid		3				3		
Swollen tongue		5				4		1
Syncope	1	11					1	11
Systolic hypertension		1						1
Tachycardia		4				3		1
Tachypnoea		1				1		
Taste disorder		3				3		
Temporomandibular joint syndrome		1				1		
Tenderness	1	3			1	3		
Tendonitis		1				1		

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	4		
			3		1
			2		
		3	13		
					1
		1	13		1
		9	22	1	7
		1	4	1	5
			1		
			1		
					1
		1	2		
			1		
				1	1
				1	1
			1		
			1		
					1
		1	3	2	5
		5	19		3
		7	22		3
			3		
			4		1
				1	11
					1
			3		1
			1		
			3		
			1		
		1	3		
			1		

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 \* AE=Adverse Event  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Terminal insomnia		1
Therapeutic response unexpected	6	9
Thinking abnormal	1	3
Thirst	2	2
Thoracic vertebral fracture		1
Throat irritation	4	9
Throat tightness	1	10
Thrombocytopenia	1	1
Thrombosis	8	19
Thyroid disorder	1	2
Tic		1
Tinnitus	3	10
T-lymphocyte count increased		1
Tongue biting		1
Tongue blistering		1
Tongue discomfort		2
Tongue disorder		2
Tongue dry		1
Tongue erythema	1	2
Tonsillar hypertrophy		1
Tooth abscess	1	1
Toothache	1	1
Tooth infection		1
Transient ischaemic attack		10
Tremor	6	26
Trismus	1	1
Troponin increased	1	1
Type V hyperlipidaemia		1
Ulcer		1
Ulcer haemorrhage		1
Underdose		4
Unresponsive to stimuli	3	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		6	9		
		1	3		
		2	2		
					1
		4	9		
		1	7		3
				1	1
1	1			8	19
			1	1	1
					1
		1	6	2	4
			1		
					1
			1		
			2		
			2		
			1		
		1	2		
			1		
		1	1		
		1	1		
			1		
					10
		2	15	4	11
		1	1		
				1	1
					1
			1		
					1
			4		
				3	11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Upper respiratory tract congestion		1
Upper respiratory tract infection		1
Urinary incontinence		2
Urinary retention		2
Urinary tract infection	1	10
Urinary tract infection bacterial		1
Urine output decreased	1	1
Urine output increased		1
Urosepsis		1
Urticaria	5	23
Vaccination failure	7	13
Vaccination site bruising	3	8
Vaccination site discolouration		5
Vaccination site discomfort	2	7
Vaccination site dryness	1	1
Vaccination site erythema	7	36
Vaccination site haematoma		1
Vaccination site haemorrhage	1	5
Vaccination site hypoaesthesia		2
Vaccination site induration	1	4
Vaccination site inflammation		1
Vaccination site irritation		1
Vaccination site mass	1	7
Vaccination site movement impairment		1
Vaccination site pain	18	110
Vaccination site pruritus	3	17
Vaccination site rash	1	6
Vaccination site reaction		1
Vaccination site scab		1
Vaccination site swelling	5	20
Vaccination site warmth	2	13
Varicella		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			2		
					2
			3	1	7
					1
		1	1		
			1		
					1
		4	20	1	3
1	1			7	13
		3	8		
			4		1
		2	6		1
		1	1		
		7	35		1
			1		
		1	3		2
			1		1
		1	3		1
			1		
		1	6		1
			1		
		18	103		7
		3	15		2
		1	6		
			1		
			1		
		5	19		1
		2	12		1
			1		

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\* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vascular dementia		1							1
Vascular pain	1	1			1	1			
Vertigo	5	17			3	13	2		4
Vestibular neuronitis		1							1
Viral myocarditis		1							1
Vision blurred	2	15			2	13			2
Visual acuity reduced		1				1			
Visual field defect		1				1			
Visual impairment	1	13				8	1		5
Vitamin B12 decreased	1	1					1		1
Vitamin D decreased	1	1					1		1
Volvulus		1							1
Vomiting	14	64			11	52	3		12
Walking aid user	1	1			1	1			
Weight decreased	4	17			2	14	2		3
Weight fluctuation		1				1			
Weight increased	1	2			1	2			
Wheezing	1	5			1	3			2
White blood cell count decreased	1	3				2	1		1
Wound		2				2			
Wound complication	1	1			1	1			
Wound haemorrhage	1	1			1	1			
Wound secretion		1							1
Wrong product administered	1	2			1	2			
Wrong technique in device usage process		1				1			
Wrong technique in product usage process		4				4			
	1,421	5,871	3	5	1047	4340	374		1531

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\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	10	29	10	29		
Abdominal distension	1	5	1	5		
Abdominal pain	3	15	3	14		1
Abdominal pain lower	1	2	1	2		
Abdominal pain upper	7	33	7	32		1
Abdominal rigidity	2	2	2	2		
Abnormal dreams	2	4	2	4		
Abnormal faeces		1		1		
Abnormal sensation in eye		2		2		
Abortion spontaneous		2				2
Accident	3	3	1	1	2	2
Accidental exposure to product	5	29	5	29		
Accidental overdose	2	26	2	26		
Accidental underdose		2		2		
Acne	2	2	2	2		
Acute myeloid leukaemia		1				1
Adverse event	2	7	2	7		
Adverse event following immunisation	1	1	1	1		
Affective disorder		1		1		
Ageusia	11	27	10	23	1	4
Aggression		1		1		
Agitation	2	2	2	2		
Allergic cough	1	1	1	1		
Allergic reaction to excipient		1		1		
Allergy to vaccine	1	11	1	10		1
Alopecia	3	4	3	4		
Amenorrhoea	1	1	1	1		
Amnesia	2	3	2	3		
Anaemia		1				1
Anaesthesia	1	2	1	2		
Anal incontinence	1	1	1	1		
Anaphylactic reaction	54	92			54	92

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\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactic shock	1	3
Anger		1
Angina pectoris	6	7
Angioedema	3	6
Angiopathy		1
Anhedonia	1	1
Animal bite	1	2
Ankylosing spondylitis		1
Anosmia	6	25
Antibody test abnormal		3
Antibody test negative		2
Anxiety	11	33
Aphasia	1	5
Aphonia	1	3
Aphthous ulcer	1	4
Appendicitis	4	6
Appetite disorder		2
Arrhythmia	3	6
Arthralgia	44	199
Arthritis	1	9
Arthropathy	3	8
Arthropod bite	3	5
Aspiration		1
Asthenia	29	97
Asthenopia		1
Asthma	3	13
Asymptomatic COVID-19	4	18
Atrial fibrillation	7	13
Atypical pneumonia		1
Autoimmune disorder	1	3
Axillary mass		2
Axillary pain	2	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
	1		
		6	7
1	1	2	5
	1		
1	1		
1	2		
			1
6	22		3
	3		
	2		
10	31	1	2
1	4		1
1	3		
1	4		
		4	6
	2		
		3	6
44	194		5
1	9		
3	8		
3	5		
			1
29	94		3
	1		
2	11	1	2
1	5	3	13
		7	13
			1
		1	3
	2		
2	11		

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 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back disorder		3		3		
Back pain	32	97	28	91	4	6
Bacteraemia		1				1
Bacterial vaginosis	1	1	1	1		
Balance disorder	4	7	3	6	1	1
Basal cell carcinoma		1				1
Basedow's disease		1				1
Bedridden	1	2	1	2		
Bladder discomfort		1		1		
Bladder disorder	1	1	1	1		
Blepharospasm	2	2	2	2		
Blindness	1	6			1	6
Blister	1	12		11	1	1
Blood bilirubin increased		1				1
Blood blister	1	1	1	1		
Blood cholesterol increased	1	2	1	2		
Blood count abnormal	1	2	1	2		
Blood creatinine increased		1		1		
Blood disorder	1	3	1	1		2
Blood glucose abnormal		1		1		
Blood glucose decreased		5		4		1
Blood glucose fluctuation		1		1		
Blood glucose increased	3	13	2	11	1	2
Blood immunoglobulin G decreased		1		1		
Blood immunoglobulin G increased		1		1		
Blood magnesium decreased		1				1
Blood potassium decreased	1	2	1	1		1
Blood potassium increased		1				1
Blood pressure abnormal		3		3		
Blood pressure decreased		4		4		
Blood pressure fluctuation	1	2	1	2		
Blood pressure increased	10	32	5	19	5	13

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\* AE=Adverse Event

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	1		1
	1		
	1		
	1		
	1		
1	2		1
1	5		
	4		1
4	14		
1	1		
		1	1
4	17		
	2		
	1		
	1	1	1
1	1		
		2	2
	1		1
	1		
	2		
	1		
	1		
	3		
	1		
	1		1
1	1		
	3	2	4
	1		1

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 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	7	22	5	20	2	2
Burning sensation mucosal		1		1		
Cardiac arrest	4	6			4	6
Cardiac disorder	8	14	5	10	3	4
Cardiac failure congestive	1	2			1	2
Cardiac fibrillation	1	1			1	1
Cardiac flutter	4	7			4	7
Cardiac valve disease		1				1
Cardiospasm	1	1	1	1		
Carpal tunnel syndrome		1		1		
Cataract	2	2			2	2
Cellulitis	7	10			7	10
Cerebral artery occlusion	1	1			1	1
Cerebral haemorrhage	1	3			1	3
Cerebrovascular accident	11	21			11	21
Chapped lips		2		2		
Chest discomfort	11	36	7	27	4	9
Chest pain	14	36	11	25	3	11
Chillblains		1		1		
Chills	109	478	106	472	3	6
Choking	1	1			1	1
Chromaturia	1	1	1	1		
Chronic kidney disease	1	1			1	1
Chronic lymphocytic leukaemia	2	2			2	2
Chronic obstructive pulmonary disease	1	5	1	2		3
Circumoral swelling	1	1	1	1		
Circumstance or information capable of leading to device use error		1		1		
Circumstance or information capable of leading to medication error	28	230	28	230		
Clumsiness	1	2	1	2		
Cluster headache		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coagulopathy	1	2
Cognitive disorder	1	4
Cold sweat	2	12
Colitis	1	1
Colitis ulcerative		1
Completed suicide	1	1
Complication associated with device		1
Computerised tomogram normal		1
Concussion		2
Condition aggravated	9	29
Confusional state	2	7
Conjunctivitis		1
Conjunctivitis allergic		1
Constipation	2	5
Contraceptive diaphragm	1	1
Contraindicated product administered		3
Contraindication to vaccination		2
Contusion	8	15
Coordination abnormal		2
Coronavirus test positive	1	2
Cough	26	92
COVID-19	467	1,086
COVID-19 pneumonia	3	6
C-reactive protein increased		1
Crohn's disease	2	4
Crying	1	4
Cyanosis		2
Cystitis	1	5
Daydreaming	1	1
Deafness	6	11
Deafness unilateral	3	3
Death	16	40

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
1	4		
2	12		
1	1		
			1
		1	1
			1
	1		
	2		
6	21	3	8
1	6	1	1
	1		
	1		
2	5		
1	1		
	3		
	2		
8	14		1
	1		1
		1	2
23	88	3	4
152	257	315	829
		3	6
	1		
		2	4
1	4		
	2		
1	5		
1	1		
		6	11
		3	3
		16	40

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	6	28	6	28		
Deep vein thrombosis	3	4			3	4
Defaecation urgency	1	2	1	2		
Dehydration		4		3		1
Delirium	1	2			1	2
Dementia	1	5			1	5
Dental discomfort		7		7		
Dental restoration failure		1		1		
Depressed mood	1	4	1	4		
Depression		1		1		
Derealisation		1		1		
Dermatitis		3		3		
Dermatitis acneiform		2		2		
Dermatitis contact		1		1		
Dermo-hypodermatitis	1	1	1	1		
Diabetes mellitus		4				4
Diabetic foot infection		1		1		
Diabetic neuropathy		1		1		
Diarrhoea	38	132	37	128	1	4
Diarrhoea haemorrhagic		2				2
Diastolic hypotension		1				1
Diplopia	1	2	1	2		
Discomfort	3	16	3	16		
Disease progression		1				1
Disease recurrence	2	6	1	4	1	2
Disorientation	1	4	1	4		
Dissociation		1		1		
Disturbance in attention		4		4		
Diverticulitis	3	9			3	9
Dizziness	52	224	48	209	4	15
Dizziness postural	1	4	1	4		
Drainage	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug hypersensitivity	1	10
Drug ineffective	312	928
Drug interaction	3	5
Dry eye	2	3
Dry mouth	3	8
Dry skin		2
Dry throat	1	5
Dysaesthesia		1
Dysarthria		2
Dysgeusia	5	31
Dyskinesia	2	6
Dyspepsia	2	12
Dysphagia	3	12
Dysphemia	1	1
Dysphonia	1	10
Dyspnoea	40	105
Dysstasia	3	11
Dysuria		2
Ear congestion		1
Ear discomfort	1	5
Ear disorder		2
Ear infection	3	7
Ear neoplasm		1
Ear pain	4	14
Ear pruritus	1	2
Eating disorder	1	2
Ecchymosis	4	4
Eczema	1	2
Ejection fraction decreased		1
Emotional disorder	1	1
Encephalitis		2
Endocrine ophthalmopathy		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	9		1
		312	928
1	2	2	3
2	3		
3	7		1
	2		
1	5		
	1		
	1		1
5	31		
2	6		
2	12		
2	8	1	4
1	1		
1	7		3
25	80	15	25
2	6	1	5
	2		
	1		
1	5		
	2		
3	6		1
	1		
3	11	1	3
1	2		
	1	1	1
4	4		
1	2		
			1
1	1		
			2
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Energy increased	1	1	1	1		
Eosinophil count increased	1	1	1	1		
Eosinophilic oesophagitis	1	1	1	1		
Epigastric discomfort	1	1	1	1		
Epilepsy	2	2			2	2
Epistaxis	7	17	5	14	2	3
Erectile dysfunction		3				3
Erosive oesophagitis		1				1
Eructation		1		1		
Erythema	14	59	11	55	3	4
Erythema of eyelid	1	1	1	1		
Escherichia infection		1				1
Euphoric mood	1	2	1	2		
Expired product administered	14	35	14	35		
Exposure during pregnancy	9	21	7	17	2	4
Exposure to SARS-CoV-2	21	44	20	38	1	6
Exposure via breast milk	5	50	5	50		
Exposure via eye contact	1	3	1	3		
Exposure via skin contact	4	24	4	24		
Extra dose administered		1		1		
Eye allergy		1		1		
Eye colour change	1	2		1	1	1
Eye contusion		1		1		
Eye discharge	1	2	1	2		
Eye disorder	4	12	4	10		2
Eye haemorrhage	3	4			3	4
Eye infection		2		2		
Eye injury	1	1			1	1
Eye irritation	3	8	3	8		
Eyelid infection		1		1		
Eyelid oedema	2	2	2	2		
Eyelid pain	3	3	3	3		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid ptosis	1	1
Eyelid vascular disorder	1	1
Eye oedema		1
Eye pain	8	13
Eye pruritus	3	9
Eye swelling	5	16
Face oedema	1	1
Facial asymmetry		1
Facial bones fracture	1	1
Facial discomfort		1
Facial pain	1	6
Facial paralysis	11	46
Faeces discoloured	2	2
Faeces pale	1	1
Faeces soft	1	1
Fall	15	27
Fasciitis		1
Fatigue	124	510
Fear		3
Febrile neutropenia		1
Feeding disorder	3	9
Feeling abnormal	47	151
Feeling cold	3	42
Feeling drunk	1	5
Feeling hot	10	43
Feeling jittery		4
Feeling of body temperature change	1	7
Femur fracture	1	1
Fibrin D dimer increased	1	2
Fibromyalgia		1
Finger deformity		1
Flank pain		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
	1		
8	13		
3	9		
5	16		
1	1		
	1		
		1	1
	1		
1	6		
		11	46
2	2		
1	1		
1	1		
10	18	5	9
			1
122	505	2	5
	3		
			1
3	9		
43	142	4	9
3	42		
1	4		1
9	40	1	3
	4		
1	7		
		1	1
		1	2
			1
	1		
	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence	2	4	2	4		
Fluid intake reduced	1	1	1	1		
Fluid retention	2	3	2	3		
Flushing	3	32	3	28		4
Foetal cystic hygroma		1				1
Foetal death		1				1
Foetal exposure during pregnancy		1				1
Foetal heart rate abnormal		1				1
Foetal heart rate decreased	1	1			1	1
Foetal hypokinesia	1	1			1	1
Food allergy	1	2		1	1	1
Food poisoning	1	1	1	1		
Formication	2	2	2	2		
Frustration tolerance decreased	1	3	1	3		
Fungal infection	1	2	1	2		
Furuncle		1		1		
Gait disturbance	6	22	6	20		2
Gait inability	3	8	2	6	1	2
Gallbladder disorder		1		1		
Gastric disorder	2	2	2	2		
Gastric haemorrhage	1	2			1	2
Gastritis	1	1	1	1		
Gastroenteritis viral	1	1			1	1
Gastrointestinal disorder	5	13	5	13		
Gastrointestinal haemorrhage		1				1
Gastrointestinal pain		2		2		
Gastrointestinal sounds abnormal		1		1		
Gastrooesophageal reflux disease	1	4	1	4		
Generalised tonic-clonic seizure		1				1
Genital haemorrhage		1				1
Gingival swelling	1	5	1	5		
Gingivitis	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glare		1
Glassy eyes		1
Glaucoma	1	3
Glomerular filtration rate decreased		1
Glossitis		1
Glossodynia	2	5
Gout		5
Granulocytes abnormal	1	1
Groin pain	1	1
Growing pains		1
Guillain-Barre syndrome	1	4
Haemangioma		1
Haematemesis		1
Haematochezia	1	6
Haematoma	1	1
Haematuria		2
Haemolytic anaemia	1	1
Haemoptysis	1	3
Haemorrhage	5	11
Haemorrhage urinary tract		1
Haemorrhoidal haemorrhage		1
Haemorrhoids	1	1
Hallucination	2	4
Hallucination, visual	1	2
Hand deformity		1
Hangover		3
Headache	174	716
Head banging		1
Head discomfort	1	7
Head injury	2	3
Head titubation	1	2
Heart rate abnormal		4

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
		1	3
	1		
	1		
2	5		
	5		
1	1		
1	1		
	1		
		1	4
			1
			1
		1	6
1	1		
	1		1
		1	1
1	3		
		5	11
			1
	1		
1	1		
		2	4
		1	2
			1
	3		
170	700	4	16
	1		
1	7		
2	3		
1	2		
	4		

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		1
21	64	2	12
4	4	1	2
		3	4
			1
		1	1
	1		1
		1	1
			1
1	1		
		1	1
			1
1	1		
1	5		
15	50	1	2
			1
	3		
		1	2
1	1		
5	10	1	1
	1		
1	1		
1	3		
8	37	1	1
	1		
17	56	8	14
			1
2	9		
6	19	3	10
			1
1	8		
23	54	7	12

Heart rate decreased		3
Heart rate increased	23	76
Heart rate irregular	5	6
Hemiparesis	3	4
Hepatic cirrhosis		1
Hepatic enzyme abnormal	1	1
Hepatic enzyme increased		2
Hepatic haemorrhage	1	1
Hepatic lesion		1
Hepatitis A virus test positive	1	1
Hepatitis D	1	1
Hernia		1
Hernia repair	1	1
Herpes virus infection	1	5
Herpes zoster	16	52
Herpes zoster oticus		1
Hiccups		3
Hip fracture	1	2
HIV test false positive	1	1
Hot flush	6	11
Hunger		1
Hyperacusis	1	1
Hyperaesthesia	1	3
Hyperhidrosis	9	38
Hyperphagia		1
Hypersensitivity	25	70
Hypersensitivity vasculitis		1
Hypersomnia	2	9
Hypertension	9	29
Hyperventilation		1
Hypoacusis	1	8
Hypoaesthesia	30	66

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia eye		1
Hypoaesthesia oral	4	21
Hypogeusia		3
Hypokinesia		4
Hypophagia	1	1
Hyposmia		1
Hypotension	3	6
Hypothermia		1
Hypotonia		1
Hypoxia	3	3
Illness	47	123
Immune system disorder	2	7
Immune thrombocytopenia	2	4
Immunodeficiency	1	1
Immunoglobulins decreased		1
Impaired driving ability		2
Impaired gastric emptying	1	1
Impaired work ability		1
Inappropriate schedule of product administration	59	256
Incomplete course of vaccination	3	8
Incontinence	1	1
Incorrect dose administered	5	25
Incorrect route of product administration	5	56
Increased appetite		1
Increased viscosity of upper respiratory secretion	1	1
Induration		2
Infection	1	9
Infection parasitic		1
Infectious mononucleosis	2	3
Inflammation	2	10
Influenza	13	32

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
3	19	1	2
	3		
	4		
1	1		
	1		
	2	3	4
			1
	1		
		3	3
39	115	8	8
2	7		
		2	4
		1	1
	1		
	2		
		1	1
	1		
59	256		
3	8		
1	1		
5	25		
5	55		1
	1		
1	1		
	1		1
1	7		2
	1		
2	3		
2	10		
13	32		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	18	78
Infrequent bowel movements		1
Initial insomnia	1	1
Injection site bruising		1
Injection site discomfort	1	4
Injection site erythema	3	6
Injection site extravasation	1	3
Injection site mass		3
Injection site nodule	1	1
Injection site pain	7	30
Injection site pruritus		1
Injection site reaction		2
Injection site swelling	1	6
Injection site warmth	1	1
Injury	4	6
Insomnia	18	51
Intentional dose omission		2
Intentional overdose		1
Intentional product misuse	1	2
Intercepted medication error		2
Internal haemorrhage	2	2
International normalised ratio increased		1
Intervertebral disc protrusion	2	2
Intraocular pressure increased		1
Irregular breathing	1	1
Irritability	1	3
Irritable bowel syndrome	1	1
Jaundice		1
Jaw disorder	1	1
Joint effusion		1
Joint injury	2	4
Joint lock	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
18	78		
	1		
1	1		
	1		
1	4		
3	6		
1	3		
	3		
1	1		
7	30		
	1		
	2		
1	6		
1	1		
1	3	3	3
17	50	1	1
	2		
	1		
1	2		
	2		
		2	2
	1		
1	1	1	1
	1		
1	1		
1	3		
1	1		
			1
1	1		
	1		
2	4		
2	2		

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\* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased	3	7	3	7		
Joint swelling	5	14	4	11	1	3
Kidney infection	3	5			3	5
Laboratory test abnormal	2	2	2	2		
Laboratory test normal		1		1		
Lacrimation increased	2	11	2	11		
Laryngeal pain	1	1	1	1		
Laryngitis		1		1		
Laryngospasm		1		1		
Lethargy	12	33	12	32		1
Leukaemia	1	1			1	1
Leukaemia recurrent	1	1			1	1
Leukocytosis		1				1
Lichen planus		1		1		
Limb discomfort	9	29	9	28		1
Limb injury	2	10	2	9		1
Limb mass	1	3	1	2		1
Lip blister	1	3	1	3		
Lip oedema		1		1		
Lip pain		1		1		
Lip pruritus		2		2		
Lip swelling	4	14	2	11	2	3
Liquid product physical issue	1	7	1	7		
Liver disorder	1	1	1	1		
Localised infection		2		2		
Loss of consciousness	12	28			12	28
Loss of control of legs	1	1			1	1
Loss of personal independence in daily activities	4	17	4	15		2
Low density lipoprotein increased		1		1		
Lower limb fracture	2	2			2	2
Lower respiratory tract infection		1				1
Lung disorder	2	4	1	2	1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung neoplasm malignant		2				2
Lyme disease	1	3			1	3
Lymphadenitis	1	4	1	4		
Lymphadenopathy	27	106	25	101	2	5
Lymph node pain	2	12	2	12		
Lymphoedema		3		3		
Macular degeneration		2				2
Macule		1		1		
Malaise	68	254	66	243	2	11
Mass	1	3	1	3		
Maternal exposure before pregnancy		1		1		
Maternal exposure during breast feeding		1		1		
Maternal exposure during pregnancy	8	54	4	48	4	6
Maternal exposure timing unspecified	1	2	1	2		
Medication error		3		3		
Memory impairment	4	7	4	7		
Meningitis viral		3				3
Menopause	1	1	1	1		
Menorrhagia		1		1		
Menstrual discomfort	1	1	1	1		
Menstrual disorder		4		4		
Menstruation irregular	2	5	2	5		
Mental disorder	1	2	1	2		
Mental fatigue	1	1	1	1		
Mental impairment	1	4			1	4
Mental status changes	1	1	1	1		
Metrorrhagia	1	2	1	2		
Microembolism		1				1
Micturition urgency	1	3	1	2		1
Middle insomnia		5		5		
Migraine	12	41	8	34	4	7
Moaning	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mobility decreased	4	12
Motor dysfunction		1
Mouth haemorrhage		1
Mouth injury	1	2
Mouth swelling	1	2
Movement disorder	4	20
Mucosal dryness		1
Mucous stools		1
Multiple allergies	1	1
Multiple sclerosis		2
Multiple sclerosis relapse	1	1
Muscle disorder	1	2
Muscle fatigue	2	2
Muscle spasms	7	28
Muscle strain		3
Muscle tightness	3	7
Muscle twitching		7
Muscular weakness	4	17
Musculoskeletal chest pain		5
Musculoskeletal discomfort	2	7
Musculoskeletal disorder	4	4
Musculoskeletal pain	1	3
Musculoskeletal stiffness	5	31
Myalgia	36	195
Mydriasis	1	2
Myelitis transverse		1
Myocardial infarction	8	13
Nail discolouration	1	1
Nasal congestion	18	55
Nasal discomfort	1	6
Nasal disorder	1	1
Nasal injury		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	8	1	4
			1
	1		
1	2		
1	2		
2	17	2	3
	1		
	1		
1	1		
			2
		1	1
1	2		
2	2		
6	27	1	1
	3		
3	7		
	7		
3	15	1	2
	5		
2	7		
4	4		
1	3		
5	31		
35	193	1	2
1	2		
			1
		8	13
1	1		
18	54		1
1	6		
1	1		
	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal oedema		1		1		
Nasopharyngitis	17	62	17	62		
Nausea	49	250	48	245	1	5
Near death experience	3	5			3	5
Neck injury	1	1	1	1		
Neck mass	1	4	1	4		
Neck pain	16	57	15	53	1	4
Needle issue		6		6		
Neoplasm malignant	1	5			1	5
Nephrolithiasis	3	4			3	4
Nerve compression	1	4	1	4		
Nerve injury	1	2	1	2		
Nervousness	6	16	6	15		1
Nervous system disorder	1	6	1	5		1
Neuralgia	4	9	4	9		
Neuritis		1		1		
Neurological examination normal		1		1		
Neurological symptom	1	1	1	1		
Neuropathy peripheral	4	8			4	8
Neutropenia	1	2			1	2
Neutrophil count decreased	1	1	1	1		
Nightmare	2	6	2	6		
Night sweats		11		11		
No adverse event	17	51	17	51		
Noninfective gingivitis		3		3		
Occupational exposure to product	5	8	5	8		
Occupational exposure to SARS-CoV-2		2		1		1
Ocular discomfort	2	3	2	3		
Ocular hyperaemia	5	12	5	12		
Odynophagia	2	2	2	2		
Oedema peripheral	1	2	1	2		
Oesophageal disorder		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oesophageal pain		1
Off label use	31	217
On and off phenomenon		1
Ophthalmic vein thrombosis	1	1
Optic neuritis	1	1
Oral discomfort	2	3
Oral disorder	1	6
Oral dysaesthesia		1
Oral fungal infection		1
Oral herpes	1	12
Oral mucosal blistering	1	2
Oral pain	2	4
Oral pruritus	1	2
Oral viral infection		1
Organ failure	1	1
Oropharyngeal discomfort	2	8
Oropharyngeal pain	30	90
Oropharyngeal spasm		1
Orthostatic hypotension		1
Osteoarthritis		1
Overdose	98	161
Oxygen consumption		1
Oxygen saturation decreased	1	9
Pain	111	484
Pain in extremity	146	579
Pain in jaw	4	8
Pain of skin	3	4
Palatal swelling	1	1
Pallor		3
Palmar erythema		1
Palpitations	7	30
Pancreatic disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
31	217		
	1		
		1	1
		1	1
2	3		
1	6		
			1
	1		
1	12		
1	2		
2	4		
	1	1	1
	1		
		1	1
2	7		1
28	87	2	3
			1
	1		
	1		
98	161		
	1		
	2	1	7
105	474	6	10
145	575	1	4
3	7	1	1
2	3	1	1
1	1		
	3		
	1		
5	25	2	5
			1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pancreatitis		2					2
Pancytopenia		1					1
Panic attack	3	4	2	3	1		1
Panic reaction	1	1	1	1			
Papule		1		1			
Paraesthesia	21	84	18	78	3		6
Paraesthesia oral	7	31	5	29	2		2
Paralysis	4	5			4		5
Paranasal sinus discomfort	1	2	1	2			
Paranasal sinus hypersecretion		2		2			
Paranoia		1		1			
Parkinson's disease	1	1			1		1
Parosmia		3		3			
Pelvic pain	1	2	1	2			
Pericardial effusion		3					3
Pericarditis		2					2
Periodontitis		1		1			
Periorbital swelling		3		3			
Peripheral artery thrombosis	1	1			1		1
Peripheral coldness	1	5	1	5			
Peripheral swelling	18	88	16	85	2		3
Peripheral vascular disorder		1		1			
Peripheral venous disease	1	1	1	1			
Petechiae		1		1			
Phantom limb syndrome		1		1			
Pharyngeal disorder	1	3	1	3			
Pharyngeal hypoaesthesia		1		1			
Pharyngeal inflammation		3		3			
Pharyngeal oedema	1	1			1		1
Pharyngeal paraesthesia	1	4		2	1		2
Pharyngeal swelling	4	12	2	8	2		4
Pharyngitis	2	2	2	2			

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia	1	4	1	4		
Photopsia	1	2	1	1		1
Piloerection	1	1	1	1		
Plantar erythema		1		1		
Platelet count decreased	3	9	3	7		2
Platelet count increased		1		1		
Platelet disorder		1		1		
Pleural effusion	1	1			1	1
Pleurisy		1				1
Pneumonia	10	29			10	29
Pneumonia aspiration		1				1
Poisoning	1	1			1	1
Pollakiuria	1	4	1	4		
Polyneuropathy		1				1
Poor quality product administered	56	284	56	284		
Poor quality sleep		5		5		
Post procedural complication		1				1
Potentiating drug interaction		5		5		
Premature baby	5	7			5	7
Presyncope	5	8	4	6	1	2
Product administered at inappropriate site	7	30	7	30		
Product administered to patient of inappropriate age	1	1	1	1		
Product administration error	2	16	2	16		
Product colour issue	1	3	1	3		
Product complaint	1	2	1	2		
Product confusion		1		1		
Product container issue		2		2		
Product dose omission in error		2		2		
Product dose omission issue	23	42	23	42		
Productive cough	1	4	1	3		1
Product leakage		10		10		

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	4		
1	1		1
1	1		
	1		
3	7		2
	1		
	1		
		1	1
			1
		10	29
			1
		1	1
1	4		
			1
56	284		
	5		
			1
	5		
		5	7
4	6	1	2
7	30		
1	1		
2	16		
1	3		
1	2		
	1		
	2		
	2		
23	42		
1	3		1
	10		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	4		
17	91		
98	168		
	2		
2	8		
16	23		
6	10		
42	174		
8	136		
		2	3
	1		
23	107	3	3
	1		1
	1		1
3	4	3	4
5	7	5	7
	1		1
	1		1
2	2	2	2
1	1	1	1
1	3	1	3
1	3		1
	2		
115	560	3	10
	1		
40	144	2	6
2	13	1	1
2	12	1	2
	2		
2	4		
4	16		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash vesicular		2
Raynaud's phenomenon		1
Reaction to excipient	1	2
Reaction to preservatives	1	1
Rectal haemorrhage	1	1
Red blood cell abnormality	1	1
Red blood cell count abnormal	1	1
Red blood cell count decreased	1	2
Renal disorder	2	5
Renal failure	2	3
Renal pain		3
Respiration abnormal		1
Respiratory arrest		2
Respiratory disorder	1	6
Respiratory disorder neonatal	1	1
Respiratory distress	1	1
Respiratory symptom	1	2
Respiratory tract congestion	2	4
Respiratory tract infection		2
Restless legs syndrome		1
Restlessness		2
Retching	1	8
Retinal haemorrhage	1	1
Rheumatoid arthritis	4	6
Rhinalgia		2
Rhinitis allergic	1	2
Rhinorrhoea	21	69
Rhinovirus infection		1
Rib fracture	1	2
Road traffic accident		1
Rotator cuff syndrome		1
Rubber sensitivity		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
	1		
1	2		
1	1		
		1	1
		1	1
1	1		
		1	2
1	2	1	3
		2	3
	2		1
	1		
			2
	5	1	1
		1	1
		1	1
1	2		
2	4		
			2
	1		
	2		
1	8		
		1	1
		4	6
	2		
1	2		
21	69		
	1		
		1	2
	1		
	1		
	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Ruptured cerebral aneurysm		1				1	
Sacroiliitis	1	1	1	1			
Saliva discolouration		1					1
Salivary hypersecretion	1	1	1	1			
Sarcoidosis	1	1			1		1
SARS-CoV-2 antibody test negative	2	24	2	24			
SARS-CoV-2 antibody test positive	2	9	1	7	1		2
SARS-CoV-2 test false positive	1	1	1	1			
SARS-CoV-2 test negative	1	1	1	1			
SARS-CoV-2 test positive	28	149	8	16	20		133
Sciatica	1	1	1	1			
Scratch	1	2	1	1			1
Screaming		1		1			
Seasonal allergy	3	9	3	9			
Secretion discharge	1	3	1	3			
Sedation		4		4			
Seizure	12	20			12		20
Sensation of foreign body		6		6			
Sensitive skin		3		3			
Sensitivity to weather change	1	1	1	1			
Sensory disturbance	3	6	2	5	1		1
Sensory loss		1		1			
Sepsis	3	5			3		5
Shock symptom		1					1
Sinus congestion	1	2	1	2			
Sinus disorder	3	14	3	14			
Sinus headache	2	6	2	6			
Sinusitis	7	19	5	16	2		3
Sinus pain	1	2	1	2			
Sitophobia		1		1			
Skin burning sensation	1	6	1	6			
Skin discolouration	1	6	1	3			3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	5		
		1	1
1	1		
	1		
1	1		
	4		
	2		
1	1		
	1		
	2	1	1
	1		
1	1		
3	10		
2	2		
8	24		
1	1		
1	1		
5	27		1
2	10	1	1
1		1	1
			1
	4		
	1		
2	3		
			1
			1
			2
	5		
			1
	1		
	1		
	2		1

Skin disorder 2 5

Skin exfoliation 1 1

Skin fissures 1 1

Skin haemorrhage 1 1

Skin infection 1 1

Skin irritation 4

Skin laceration 2

Skin mass 1 1

Skin odour abnormal 1 1

Skin reaction 1 3

Skin swelling 1 1

Skin warm 1 1

Sleep disorder 3 10

Sluggishness 2 2

Sneezing 8 24

Soft tissue swelling 1 1

Somnambulism 1 1

Somnolence 5 28

Speech disorder 2 11

Spinal compression fracture 1 1

Spinal cord disorder 1 1

Spinal pain 4

Spinal stenosis 1 1

Sputum discoloured 2 3

Staphylococcal infection 1 1

Streptobacillus infection 1 1

Streptococcus test positive 2 2

Stress 5

Suicidal ideation 1 1

Sunburn 1 1

Suppressed lactation 1 1

Supraventricular tachycardia 3 3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected counterfeit product		1		1		
Suspected COVID-19	11	31	3	13	8	18
Swelling	15	55	14	53	1	2
Swelling face	13	34	8	28	5	6
Swelling of eyelid	1	3	1	3		
Swollen tongue	9	18	5	11	4	7
Syncope	11	22			11	22
Syphilis		1				1
Syringe issue		2		2		
Systemic inflammatory response syndrome		1				1
Systemic lupus erythematosus	2	3	1	1	1	2
Tachycardia	2	24	1	18	1	6
Tachycardia foetal		1				1
Tachypnoea		1		1		
Taste disorder	1	6	1	5		1
Teeth brittle	1	1	1	1		
Tenderness	1	7	1	7		
Tendonitis	1	1	1	1		
Tension		1		1		
Tension headache	1	1	1	1		
Thanatophobia		1		1		
Therapeutic product effect incomplete		1				1
Therapeutic response unexpected	7	16	7	16		
Thirst		1		1		
Throat irritation	8	30	7	26	1	4
Throat tightness	6	20	5	15	1	5
Thrombocytopenia	1	4			1	4
Thrombosis	19	29	2	2	17	27
Thyroid cancer	1	1			1	1
Thyroid disorder	1	1	1	1		
Thyroid function test abnormal		1		1		
Thyroid hormones increased	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	20	29	18	26	2	3
Tongue biting	1	1	1	1		
Tongue blistering	1	1	1	1		
Tongue dry		1		1		
Tongue fungal infection	1	1	1	1		
Tongue paralysis	2	2			2	2
Tongue pruritus	1	2	1	1		1
Tongue ulceration		1		1		
Tonic clonic movements		1				1
Tonsillar disorder		1		1		
Tonsillar erythema		1		1		
Tonsillar hypertrophy		2		2		
Tooth abscess	1	1	1	1		
Toothache	8	17	7	15	1	2
Tooth disorder	1	3	1	3		
Tooth extraction	2	2	2	2		
Tooth infection		2		2		
Tooth injury	1	1	1	1		
Transient global amnesia	1	1	1	1		
Transient ischaemic attack	1	1			1	1
Tremor	14	51	12	45	2	6
Trigeminal nerve disorder		1		1		
Tuberculosis		2				2
Tunnel vision		1				1
Ulcer		1		1		
Underdose	22	147	22	147		
Unresponsive to stimuli		1				1
Upper airway obstruction		1				1
Upper limb fracture	2	2			2	2
Upper respiratory tract congestion		4		4		
Upper respiratory tract infection		1		1		
Urethral haemorrhage		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	2
11	28	2	5
1	1		
	1		
			1
10	67	2	5
	2		
2	3		
		16	23
2	6		1
1	4		
1	4		
2	11		
12	53		
4	11		
7	18		
	1		
1	4		
1	10		1
2	4		
	2		
1	2		
1	2		
1	1		
7	22		2
1	4		
1	1		
51	294	1	1
1	7		2
6	21		1
6	17		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	2	12	2	12		
Vaccination site scab		1		1		
Vaccination site scar		1		1		
Vaccination site swelling	14	49	13	48	1	1
Vaccination site urticaria		3		3		
Vaccination site vesicles		2		2		
Vaccination site warmth	2	20	2	20		
Vaginal haemorrhage		2		2		
Vagus nerve disorder	1	1			1	1
Varicella		1		1		
Vasculitis	1	1	1	1		
Vasodilatation		1		1		
Ventricular extrasystoles		1				1
Vertigo	8	30	4	25	4	5
Vessel puncture site haemorrhage		1		1		
Vessel puncture site injury		1		1		
Vestibular neuronitis		1		1		
Viral infection	1	4		1	1	3
Vision blurred	4	12	4	11		1
Visual impairment	6	12	5	10	1	2
Vitamin D deficiency		1		1		
Vitreous degeneration		1				1
Vitreous detachment	1	1			1	1
Vitreous floaters		3		3		
Vomiting	25	94	24	93	1	1
Vomiting projectile		2		2		
Von Willebrand's disease		1				1
Water pollution		1		1		
Weight decreased	1	7	1	6		1
Wheezing	2	10	1	7	1	3
White blood cell count abnormal	1	1	1	1		
White blood cell count decreased	2	4	2	3		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count increased	1	2			1	2
Wound haemorrhage		1				1
Wrong dose		1		1		
Wrong product administered	2	21	2	21		
Wrong schedule		1		1		
Wrong technique in product usage process	6	61	6	61		
Yellow skin		1				1
		1		1		
	4,629	16,171	3351	12858	1278	3313

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED STATES MINOR OUTLYING ISLA**

Age Range

**51 - 64 years**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain		1		1
		1		1

Age Range

**Unknown**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**URUGUAY**

Age Range

**Unknown**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inflammation	1	1	1	1
Pain	1	1	1	1
Synovial cyst	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

**APPENDIX 2.5.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Gender by Preferred Term per Country**

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

Total Number of Adverse Events (PT): 112,695 (Interval) / 414,597 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Erythema		1		1		
Facial paralysis		1				1
Feeling of body temperature change		1		1		
Muscle tightness		1		1		
Paraesthesia		1		1		
Pruritus		1		1		
Rash		1		1		
Swelling face		1		1		
		9		8		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ALBANIA**

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
Off label use	1	1	1	1
Product use issue	1	1	1	1
	2	4	2	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AMERICAN SAMOA**

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
		2		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ANDORRA**

Gender

**MALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous

Nonserious

I

C

Product administered to patient of inappropriate age

1

1

1

1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**ANGOLA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration		1		1		
Nasopharyngitis		1				1
Pyrexia		1				1
Swollen tongue		1				1
Vomiting		1				1
		5		1		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ARGENTINA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumstance or information capable of leading to medication error		1		1		
Diabetes mellitus	1	1			1	1
Hypersensitivity	1	1	1	1		
Intentional product misuse	1	1	1	1		
Pain in extremity		1		1		
	3	5	2	4	1	1

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
SARS-CoV-2 ant body test negative		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRALIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	7	7	6	6	1	1
Abdominal tenderness	1	1	1	1		
Accidental overdose		1		1		
Acute coronary syndrome		1				1
Acute kidney injury	1	2			1	2
Adverse event following immunisation	1	1			1	1
Altered state of consciousness		1				1
Anal haemorrhage	1	1	1	1		
Anaphylactic reaction	28	34			28	34
Angioedema	3	3			3	3
Anxiety	2	6	1	1	1	5
Aphasia		1				1
Apnoea	1	1			1	1
Areflexia	1	1			1	1
Arrhythmia	2	2			2	2
Arthralgia	15	16	15	16		
Aspiration		1				1
Asthenia	1	1	1	1		
Balance disorder		1				1
Blood creatine phosphokinase increased	1	1			1	1
Blood pressure decreased	2	2	2	2		
Blood pressure increased	2	4	2	2		2
Bradycardia	1	1			1	1
Cardiac arrest	3	3			3	3
Cellulitis	1	1			1	1
Chest discomfort	10	10	9	9	1	1
Chest pain	1	1	1	1		
Chills	14	15	14	14		1
Circulatory collapse		1				1
Circumstance or information capable of leading to medication error	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cognitive disorder		1					1
Cold sweat	3	6	3	3			3
Coma scale abnormal		1					1
Condition aggravated		2					2
Confusional state	2	4	2	3			1
Conjunctival haemorrhage	1	1			1		1
Consciousness fluctuating		1					1
Contusion	2	3	2	2			1
Cough	15	20	15	20			
Crying		1		1			
Cyanosis	2	2	1	1	1		1
Deafness	1	1			1		1
Death	2	3			2		3
Decreased appetite	1	3	1	2			1
Deep vein thrombosis		1					1
Delirium	1	2			1		2
Demyelination	1	1			1		1
Depressed level of consciousness	1	2			1		2
Depressed mood		1		1			
Diabetes mellitus	1	1			1		1
Diabetic ketoacidosis		1					1
Diarrhoea	7	7	7	7			
Disorientation	1	1	1	1			
Dizziness	16	23	16	18			5
Drooling	1	1			1		1
Dry throat	2	2	2	2			
Dysarthria	1	3			1		3
Dysgeusia	2	2	2	2			
Dyskinesia		1		1			
Dysphagia	2	4	2	2			2
Dysphonia		1		1			
Dyspnoea	14	16	9	10	5		6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
3	6		
1	1	1	1
1	1		
2	2		
1	1		
1	1		
5	7	5	7
1	3	1	2
21	24		
1	3		1
4	6		1
	1		
2	2		
6	8		
	1		1
	1		
2	2		
1	1	1	1
1	1	1	1
2	2	2	2
	1		1
46	50	45	49
1	1	1	1
2	2		
	1		1
1	1	1	1
2	2		
1	2		
	1		1
	1		1
	1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	4	5	3	4	1	1
Hypersensitivity	1	1	1	1		
Hypertension	9	9	8	8	1	1
Hypoaesthesia	4	5	4	5		
Hypophagia		1				1
Hypopnoea		1		1		
Hypotension	6	8	6	6		2
Hypoxia	1	2			1	2
Illness	1	1	1	1		
Inadequate aseptic technique in use of product	1	1	1	1		
Incontinence	1	1	1	1		
Inflammation	1	1	1	1		
Influenza like illness	2	2	2	2		
Injected limb mobility decreased	1	1	1	1		
Insomnia	2	2	2	2		
Ischaemic stroke	1	2			1	2
Joint stiffness	1	1	1	1		
Lethargy	21	23	19	21	2	2
Limb discomfort	1	1	1	1		
Lip swelling	3	3	3	3		
Liver function test increased	1	1	1	1		
Localised oedema	1	1	1	1		
Loss of consciousness	1	3			1	3
Lymphadenopathy	6	6	5	5	1	1
Malaise	7	9	5	6	2	3
Migraine	1	1	1	1		
Migraine with aura	1	1	1	1		
Monoplegia		1				1
Multiple sclerosis	2	2			2	2
Multiple sclerosis relapse	1	1			1	1
Muscle spasms		1		1		
Muscle tightness	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	20	23	20	22		1
Mydriasis		2				2
Myocardial infarction	1	1			1	1
Nasal congestion	2	2	2	2		
Nasopharyngitis	1	1	1	1		
Nausea	22	30	22	28		2
Neck pain	3	3	3	3		
Nerve injury	1	1	1	1		
Nervousness		2		1		1
Neuropathy peripheral	1	1			1	1
Neutrophil count decreased	1	1	1	1		
Occipital neuralgia	1	1	1	1		
Ocular discomfort	1	1	1	1		
Ocular hyperaemia	2	2	2	2		
Odynophagia	1	1	1	1		
Off label use	2	2	2	2		
Oral herpes	1	1	1	1		
Oropharyngeal pain	7	8	7	8		
Orthostatic tremor	1	1	1	1		
Oxygen saturation decreased	2	3	1	1	1	2
Pain	2	3	2	3		
Pain in extremity	5	5	5	5		
Pallor	1	2	1	1		1
Palpitations	3	5	3	5		
Pancreatitis	1	1			1	1
Panic reaction	1	1	1	1		
Paraesthesia	8	9	8	9		
Paraesthesia oral	7	7	6	6	1	1
Pelvic fracture		1				1
Peripheral circulatory failure	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	1	1	1	1		
Peripheral swelling		1		1		
Pharyngeal swelling	1	2			1	2
Photophobia	1	1	1	1		
Pleuritic pain	1	1	1	1		
Pneumonia	3	3			3	3
Pneumonia aspiration	1	2			1	2
Poor quality product administered	1	1	1	1		
Presyncope	5	5	5	5		
Product preparation error		1		1		
Product use issue	2	2	2	2		
Pruritus	7	10	7	10		
Pulmonary congestion	1	1			1	1
Pulmonary embolism	4	4			4	4
Pulmonary sepsis		1				1
Pupil fixed	1	3			1	3
Pupils unequal		1				1
Pyrexia	26	29	26	28		1
Rash	13	15	12	14	1	1
Rash macular		1				1
Rash pruritic	2	3	2	3		
Rectal haemorrhage	1	1			1	1
Respiratory distress	1	1			1	1
Respiratory rate increased		1				1
Respiratory tract infection	1	1			1	1
Rhinorrhoea	4	6	4	6		
Rhinovirus infection	1	1	1	1		
Scar	1	1	1	1		
Seizure	1	2			1	2
Sensitive skin	1	1	1	1		
Sensory disturbance		1		1		
Sensory loss	1	1	1	1		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
1	1		
1	1		
			1
	2		1
1	1		
1	1		
2	2		
1	2	1	1
22	26	22	26
7	7	1	3
1	1		1
4	4		
3	4	2	2
1	1		
		1	1
2	4		
1	1		
		4	5
			1
6	8		
	1		
1	1		
1	1		
1	2		1
7	11		1
11	11		
2	4		1
1	1		
1	1		
			1
1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	3	3	3	3		
Vomiting	16	20	11	12	5	8
Weight decreased		1				1
Wheezing	2	3	2	3		
White blood cell count decreased	1	1	1	1		
	666	858	519	606	147	252

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
Acute pulmonary oedema		1				1
Adrenocortical insufficiency acute	1	1			1	1
Adverse event following immunisation	1	1			1	1
Anaphylactic reaction	2	3			2	3
Arthralgia		1		1		
Balance disorder	1	1	1	1		
Blood pressure increased		1		1		
Body temperature increased		1		1		
Bradycardia	1	3			1	3
Burning sensation	1	1	1	1		
Cardiac arrest		2				2
Cellulitis	1	1			1	1
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	2			1	2
Chest discomfort	2	2	2	2		
Chills	2	2	2	2		
Cold sweat	1	2	1	2		
Concomitant disease aggravated	1	1			1	1
Condition aggravated		1				1
Conjunctival haemorrhage	1	1			1	1
Contusion	3	3	3	3		
Cough	4	6	3	4	1	2
COVID-19		1		1		
Deafness	1	1			1	1
Death	1	3			1	3
Decreased appetite	1	1			1	1
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness	2	2			2	2
Diarrhoea	2	2	2	2		
Disease progression	1	1			1	1
Disorientation	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	4	2	3		1
Dyspnoea	4	6	1	1	3	5
Exposure via breast milk	1	1	1	1		
Extensive swelling of vaccinated limb	1	1	1	1		
Eye discharge		1		1		
Eye pain	1	2	1	2		
Facial paralysis	1	1			1	1
Fall	1	2	1	1		1
Fatigue	3	5	2	4	1	1
Feeling abnormal		1		1		
Flushing	1	1	1	1		
Gait disturbance		1		1		
Gastrointestinal haemorrhage		1				1
General physical health deterioration	1	3			1	3
Headache	5	7	5	6		1
Heart rate increased		1				1
Hyperhidrosis	2	3	2	3		
Hypertension	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral		1				1
Hyporesponsive to stimuli		1				1
Hypotension	2	4	2	3		1
Hypoxia		1				1
Influenza like illness	1	1	1	1		
Lethargy	2	2	2	2		
Loss of consciousness	3	5			3	5
Lymphadenopathy	2	2	2	2		
Malaise	3	4	1	1	2	3
Migraine	1	2	1	2		
Multiple organ dysfunction syndrome		1				1
Muscle spasms	1	1	1	1		
Myalgia	4	5	4	5		

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
	1		
			1
2	3		
	1		2
	1		
2	2		
		3	7
		1	1
			1
1	2	2	2
	1		
1	1		
2	3	3	4
			1
2	2	1	1
		2	2
		1	1
		2	3
	1	1	1
		1	1
3	5		
		3	3
			1
1	1		
		2	1
		4	7
		1	1
1	3		
		3	4
			1
			1

Nausea 1 2  
 Ocular hyperaemia 1  
 Oedema peripheral 1  
 Oropharyngeal pain 2 3  
 Oxygen saturation decreased 3  
 Pain in extremity 1  
 Paraesthesia 2 2  
 Pneumonia 3 7  
 Pneumonia aspiration 1 1  
 Pneumonia viral 1  
 Presyncope 3 4  
 Product preparation error 1  
 Pruritus 1 1  
 Pyrexia 5 7  
 Rales 1  
 Rash 3 3  
 Rectal haemorrhage 2 2  
 Respiratory distress 1 1  
 Respiratory failure 2 3  
 Respiratory rate increased 1 2  
 Retinal artery occlusion 1 1  
 Rhinorrhoea 3 5  
 Seizure 3 3  
 Septic shock 1  
 Soft tissue inflammation 1 1  
 Somnolence 1 3  
 Syncope 4 7  
 Transient ischaemic attack 1 1  
 Tremor 1 3  
 Unresponsive to stimuli 3 4  
 Urinary incontinence 1  
 Urosepsis 1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	2	2	2	2		
Vaccination site bruising	1	1	1	1		
Vaccination site pain	3	3	3	3		
Vaccination site reaction	4	4	4	4		
Vaccination site swelling	1	1	1	1		
Vasoconstriction	1	1	1	1		
Venous thrombosis	1	1	1	1		
Vomiting	1	2			1	2
Wheezing	2	4	2	3		1
	138	222	80	115	58	107

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anaphylactic reaction	3	17			3	17
Appendicitis	1	1			1	1
Asthenia	2	2	2	2		
Back pain	1	1	1	1		
Blood disorder	1	1	1	1		
Blood pressure increased	1	1	1	1		
Cerebrovascular accident	3	5			3	5
Chest discomfort	1	1	1	1		
Chest pain	1	1	1	1		
Chills	1	1	1	1		
Cold sweat	1	1	1	1		
Cough	4	4	4	4		
COVID-19	1	1			1	1
Deafness	1	1			1	1
Deafness unilateral	2	2			2	2
Decreased appetite		1		1		
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea	1	1	1	1		
Dizziness	3	3	3	3		
Drug ineffective	1	1			1	1
Dyspnoea	2	2	1	1	1	1
Erythema	1	1	1	1		
Facial paralysis	1	1			1	1
Facial paresis	3	5		1	3	4
Fatigue	2	2	2	2		
Feeling hot	1	1	1	1		
Flushing	2	2	2	2		
Headache	3	3	3	3		
Heart rate increased	1	1	1	1		
Hot flush		1		1		

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Gender

**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
3	3		
		2	2
1	1		
1	1		
		1	1
2	3		
		1	1
		1	1
1	1		
1	1		
		1	1
1	1		
1	1		
2	2		
1	1		
3	3		
1	1		
1	1		
3	3		
1	1		
1	1		
1	1		
			1
1	1		
	1		
2	2		
		1	1
		1	1
5	5		
6	6		
1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	4	5			4	5
Sensation of foreign body	1	1	1	1		
Swollen tongue	1	1	1	1		
Syncope	6	6			6	6
Tachycardia	1	1	1	1		
Tachypnoea	1	1	1	1		
Throat irritation	2	2	2	2		
Thrombophlebitis	1	1	1	1		
Tinnitus	2	2	2	2		
Tremor	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site reaction	3	3	3	3		
Vomiting	1	1	1	1		
	124	149	88	93	36	56

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Country Where Event Occurred

**AUSTRIA**

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain	1	4		1	1	3
Abdominal pain lower	1	2			1	2
Abdominal pain upper	1	3	1	2		1
Activated partial thromboplastin time prolonged	1	1			1	1
Acute coronary syndrome	1	1			1	1
Acute disseminated encephalomyelitis	1	3			1	3
Acute kidney injury	1	1			1	1
Acute left ventricular failure	1	1			1	1
Acute macular outer retinopathy	1	1			1	1
Acute myocardial infarction		1				1
Administration site hypoaesthesia	1	1	1	1		
Administration site joint pain		1		1		
Ageusia		2		2		
Agitation		1		1		
Alanine aminotransferase increased		1		1		
Alopecia		2		2		
Altered visual depth perception	1	1	1	1		
Amenorrhoea		1				1
Analgesic drug level above therapeutic		1				1
Anaphylactic reaction	2	8			2	8
Anaphylactic shock		3				3
Anaphylactoid reaction		2				2
Aneurysm ruptured		1				1
Angina pectoris	1	3			1	3
Angioedema	1	1			1	1
Anosmia		1		1		
Antibody test abnormal		1		1		
Antiphospholipid syndrome		1				1
Anxiety	1	3		1	1	2
Apathy		2		2		
Aphasia	1	2		1	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Aphonia		1					1
Apnoea	1	1			1		1
Application site pain		1		1			
Arrhythmia	2	6			2		6
Arterial occlusive disease	1	1			1		1
Arteriosclerosis		1					1
Arteriosclerosis coronary artery		1					1
Arthralgia	8	50	4	27	4		23
Arthritis		1		1			
Aspartate aminotransferase increased		1		1			
Asthenia	6	20	5	16	1		4
Asthma		2					2
Asymptomatic COVID-19	8	8			8		8
Atelectasis		1					1
Atrial fibrillation	1	4			1		4
Autoimmune thyroiditis		1					1
Axillary pain	1	1			1		1
Back pain	3	8	1	3	2		5
Balance disorder	1	2	1	1			1
Basilar migraine	1	1			1		1
Bedridden	1	1	1	1			
Beta globulin increased		1		1			
Biliary colic	1	1			1		1
Blepharospasm		1					1
Blood albumin decreased		1		1			
Blood creatine phosphokinase MB increased		1					1
Blood glucose fluctuation		1					1
Blood glucose increased	1	1			1		1
Blood lactate dehydrogenase increased		1		1			
Blood pressure abnormal	1	2			1		2
Blood pressure decreased		2					2
Blood pressure immeasurable		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	7	1	3		4
Blood pressure systolic increased		1				1
Blood urea increased		1		1		
Body temperature increased	2	12	2	11		1
Bone marrow oedema		1				1
Bone pain		1		1		
Bradycardia		3				3
Breast pain		1		1		
Breath sounds		1		1		
Breath sounds abnormal	1	1			1	1
Bronchial obstruction	1	1			1	1
Bronchiolitis		1				1
Bundle branch block left	1	1			1	1
Bundle branch block right		1				1
Burning sensation		2		1		1
Bursitis		2		1		1
Cachexia	1	1			1	1
Cardiac arrest	2	3			2	3
Cardiac death		1				1
Cardiac failure		5				5
Cardiac hypertrophy		1				1
Cardiomegaly		1		1		
Cardiomyopathy		1				1
Cardiopulmonary failure	1	1			1	1
Cardio-respiratory arrest		2				2
Cardiovascular disorder	2	11	1	9	1	2
Cerebral haemorrhage	2	3			2	3
Cerebral infarction	2	2			2	2
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	1	3			1	3
Chapped lips		1				1
Chest discomfort	1	7		2	1	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	2	8	1	4	1	4
Chills	10	72	10	45		27
Choking		1				1
Cholestasis		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse	6	18			6	18
Coagulopathy	1	1			1	1
Cold sweat		1				1
Concomitant disease aggravated		2				2
Concussion	1	1			1	1
Condition aggravated	1	2			1	2
Confusional state	1	2			1	2
Congestive hepatopathy		1				1
Conjunctival haemorrhage	2	2			2	2
Conjunctivitis		1				1
Contusion	1	1			1	1
Cough	2	11	2	10		1
COVID-19	3	20		4	3	16
COVID-19 pneumonia		3				3
C-reactive protein increased		3		1		2
Death	3	11			3	11
Decreased appetite	1	4	1	4		
Deep vein thrombosis	3	6			3	6
Defaecation urgency		1		1		
Dehydration	1	1			1	1
Delirium	1	1			1	1
Depressed level of consciousness		1				1
Dermatitis allergic		2				2
Diarrhoea	5	22	5	17		5
Diarrhoea haemorrhagic	1	2			1	2
Diplopia		2		1		1
Discomfort		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Disease progression		1					1
Disease recurrence	1	2			1		2
Disorganised speech		1		1			
Disorientation		2		1			1
Disseminated varicella zoster virus infection	1	1			1		1
Disturbance in attention	2	6	2	3			3
Dizziness	12	57	10	37	2		20
Drug eruption		2					2
Drug ineffective	1	9			1		9
Dry mouth		5		3			2
Dry throat		1		1			
Dysaesthesia	3	4	1	1	2		3
Dysarthria		1					1
Dysgeusia	2	8	1	4	1		4
Dysgraphia		1		1			
Dysphagia		7		3			4
Dyspnoea	11	35	3	7	8		28
Dyspnoea exertional	1	5		1	1		4
Dysstasia		1		1			
Dysuria		1		1			
Ear discomfort		2		2			
Ear infection		1					1
Ear pain		1		1			
Eczema		2		1			1
Electrocardiogram abnormal		1		1			
Emphysema		2		1			1
Endocrine ophthalmopathy	1	1			1		1
Epilepsy	1	2			1		2
Epistaxis	1	3	1	2			1
Erysipelas		1					1
Erythema	3	12	2	6	1		6
Exercise tolerance decreased		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
External ear pain	1	1			1	1
Extrasystoles	1	3		1	1	2
Eye contusion	1	1			1	1
Eye haemorrhage		1				1
Eye irritation		1				1
Eyelid contusion	1	1			1	1
Eyelid oedema		1				1
Eye movement disorder		1				1
Eye pain	1	3		2	1	1
Eye pruritus		2		2		
Eye swelling		1		1		
Face oedema		3				3
Facial asymmetry	1	1			1	1
Facial bones fracture	1	1			1	1
Facial paralysis	2	4			2	4
Facial paresis	4	9			4	9
Facial spasm		1				1
Faecal calprotectin increased	1	1			1	1
Fall	4	5		1	4	4
Fatigue	13	99	11	77	2	22
Feeling abnormal	1	5	1	4		1
Feeling cold		5		1		4
Feeling drunk		2		2		
Feeling hot	1	9		4	1	5
Feeling of body temperature change		2		2		
Fibrin D dimer increased		1		1		
Flank pain	1	1			1	1
Flatulence	1	1	1	1		
Flushing		9		1		8
Foreign body aspiration		1				1
Formication		1		1		
Gait disturbance	2	7	1	4	1	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gastroenteritis		1		1			
Gastrointestinal disorder		2		2			
Gastrointestinal hypermotility		1		1			
Gastrointestinal motility disorder		1		1			
Generalised oedema		1		1			
Generalised tonic-clonic seizure		3					3
General physical health deterioration	3	9		2	3		7
Gingivitis	1	1	1	1			
Glossopharyngeal nerve disorder	1	1			1		1
Groin pain		1		1			
Grunting		1		1			
Haematoma	1	1			1		1
Haematuria	1	1			1		1
Haemorrhage		1					1
Hallucination		1					1
Hand dermatitis	1	1	1	1			
Hangover		1		1			
Headache	21	131	13	92	8		39
Head discomfort		1		1			
Heart rate decreased		2					2
Heart rate increased		3		1			2
Helicobacter infection		1					1
Hemianaesthesia		1					1
Hemidysaesthesia		2					2
Hemiparaesthesia	1	2			1		2
Hemiparesis	2	3			2		3
Hepatic pain	1	2		1	1		1
Hepatic steatosis		1		1			
Herpes zoster	1	7		5	1		2
Herpes zoster cutaneous disseminated		1					1
Hirsutism		1		1			
Histamine intolerance		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		4		2		2
Hyperaesthesia		1				1
Hyperglycaemia		1				1
Hyperhidrosis	1	2	1	1		1
Hypernatraemia		1				1
Hypersensitivity	2	13		1	2	12
Hypersomnia		1		1		
Hypertension	1	9		1	1	8
Hypertensive crisis	2	7			2	7
Hypertensive emergency		1				1
Hyperventilation	1	2			1	2
Hypoaesthesia	4	20	2	8	2	12
Hypoaesthesia oral	1	7	1	2		5
Hypogeusia		2		1		1
Hypoglossal nerve paresis	1	1			1	1
Hypoglycaemia		1				1
Hypokalaemia	1	1			1	1
Hypokinesia		1		1		
Hypophagia		1				1
Hypopnoea	1	1			1	1
Hyposmia		1				1
Hypotension	1	7		1	1	6
Hypotonia		4		3		1
Illness		1				1
Impaired driving ability		1				1
Impaired work ability	2	8	1	4	1	4
Inappropriate schedule of product administration		2		2		
Incontinence	1	1			1	1
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	1	8	1	8		
Inflammation		1				1
Influenza like illness	1	4	1	3		1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
	2		
	1		
1		1	1
	4		1
			1
		1	1
1		1	1
1		1	1
1		1	1
1	1	1	2
	1		
1	1		
			1
			1
			1
			1
1		1	1
1		1	2
			1
	1		
		1	1
1		1	6
	1		
			1
1		1	1
1		1	6
1		1	2
	1		
			1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	2	23	1	9	1	14
Lymph node pain		2		2		
Lymphopenia		1		1		
Malaise	1	8		4	1	4
Marasmus		1				1
Maternal exposure during pregnancy	1	1	1	1		
Memory impairment	1	3		1	1	2
Meningism		1				1
Menorrhagia	1	1			1	1
Menstruation irregular	1	1			1	1
Metrorrhagia		1				1
Migraine	1	3	1	3		
Monoparesis		2				2
Monoplegia	1	2			1	2
Mouth swelling		2				2
Movement disorder		2		2		
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis		2				2
Muscle contractions involuntary		1		1		
Muscle disorder	1	1			1	1
Muscle spasms	1	6		3	1	3
Muscle twitching		1		1		
Muscular weakness	2	7		1	2	6
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal disorder	1	1			1	1
Myalgia	4	44	4	30		14
Myocardial infarction	2	4			2	4
Myocarditis		2				2
Narcolepsy		1				1
Nausea	14	63	12	40	2	23
Neck pain		6		5		1
Neoplasm malignant		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nerve conduction studies abnormal		1					1
Neuralgia		3		1			2
Neuralgic amyotrophy		1					1
Neuritis		1					1
Neuropathy peripheral		1					1
Night sweats		2		1			1
Nuchal rigidity		2		1			1
Obstructive airways disorder		1		1			
Ocular hyperaemia		2		2			
Oedema		1					1
Oedema mucosal		1		1			
Oedema peripheral	1	2			1		2
Off label use	1	7	1	7			
Onychoclasia		1		1			
Opiates positive		1					1
Oral discomfort		2					2
Oral mucosal erythema		1					1
Oral pruritus		2					2
Oral pustule		1		1			
Oropharyngeal pain	1	7	1	4			3
Oxygen saturation		1					1
Oxygen saturation decreased	2	6		2	2		4
Oxygen saturation immeasurable		1					1
Pain	1	13		7	1		6
Painful respiration	1	1	1	1			
Pain in extremity	13	58	7	41	6		17
Palatal swelling		1					1
Pallor	1	7		2	1		5
Palmar erythema		1					1
Palpitations	5	18	3	5	2		13
Panic attack		1					1
Panic reaction		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	7	35		13	7	22
Paraesthesia oral		5		1		4
Paresis		1				1
Pericardial effusion	2	2			2	2
Pericarditis		1				1
Periorbital swelling		1				1
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	6	1	2		4
Peroneal nerve palsy	1	1			1	1
Personality change		1				1
Petechiae		2		1		1
Pharyngeal swelling		3		1		2
Photophobia	1	4	1	4		
Platelet count increased		1		1		
Pleural effusion	1	2			1	2
Pleurisy		1				1
Pneumonia	2	6			2	6
Pneumonia aspiration		1				1
Pollakiuria	1	1	1	1		
Poor peripheral circulation		1		1		
Presyncope	4	18		4	4	14
Product administered at inappropriate site		1		1		
Productive cough		1		1		
Product use issue	1	5	1	5		
Prurigo	1	1			1	1
Pruritus	4	30		6	4	24
Pruritus allergic		1				1
Pulmonary congestion		1				1
Pulmonary embolism	7	14			7	14
Pulmonary hypertensive crisis	1	1			1	1
Pulmonary infarction		1				1
Pulmonary oedema		3				3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pupils unequal		1				1	
Pustule		1		1			
Pyrexia	20	107	14	69	6	38	
Radiculopathy		1				1	
Rales		2		1		1	
Rash	6	28	3	7	3	21	
Rash macular		5		1		4	
Rash morbilliform		1				1	
Rash pruritic		5		1		4	
Rash pustular		3		1		2	
Red blood cell sedimentation rate increased		1		1			
Reduced facial expression		1		1			
Renal disorder		1		1			
Renal failure	1	2			1	2	
Renal pain	1	3			1	3	
Respiratory depression		1				1	
Respiratory disorder		1		1			
Respiratory distress		1				1	
Respiratory failure		1				1	
Respiratory rate decreased		1				1	
Restlessness		2		2			
Retching	1	1	1	1			
Retinal artery occlusion	1	1			1	1	
Retinal tear	1	1			1	1	
Rhabdomyolysis	1	1			1	1	
Rheumatoid arthritis		1				1	
Rhinitis	1	2	1	2			
Rhinitis allergic		1				1	
Ruptured cerebral aneurysm		1				1	
SARS-CoV-2 ant body test negative	1	3		1	1	2	
SARS-CoV-2 test positive	2	3			2	3	
Seizure	1	1			1	1	

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		6				6
Sense of oppression	1	1			1	1
Sensory disturbance	1	2			1	2
Sensory level abnormal	2	2			2	2
Septic shock		1				1
Serum ferritin decreased		1		1		
Serum ferritin increased		1		1		
Shock		1				1
Sinus congestion		1		1		
Sinus tachycardia	1	2			1	2
Skin burning sensation		1				1
Skin discolouration		1				1
Skin exfoliation		1				1
Skin indentation		1		1		
Skin lesion		1				1
Skin striae		1		1		
Skin tightness		1				1
Sleep attacks		1		1		
Sleep disorder		1				1
Sleep disorder due to general medical condition, hypersomnia type		1		1		
Somatic symptom disorder		1				1
Somnolence	3	19	3	15		4
Speech disorder	1	4		1	1	3
Spinal pain	1	4		2	1	2
Stomatitis	1	1	1	1		
Strabismus		1		1		
Subarachnoid haemorrhage		2				2
Subdural haemorrhage	1	1			1	1
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19	1	1			1	1
Swelling		4		2		2

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		6
			1
	2		6
		1	17
	1		
3	2	3	12
			1
	1		
	1		1
	1		
	1		1
1		1	1
	1		
	1		1
1	1		
1	3		3
			3
2	1	1	1
1		1	1
3		3	3
			1
	1		1
	1		2
			1
1		1	1
			1
1	1	1	1
	1		
	2		1
	1		
1		1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Troponin I increased		1					1
Tunnel vision		2					2
Type I hypersensitivity	1	1			1		1
Underdose		1		1			
Unresponsive to stimuli		4					4
Urinary retention		1					1
Urinary tract infection	1	1			1		1
Urticaria	2	11			2		11
Urticaria pressure		1					1
Use of accessory respiratory muscles		1		1			
Vaccination complication		1					1
Vaccination failure	12	13			12		13
Vaccination site discolouration		2					2
Vaccination site dysaesthesia		1					1
Vaccination site erythema	4	15	2	9	2		6
Vaccination site haemorrhage		1		1			
Vaccination site hypoaesthesia		4		2			2
Vaccination site induration		4		2			2
Vaccination site inflammation	1	1			1		1
Vaccination site joint pain	1	2		1	1		1
Vaccination site lymphadenopathy		4		3			1
Vaccination site movement impairment		5		4			1
Vaccination site pain	10	76	7	62	3		14
Vaccination site paraesthesia	1	1	1	1			
Vaccination site pruritus		5		2			3
Vaccination site rash		3		2			1
Vaccination site reaction		4		4			
Vaccination site swelling	2	15	1	10	1		5
Vaccination site urticaria	1	2		1	1		1
Vaccination site warmth	1	6		4	1		2
Vaginal discharge		1		1			
Vaginal haemorrhage	1	2			1		2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular encephalopathy	1	1			1	1
Ventricular extrasystoles		1				1
Ventricular fibrillation		1				1
Vertigo	5	22	1	10	4	12
Vestibular neuronitis	1	1			1	1
Viral rash		1				1
Vision blurred	1	5	1	3		2
Visual field defect	1	1			1	1
Visual impairment	2	5		1	2	4
Vitreous haemorrhage	2	2			2	2
Vomiting	11	22	10	16	1	6
White blood cell count increased		1		1		
White blood cells urine		1				1
Wound haemorrhage	1	1			1	1
Wrong technique in product usage process		2		2		
	491	2,292	183	1062	308	1230

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Acidosis	1	1	1	1		
Acute coronary syndrome		1				1
Ageusia	1	1	1	1		
Agitation		1		1		
Agranulocytosis		1				1
Allodynia	1	1	1	1		
Amnesia	1	1	1	1		
Anaemia	1	1			1	1
Anaphylactic shock		3				3
Angina pectoris	2	2			2	2
Angioedema	1	1			1	1
Anti-platelet antibody	1	1			1	1
Anxiety		1		1		
Aphasia	2	2			2	2
Arrhythmia	1	1			1	1
Arthralgia	3	7	1	5	2	2
Asthenia	4	12	1	9	3	3
Asymptomatic COVID-19	1	1			1	1
Atrial f brillation	1	3			1	3
Autoimmune disorder		1				1
Autoimmune haemolytic anaemia		1				1
Axillary pain		1		1		
Back pain	1	3		1	1	2
Bacterial sepsis		1				1
Balance disorder		1		1		
Basal ganglia stroke	1	1			1	1
Blister		1				1
Blood creatine phosphokinase increased	1	3		1	1	2
Blood pressure abnormal	1	1			1	1
Blood pressure decreased		1		1		
Blood pressure increased		4		2		2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Body temperature abnormal		1		1			
Body temperature increased	1	3	1	2			1
Bradycardia		1					1
Bradykinesia		2		1			1
Brain natriuretic peptide increased		1					1
Bronchitis	1	1			1		1
Burning sensation	1	1	1	1			
Cachexia		1					1
Cardiac arrest	1	1			1		1
Cardiac failure	2	3			2		3
Cardiopulmonary failure		1					1
Central nervous system infection		1					1
Cerebellar stroke	1	1			1		1
Cerebral artery occlusion	1	1			1		1
Cerebral infarction	1	1			1		1
Cerebral ischaemia		1					1
Cerebrovascular accident	2	4			2		4
Chest discomfort	2	3			2		3
Chest pain	3	6	1	1	2		5
Chills	7	17	7	11			6
Chronic obstructive pulmonary disease	1	1	1	1			
Circulatory collapse	3	6			3		6
Clonus		1					1
Colitis		1					1
Complication associated with device		1		1			
Concomitant disease progression		1					1
Condition aggravated	1	1	1	1			
Confusional state	3	5	1	1	2		4
Cough		2					2
COVID-19	5	15	1	1	4		14
COVID-19 pneumonia		1					1
Craniocerebral injury	1	1			1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased		1		1		
Daydreaming		1				1
Death	1	7			1	7
Decreased appetite	1	2		1	1	1
Deep vein thrombosis	1	2			1	2
Dermatitis bullous	1	1			1	1
Diarrhoea		4		2		2
Diarrhoea haemorrhagic		1				1
Disorientation		1		1		
Disturbance in attention	1	1			1	1
Dizziness	6	13	4	8	2	5
Dizziness postural		1		1		
Drug ineffective	1	9			1	9
Dry mouth	1	3	1	3		
Dysaesthesia	1	3		1	1	2
Dysarthria	1	1			1	1
Dyskinesia	1	1			1	1
Dysphagia	3	3			3	3
Dyspnoea	4	11			4	11
Dyspnoea exertional		4		1		3
Dysstasia		1				1
Ear pain		1		1		
Eczema		1				1
Electrocardiogram change		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram ST-T change	1	1			1	1
Epilepsy	1	2			1	2
Erythema		3		3		
Escherichia sepsis		1				1
Eyelid ptosis		1				1
Face oedema		1		1		
Facial paralysis	2	4	1	1	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paresis	1	2			1	2
Fall	1	3			1	3
Fatigue	7	29	6	21	1	8
Febrile convulsion		1		1		
Feeling abnormal	1	2	1	1		1
Feeling cold		1				1
Feeling jittery		1		1		
Fibrin D dimer increased		1				1
Flushing		2				2
Gait disturbance		1		1		
Gastrointestinal pain		1				1
General physical health deterioration	1	3			1	3
Glossodynia		1				1
Haematemesis		2				2
Haematoma	1	1			1	1
Haematuria		1				1
Headache	5	31	4	21	1	10
Head banging		1				1
Head discomfort		1				1
Head injury		1				1
Heart rate increased	1	1	1	1		
Hemiplegia	1	1			1	1
Hereditary angioedema with normal C1 esterase inhibitor		1				1
Herpes simplex encephalitis	1	1			1	1
Herpes zoster	1	2			1	2
Hot flush	1	1			1	1
Hyperhidrosis	3	3	3	3		
Hyperreflexia		1				1
Hypersensitivity	1	3			1	3
Hypersomnia		1		1		
Hypertension	1	3			1	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive crisis		3				3
Hypertonia		1				1
Hyperventilation	1	1	1	1		
Hypoacusis	1	1			1	1
Hypoaesthesia		4		2		2
Hypoaesthesia oral		2		2		
Hypotension		5		2		3
Idiopathic angioedema		1				1
Immune thrombocytopenia		1				1
Impaired quality of life	1	1			1	1
Impaired work ability		4		1		3
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		2		2		
Infection	1	1			1	1
Influenza		1		1		
Influenza like illness	3	7	3	6		1
Insomnia		1				1
Intraocular pressure increased		1				1
Joint range of motion decreased		1				1
Joint swelling	2	3	1	1	1	2
Lack of spontaneous speech	1	1			1	1
Left ventricular failure		2				2
Leukocytosis		1				1
Leukopenia		2				2
Loss of consciousness	1	2			1	2
Lymphadenopathy	1	8		6	1	2
Lymph node pain	1	5		3	1	2
Lymph node palpable		1		1		
Lymphocyte count increased		1				1
Lymphocytosis		1				1
Malaise	1	6	1	4		2
Mania		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Memory impairment	1	2
Meningitis bacterial		1
Migraine	1	3
Movement disorder		1
Multiple organ dysfunction syndrome	1	2
Muscle contractions involuntary	1	2
Muscle spasms	1	3
Muscle spasticity		1
Muscular weakness	1	3
Musculoskeletal disorder	1	1
Myalgia	2	10
Myocarditis		1
Myoclonus	1	1
Nasopharyngitis		1
Nausea	5	16
Nervous system disorder		1
Neurological symptom		1
Neutropenia		1
Occipital neuralgia		1
Off label use		2
Oral disorder	1	1
Oral mucosa erosion	1	1
Oropharyngeal pain	2	3
Oxygen saturation decreased	1	1
Pain	3	5
Pain in extremity	3	12
Pain of skin		2
Palpitations	1	3
Pancytopenia	1	1
Paraesthesia	4	7
Parosmia		2
Pemphigus		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
			1
	2	1	1
			1
		1	2
1	2		1
			1
	1	1	2
		1	1
2	5		5
			1
		1	1
	1		
4	10	1	6
			1
			1
			1
	1		
	2		
1	1		
1	1		
2	3		
		1	1
2	4	1	1
3	8		4
	1		1
	2	1	1
		1	1
1	3	3	4
	2		
			1

\* I=Interval, C=Cumulative  
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\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Performance status decreased	1	3	1	2		1
Peripheral coldness		2		1		1
Peripheral swelling	1	4		2	1	2
Peripheral vascular disorder	1	1	1	1		
Petechiae		1				1
Petit mal epilepsy		1				1
Pharyngeal lesion	1	1	1	1		
Pharyngeal swelling	1	4		1	1	3
Pleural effusion		1				1
Pneumonia	1	4			1	4
Pneumonia aspiration		3				3
Pneumonia bacterial		2				2
Pneumothorax spontaneous	1	1			1	1
Poor quality product administered		1		1		
Post herpetic neuralgia	1	1			1	1
Presyncope		2				2
Product preparation error		1		1		
Product use issue		1		1		
Pruritus		2		1		1
Psoriasis	1	1			1	1
Psychotic disorder		1				1
Pulmonary embolism	5	8			5	8
Pulmonary function test decreased	1	1	1	1		
Pulmonary infarction		1				1
Pupillary reflex impaired		1				1
Pyrexia	10	35	6	18	4	17
Radial nerve palsy	1	1			1	1
Rash		3				3
Rash pruritic	2	2	1	1	1	1
Respiratory failure		1				1
Restlessness		3		2		1
Retching		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rib fracture	1	1			1	1
Road traffic accident	1	1			1	1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive		2				2
Seizure	1	4			1	4
Sepsis	1	2			1	2
Shift to the left		1				1
Sinus tachycardia		1				1
Skin exfoliation	1	1	1	1		
Skin reaction		1		1		
Skin wrinkling	1	1	1	1		
Somnolence	2	8	1	3	1	5
Sopor	1	1			1	1
Speech disorder	1	1			1	1
Splenic vein thrombosis	1	1			1	1
Spontaneous haematoma	1	1			1	1
Status epilepticus		1				1
Subcutaneous haematoma	1	1			1	1
Sudden hearing loss	2	2			2	2
Suspected COVID-19		1				1
Swelling		4		3		1
Swollen tongue		2				2
Syncope	1	6			1	6
Systemic inflammatory response syndrome		1				1
Tachycardia	1	2			1	2
Taste disorder		1		1		
Throat tightness		1				1
Thrombocytopenia	2	4			2	4
Thrombosis	1	1			1	1
Tinnitus	2	2	2	2		
Tongue discomfort		1				1
Transient ischaemic attack	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	1			1	1
Troponin increased		1				1
Troponin T increased	1	3			1	3
Urine ketone body present	1	1	1	1		
Urticaria	1	6	1	2		4
Vaccination failure	3	4			3	4
Vaccination site anaesthesia		1				1
Vaccination site hypoaesthesia		2		1		1
Vaccination site lymphadenopathy	1	3	1	2		1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	4	18	4	16		2
Vaccination site paraesthesia		1				1
Vaccination site pustule		1		1		
Vaccination site rash		1		1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	5		3	1	2
Vasculitis		1				1
Venous thrombosis limb	3	5		1	3	4
Vertigo	1	2		1	1	1
Viral infection		1		1		
Vision blurred		1		1		
Visual field defect		1				1
Visual impairment	3	4			3	4
Vomiting	1	7		3	1	4
Weight bearing difficulty	1	1	1	1		
	238	734	91	292	147	442

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Antibody test abnormal		1		1		
Asthenia		1				1
Balance disorder		1				1
Coronavirus infection		1				1
COVID-19	1	12			1	12
Drug ineffective	1	13			1	13
Fatigue		1				1
General physical health deterioration		1				1
Headache		2		1		1
Hemianaesthesia		1				1
Hyperglycaemia		1				1
Lymphadenopathy		1				1
Nausea		1				1
Neutralising ant bodies negative		1		1		
Pain in extremity		1		1		
Pulmonary embolism		1				1
Pyrexia		1				1
Rash		1				1
Vaccination site hypoaesthesia		1		1		
Vaccination site lymphadenopathy		1				1
Vaccination site pain		1				1
Wrong technique in product usage process		1		1		
	2	46		6	2	40

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**BAHRAIN**

*Gender*

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chills		2		2
Hot flush		1		1
Lymphadenopathy		1		1
Myalgia		1		1
Nausea		1		1
Neck pain		1		1
Pain		1		1
Pruritus		1		1
Pyrexia		2		2
		11		11

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	1	1			1	1
Chills	1	1			1	1
Dyspnoea	1	1			1	1
Headache		1		1		
Heart rate increased	1	1			1	1
Hyperhidrosis	1	1			1	1
Muscle spasms	1	1			1	1
Myalgia		1		1		
Pain	1	1			1	1
Paraesthesia	1	1			1	1
Pyrexia	1	1			1	1
Swelling	1	1			1	1
Vaccination site pain		1		1		
	10	13		3	10	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**BELGIUM**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	3	2	2		1
Abdominal distension		2		1		1
Abdominal pain		7		1		6
Abdominal pain upper	4	8	1	2	3	6
Abdominal symptom		1		1		
Abnormal dreams		1				1
Acute kidney injury		2				2
Acute macular outer retinopathy		1				1
Acute pulmonary oedema		1				1
Acute respiratory failure		3				3
Ageusia	1	1	1	1		
Agitation	1	4	1	1		3
Alanine aminotransferase increased	1	1	1	1		
Allergic reaction to excipient	1	1			1	1
Allergy to vaccine		1				1
Allodynia		1				1
Altered state of consciousness		4				4
Anal incontinence	1	1	1	1		
Anaphylactic reaction	5	30			5	30
Anaphylactic shock	1	5			1	5
Anaphylactoid reaction		1				1
Angina pectoris		3				3
Angioedema		4				4
Anosmia		1				1
Anxiety	1	7	1	1		6
Apathy		1				1
Aphasia	1	2			1	2
Aphonia		1		1		
Aphthous ulcer		2				2
Appendicitis		2				2
Arrhythmia	2	3			2	3
Arthralgia	52	150	7	12	45	138

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis	1	4		1	1	3
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	8	28	4	6	4	22
Asthma		2				2
Asthma exercise induced		1				1
Atrial fibrillation		1				1
Atrioventricular block complete		1				1
Autoimmune disorder	5	6			5	6
Axillary mass		1				1
Axillary pain	3	7		1	3	6
Back pain		6		2		4
Balance disorder	3	7			3	7
Biliary colic		1				1
Blindness	1	3			1	3
Blood glucose decreased		1		1		
Blood lactic acid increased		2				2
Blood pressure abnormal	1	3	1	1		2
Blood pressure decreased	5	10		1	5	9
Blood pressure increased	2	6	1	1	1	5
Blood pressure systolic increased		1		1		
Blood test abnormal	1	1			1	1
Blood urine present		1				1
Body temperature decreased		1				1
Body temperature increased	6	10	4	5	2	5
Bone pain		5				5
Bradycardia	1	9			1	9
Bradypnoea		1				1
Breast pain	3	3	1	1	2	2
Breath odour		1				1
Bronchospasm		3				3
Bundle branch block left		1				1
Burning sensation	4	6	1	2	3	4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cardiac arrest		5					5
Cardiac disorder		2					2
Cardiac failure		2					2
Cardiogenic shock		1					1
Cardio-respiratory arrest		3					3
Cardiovascular disorder	15	44	4	7	11		37
Cerebral haemorrhage	1	1			1		1
Cerebral ischaemia	1	1			1		1
Cerebral thrombosis		1					1
Cerebrovascular accident	2	7			2		7
Chest discomfort	1	10	1	2			8
Chest pain	10	20	3	5	7		15
Cheyne-Stokes respiration		1					1
Chillblains		1					1
Chills	116	327	22	29	94		298
Coagulopathy	7	13		3	7		10
Cold sweat		1					1
Coma		1					1
Concussion		1					1
Condition aggravated	1	2	1	1			1
Confusional state	1	1	1	1			
Contusion	2	3	1	1	1		2
Cough	5	14	1	2	4		12
COVID-19	12	30	3	5	9		25
COVID-19 pneumonia		1					1
C-reactive protein increased		2		1			1
Crying		2					2
Cyanosis	1	3			1		3
Deafness	1	2			1		2
Deafness unilateral		1					1
Death	2	4			2		4
Decreased appetite	4	11	1	1	3		10

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		2	3
			1
			1
			7
			1
1	1	1	1
8	26	5	20
1	1	1	1
			1
3	4	3	3
			2
			1
2	2	1	1
17	50	14	40
			1
		1	
8	16	8	16
			1
1	3	1	3
		1	1
1	1	1	1
			1
1	6		4
1	1	1	1
1	5		3
		1	2
16	46	14	44
2	4	2	4
1	1	1	1
1	1	1	1
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	1	2	4
		1	1
			2
1	10	1	10
			1
3	16	1	14
			1
			2
			1
			1
7	8	6	7
1	1	1	1
			3
			3
1	3		1
1	1	1	1
			1
2	2	1	1
3	13	3	13
1	6	1	6
2	2		
			1
3	7	3	6
137	404	107	353
5	10	3	7
1	6	1	6
		1	
1	5	1	3
2	5	2	5
1	2	1	2
2	2		

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Flushing		1					1
Food allergy	1	1			1		1
Formication		1					1
Gait disturbance		1					1
Gamma-glutamyltransferase increased	1	1	1	1			
Gastric disorder		1					1
Gastrointestinal disorder	1	2			1		2
Gastrointestinal pain		3					3
Gastroesophageal reflux disease	1	1			1		1
Generalised tonic-clonic seizure		2					2
General physical health deterioration	1	11		1	1		10
Gingival pain		1					1
Haematoma	1	2	1	1			1
Haemorrhage intracranial		1					1
Hallucination		1					1
Hallucination, visual		1					1
Headache	148	434	33	58	115		376
Head discomfort		1					1
Heart rate decreased		2					2
Heart rate increased	1	9		3	1		6
Heart rate irregular		1		1			
Hemianaesthesia		1					1
Hemiparaesthesia		1					1
Hemiparesis		2					2
Hemiplegia		2					2
Hepatic enzyme increased	1	1	1	1			
Hepatic failure		1					1
Hepatitis	1	2			1		2
Herpes ophthalmic		1					1
Herpes simplex		1					1
Herpes virus infection	1	1			1		1
Herpes zoster		3		2			1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	2	8	1	2	1	6
Hyperacusis		2				2
Hyperaesthesia	1	1			1	1
Hyperaesthesia teeth		1				1
Hyperhidrosis	4	12	1	3	3	9
Hypersensitivity	6	19		2	6	17
Hypersensitivity vasculitis	1	1			1	1
Hypersomnia		2				2
Hypertension	10	32	2	3	8	29
Hypertensive crisis		1				1
Hyperthermia	1	1	1	1		
Hyperventilation	1	4		1	1	3
Hypoacusis		1				1
Hypoaesthesia	4	10	2	3	2	7
Hypoaesthesia oral	1	1	1	1		
Hypoglycaemia		4				4
Hypokalaemia		1				1
Hyponatraemia		1				1
Hyporeflexia		1				1
Hyporesponsive to stimuli		1				1
Hypotension	2	13	1	2	1	11
Hypothermia	2	3			2	3
Hypoxia		1				1
Illness	1	4		3	1	1
Illusion		1				1
Immobile		1				1
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		3		3		
Infection	1	3	1	2		1
Inflammation		2				2
Influenza	2	4	1	2	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	21	58	7	13	14	45
Injection site discomfort	1	1	1	1		
Injection site erythema	1	1			1	1
Injection site haematoma		1		1		
Injection site hypersensitivity		1				1
Injection site pain	1	2	1	2		
Injection site reaction	3	6	1	2	2	4
Insomnia	6	18	2	4	4	14
Intestinal dilatation		1				1
Intestinal ischaemia		1				1
Irritability		1				1
Jaw disorder	1	1	1	1		
Joint range of motion decreased	2	2			2	2
Joint stiffness		1				1
Joint swelling		1				1
Ketoacidosis		3				3
Lacrimation increased	1	1			1	1
Lactic acidosis		1				1
Laryngeal oedema		1				1
Laryngitis		1				1
Laryngospasm		1				1
Lethargy		2				2
Leukocytosis		1				1
Leukocyturia		1		1		
Limb discomfort	2	5		1	2	4
Lip swelling		5		1		4
Livedo reticularis		1				1
Liver disorder	3	4	2	2	1	2
Liver function test abnormal		1				1
Localised infection		1				1
Loss of consciousness	1	9			1	9
Loss of personal independence in daily activities	1	1	1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lower respiratory tract congestion		1
Lung disorder	1	1
Lung infiltration		1
Lymphadenitis	1	2
Lymphadenopathy	12	26
Lymph node pain	3	7
Lymphoedema		1
Malaise	79	244
Maternal exposure during pregnancy		1
Memory impairment	1	2
Migraine	3	13
Migraine with aura		1
Mobility decreased	2	4
Multiple organ dysfunction syndrome		2
Muscle contractions involuntary	1	1
Muscle fatigue	1	1
Muscle spasms	1	3
Muscle strain	5	9
Muscle tightness		1
Muscular weakness	1	3
Musculoskeletal chest pain		2
Musculoskeletal discomfort		1
Musculoskeletal stiffness	16	32
Myalgia	109	337
Myosclerosis		1
Nasal congestion		1
Nasopharyngitis	1	2
Nausea	81	272
Neck pain	4	12
Nervous system disorder	6	29
Neuralgia	1	3
Neuritis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
			1
1	1		1
4	4	8	22
		3	7
			1
15	27	64	217
	1		
	1	1	1
		3	13
			1
	1	2	3
			2
		1	1
		1	1
	1	1	2
1	2	4	7
			1
		1	3
	1		1
			1
11	14	5	18
25	42	84	295
			1
	1		
		1	2
19	30	62	242
	1	4	11
2	5	4	24
	1	1	2
			1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neurogenic shock		1					1
Neuropathy peripheral		1					1
Nightmare	1	1			1		1
Night sweats		1					1
Noninfective gingivitis		1					1
N-terminal prohormone brain natriuretic peptide increased		1					1
Oedema peripheral	1	1			1		1
Off label use	2	4	2	4			
Oral herpes	1	3			1		3
Oropharyngeal discomfort		1		1			
Oropharyngeal pain	3	11	3	4			7
Orthostatic hypotension		1		1			
Orthostatic intolerance		1					1
Oxygen saturation decreased	3	19	1	1	2		18
Pain	10	19	3	5	7		14
Painful respiration	1	3			1		3
Pain in extremity	22	49	17	24	5		25
Pain in jaw		1					1
Pain of skin	2	4		1	2		3
Pallor		2					2
Palmoplantar pustulosis		1		1			
Palpitations	4	14	3	5	1		9
Papule	1	1			1		1
Paraesthesia	8	20	4	9	4		11
Paraesthesia oral	1	6	1	1			5
Paralysis		1					1
Parapharyngeal space infection		1					1
Paresis		1					1
Parkinson's disease		2					2
Parosmia	1	2	1	1			1
Pericardial effusion		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericarditis	1	1			1	1
Peripheral motor neuropathy	1	1			1	1
Peripheral swelling	12	39	5	7	7	32
Pharyngeal erythema		1				1
Pharyngeal swelling	1	6			1	6
Phlebitis		1				1
Photophobia	1	3			1	3
Photopsia		1				1
Pleural effusion		2				2
Pneumonia		3				3
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Pneumonitis		2				2
Polyneuropathy		1				1
Poor quality sleep		2				2
Posture abnormal	1	1	1	1		
Presyncope	3	9	2	2	1	7
Procedural pain	1	1			1	1
Product administered at inappropriate site	1	1			1	1
Productive cough		1				1
Product use issue	2	4	2	4		
Pruritus	8	22	4	7	4	15
Pruritus allergic		1				1
Pulmonary arterial hypertension	1	1			1	1
Pulmonary embolism	3	5			3	5
Pulmonary oedema		2				2
Pyelonephritis	1	2			1	2
Pyrexia	127	329	38	49	89	280
Rales		1				1
Rash	3	10	3	4		6
Rash erythematous	3	4	3	3		1
Rash macular	1	2			1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular		1				1
Rash pruritic		1				1
Red blood cell sedimentation rate increased		1		1		
Renal disorder	1	3			1	3
Renal failure		1				1
Renal pain		3				3
Respiration abnormal		2				2
Respiratory arrest		1				1
Respiratory disorder	21	50	1	3	20	47
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory rate increased		1				1
Respiratory tract infection		1				1
Restless legs syndrome		1		1		
Restlessness		2		1		1
Retching	1	4			1	4
Rhinorrhoea	1	6		3	1	3
Rhythm idioventricular		1				1
Salivary hypersecretion		2		1		1
SAPHO syndrome		1				1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		1				1
Scarlet fever		1				1
Scleral discolouration		1				1
Sedation		2				2
Seizure	2	10			2	10
Sensation of foreign body		2		1		1
Sense of oppression	1	4	1	2		2
Sensitive skin	3	4	1	1	2	3
Sensory disturbance		2		2		
Sensory loss		1				1
Sepsis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sinus headache		1					1
Sinusitis		1					1
Sinus pain		1					1
Sinus tachycardia		1					1
Skin burning sensation		1					1
Skin disorder	13	37	4	5	9		32
Skin sensitisation		1					1
Sleep disorder	1	3	1	1			2
Sleep disorder due to a general medical condition		1		1			
Sneezing	2	3	1	1	1		2
Somnolence	2	10		1	2		9
Speech disorder	1	2	1	2			
Spinal pain		2		2			
Stomatitis		1					1
Stress cardiomyopathy		1		1			
Sudden death	1	8			1		8
Sudden hearing loss		1					1
Suffocation feeling		1					1
Suppressed lactation	1	1			1		1
Supraventricular tachycardia	1	1			1		1
Suspected COVID-19	1	1			1		1
Swelling		2					2
Swelling face	1	5	1	1			4
Swelling of eyelid		1					1
Swollen tongue	1	7		1	1		6
Syncope	4	24			4		24
Tachyarrhythmia		1					1
Tachycardia	9	26		2	9		24
Tachypnoea		1					1
Taste disorder		1		1			
Tetany		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thinking abnormal		1				1
Thirst		1		1		
Thoracic outlet syndrome		1				1
Throat tightness	1	3			1	3
Thrombocytopenia		2				2
Thrombosis	1	1			1	1
Tinnitus	1	5			1	5
Tongue discomfort		1				1
Tonsillitis		1				1
Transient ischaemic attack	1	1			1	1
Tremor	2	10			2	10
Troponin increased		1				1
Unresponsive to stimuli		3				3
Upper airway obstruction		1				1
Urinary retention		1				1
Urosepsis		1				1
Urticaria	1	6			1	6
Vaccination failure		1				1
Vaccination site erythema	17	32	16	22	1	10
Vaccination site haematoma	1	5	1	3		2
Vaccination site hypersensitivity		1				1
Vaccination site hypertrophy		1				1
Vaccination site induration	4	10	4	6		4
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy	1	2			1	2
Vaccination site movement impairment		3		1		2
Vaccination site pain	26	66	15	20	11	46
Vaccination site pruritus		3		1		2
Vaccination site rash		1		1		
Vaccination site reaction	78	190	20	27	58	163
Vaccination site swelling	9	20	7	10	2	10
Vaccination site warmth	2	9	1	3	1	6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaginal haemorrhage		1				1
Vasculitis		2		1		1
Ventricular tachycardia		1				1
Vertigo	7	21	3	4	4	17
Vertigo positional		1		1		
Vestibular neuronitis		1				1
Vision blurred	3	7	1	2	2	5
Visual field defect		2				2
Visual impairment	2	4	1	1	1	3
Vitamin D deficiency		1				1
Vomiting	10	41	3	4	7	37
Weight decreased		1				1
Wheezing	1	2			1	2
White blood cell count decreased		1		1		
Wrong product administered	1	1	1	1		
Yellow skin		1				1
	1,587	4,790	440	750	1147	4040

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	1	3			1	3
Acute kidney injury	1	1			1	1
Acute psychosis	1	1			1	1
Acute respiratory failure		1				1
Agitation		2				2
Altered state of consciousness		1				1
Amnesia		1				1
Anaphylactic reaction		3				3
Angle closure glaucoma		1				1
Anxiety		1				1
Apathy	1	2		1	1	1
Aphthous ulcer	1	1			1	1
Arrhythmia		1				1
Arthralgia	7	26	2	3	5	23
Asthenia	5	8	2	3	3	5
Asthenopia	1	2	1	2		
Asymptomatic COVID-19		1				1
Atrial f brillation		2				2
Atrioventricular block complete		1				1
Back pain	1	2			1	2
Balance disorder		1				1
Blood glucose increased		1		1		
Blood pressure increased		2				2
Body temperature fluctuation		1				1
Body temperature increased	1	2			1	2
Bradycardia		1				1
Brain injury	1	1			1	1
Breath odour		1				1
Bronchial disorder		1				1
Cardiac arrest	2	4	1	1	1	3
Cardiac failure	1	2			1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiogenic shock	1	1			1	1
Cardiomegaly	1	1			1	1
Cardiovascular disorder	2	13		1	2	12
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	3	4			3	4
Chest discomfort		3				3
Chest pain		4		1		3
Chills	20	58	4	7	16	51
Coagulopathy	2	4			2	4
Cold sweat		1				1
Confusional state	1	4	1	1		3
Constipation	1	1			1	1
Coronary artery thrombosis		1				1
Cough	1	2	1	1		1
COVID-19	10	15	3	3	7	12
COVID-19 pneumonia	1	2			1	2
C-reactive protein increased		1				1
Decreased appetite	1	2	1	2		
Deep vein thrombosis	2	2			2	2
Depressed level of consciousness		3				3
Diabetic complication		1				1
Diarrhoea	3	4		1	3	3
Disorientation		1				1
Dizziness	1	4			1	4
Drug ineffective	4	8			4	8
Dry skin		1				1
Dysgeusia	1	4	1	1		3
Dyspnoea	1	8		2	1	6
Dyspnoea exertional	1	1			1	1
Dysstasia		1				1
Ear pain		1				1
Eczema	1	1	1	1		

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
3	4		1
			1
	1		
1		1	1
			1
2	4		
1		1	1
	1		3
30	20	22	61
	1		
1	3	1	1
	2		
			1
			1
			2
2	1	1	1
1		1	1
1		1	5
			1
			1
			1
1		1	3
21	17	17	60
			2
1		1	1
			2
	2		
	1		3
			1
1	1		1

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\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	1	4			1	4
Hyperthermia	1	1	1	1		
Hypoglycaemia		1				1
Hypotension		5				5
Hypothermia		1				1
Hypovolaemic shock		1				1
Illness		1		1		
Incorrect dose administered	1	1	1	1		
Influenza like illness	6	17		1	6	16
Injection site pain	1	1	1	1		
Injection site reaction	1	2			1	2
Insomnia		3		2		1
Intestinal ischaemia		1				1
Intestinal obstruction	1	1			1	1
Lacrimation increased		1		1		
Lactic acidosis	1	1			1	1
Limb discomfort		1				1
Liver function test abnormal		2				2
Lymphadenopathy	2	7			2	7
Lymph node pain	1	1			1	1
Malaise	12	44	1	1	11	43
Metabolic acidosis		1				1
Migraine		2				2
Migraine with aura		1				1
Muscle contracture		1				1
Muscle fatigue	1	1	1	1		
Muscle strain	2	2			2	2
Muscular weakness		2		1		1
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness	6	19	6	14		5
Myalgia	15	51	3	8	12	43
Myocardial infarction		1				1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	8	34
			1
1	1	5	8
			1
			1
			1
			1
	1		
2	2		
	1		
	1		
	1		1
			1
	2		
			1
			6
1	1		
3	7	1	2
			1
1	1		
	1		
			1
			1
			3
1	1	1	1
	2		
	3		3
1	1	1	1
1	2		1
1	4	1	4
	1		1
1	1	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	24	72	8	18	16	54
Rales	1	1			1	1
Rash	1	1	1	1		
Renal disorder	1	2			1	2
Renal failure		2				2
Respiratory acidosis	1	1			1	1
Respiratory disorder	3	6			3	6
Respiratory distress		3				3
Respiratory tract infection	1	2			1	2
Restlessness	1	1			1	1
Rhinitis		1				1
Rhinorrhoea		1				1
Seizure	1	2			1	2
Sense of oppression	1	2		1	1	1
Sepsis		1				1
Septic shock	1	2			1	2
Serum ferritin increased	1	1	1	1		
Skin mass	1	1			1	1
Sleep deficit		1				1
Sleep disorder	1	3	1	1		2
Sneezing		1		1		
Somnolence		1		1		
Speech disorder		1		1		
Staring		1				1
Sudden death	2	7			2	7
Swollen tongue		1				1
Syncope		6				6
Tachycardia		3				3
Tachypnoea		1				1
Therapeutic response unexpected	1	1	1	1		
Thirst		1				1
Thrombophlebitis		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Thrombosis		1					1
Tinnitus	1	2	1	1			1
Tonsillar inflammation		1					1
Tonsillitis		1		1			
Tremor	1	3	1	2			1
Troponin increased		2					2
Troponin T increased	1	1			1		1
Urinary tract infection		1		1			
Vaccination failure	2	2			2		2
Vaccination site discomfort	1	1	1	1			
Vaccination site erythema	2	2	2	2			
Vaccination site movement impairment		1					1
Vaccination site pain	6	19	5	12	1		7
Vaccination site reaction	10	30	2	2	8		28
Vaccination site swelling		2		1			1
Vertigo	2	7	1	2	1		5
Vision blurred	1	2	1	2			
Visual impairment		1					1
Vomiting	1	3			1		3
Wheezing		1					1
	298	944	85	198	213		746

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	3	24			3	24
Axillary pain		1		1		
Body temperature increased		1		1		
Cough		1		1		
COVID-19	1	46		9	1	37
C-reactive protein increased	1	1	1	1		
Decreased appetite		1		1		
Dizziness		1		1		
Drug ineffective	3	44			3	44
Exposure via breast milk	1	2	1	2		
Fatigue		2		2		
General physical health deterioration		1				1
Headache		3		3		
Hyperhidrosis		1		1		
Incorrect route of product administration	34	125	34	125		
Inflammation	1	1	1	1		
Influenza		1		1		
Injection site reaction	1	1	1	1		
Limb discomfort		1		1		
Lymphadenopathy	1	2	1	2		
Malaise		1		1		
Musculoskeletal stiffness	1	3	1	3		
Myalgia		1		1		
Mydriasis	1	1	1	1		
Nausea		4		3		1
Neck pain	1	1	1	1		
Pain in extremity	1	3	1	3		
Product preparation issue		1		1		
Pyrexia	1	4	1	4		
Sudden death		1				1
Syringe issue		1		1		
Underdose		1		1		

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination failure		14				14
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vision blurred	1	1	1	1		
Visual impairment	1	1	1	1		
Wrong product administered		1		1		
Wrong technique in product usage process	34	112	34	112		
	89	413	82	291	7	122

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**BERMUDA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Chills		1		1		
Diarrhoea		1		1		
Dizziness		1		1		
Dyspnoea	1	1			1	1
Ear congestion	1	1	1	1		
Ear discomfort	1	1	1	1		
Erythema	1	1			1	1
Feeling cold		1		1		
Night sweats		1		1		
Pain	1	1			1	1
Paraesthesia		1		1		
Peripheral swelling	1	1			1	1
Pyrexia		1		1		
Rash	1	1	1	1		
Sudden visual loss		1				1
	7	16	3	11	4	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**BOSNIA AND HERZEGOVINA**

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**BRAZIL**

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Pain	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BULGARIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		1				1
Agitation		1		1		
Anaphylactoid reaction		1				1
Angina pectoris		1				1
Anosmia		1		1		
Antibody test abnormal	1	1	1	1		
Anti-thyroid antibody positive		1				1
Arrhythmia	1	1			1	1
Arthralgia	4	19	4	19		
Arthritis		1		1		
Asthenia	1	10	1	9		1
Back pain		4		4		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic decreased		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased	2	5	1	3	1	2
Body temperature abnormal		1		1		
Body temperature increased	1	20	1	18		2
Bone pain	1	1	1	1		
Breast pain	1	1	1	1		
Bronchitis	1	1	1	1		
Chest pain		1		1		
Chills	4	20	4	17		3
Communication disorder		1		1		
Condition aggravated	1	1	1	1		
Conjunctivitis allergic		1		1		
Cough	1	3	1	3		
COVID-19	3	7			3	7
COVID-19 pneumonia		2				2
Deafness unilateral		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Decreased appetite		2		1			1
Dental discomfort		1		1			
Discomfort		2		2			
Disturbance in attention		1		1			
Dizziness	2	11	2	10			1
Dizziness postural		1		1			
Drug ineffective	3	7			3		7
Dry mouth		1		1			
Dyspnoea	2	4	2	3			1
Erythema	1	4	1	4			
Extrasystoles		2		2			
Eye pain		2		2			
Facial paralysis	1	1			1		1
Fatigue	5	18	5	18			
Gait disturbance	1	2		1	1		1
Gastrointestinal disorder		1		1			
Haematoma	1	1			1		1
Headache	7	30	7	26			4
Head discomfort		2		1			1
Heart rate irregular	1	1	1	1			
Herpes simplex		1		1			
Hyperhidrosis		2					2
Hypersensitivity		1		1			
Hypertension	1	1	1	1			
Hypothermia		1					1
Influenza like illness		1		1			
Injection site erythema		2		2			
Injection site oedema		1		1			
Injection site pain		5		5			
Injection site swelling		2		2			
Insomnia		2		2			
Interstitial lung disease		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lacrimation increased		1		1			
Leukopenia	1	1		1	1	1	
Limb discomfort	1	2	1	2			
Lip swelling		1				1	
Lymphadenopathy	1	9	1	9			
Lymph node pain	1	2	1	2			
Lymphocyte count decreased		1		1			
Malaise	2	7	2	7			
Mastication disorder		1		1			
Mobility decreased		1		1			
Movement disorder	1	2	1	1		1	
Muscle spasms		1		1			
Musculoskeletal pain	1	1	1	1			
Musculoskeletal stiffness		2		1		1	
Myalgia	4	26	4	26			
Myelitis transverse		1				1	
Nasopharyngitis	2	2	2	2			
Nausea	1	11	1	10		1	
Neck pain		1		1			
Neuromyelitis optica spectrum disorder		1				1	
Oedema peripheral	1	2	1	2			
Oropharyngeal pain		3		3			
Overdose	2	2	2	2			
Pain	1	3	1	3			
Painful respiration		1		1			
Pain in extremity	5	7	5	7			
Pallor		1		1			
Palpitations	2	3	1	2	1	1	
Paraesthesia	2	5	2	4		1	
Paraesthesia oral		1		1			
Paranasal sinus discomfort	1	1	1	1			
Peripheral coldness		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	1		
	1	1	1
1	1		
2	2	1	1
6	20		2
2	4		
	1		
	1	1	1
	1		
	1		
	1		1
	1		1
	1		
	1		1
	1		1
	1		
	1		1
1	1		
	1		
	2		
	1		1
	1	1	1
	1		
	1		1
1	1		
	1		
	1		1
	1		1
	1		
	3	1	1
	1		
	2		1
	1		
	14	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	1	1			1	1
Vaccination site oedema		1		1		
Vaccination site pain	10	46	10	45		1
Vaccination site paraesthesia		1		1		
Vaccination site reaction		1				1
Vaccination site swelling		17		15		2
Vasodilatation	1	1	1	1		
Vasospasm		1				1
Vertigo	1	9		5	1	4
Vomiting		4		3		1
	111	489	89	405	22	84

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Ageusia		1		1		
Agitation		1		1		
Allergy to vaccine	1	1	1	1		
Anosmia		1		1		
Arthralgia	3	9	3	9		
Asthenia	1	8	1	7		1
Axillary pain	1	1	1	1		
Back pain	1	1	1	1		
Blood glucose increased	1	1			1	1
Blood pressure ambulatory increased	1	1			1	1
Blood pressure fluctuation		1		1		
Blood pressure increased	1	2	1	2		
Body temperature increased		10		10		
Chills	4	8	4	8		
Circulatory collapse	1	1			1	1
Cold sweat		1		1		
Cough	1	2	1	2		
COVID-19	1	5	1	3		2
C-reactive protein increased	1	1			1	1
Decreased appetite		1		1		
Diarrhoea		2		2		
Dizziness	1	3	1	3		
Drug eruption		1		1		
Drug ineffective		2				2
Dry mouth		1		1		
Dysphonia	1	1	1	1		
Dyspnoea	1	2	1	1		1
Epigastric discomfort		1		1		
Epistaxis	1	1	1	1		
Erectile dysfunction		1				1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1	1	1		
Facial bones fracture	1	1			1	1
Facial paralysis		2				2
Fatigue	6	9	6	9		
Feeling cold		1		1		
Feeling hot	1	1	1	1		
Gait disturbance		1		1		
Groin abscess		1				1
Headache	4	16	4	16		
Heart alternation	1	1	1	1		
Heart rate increased		1		1		
HIV test positive	1	1	1	1		
Hot flush		1		1		
Hyperhidrosis		4		4		
Hypertension	1	2		1	1	1
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Influenza like illness	1	1	1	1		
Injection site pain		1		1		
Injection site swelling		1		1		
Joint injury	1	1			1	1
Jugular vein distension		1				1
Lacrimation increased	1	1	1	1		
Lymphadenopathy	1	7	1	6		1
Lymph node pain	1	2	1	2		
Malaise	2	5	2	5		
Meningism		1		1		
Myalgia	2	11	2	11		
Nasopharyngitis	1	1	1	1		
Nausea	3	4	3	4		
Neuralgia		1		1		
Off label use		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	2	2	2	2		
Pain	1	2	1	2		
Pain in extremity	3	5	3	5		
Palpitations		1		1		
Paraesthesia	2	4	2	4		
Productive cough	1	1	1	1		
Pyrexia	4	10	4	10		
Rhinorrhoea	1	1	1	1		
Sweating fever		1				1
Swelling	1	1	1	1		
Syncope	1	1			1	1
Tachycardia	2	2	1	1	1	1
Tinnitus	1	1	1	1		
Tremor		2		2		
Urticaria		1		1		
Vaccination site erythema		3		3		
Vaccination site extravasation		1		1		
Vaccination site induration		1		1		
Vaccination site pain	2	12	2	12		
Vaccination site reaction		1		1		
Vaccination site swelling		2		2		
Ventricular extrasystoles		1				1
Vertigo	2	2	2	2		
Vomiting		1		1		
	75	217	66	194	9	23

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased		1		1		
COVID-19	1	3		1	1	2
Dizziness		1		1		
Drug ineffective	1	2			1	2
Fatigue		1		1		
Headache		1		1		
Lethargy	1	1	1	1		
Swelling face		1		1		
Vertigo		1		1		
	3	12	1	8	2	4

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Country Where Event Occurred

**CANADA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal pain		3		2		1
Abdominal pain lower		2		2		
Abdominal pain upper	2	6	1	5	1	1
Abortion induced	1	1	1	1		
Abortion spontaneous	1	3			1	3
Accidental exposure to product		1		1		
Acne		1		1		
Affect lability		1		1		
Ageusia	1	3	1	3		
Allergy to vaccine		1		1		
Anaphylactic reaction	4	17			4	17
Anaphylactic shock	2	3			2	3
Angioedema	1	2			1	2
Angiopathy		1		1		
Anosmia	1	1	1	1		
Anxiety	3	7	3	6		1
Aphasia	1	2	1	2		
Aphthous ulcer		2		2		
Arrhythmia	1	2			1	2
Arthralgia	5	30	3	26	2	4
Asthenia	6	19	4	14	2	5
Asymptomatic COVID-19		1				1
Ataxia	1	1	1	1		
Atrial fibrillation	2	3			2	3
Autoimmune disorder	1	1			1	1
Axillary mass		2		2		
Axillary pain		3		3		
Back pain	1	5	1	3		2
Balance disorder	2	3	1	2	1	1
Beta haemolytic streptococcal infection		1				1
Bladder spasm		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness	1	1			1	1
Blood glucose decreased	1	2			1	2
Blood glucose increased		1		1		
Blood pressure decreased	2	4		1	2	3
Blood pressure increased	2	3	1	2	1	1
Blood urine present		1		1		
Body temperature increased		1		1		
Bradycardia		1				1
Breast pain		2		1		1
Breast tenderness		1		1		
Bronchitis	1	1	1	1		
Bronchospasm		1				1
Burning sensation	1	2	1	2		
Bursitis	1	1	1	1		
Cardiac disorder	1	1			1	1
Cardiac flutter	1	2			1	2
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cerebrovascular accident	2	4			2	4
Cerumen impaction		1		1		
Change of bowel habit		1		1		
Chapped lips		1		1		
Chest discomfort	2	12	1	7	1	5
Chest pain		5		4		1
Chills	8	45	6	43	2	2
Chronic obstructive pulmonary disease	1	1			1	1
Coeliac disease		1				1
Cognitive disorder		1		1		
Cold sweat	2	4	1	3	1	1
Condition aggravated	4	5	1	1	3	4
Confusional state	1	2	1	2		
Conjunctivitis		1		1		

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		2
2	7	1	2
1	3	2	9
			1
		1	1
			1
	4		
		1	1
	1		
	1		
			1
1	2		
1	1		
1	1		
		1	1
3	18	2	3
1	1		1
1	3		
	1		2
	1		
2	5	1	1
10	33	7	11
		3	8
1	1		
3	3	1	1
		1	1
5	9		
	1		
1	2		
3	8	1	1
1	1		1
7	17	4	9

Contusion	2	5
Cough	3	9
COVID-19	3	12
COVID-19 pneumonia		1
Deafness	1	1
Death		1
Decreased appetite		4
Deep vein thrombosis	1	1
Defaecation urgency		1
Dehydration		1
Depressed level of consciousness		1
Depression	1	2
Dermatitis infected	1	1
Dermatochalasis	1	1
Diabetes mellitus	1	1
Diarrhoea	5	21
Diplopia	1	2
Discomfort	1	3
Disease recurrence		3
Distractibility		1
Disturbance in attention	3	6
Dizziness	17	44
Drug ineffective	3	8
Dry eye	1	1
Dry mouth	4	4
Dysarthria	1	1
Dysgeusia	5	9
Dyskinesia		1
Dysmenorrhoea	1	2
Dysphagia	4	9
Dysphonia	1	2
Dyspnoea	11	26

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysuria	1	1			1	1
Ear discomfort	2	5	2	5		
Ear pruritus		1		1		
Ectopic pregnancy		1				1
Eczema		1		1		
Eosinophil count increased		1		1		
Erythema	5	11	4	8	1	3
Erythema multiforme		1				1
Excessive cerumen production		1		1		
Exposure during pregnancy	1	12	1	12		
Exposure via breast milk		5		5		
Eyelid function disorder		1				1
Eyelid oedema		1				1
Eyelid ptosis	1	1			1	1
Eyelid sensory disorder		1		1		
Eyelids pruritus		1				1
Eye pain		1		1		
Eye pruritus		1		1		
Eye swelling		2		2		
Face oedema		1				1
Facial asymmetry	1	1	1	1		
Facial pain		3		3		
Facial paralysis	2	8			2	8
Faeces soft	1	1	1	1		
Fall	2	4		1	2	3
Fatigue	17	86	13	76	4	10
Fear		1		1		
Feeling abnormal	4	12	4	12		
Feeling cold	1	4	1	2		2
Feeling drunk		1		1		
Feeling hot		10		9		1
Feeling of body temperature change	1	2	1	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Fibromyalgia		1		1			
Fluid retention	1	3	1	3			
Flushing		4		3			1
Gait disturbance	1	1			1		1
Gastric disorder		1		1			
Gastric ulcer	1	1			1		1
Gastroenteritis		1		1			
Gastroenteritis viral		1		1			
Gastrointestinal disorder	1	1	1	1			
Gastrointestinal pain	1	1	1	1			
Gastroesophageal reflux disease		1		1			
Generalised tonic-clonic seizure		1					1
Gestational diabetes		1					1
Grip strength decreased		1		1			
Haematemesis		1					1
Headache	26	96	20	87	6		9
Head discomfort		1		1			
Heart rate decreased		2					2
Heart rate increased	4	8	1	3	3		5
Hemiparaesthesia	1	1			1		1
Hepatic enzyme increased		1					1
Herpes zoster	5	6	4	5	1		1
Herpes zoster oticus	1	1			1		1
Hip fracture	1	1			1		1
Hot flush	2	2	1	1	1		1
Hyperaesthesia		3		3			
Hyperaesthesia teeth		1		1			
Hyperhidrosis		4		2			2
Hypersensitivity	5	9	2	4	3		5
Hypersomnia		2		2			
Hypertension	4	12	2	4	2		8
Hypertensive crisis		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3		
7	14	4	10
	1		
2	3	1	5
1	5		3
	1		
1	1		
	2		
1	16		
	1		
	1		
	1		
	1		
1	1		
1	7	1	1
1	1		
	1		
1	2		
	1		
3	12		
	1		
	1		
2	3		
	1		
			1
	1		
1	2	1	2
1	1		
			1
	1		
1	1		
	2		

Hypoacusis	1	3
Hypoesthesia	11	24
Hypoesthesia eye		1
Hypoesthesia oral	3	8
Hypotension	1	8
Illness		1
Impaired quality of life	1	1
Impaired work ability		2
Inappropriate schedule of product administration	1	16
Incomplete course of vaccination		1
Incorrect dose administered		1
Incorrect route of product administration		1
Infection		1
Inflammation	1	1
Influenza like illness	2	8
Infusion site warmth	1	1
Injection site bruising		1
Injection site erythema	1	2
Injection site hypersensitivity		1
Injection site pain	3	12
Injection site scar		1
Injection site swelling		1
Insomnia	2	3
Intentional product use issue		1
IVth nerve paralysis		1
Joint noise		1
Joint swelling	2	4
Lacrimation increased	1	1
Laryngospasm		1
Leukoplakia		1
Ligament sprain	1	1
Limb discomfort		2

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
	1		
	1		
	1		
	1		
4	5		2
			1
		2	4
2	2		1
			1
	18	1	4
	2		
4	20	1	1
	1		
1	3		
3	19		
	2		
1	2	1	1
	1		
	1		
1	3		
		1	1
	1		
2	11	1	2
	2		
	1		
	1		
	1		1
1	1		
1	1	1	1
1	1	1	1
	1		

Lip blister 1  
 Lip haemorrhage 1  
 Lipoma 1  
 Lip pain 1  
 Lip pruritus 1  
 Lip swelling 4 7  
 Liver function test increased 1  
 Loss of consciousness 2 4  
 Loss of personal independence in daily activities 2 3  
 Lung disorder 1  
 Lymphadenopathy 1 22  
 Lymph node pain 2  
 Malaise 5 21  
 Mass 1  
 Maternal exposure before pregnancy 1 3  
 Maternal exposure during pregnancy 3 19  
 Maternal exposure timing unspecified 2  
 Menorrhagia 2 3  
 Menstrual disorder 1  
 Menstruation delayed 1  
 Menstruation irregular 1 3  
 Mental impairment 1 1  
 Micturition urgency 1  
 Migraine 2 11  
 Mobility decreased 2  
 Monocyte count increased 1  
 Motion sickness 1  
 Mouth swelling 1  
 Mucosal discolouration 1 1  
 Multiple sclerosis 1 1  
 Multiple sclerosis relapse 1 1  
 Muscle injury 1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscle spasms		2		1			1
Muscle tightness		1		1			
Muscle twitching	1	2	1	2			
Muscular weakness		6		5			1
Musculoskeletal pain		1		1			
Musculoskeletal stiffness	2	7	2	7			
Myalgia	5	39	4	36	1		3
Myocardial infarction	1	1			1		1
Myocarditis	1	1			1		1
Nasal congestion	1	2		1	1		1
Nasopharyngitis		2		2			
Nausea	17	57	12	48	5		9
Neck pain	3	8	3	7			1
Necrosis		1					1
Nervousness		1					1
Neuralgia		2					2
Neurological symptom	1	1			1		1
Neutrophil count decreased		1		1			
Night sweats	2	2	1	1	1		1
No adverse event		1		1			
Odynophagia		1		1			
Oedema		1					1
Oedema peripheral		1		1			
Oesophageal disorder		1					1
Off label use	2	52	2	51			1
Oral candidiasis		1		1			
Oral discomfort	1	3	1	3			
Oral herpes		2		2			
Oral mucosal blistering		1		1			
Oral pain		1		1			
Oropharyngeal discomfort	1	1	1	1			
Oropharyngeal pain		8		8			

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	4		
	1		
	1		1
5	26	2	3
6	35		5
	2	1	1
1	2		
1	2		1
1	4		1
2	15	4	13
1	7		3
		1	1
1	1		
		1	1
			1
1	2		
1	1		1
2	5		1
	2		
	2		1
			1
1	2		2
		1	1
	1		
1	3		
	1		
1	1		
	1		
	4		3
	3		
1	1		1
	2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
1	39		1
5	16	2	6
			1
			2
			1
		1	1
			1
	1		1
	1		
6	45	2	3
7	22		1
2	4		1
	2		
1	1		
1	1		1
	2		2
		1	1
		1	1
			1
1	1		
			2
3	3		1
		1	1
	1		
1	1		
	1		
		1	1
			1
	1		
	1		

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation		2		2		
Skin discolouration	1	1	1	1		
Skin exfoliation		1		1		
Skin laceration	1	1	1	1		
Skin lesion		1		1		
Skin reaction	1	2	1	2		
Skin warm		1		1		
Sleep disorder	1	1	1	1		
Sneezing	1	2	1	2		
Somnolence	1	5		2	1	3
Speech disorder	1	2	1	2		
Stevens-Johnson syndrome		1				1
Stomatitis		1		1		
Stress		1		1		
Superior sagittal sinus thrombosis	1	1			1	1
Suspected COVID-19	2	2	1	1	1	1
Swelling		5		4		1
Swelling face	3	10	2	6	1	4
Swelling of eyelid		2		2		
Swollen tongue	3	8	3	6		2
Syncope	5	10			5	10
Systemic lupus erythematosus		1				1
Tachycardia	3	12	2	6	1	6
Tachypnoea		1		1		
Taste disorder		2		2		
Temporomandibular joint syndrome		1		1		
Tendon disorder		1		1		
Tendonitis	1	1	1	1		
Tension headache	1	1	1	1		
Therapeutic response unexpected	1	2	1	2		
Thirst	1	2	1	2		
Threatened labour		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Throat irritation		2		2			
Throat tightness	1	6		1	1	5	
Thrombocytopenia		2				2	
Thrombosis	2	4			2	4	
Thyroid disorder	1	1	1	1			
Tinnitus	4	9	2	6	2	3	
Tongue disorder	1	5	1	4		1	
Tongue pruritus		2		2			
Transient ischaemic attack	2	3	1	1	1	2	
Tremor	1	6	1	5		1	
Type I hypersensitivity		2				2	
Type IV hypersensitivity reaction		1		1			
Underdose		2		2			
Upper-airway cough syndrome		1		1			
Urinary incontinence		1				1	
Urinary tract infection		1		1			
Urticaria	5	24	3	19	2	5	
Uveitis		1				1	
Vaccination failure		2				2	
Vaccination site discomfort	2	2	1	1	1	1	
Vaccination site erythema	2	6	2	6			
Vaccination site induration		2		2			
Vaccination site inflammation		1		1			
Vaccination site joint movement impairment	1	1	1	1			
Vaccination site lymphadenopathy		1		1			
Vaccination site movement impairment		1		1			
Vaccination site oedema		3		3			
Vaccination site pain	7	45	7	43		2	
Vaccination site rash	1	2	1	2			
Vaccination site reaction		1		1			
Vaccination site swelling	1	7	1	7			
Vaccination site urticaria	1	5		3	1	2	

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth	2	5	2	5		
Vaginal discharge		1		1		
Vaginal haemorrhage		3		3		
Ventricular tachycardia		1				1
Vertebral artery dissection		1				1
Vertigo	2	4	1	3	1	1
Viral rash		1		1		
Vision blurred	2	5	1	3	1	2
Visual impairment		1				1
Vitreous detachment		1				1
Vitreous floaters		1		1		
Vomiting	8	18	5	13	3	5
Vomiting projectile		1		1		
Vulval disorder		1				1
Vulvitis		1		1		
Weight decreased		2		2		
Weight increased		1		1		
Wheezing		4		3		1
White blood cell count decreased		1		1		
	477	1,863	313	1422	164	441

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain		1		1		
Abdominal pain upper		1		1		
Acute kidney injury		1				1
Agitation		1		1		
Alanine aminotransferase increased	2	2	1	1	1	1
Anaphylactic reaction	1	1			1	1
Anxiety		1		1		
Arrhythmia	1	1			1	1
Arthralgia		1		1		
Aspartate aminotransferase increased	1	1			1	1
Asthenia	2	5	2	4		1
Axillary pain		2		2		
Back pain	1	1	1	1		
Balance disorder	1	1			1	1
Blood creatine phosphokinase increased	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood urine		1		1		
Blood urine present	1	1	1	1		
Cardiac flutter	1	1			1	1
Cellulitis		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	2	1	2		
Chest pain		1		1		
Chills	3	6	3	6		
Chromaturia		1		1		
Circumstance or information capable of leading to medication error		1		1		
Colitis ulcerative	1	1			1	1
Condition aggravated	2	2			2	2
Contusion	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1		1		
COVID-19	2	6			2	6
C-reactive protein increased	2	2	1	1	1	1
Deafness		1				1
Deafness unilateral	1	1			1	1
Death	1	1			1	1
Decreased appetite	2	4	2	3		1
Delirium	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dermatitis	1	1			1	1
Diarrhoea	1	4	1	4		
Disease recurrence	2	2			2	2
Disseminated varicella zoster virus infection		1				1
Disturbance in attention	1	1	1	1		
Dizziness	3	7	3	7		
Drug ineffective	2	4			2	4
Drug interaction	2	2			2	2
Drug level increased	2	2	1	1	1	1
Dysgeusia		1		1		
Dysphagia	1	1			1	1
Dysphonia		1		1		
Dyspnoea	3	4	2	3	1	1
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		
Ear swelling	1	1	1	1		
Erythema	1	1			1	1
Exposure via breast milk		3		3		
Eye irritation		1				1
Eyelid disorder	1	1	1	1		
Eye swelling	1	1	1	1		
Facial paralysis	3	6			3	6
Fall	2	2			2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	4	9	2	7	2	2
Feeling abnormal	2	2	2	2		
Flatulence	1	1	1	1		
Fungal skin infection		1		1		
Gait disturbance	1	1			1	1
Gastric ulcer	1	1			1	1
Gout		2		2		
Haemoglobin decreased	1	1	1	1		
Haemorrhage urinary tract	3	4			3	4
Headache	4	14	4	14		
Heart rate decreased	1	1			1	1
Heart rate increased		1		1		
Hemiparesis	1	1			1	1
Hepatic enzyme increased	1	1			1	1
Herpes simplex	1	1			1	1
Herpes zoster	1	2	1	2		
Hiatus hernia	1	1	1	1		
Hot flush		1		1		
Hyperaesthesia	1	1			1	1
Hyperhidrosis		1		1		
Hypersensitivity	1	1	1	1		
Hypersomnia	2	2	2	2		
Hypertension	1	1	1	1		
Hyperuricaemia	1	1	1	1		
Hypoaesthesia	1	1			1	1
Hypokinesia		1		1		
Hypotension	1	1			1	1
Inappropriate schedule of product administration	1	2	1	2		
Incontinence	1	1			1	1
Incorrect route of product administration		1		1		
Injection site pain		1		1		
Insomnia	1	2	1	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke	1	1			1	1
Joint range of motion decreased		1		1		
Lacrimation increased	1	2	1	2		
Lethargy		2		2		
Limb discomfort		1		1		
Lip disorder	1	1	1	1		
Lip pain	1	1	1	1		
Loss of consciousness	3	3			3	3
Loss of personal independence in daily activities	1	1	1	1		
Lung disorder	1	1			1	1
Lymphadenopathy		4		4		
Lymphoedema		1		1		
Malaise	2	4	2	4		
Memory impairment	1	1			1	1
Meningitis aseptic		1				1
Monoparesis	1	1			1	1
Mucosal disorder		1		1		
Muscle spasms		1		1		
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	2	2	2	2		
Myalgia	1	7	1	7		
Myocardial infarction	1	1			1	1
Myocarditis	1	1			1	1
Nausea	2	5	2	5		
Neck pain		2		2		
Nervous system disorder	1	1			1	1
No adverse event	1	1	1	1		
Ocular hyperaemia	1	1	1	1		
Oedema		1		1		
Oesophagitis	1	1			1	1
Off label use	1	1	1	1		
Oropharyngeal pain	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Overdose		1		1		
Pain	4	9	2	7	2	2
Pain in extremity	2	8	2	8		
Palpitations	1	1	1	1		
Penis disorder		1				1
Periorbital swelling	1	1	1	1		
Peripheral arterial occlusive disease	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pharyngeal swelling		1		1		
Pneumonia	1	2			1	2
Product administered at inappropriate site	1	2	1	2		
Productive cough		1		1		
Product preparation issue		1		1		
Pruritus	2	5	1	4	1	1
Pulmonary embolism	1	1			1	1
Pyrexia	5	10	4	9	1	1
Rash	3	6	1	4	2	2
Rash erythematous	1	1	1	1		
Rash macular		1		1		
Rash maculo-papular		1				1
Rash pruritic	1	2	1	2		
Rash pustular		1		1		
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	1	2	1	2		
Secretion discharge		1		1		
Seizure	3	3			3	3
Sepsis	2	2			2	2
Shoulder injury related to vaccine administration	1	1	1	1		
Skin injury		1		1		
Sleep disorder	1	2	1	2		
Sneezing		1		1		
Somnolence	1	3		2	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Splenitis	1	1			1	1
Suicidal ideation	1	1			1	1
Suspected COVID-19	1	1	1	1		
Swelling		1		1		
Syncope	4	5			4	5
Tenderness		1		1		
Tendonitis		1		1		
Testicular pain		1		1		
Testicular retraction		1				1
Therapeutic response unexpected	1	1	1	1		
Thirst	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	1	1	1	1		
Thrombosis	2	2			2	2
Tinnitus	1	2		1	1	1
Toxicity to various agents	1	1			1	1
Troponin increased	1	1	1	1		
Underdose		1		1		
Urticaria	5	7	4	6	1	1
Vaccination failure		1				1
Vaccination site bruising		1		1		
Vaccination site mass		1		1		
Vaccination site pain	1	5	1	5		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Varicella		1		1		
Vision blurred		1		1		
Visual impairment		1		1		
Vital functions abnormal		1				1
Vitamin B12 increased	1	1			1	1
Vomiting	3	5	2	4	1	1
Wrong product administered	1	2	1	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	184	355	95	241	89	114

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anaphylactic reaction		21				21
Anaphylactic shock		1				1
Arthralgia	2	2	2	2		
Balance disorder	1	1	1	1		
Circumstance or information capable of leading to medication error		1		1		
Condition aggravated	1	1	1	1		
COVID-19	2	29			2	29
Diarrhoea	1	2	1	2		
Disease recurrence		1		1		
Drug ineffective	2	30			2	30
Dysphonia		1		1		
Ear infection		1				1
Exposure during pregnancy		2				2
Exposure via breast milk		17		17		
Fatigue	1	3	1	3		
Foetal growth restriction	1	3			1	3
Gait disturbance	1	1	1	1		
Headache		2		2		
Herpes zoster		1				1
Hypersensitivity		7				7
Hypertension		3		3		
Inappropriate schedule of product administration		27		27		
Incomplete course of vaccination		1		1		
Incorrect dose administered		2		2		
Lethargy		2		2		
Malaise		1		1		
Maternal exposure before pregnancy	1	1			1	1
Musculoskeletal stiffness		1		1		
Myalgia	1	2	1	2		
Nasopharyngitis		1		1		

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		1		1		
Neck pain	1	1	1	1		
No adverse event	1	1	1	1		
Off label use		27		27		
Overdose		6		6		
Pain in extremity		2		2		
Product complaint	4	4	4	4		
Product container issue		1		1		
Product physical issue		1		1		
Product preparation error		2		2		
Product preparation issue		10		10		
Product quality issue		1		1		
Product use issue		1		1		
Pyrexia	1	3	1	2		1
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Stress	1	1	1	1		
Syncope		1				1
Taste disorder	1	1	1	1		
Therapeutic response unexpected		1		1		
Thrombosis	1	1			1	1
Underdose	4	10	4	10		
Vaccination site pain		1		1		
Vaccination site rash	1	1	1	1		
Wrong technique in product usage process		1		1		
	31	251	23	150	8	101

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**CAYMAN ISLANDS**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dyspepsia		1		1
Fatigue		1		1
Headache		1		1
Irritability		1		1
Muscle spasms		1		1
Muscle twitching		1		1
Palpitations		1		1
		8		8

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CHILE**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	2	2	2		
Abdominal pain upper	2	4	2	3		1
Abnormal faeces		1		1		
Anaphylactic reaction		2				2
Anxiety	1	1	1	1		
Aphasia	1	1			1	1
Arrhythmia		1				1
Arthralgia	2	7	2	6		1
Arthritis		1				1
Asthenia	1	2	1	2		
Aversion	1	1	1	1		
Axillary mass	1	1	1	1		
Axillary pain		1		1		
Back pain	1	3	1	3		
Blood glucose decreased	1	1	1	1		
Blood test abnormal		1		1		
Bone pain	1	2	1	2		
Breast engorgement	1	1	1	1		
Breast pain		1		1		
Burning sensation		1		1		
Chest discomfort	1	1	1	1		
Chest pain	1	2	1	1		1
Chills	6	11	6	10		1
Choking		1				1
Colitis	1	1	1	1		
Complement factor C3 decreased		1		1		
Cough	1	1	1	1		
C-reactive protein decreased		1		1		
Crying		1				1
Cyst	1	1	1	1		
Decreased appetite		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressed mood	1	1	1	1		
Dermatitis allergic	1	1			1	1
Diarrhoea	1	6	1	6		
Discomfort		1		1		
Discouragement		1		1		
Disease recurrence		1		1		
Dizziness	2	3	2	3		
Drug-induced liver injury	1	1			1	1
Dry mouth		1				1
Dry skin		1		1		
Dysbiosis		1				1
Dysgeusia		1				1
Dyspnoea		3		1		2
Ear discomfort		1		1		
Emotional distress	1	1	1	1		
Erythema	1	2	1	2		
Erythema nodosum	1	1			1	1
Eye discharge	1	1	1	1		
Eye movement disorder	1	1			1	1
Eye swelling	1	1	1	1		
Face oedema		1				1
Facial paralysis	1	1			1	1
Fatigue	5	9	5	9		
Fear	1	1	1	1		
Feeling abnormal		1		1		
Feeling cold	2	3	2	3		
Gait disturbance	2	3	1	2	1	1
Gait inability	1	1			1	1
Galactostasis	1	1	1	1		
Glossitis		1		1		
Guillain-Barre syndrome		1				1
Headache	15	26	15	25		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort	1	1	1	1		
Hemiparesis		1				1
Hyperaesthesia	2	2	2	2		
Hyperhidrosis		1		1		
Hypersensitivity	3	7	3	7		
Hypertension	1	1	1	1		
Hyperventilation		1				1
Hypoaesthesia	3	4	3	3		1
Hypotension		1				1
Incomplete course of vaccination		1		1		
Inflammation		1		1		
Insomnia	2	2	2	2		
Joint swelling		2		1		1
Limb discomfort	1	1	1	1		
Loss of consciousness	1	2			1	2
Loss of personal independence in daily activities		1		1		
Lymphadenopathy	2	6	2	5		1
Lymph node pain		3		3		
Malaise	7	13	7	13		
Mass	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Maternal exposure timing unspecified		1		1		
Monocyte count decreased		1		1		
Muscle discomfort	1	1	1	1		
Muscle spasms	1	3	1	3		
Muscular weakness		1		1		
Musculoskeletal pain	1	1	1	1		
Myalgia	11	17	11	16		1
Nasal congestion		1		1		
Nausea	7	10	7	9		1
Neck pain	2	2	2	2		
Neuralgia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oedema peripheral		1		1			
Off label use	1	2	1	2			
Overdose		1		1			
Oxygen saturation decreased	1	1	1	1			
Pain	7	11	7	10			1
Pain in extremity	4	6	4	6			
Pallor		1					1
Pancreatitis		1					1
Panic attack	1	1	1	1			
Panic reaction	1	1	1	1			
Paraesthesia	2	6	2	4			2
Peripheral swelling	3	3	2	2	1		1
Photophobia		1					1
Product preparation error		1		1			
Product use issue	1	2	1	2			
Pruritus	1	2	1	2			
Pyrexia	14	22	14	21			1
Rash		2		1			1
Rash pruritic		1					1
Respiratory disorder		1					1
Rhabdomyolysis		1					1
Rhinorrhoea	1	1	1	1			
SARS-CoV-2 ant body test negative		1		1			
Seizure	1	1			1		1
Sensory loss		1		1			
Skin burning sensation	1	1	1	1			
Somnolence	2	2	2	2			
Stenosis	1	1	1	1			
Stress	1	1	1	1			
Suspected COVID-19		1					1
Swollen tongue		1		1			
Synovial cyst		1		1			

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tachycardia		1				1	
Throat irritation	2	2	2	2			
Tinnitus	1	1	1	1			
Tongue movement disturbance	1	1			1	1	
Transaminases increased	1	1	1	1			
Urine analysis abnormal		1				1	
Urticaria		1				1	
Vaccination site discomfort	1	1	1	1			
Vaccination site erythema	2	2	2	2			
Vaccination site inflammation	3	3	3	3			
Vaccination site pain	6	11	6	9		2	
Vaccination site paraesthesia		1		1			
Vaccination site swelling	1	1	1	1			
Vasculitis	1	1			1	1	
Venous thrombosis		1				1	
Vestibular disorder		1		1			
Vomiting	1	2	1	2			
Wrong product administered	2	2	2	2			
	180	343	166	284	14	59	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic reaction		1				1	
Angina pectoris	1	1			1		1
Angioedema		1					1
Arthralgia	1	1	1	1			
Blood glucose increased	1	1			1		1
Blood pressure increased	1	1	1	1			
Chills	1	1	1	1			
Cough		1		1			
COVID-19	1	1			1		1
Decreased appetite		1		1			
Diarrhoea	2	3	2	3			
Dizziness	1	1	1	1			
Drug ineffective	1	1			1		1
Dyspnoea		1					1
Exposure via breast milk	1	1	1	1			
Eye pruritus		1					1
Eye swelling		1					1
Fall		1					1
Fatigue	2	5	2	5			
Headache	7	10	7	10			
Head injury		1					1
Hemiparaesthesia	1	1			1		1
Hepatic enzyme increased		1					1
Hepatic steatosis		1		1			
Hypertonia	1	1	1	1			
Hypoaesthesia	1	1	1	1			
Inappropriate schedule of product administration	1	2	1	2			
Incorrect route of product administration		1		1			
Insomnia	1	1	1	1			
Internal haemorrhage	1	1			1		1
Malaise	2	2	2	2			
Myalgia	5	7	5	7			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal congestion	1	1	1	1		
Nausea	1	3	1	3		
Ocular hyperaemia		1				1
Off label use		1		1		
Pain	1	1	1	1		
Pain in extremity	2	3	2	3		
Paraesthesia	1	1	1	1		
Product supply issue	1	1	1	1		
Pyrexia	4	4	4	4		
Respiratory distress		1				1
Rhinorrhoea	2	2	2	2		
Seizure		1				1
Skin burning sensation	1	1	1	1		
Somnolence		1		1		
Splenic rupture	1	1			1	1
Splenomegaly	1	1			1	1
Swelling face		1				1
Tachycardia	1	1	1	1		
Toothache	1	1	1	1		
Vaccination site pain	4	7	3	6	1	1
Wound haemorrhage		1				1
	55	90	46	68	9	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	2	2	2	2		
Angioedema		1				1
Blood pressure fluctuation	1	1	1	1		
Burning sensation		1		1		
Chest discomfort	1	1	1	1		
Chest pain	2	2	2	2		
Cold sweat	1	1	1	1		
Contusion	2	2	2	2		
Dermatitis allergic		4		4		
Discomfort	1	1	1	1		
Dizziness		1		1		
Dyspnoea	1	1	1	1		
Erythema		1		1		
Face oedema		1				1
Fatigue	3	4	3	4		
Feeling cold	1	1	1	1		
Gait disturbance	1	1	1	1		
Guillain-Barre syndrome		1				1
Headache	4	6	4	6		
Hemiplegia		1				1
Hot flush	1	1	1	1		
Hypersensitivity		1		1		
Incomplete course of vaccination		8		8		
Localised oedema		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenopathy		1		1		
Malaise	1	2	1	2		
Mental disorder		1		1		
Musculoskeletal chest pain	1	1	1	1		
Myalgia	4	5	4	5		
Nausea	2	2	2	2		
Oropharyngeal pain	1	2	1	2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain		1		1		
Pain in extremity	1	1	1	1		
Peripheral swelling		1		1		
Polydipsia		1		1		
Pyrexia	3	4	3	4		
Syncope	1	1			1	1
Tachycardia	2	2	2	2		
Therapeutic response unexpected	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site inflammation		1		1		
Vaccination site mass		1		1		
Vaccination site pain		3		3		
Vaccination site pruritus		1		1		
Vomiting	1	1	1	1		
	40	81	39	75	1	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**COLOMBIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Arthralgia	2	4	2	4		
Asphyxia		1				1
Asthenia	1	4	1	3		1
Back pain	1	1	1	1		
Blister		1		1		
Blood pressure increased		1		1		
Bone pain		1		1		
Burning sensation		1		1		
Chest pain	1	1	1	1		
Chills	2	5	2	4		1
Cough	1	5	1	4		1
Cyanosis		1		1		
Death	1	1			1	1
Diarrhoea	1	2	1	1		1
Discomfort		2		1		1
Dizziness	1	1	1	1		
Drug hypersensitivity	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	2	3	2	2		1
Erythema	2	3	2	3		
Exposure during pregnancy	1	1	1	1		
Eye pain		1		1		
Fatigue		1				1
Feeling hot		2		2		
Gait inability		1		1		
Headache	3	11	3	10		1
Hyperhidrosis		1		1		
Hypersensitivity	1	2	1	2		
Hypertension		2		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	1		
1	2		
	1		
1	1		
1	1		
	1		
3	5		1
1	1		
	1		
1	4		
	1		
1	1		
1	2		
1	2		
1	3		
	1		
1	1		
3	4		
	1		1
			1
1	1		
	1		
1	1		
			1
1	1		
1	2		
	3		
			1
1	2		1

Hypoaesthesia  
Inappropriate schedule of product administration  
Influenza  
Influenza like illness  
Lymphadenopathy  
Lymph node pain  
Lymph node palpable  
Malaise  
Muscle spasms  
Musculoskeletal pain  
Myalgia  
Nausea  
Odynophagia  
Oedema  
Oropharyngeal pain  
Pain  
Paraesthesia  
Pruritus  
Puncture site pain  
Pyrexia  
Rash  
Respiratory distress  
Secretion discharge  
Skin discolouration  
Skin plaque  
Sneezing  
Syncope  
Tachycardia  
Urticaria  
Vaccination site pain  
Vertigo  
Vomiting

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
42	101	1	20

43

1  
121

42

101

1

20

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	2	1	2		
Asthenia		1		1		
Asymptomatic COVID-19	1	1			1	1
Candida infection		1		1		
Chills	1	2	1	2		
Cough	1	1	1	1		
COVID-19	2	4	2	3		1
Decreased appetite	1	1	1	1		
Dizziness		2		2		
Dyspnoea		1		1		
Erythema		1		1		
Feeling hot		1		1		
Gingivitis		1		1		
Headache	2	3	2	3		
Hypersensitivity	1	2	1	2		
Leukocytosis		1		1		
Lymphadenopathy	1	1	1	1		
Malaise	3	5	3	5		
Nausea	1	1	1	1		
Ocular hyperaemia		1		1		
Off label use		1		1		
Oral candidiasis		1		1		
Oxygen saturation decreased		1		1		
Pharyngeal erythema	1	1	1	1		
Product use issue		1		1		
Pyrexia		1		1		
Rhinorrhoea	1	1	1	1		
Stomatitis		1		1		
Underdose	1	1	1	1		
Urticaria	1	2	1	2		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	4	3	4		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	23	49	22	47	1	2

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Anxiety		1				1
Headache		1				1
Pyrexia		1				1
Rash		3		2		1
Seizure		1				1
		8		2		6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**COSTA RICA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	4		1	1	3
Abortion spontaneous		1				1
Adnexa uteri pain		2		2		
Anaphylactic reaction		1				1
Anaphylactic shock	1	2			1	2
Aphonia		1		1		
Aphthous ulcer		1		1		
Application site inflammation		1		1		
Application site pain		3		3		
Arthralgia	1	5	1	5		
Asthenia		5		3		2
Back pain	1	1	1	1		
Blood pressure increased	1	1	1	1		
Bronchospasm	1	1	1	1		
Burning sensation		2		2		
Cerebrovascular accident	2	2			2	2
Chest discomfort		1				1
Chest pain		1				1
Chills	1	8	1	6		2
Cold sweat		1		1		
Condition aggravated		1				1
Constipation		1		1		
Contusion	1	1			1	1
Cough	1	1	1	1		
COVID-19	3	5	1	1	2	4
Death	1	1			1	1
Depression		1		1		
Dermatitis allergic		1				1
Diarrhoea	3	5	2	4	1	1
Discomfort		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	3	7	2	4	1	3
Drug ineffective	1	3			1	3
Dry mouth		1				1
Dysgeusia		1				1
Dyspepsia	1	2			1	2
Dysphonia	1	2	1	2		
Dyspnoea	1	6	1	4		2
Dysstasia		1		1		
Ecchymosis	1	1	1	1		
Encephalopathy		1				1
Energy increased		1		1		
Epistaxis	2	2	1	1	1	1
Erythema		1		1		
Euphoric mood		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye allergy		1		1		
Eye inflammation		1		1		
Eye pain		2		2		
Eye pruritus		2		2		
Fall		1				1
Fatigue	10	25	9	22	1	3
Feeling abnormal	1	4		3	1	1
Feeling cold		2		2		
Feeling hot		1		1		
Gastric disorder		1		1		
Gastritis		2		1		1
Haemorrhage	1	1			1	1
Headache	9	27	8	23	1	4
Heart rate increased		1				1
Hyperhidrosis		3		2		1
Hypertension		1				1
Hypertensive crisis		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthermia		1		1		
Hypoaesthesia		2		2		
Hyposmia	1	1	1	1		
Hypothermia		1				1
Immune thrombocytopenia	1	1			1	1
Impaired work ability		1		1		
Incoherent		1		1		
Incorrect route of product administration		2		2		
Infection	1	1	1	1		
Influenza		1		1		
Influenza like illness		1				1
Insomnia		1		1		
Ischaemia	1	1	1	1		
Joint swelling	1	1	1	1		
Limb discomfort	1	2	1	2		
Loss of personal independence in daily activities		1		1		
Lung disorder	1	2	1	1		1
Lymphadenopathy	1	3	1	3		
Lymphangitis		1				1
Lymph node pain		2		2		
Malaise	1	3	1	3		
Migraine		3		2		1
Miosis		1				1
Mobility decreased		1		1		
Muscle contracture		1		1		
Muscle spasms		2		2		
Myalgia	1	11	1	10		1
Myocardial infarction		1				1
Nasal congestion	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	2	10	1	8	1	2
Nervous system disorder		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular hyperaemia		2		2		
Odynophagia	1	1	1	1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	2	3	2	3		
Oxygen saturation abnormal	1	1	1	1		
Oxygen saturation decreased		2				2
Pain	6	12	6	12		
Pain in extremity	10	23	10	23		
Paraesthesia	1	3	1	3		
Peripheral swelling	1	2	1	2		
Petechiae	2	2	1	1	1	1
Photopsia		1		1		
Platelet count abnormal	2	2			2	2
Pruritus	2	3	2	3		
Pyrexia	6	15	5	14	1	1
Rash	1	3	1	3		
Rash papular	1	1	1	1		
Renal disorder	1	1	1	1		
Respiratory disorder	1	1			1	1
Respiratory distress		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 ant body test negative		1		1		
Seizure		1				1
Sensation of foreign body		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Skin lesion		1		1		
Somnolence	2	4	2	4		
Tachycardia		3		3		
Tachypnoea	1	2	1	2		
Thirst		2				2
Throat irritation	1	1	1	1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness		1				1
Tinnitus	2	2	2	2		
Urticaria		1		1		
Vaccination failure	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site induration		1		1		
Vaccination site mass		1		1		
Vaccination site movement impairment		1		1		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	13	27	13	27		
Vaccination site urticaria		1		1		
Venous thrombosis		1				1
Vomiting	1	4		3	1	1
	125	377	98	295	27	82

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		3		3		
Asthenia	2	3	2	3		
Axillary pain	1	1	1	1		
Back pain		1		1		
Bone pain		1		1		
Cerebrovascular accident	1	1			1	1
Chills	1	5	1	5		
Communication disorder		1		1		
Condition aggravated		1		1		
Constipation		1		1		
Contusion		1		1		
Cough	2	3	2	3		
COVID-19	3	6		1	3	5
Deafness	1	1			1	1
Death	1	1			1	1
Dermatitis allergic		1		1		
Diarrhoea	1	3	1	2		1
Dizziness		2		2		
Drug ineffective	2	3			2	3
Dry eye	1	1	1	1		
Dysgeusia		2		2		
Dyspnoea	1	2	1	2		
Ear discomfort	1	1	1	1		
Erythema of eyelid	1	1	1	1		
Eyelid irritation	1	1	1	1		
Faeces soft		1		1		
Fatigue	5	9	5	9		
Feeling abnormal		1		1		
Feeling cold		3		3		
Fibrin D dimer increased		1		1		
Flatulence		1		1		
Gastrointestinal pain		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	1		
1	1		
1	1		
1	1		
	10		
	1		
	1		1
	1		
	1		
1	1		
	1		1
2	2		
1	2		
1	1		
	3		1
	1		
1	1		1
	1		
	1		
3	11		1
1	1	1	1
1	1		
1	1		
1	1	1	1
	1		1
2	7		
3	6		
1	1		
	1		1
	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pneumonitis		1				1	
Pruritus	3	4	3	4			
Pyrexia	2	10	2	9		1	
Rash		1		1			
Red blood cell sedimentation rate increased		1		1			
Respiratory tract congestion	1	1	1	1			
Sleep disorder		1		1			
Splenomegaly		1					1
Suspected COVID-19		1		1			
Swelling face		1		1			
Syncope	1	1			1	1	
Throat clearing		1		1			
Throat irritation	1	1	1	1			
Tooth disorder	1	1	1	1			
Tremor		1		1			
Vaccination failure	1	1			1	1	
Vaccination site discomfort		1		1			
Vaccination site pain	10	16	10	16			
Vasculitis		1		1			
Vision blurred		1		1			
Vomiting		2		1			1
	68	181	56	154	12	27	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
Malaise	1	1	1	1
Pain	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**CROATIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		2		2		
Abortion spontaneous	1	1			1	1
Anaphylactic reaction		2				2
Anaphylactic shock		2				2
Angioedema		2				2
Aphthous ulcer		1		1		
Application site oedema		1		1		
Arrhythmia	3	4			3	4
Arthralgia		12		12		
Asthenia	5	25	4	21	1	4
Asthma		1				1
Atrial fibrillation		2				2
Back pain		5		3		2
Balance disorder	2	2			2	2
Blister		1				1
Blood creatine phosphokinase increased	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	2	1	2		
Blood pressure increased	5	11	3	5	2	6
Body temperature increased		15		14		1
Bone pain	2	7	2	7		
Breast pain	1	1	1	1		
Breath sounds abnormal		1				1
Bronchitis		1				1
Bronchospasm		4				4
Burning sensation		2				2
Capillary fragility		1		1		
Cardiac arrest		1				1
Cardiac disorder	1	1			1	1
Cardiac failure		2				2
Cardiac failure acute	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cardiac failure congestive		1					1
Cardiomyopathy		1					1
Cerebral haemorrhage	1	2			1		2
Cerebrovascular accident		1					1
Chest discomfort	2	6	1	2	1		4
Chest pain	2	5	1	3	1		2
Chills	11	42	9	35	2		7
Choking sensation		1					1
Cold sweat		1		1			
Coma	1	1			1		1
Condition aggravated		1					1
Confusional state		3		2			1
Conjunctival haemorrhage	1	3			1		3
Conjunctivitis allergic		1					1
Cough	1	7	1	3			4
COVID-19	10	13		1	10		12
Cyanosis		2					2
Deafness bilateral		1					1
Deafness unilateral	1	1			1		1
Decreased appetite	1	4	1	4			
Deep vein thrombosis		1					1
Defaecation urgency	1	1	1	1			
Dermatitis allergic		1					1
Diabetes mellitus		1					1
Diaphragmatic spasm		1					1
Diarrhoea	2	4	1	3	1		1
Disturbance in attention		2		2			
Dizziness		8		7			1
Drug ineffective	1	2			1		2
Dry eye	1	1			1		1
Dry mouth		1		1			
Dysgeusia		2		1			1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dyskinesia		1					1
Dysphagia		3					3
Dysphonia		1					1
Dyspnoea		14		4			10
Dyspnoea exertional		1		1			
Ear infection	1	1			1		1
Encephalitis post immunisation		1					1
Erythema	2	20		4	2		16
Escherichia urinary tract infection		1					1
Exposure during pregnancy	1	1	1	1			
Extensive swelling of vaccinated limb	1	17			1		17
Extensor plantar response	1	1	1	1			
Extrapyramidal disorder		1					1
Eye haematoma		1					1
Eye haemorrhage		1					1
Eyelid oedema		2		1			1
Eyelid pain		1		1			
Eyelid ptosis		1					1
Eye opacity		1		1			
Eye pain		2		2			
Facial nerve disorder		1		1			
Facial pain		1		1			
Facial paresis	1	5		1	1		4
Fall	2	2			2		2
Fatigue	6	27	4	22	2		5
Fear		1					1
Feeding disorder		1		1			
Feeling abnormal		1		1			
Feeling cold		1		1			
Feeling hot	1	8	1	4			4
Gait disturbance	1	1			1		1
Gastrointestinal pain		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
General physical health deterioration		1					1
Gingival bleeding		1		1			
Haematoma	1	1	1	1			
Haemorrhage subcutaneous		1					1
Headache	10	62	8	48	2		14
Head discomfort		1					1
Head titubation	1	1			1		1
Heart rate increased	1	2	1	1			1
Hemiparesis	2	2			2		2
Hemiplegia	1	1			1		1
Hot flush		1					1
Hyperaesthesia		1		1			
Hyperhidrosis	2	8	2	6			2
Hypersensitivity		4					4
Hypertension	4	8		1	4		7
Hypoacusis		1		1			
Hypoaesthesia	2	4	1	3	1		1
Hypoaesthesia oral		1					1
Hypogeusia		1		1			
Hypokinesia		1		1			
Hypopnoea		1					1
Hypotension		2		1			1
Illness		1		1			
Incorrect dose administered		1					1
Insomnia	2	3	2	3			
Intraocular pressure increased		1		1			
Irritable bowel syndrome		1		1			
Ischaemic cerebral infarction		1					1
Ischaemic stroke	1	1			1		1
Lacrimation increased		1		1			
Lip disorder		1					1
Lip oedema	1	2			1		2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lip swelling		1					1
Livedo reticularis		1					1
Localised oedema		1		1			
Loss of consciousness	2	3			2		3
Loss of personal independence in daily activities	2	2			2		2
Lymphadenitis		2		1			1
Lymphadenopathy	1	6	1	5			1
Lymph node pain	1	3	1	2			1
Malaise	3	15	3	13			2
Melaena	1	1			1		1
Menstrual disorder		1		1			
Migraine		1		1			
Moaning		1					1
Monoparesis		1					1
Multi-organ disorder		1					1
Muscle contractions involuntary		1		1			
Muscle spasms	2	3	2	2			1
Muscle tightness		1		1			
Muscular weakness	1	4	1	2			2
Musculoskeletal stiffness	1	1	1	1			
Myalgia	5	41	4	38	1		3
Myosclerosis		1					1
Nausea	4	24	3	18	1		6
Neck pain	1	5	1	5			
Neuritis		1		1			
Neurological symptom	1	1	1	1			
Neutrophil count increased	1	1	1	1			
Night sweats		1		1			
Nystagmus		1					1
Ocular hyperaemia		1		1			
Oedema mouth		1					1
Oedema peripheral	1	2	1	1			1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Off label use		1		1			
Oral mucosal erythema		1		1			
Oral pain		1		1			
Organic brain syndrome		1					1
Oropharyngeal discomfort		1		1			
Oropharyngeal pain	2	3		3			
Pain	2	6	2	6			
Pain in extremity	3	17	2	14	1		3
Pallor		2					2
Palpitations	3	10	2	5	1		5
Panic attack		2					2
Paraesthesia	1	9	1	5			4
Paraesthesia oral	1	5		2	1		3
Paresis		1					1
Peripheral coldness	2	2	1	1	1		1
Peripheral swelling		3		2			1
Pharyngeal paraesthesia		1					1
Pharyngeal swelling		1		1			
Pleural effusion		1					1
Pneumonia		1					1
Pneumonia klebsiella		1					1
Pneumonia staphylococcal		1					1
Polymenorrhoea		1		1			
Poor peripheral circulation	1	1			1		1
Presyncope		1					1
Product use issue		1		1			
Pruritus	1	13		4	1		9
Pulmonary embolism		1					1
Pulmonary pain		1		1			
Pulse absent		1					1
Pyrexia	16	67	10	47	6		20
Rales		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	1	14		4	1	10
Rash erythematous	1	2	1	1		1
Rash macular	1	3			1	3
Rash maculo-papular		4				4
Rectal haemorrhage		1				1
Renal pain		1		1		
Respiratory failure		1				1
Respiratory rate decreased	1	1	1	1		
Respiratory tract oedema		1				1
Restlessness		1				1
Retching		1		1		
Rhinorrhoea		1		1		
Salivary hypersecretion		1				1
SARS-CoV-2 ant body test positive		1		1		
Sensory disturbance		1				1
Sensory loss		1				1
Serum sickness		1				1
Skin burning sensation	1	2		1	1	1
Skin discolouration	1	1			1	1
Skin oedema		1		1		
Skin reaction		1				1
Skin tightness	1	2			1	2
Sleep paralysis		1		1		
Sleep terror		1		1		
Sneezing		1				1
Somnolence		3		1		2
Speech disorder		1				1
Stress cardiomyopathy	1	1			1	1
Stridor		2				2
Suffocation feeling		1				1
Swelling face		2				2
Swollen tongue		3				3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	2	3			2	3
Tachycardia	5	13	2	6	3	7
Tachypnoea		1				1
Tension		1		1		
Throat tightness		1				1
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus	1	5		2	1	3
Tongue disorder		1				1
Tongue oedema		3				3
Tremor	1	8	1	6		2
Type I hypersensitivity	1	19			1	19
Underdose		1				1
Unresponsive to stimuli		1				1
Urinary incontinence		1				1
Urinary tract infection		1				1
Urine odour abnormal		1		1		
Urticaria		6		1		5
Use of accessory respiratory muscles		2				2
Vaccination failure	9	10			9	10
Vaccination site erythema	4	34	2	25	2	9
Vaccination site haematoma		3		3		
Vaccination site hypersensitivity		1		1		
Vaccination site induration	1	6	1	4		2
Vaccination site joint erythema		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy	2	2	2	2		
Vaccination site mass		1				1
Vaccination site oedema	2	9	1	6	1	3
Vaccination site pain	9	85	6	72	3	13
Vaccination site pruritus		4		3		1
Vaccination site reaction		1		1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	1	17	1	13		4
Vaccination site warmth		1		1		
Vertigo	1	4	1	3		1
Vision blurred		1				1
Visual impairment		1				1
Vitreous detachment		1				1
Vomiting	4	9	3	6	1	3
Wheezing		3				3
White blood cell count increased	1	1	1	1		
Wrong technique in product usage process		1		1		
	218	1,094	113	631	105	463

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Allergy to chemicals		1		1		
Anaemia		1				1
Angina pectoris	1	1			1	1
Anosmia	1	1			1	1
Arrhythmia	2	3			2	3
Arthralgia	2	5		3	2	2
Asthenia	2	7	1	3	1	4
Axillary pain	1	1			1	1
Blood creatine phosphokinase increased		1		1		
Blood glucose increased	2	2	1	1	1	1
Blood pressure increased	2	5			2	5
Body temperature increased	2	3	1	2	1	1
Burning sensation		1				1
Cardiac failure		1				1
Cardio-respiratory arrest	1	1			1	1
Catarrh	1	1			1	1
Cerebrovascular accident	1	1			1	1
Cerebrovascular disorder	1	1			1	1
Chest discomfort		1				1
Chest pain	1	1			1	1
Chills	1	9	1	9		
Cold sweat		1				1
Communication disorder		1				1
Condition aggravated		1				1
Cough	2	2	2	2		
COVID-19	4	5		1	4	4
Cyanosis	1	2			1	2
Death	1	3			1	3
Decreased appetite		2		1		1
Deep vein thrombosis	1	1			1	1
Dermatitis allergic		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
	1		
		1	1
			1
	1	1	2
			1
1	1		
1	1		
1	1	3	5
			1
1	1		2
			1
			1
	1		
			1
1		1	4
			1
			1
1	1		
			1
2	4	2	4
			1
4	10	3	2
1	2		1
	2		
	1		1
	1		1
1	1	1	
4	20	2	7
	1		
	1		
1	1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
		1	1
	1		
1	1		
			1
			2
		1	1
	1		
1	1		
	2		
	1		
1	1		
		1	2
	2	1	1
	1		
1	4		1
1	1		
			1
	1		
			1
4	10	3	3
	1		
	1		
2	4	1	1
	1		1
2	2		
	1		1
1	1		
	1		
	1		1
1	6	1	2
	1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor		1				1
Palpitations	1	2			1	2
Paraesthesia		3		2		1
Paraesthesia oral		1				1
Peripheral coldness	1	1			1	1
Pneumonia		1				1
Presyncope	1	2		1	1	1
Product preparation error		1		1		
Psoriasis		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia	4	22	2	17	2	5
Respiratory distress	1	1			1	1
Retching	1	2	1	2		
Rheumatoid factor positive		1		1		
Rhinorrhoea	2	3	1	2	1	1
Sensation of foreign body		1		1		
Skin burning sensation		1				1
Skin hypertrophy	1	1			1	1
Skin sensitisation		1		1		
Snoring	1	2		1	1	1
Somnolence		1		1		
Spinal pain		1		1		
Syncope	1	1			1	1
Throat tightness	1	1			1	1
Thrombocytopenia		1				1
Tinnitus		1		1		
Transient ischaemic attack	1	1			1	1
Tremor	1	3	1	3		
Type I hypersensitivity		1				1
Vaccination error		1		1		
Vaccination failure	4	4			4	4
Vaccination site erythema	1	3	1	2		1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema		2		2		
Vaccination site pain	3	18	2	15	1	3
Vaccination site swelling		2				2
Vertigo	1	1			1	1
Viral infection		1		1		
Vomiting	2	3	1	1	1	2
Wheezing		1				1
	106	305	38	158	68	147

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cerebral artery thrombosis	1	1	1	1
Cerebral infarction	1	1	1	1
Speech disorder	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CYPRUS**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Acute kidney injury	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Anaphylactic reaction		1				1
Angina pectoris	1	1			1	1
Aortic aneurysm	1	1			1	1
Arthralgia	2	9	2	9		
Asthenia		4		4		
Axillary pain		2		2		
Back pain		1		1		
Bacterial sepsis	1	1			1	1
Balance disorder		1		1		
Blood pressure increased		1				1
Body temperature increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Cerebrovascular accident	1	1			1	1
Cervix oedema		1		1		
Chest pain	1	1	1	1		
Chills	2	14	2	14		
Condition aggravated		2		2		
Contusion		2		2		
Cough		1		1		
COVID-19	1	2			1	2
C-reactive protein increased	1	1	1	1		
Death	1	1			1	1
Dehydration	1	1			1	1
Diarrhoea	1	2	1	2		
Dizziness		8		8		
Drug ineffective	1	2			1	2
Drug interaction		1		1		
Dysgeusia		2		2		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia		1		1		
Dyspnoea	1	4	1	2		2
Ear discomfort		1		1		
Erythema		1		1		
Eyelid ptosis		1		1		
Face oedema		2		1		1
Facial paralysis		1				1
Facial paresis		4				4
Fatigue	5	12	5	12		
Fibrin D dimer increased		1		1		
Gait disturbance		2		2		
Gait inability		1		1		
Gastrointestinal infection	1	1			1	1
Guillain-Barre syndrome		1				1
Headache	1	12	1	12		
Hyperhidrosis		3		3		
Hypersensitivity		1		1		
Hypertension		1				1
Hypoacusis		1		1		
Hypoaesthesia	2	3	2	2		1
Hypoaesthesia eye		1				1
Hypoaesthesia oral		2		1		1
Hyponatraemia	1	2	1	2		
Hypotension	1	2			1	2
Inappropriate schedule of product administration	1	2	1	2		
Inflammation		1		1		
Influenza like illness	1	2	1	2		
Injection site pain	1	1	1	1		
Insomnia		1		1		
Lymphadenopathy		5		4		1
Malaise	3	7	3	7		
Migraine		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	1
	1		
1	1	1	1
7	18		
			1
	1		
3	9		
1	2		
	1		
			2
1	3		
	1		
	1		
	1		
	1		
3	5	3	5
1	1	1	1
2	10		
	2		
	1		
			1
			1
1	1	1	1
	1		
	1		
	2		
	2		2
	1		1
	1		1
1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Unresponsive to stimuli	1	1			1	1
Upper respiratory tract congestion		1		1		
Urinary retention	1	1			1	1
Vaccination site oedema	1	3	1	3		
Vaccination site pain		9		9		
Vaccination site swelling		2		2		
Vasculitis	1	2		1	1	1
Vertigo		1		1		
Viral sepsis	1	1			1	1
Vomiting	3	7	2	6	1	1
		1		1		
	66	258	42	203	24	55

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaphylactic reaction		1				1	
Arthralgia	1	3	1	3			
Asthenia		2		2			
Back pain		1		1			
Chills	1	4	1	4			
Confusional state		2		2			
COVID-19	1	3		1	1		2
Dermatitis atopic		1		1			
Discomfort		1		1			
Drug ineffective	1	2			1		2
Dysaesthesia		1					1
Dyspnoea	1	3	1	3			
Ear pain		1		1			
Eczema		1		1			
Epistaxis		1					1
Eye pain		1		1			
Facial paresis		2					2
Fatigue		3		3			
Generalised tonic-clonic seizure		1					1
Headache	1	4	1	4			
Head titubation		1		1			
Hypertension	1	1	1	1			
Hypoaesthesia		2		2			
Hypoaesthesia oral		1					1
Hypotension		1					1
Influenza		1		1			
Influenza like illness		1		1			
Insomnia	1	2	1	2			
Lymphadenopathy		1		1			
Malaise	1	2	1	2			
Migraine		1		1			
Myalgia	2	8	2	8			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Myocardial infarction		2				2	
Nasopharyngitis		1		1			
Nausea		1		1			
Neck pain		1		1			
Overdose		1		1			
Oxygen saturation decreased		1		1			
Pulmonary embolism	1	1			1	1	
Pyrexia	1	8	1	8			
Respiratory distress		1				1	
Sialoadenitis		1				1	
Syncope		1				1	
Tachycardia		1		1			
Tremor		1		1			
Vaccination site pain	1	7	1	7			
	14	88	11	70	3	18	

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		5		5		
COVID-19		8				8
Drug ineffective		2				2
Facial paralysis		1				1
Gastric haemorrhage		1				1
Headache		1		1		
Malaise		5		5		
Myalgia		5		5		
Paraesthesia		1		1		
Vaccination failure		1				1
		30		17		13

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**CZECH REPUBLIC**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3			1	3
Abdominal pain	2	13		6	2	7
Abdominal pain lower	2	2	1	1	1	1
Abdominal pain upper	1	5	1	3		2
Abnormal dreams		1		1		
Abortion spontaneous		1				1
Acne	1	1	1	1		
Acute kidney injury		1				1
Acute respiratory failure	1	2			1	2
Acute vestibular syndrome		1				1
Ageusia	1	4		2	1	2
Airway burns		2				2
Akathisia	1	1	1	1		
Akinesia	1	1			1	1
Alanine aminotransferase increased		1		1		
Allergic oedema	1	1			1	1
Allergy to vaccine	1	6		1	1	5
Alopecia		2		1		1
Altered state of consciousness	3	4			3	4
Amnesia		1				1
Anaemia		3		1		2
Anaesthesia oral		1				1
Anaphylactic reaction	4	11			4	11
Aneurysm	1	1			1	1
Angina pectoris		2		1		1
Angioedema		1				1
Anosmia	1	6		4	1	2
Antibody test abnormal		1		1		
Anuria		1				1
Anxiety	1	10	1	7		3
Aortic stenosis	1	1			1	1
Apathy	1	5	1	2		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	2	1	1		
Aphonia		1				1
Aphthous ulcer	2	4			2	4
Apnoea	1	1			1	1
Application site coldness		1				1
Application site erythema	1	1	1	1		
Arrhythmia	1	4			1	4
Arthralgia	37	132	26	97	11	35
Aspartate aminotransferase increased		1		1		
Asthenia	19	66	14	46	5	20
Asthma		2		1		1
Atrial fibrillation	1	2			1	2
Attention deficit hyperactivity disorder	1	1	1	1		
Axillary mass	1	1	1	1		
Axillary pain	2	9	2	7		2
Back pain	4	19	3	17	1	2
Bacterial rhinitis		1				1
Balance disorder	1	1			1	1
Blindness		2				2
Blister	1	1			1	1
Blood chloride increased		1		1		
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	2	2			2	2
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation		2		1		1
Blood pressure increased	3	10		5	3	5
Blood pressure systolic increased	1	2			1	2
Blood urine present	1	1	1	1		
Body temperature decreased		1		1		
Body temperature increased	2	8	1	5	1	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone pain		1		1		
Bradycardia		1				1
Bradyphrenia		2		1		1
Brain oedema		1				1
Breast pain	1	4	1	2		2
Breast swelling	1	2		1	1	1
Bronchitis		1				1
Bronchospasm	1	1			1	1
Burning sensation	3	5	3	4		1
Burning sensation mucosal		2		2		
Cardiac arrest	1	1			1	1
Cardiac failure	1	1			1	1
Cardiac failure congestive	1	1			1	1
Cardiomyopathy		1				1
Cardio-respiratory arrest	1	2			1	2
Cerebral haemorrhage		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	2	7			2	7
Chest discomfort	6	17	3	7	3	10
Chest pain	3	12	1	6	2	6
Chills	29	152	25	132	4	20
Choking sensation		1				1
Circulatory collapse	3	7			3	7
Coagulopathy		1				1
Cognitive disorder	1	1			1	1
Cold sweat		1		1		
Coma		1				1
Communication disorder		1				1
Concussion		1				1
Condition aggravated		1		1		
Confusional state		6		1		5
Conjunctivitis allergic	1	1	1	1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	2	3			2	3
Coordination abnormal		1				1
Cough	6	21	4	16	2	5
COVID-19	16	34	1	10	15	24
COVID-19 pneumonia		4				4
Cranial nerve palsies multiple	1	1			1	1
C-reactive protein increased		3		2		1
Cyanosis		1				1
Cystitis noninfective		1		1		
Deafness neurosensory		1				1
Deafness unilateral	1	2			1	2
Death		2				2
Decreased activity	1	2	1	2		
Decreased appetite	7	20	5	14	2	6
Dehydration		2		1		1
Delirium		1				1
Depression	1	3		1	1	2
Dermatitis	1	2	1	1		1
Dermatitis allergic	4	7		1	4	6
Diarrhoea	5	32	3	22	2	10
Diplopia		2		1		1
Discomfort	1	1	1	1		
Disease recurrence	1	3			1	3
Disorientation	1	5		2	1	3
Disturbance in attention	1	4		2	1	2
Diverticulitis		1				1
Dizziness	10	34	8	27	2	7
Dizziness postural	1	1			1	1
Drug eruption	1	3			1	3
Drug hypersensitivity	2	3		1	2	2
Drug ineffective	5	11			5	11
Drug interaction	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dry eye		1					1
Dry mouth	2	4		2	2	2	2
Dry skin	1	2			1	2	2
Dry throat	1	1			1	1	1
Dysaesthesia		1					1
Dysarthria	1	2			1	2	2
Dysgeusia	3	4	2	2	1	2	2
Dyskinesia	1	1			1	1	1
Dyspepsia	3	7	2	4	1	3	3
Dysphagia	3	8		1	3	7	7
Dysphemia	1	1			1	1	1
Dysphonia		1		1			
Dyspnoea	17	55	4	12	13	43	43
Dyspnoea at rest		1					1
Dyspnoea exertional	1	2	1	1		1	1
Dysstasia	1	1			1	1	1
Dysuria	1	1			1	1	1
Ear discomfort	2	10	2	5		5	5
Ear pain		2		2			
Ear pruritus		1					1
Ear swelling		1					1
Eating disorder		2		1		1	1
Eczema	1	1			1	1	1
Eczema herpeticum		1					1
Electrocardiogram abnormal	1	1	1	1			
Enterococcal infection	1	1			1	1	1
Epilepsy		1					1
Epistaxis	3	5	1	2	2	3	3
Erysipelas	1	2			1	2	2
Erythema	9	32	4	20	5	12	12
Erythema nodosum	1	1			1	1	1
Extrasystoles		1		1			

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye haemorrhage	2	2			2	2
Eye inflammation		1		1		
Eye irritation	2	3			2	3
Eyelid function disorder		1				1
Eyelid oedema	2	4			2	4
Eye movement disorder		1		1		
Eye pain	4	8	3	6	1	2
Eye pruritus		2		1		1
Eye swelling	1	3	1	2		1
Face oedema		1				1
Facial asymmetry	1	1			1	1
Facial pain		2		1		1
Facial paralysis	4	6			4	6
Facial paresis	1	5			1	5
Fall	3	8		4	3	4
Fatigue	43	185	37	151	6	34
Fear	1	1	1	1		
Febrile convulsion		1				1
Feeling abnormal	1	8	1	7		1
Feeling cold	2	3	2	3		
Feeling hot	4	12	1	6	3	6
Flank pain	1	1	1	1		
Flatulence	1	3	1	2		1
Fluid intake reduced		1		1		
Flushing		3		1		2
Foetal death		1				1
Food intolerance		1				1
Formication		3		2		1
Frequent bowel movements		1		1		
Functional gastrointestinal disorder		1		1		
Gait disturbance	2	6		3	2	3
Gait inability	1	2	1	1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric ulcer	1	1			1	1
Gastroenteritis		1		1		
Gastrointestinal hypermotility		1				1
Gastrointestinal pain	1	1	1	1		
Gastrooesophageal reflux disease		1				1
Generalised oedema		1		1		
General physical health deterioration	4	8	2	3	2	5
Gingival pain	1	1	1	1		
Glomerular filtration rate decreased		1		1		
Gout		1		1		
Groin pain	1	1	1	1		
Haematochezia		1				1
Haematoma	3	4	1	1	2	3
Haemorrhage intracranial	1	1			1	1
Hallucination		1				1
Hallucinations, mixed	1	1			1	1
Headache	35	178	30	153	5	25
Head discomfort		2		1		1
Heart rate increased		1				1
Heart rate irregular	1	2	1	2		
Hemiparesis	1	1			1	1
Hemiplegia	1	1			1	1
Hepatic function abnormal		1				1
Hepatic infarction		1				1
Hepatitis		1				1
Herpes dermatitis	1	1			1	1
Herpes simplex	1	2			1	2
Herpes virus infection		1		1		
Herpes zoster	2	9			2	9
Hot flush	5	16	1	9	4	7
Hyperaemia		1		1		
Hyperaesthesia	1	1	1	1		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
3	15		4
	1		
5	14	13	30
		1	3
2	8	16	25
	1		
1	1	1	2
	3	1	4
	1		2
		2	4
1	2		
	1		
	2	3	13
	1		
		1	1
	1		
			1
2	7		
1	5		
	1		
1	1		
			1
	1		
28	50	7	22
	2		
			1
	1		
3	9		3
	1		1
	1		
			1

Hyperglycaemia		1
Hyperhidrosis	3	19
Hyperphagia		1
Hypersensitivity	18	44
Hypersomnia	1	3
Hypertension	18	33
Hyperventilation		1
Hypoacusis	2	3
Hypoaesthesia	1	7
Hypoaesthesia oral		3
Hypokalaemia	2	4
Hypokinesia	1	2
Hypophagia		1
Hypotension	3	15
Hypotonia		1
Hypotonic-hyporesponsive episode	1	1
Illusion		1
Immune system disorder		1
Inappropriate schedule of product administration	2	7
Incorrect route of product administration	1	5
Induration		1
Infection	1	1
Inflammation		1
Influenza		1
Influenza like illness	35	72
Injected limb mobility decreased		2
Injection site erythema		1
Injection site pain		1
Insomnia	3	12
International normalised ratio increased		2
Irritability		1
Ischaemic stroke		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Joint instability		1					1
Joint range of motion decreased	1	4	1	3			1
Joint stiffness		2		1			1
Joint swelling	2	5	1	4	1		1
Joint warmth		1		1			
Jugular vein distension		1		1			
Lacrimation increased	1	2		1	1		1
Lagophthalmos		1		1			
Language disorder		1					1
Laryngeal oedema		1					1
Laryngospasm	1	1			1		1
Lethargy	1	1	1	1			
Leukocytosis		1		1			
Leukopenia		1					1
Ligament sprain		1					1
Limb discomfort	1	1			1		1
Limb immobilisation		1		1			
Lip dry	1	1	1	1			
Lip oedema		1					1
Lip swelling	1	6		1	1		5
Livedo reticularis	1	1	1	1			
Localised oedema	1	4			1		4
Local reaction		1		1			
Logorrhoea		1		1			
Loss of consciousness	3	8			3		8
Loss of personal independence in daily activities		2		2			
Lymphadenitis	1	5		1	1		4
Lymphadenopathy	9	71	6	33	3		38
Lymph node pain		14		10			4
Malaise	4	24	4	21			3
Mass		1		1			
Maternal exposure during pregnancy		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Melaena		1				1
Memory impairment		1				1
Menstrual disorder		1		1		
Menstruation delayed		1		1		
Mental disorder		1		1		
Metrorrhagia		1		1		
Migraine	4	12	2	6	2	6
Migraine with aura		1		1		
Mobility decreased	1	5		4	1	1
Monoparesis	1	2			1	2
Movement disorder	1	1			1	1
Mucosal disorder		1				1
Mucosal dryness		1				1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis relapse		1				1
Muscle atrophy		1				1
Muscle spasms	3	4	1	2	2	2
Muscle tightness	1	1	1	1		
Muscle twitching	2	4		2	2	2
Muscular weakness	4	13	2	10	2	3
Musculoskeletal chest pain	1	2	1	2		
Musculoskeletal disorder		1		1		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	2	11		7	2	4
Myalgia	21	94	18	71	3	23
Nasal congestion	3	4	3	4		
Nasal discomfort		1				1
Nasal oedema		1		1		
Nasopharyngitis	1	1	1	1		
Nausea	17	89	12	72	5	17
Neck pain	2	7		5	2	2
Nervousness		1				1

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	4
			1
	3	1	1
		1	1
	1		
1	2		
			2
	1		
1	3		
			1
4	6	1	5
	1		
	9		
2	2		2
1	1	1	1
	1		
	1		
1	1	1	1
	2		1
4	7	1	2
1	4		
	1	1	2
7	17	3	5
31	64	7	18
1	1		
	2		1
2		2	2
1	2		2
4	6	3	13
			1
3	19	11	36
			1

Neuropathy peripheral 1 4  
 Neutropenia 1 1  
 Night sweats 1 4  
 Nodule 1 1  
 Nuchal rigidity 1 1  
 Nystagmus 1 2  
 Ocular discomfort 2 2  
 Ocular hyperaemia 1 1  
 Oedema 1 3  
 Oedema mouth 1 1  
 Oedema peripheral 5 11  
 Oesophageal irritation 1 1  
 Off label use 9 9  
 Oral discomfort 2 4  
 Oral herpes 2 2  
 Oral mucosal blistering 1 1  
 Oral pruritus 1 1  
 Orbital oedema 1 1  
 Oropharyngeal discomfort 3 3  
 Oropharyngeal pain 4 9  
 Overdose 1 4  
 Oxygen saturation decreased 1 3  
 Pain 7 22  
 Pain in extremity 31 82  
 Pain in jaw 1 1  
 Pain of skin 3 3  
 Palatal swelling 2 2  
 Pallor 1 4  
 Palpitations 4 19  
 Pancreatic infarction 1 1  
 Paraesthesia 14 55  
 Paraesthesia mucosal 1 1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia oral	13	26		1	13	25
Paralysis	1	3			1	3
Paraparesis		1				1
Paresis	1	2			1	2
Paresis cranial nerve		1				1
Parosmia	1	2		1	1	1
Patient uncooperative	1	1	1	1		
Peripheral coldness	2	9	1	7	1	2
Peripheral nerve palsy	1	1			1	1
Peripheral swelling	4	14	3	6	1	8
Petechiae	2	2			2	2
Pharyngeal oedema		2				2
Pharyngeal swelling	2	6			2	6
Photophobia	1	4	1	4		
Photopsia		2		1		1
Photosensitivity reaction		1		1		
Pneumonia	1	1			1	1
Polyarthrits	2	2			2	2
Poor quality product administered		60		60		
Posture abnormal	1	1	1	1		
Presyncope	1	7		1	1	6
Product administered at inappropriate site		2		2		
Productive cough		3		1		2
Product preparation error	1	60	1	60		
Product preparation issue		1		1		
Product use issue		5		5		
Prolonged expiration		1		1		
Pruritus	11	36	4	13	7	23
Pulmonary embolism	1	3			1	3
Pulmonary oedema	1	1			1	1
Pulmonary pain	1	2		1	1	1
Pulmonary sensitisation		2		1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulpitis dental	1	1			1	1
Pulse abnormal		1		1		
Puncture site oedema		1		1		
Pyrexia	49	219	26	135	23	84
Quadripareisis		1				1
Radiculitis brachial		1				1
Radiculopathy		1				1
Rash	15	45	2	16	13	29
Rash erythematous	1	3			1	3
Rash macular	6	8			6	8
Rash maculo-papular	1	2			1	2
Rash pruritic	4	10	2	2	2	8
Rash pustular		1		1		
Red blood cell sedimentation rate increased		1		1		
Renal disorder		1		1		
Renal failure	1	2			1	2
Renal impairment		1				1
Renal pain	2	2	2	2		
Respiration abnormal		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory failure		1				1
Restlessness	1	3	1	3		
Retching	3	6	1	2	2	4
Rheumatoid arthritis	1	1			1	1
Rhinalgia	1	1	1	1		
Rhinitis	3	5	3	5		
Rhinorrhoea	3	11	2	9	1	2
Salivary hypersecretion		1				1
SARS-CoV-2 ant body test negative	1	1			1	1
SARS-CoV-2 test positive		2		2		
Scab	1	2	1	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	2	4			2	4
Sensation of foreign body	1	4			1	4
Sinus bradycardia		1		1		
Sinus pain	1	1	1	1		
Sinus tachycardia	1	1			1	1
Sitting disability		1				1
Skin burning sensation	6	6	3	3	3	3
Skin discolouration		1		1		
Skin disorder		1				1
Skin exfoliation	1	2	1	1		1
Skin mass		1		1		
Skin reaction		1		1		
Sleep deficit		1				1
Sleep disorder		2		1		1
Sleep talking		1		1		
Sneezing		1		1		
Somnolence	5	21	4	15	1	6
Speech disorder	1	3		2	1	1
Spinal disorder		1				1
Spinal pain	3	6	1	2	2	4
Splenic infarction		1				1
Sputum purulent	1	1			1	1
Stridor		1		1		
Sudden death		1				1
Supraventricular tachycardia		1				1
Swelling	1	7	1	5		2
Swelling face	6	22	1	2	5	20
Swelling of eyelid	1	2			1	2
Swollen tongue	3	6			3	6
Syncope	5	15			5	15
Tachycardia	8	28	1	14	7	14
Tachypnoea	2	6		2	2	4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder	1	1			1	1
Tenderness		1				1
Tendon pain	1	1			1	1
Tension headache	1	3		1	1	2
Thirst		1		1		
Throat irritation	3	4	1	2	2	2
Throat tightness	2	7		1	2	6
Thrombocytopenia		1				1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus	3	8	2	2	1	6
Tongue discomfort	1	3	1	2		1
Tongue oedema	2	6			2	6
Toothache	2	4	2	3		1
Tooth infection		1				1
Transient ischaemic attack		1				1
Tremor	6	13	1	6	5	7
Truncus coeliacus thrombosis		1				1
Urinary incontinence	1	2			1	2
Urinary tract infection	1	3		1	1	2
Urinary tract infection enterococcal		1				1
Urinary tract inflammation	1	3	1	1		2
Urogenital infection bacterial	1	1			1	1
Urosepsis		1				1
Urticaria	3	9		2	3	7
Vaccination complication		3		2		1
Vaccination failure	6	8			6	8
Vaccination site atrophy		2		1		1
Vaccination site bruising		2		1		1
Vaccination site cellulitis	1	1			1	1
Vaccination site discolouration		1		1		
Vaccination site discomfort		3		2		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	16	74	8	38	8	36
Vaccination site extravasation	1	1	1	1		
Vaccination site haematoma	1	3	1	1		2
Vaccination site induration	4	10	3	5	1	5
Vaccination site joint movement impairment	1	2		1	1	1
Vaccination site joint pain		2		2		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		3		1		2
Vaccination site movement impairment	1	5	1	4		1
Vaccination site oedema	8	32	4	17	4	15
Vaccination site pain	27	137	21	105	6	32
Vaccination site papule		1				1
Vaccination site paraesthesia		2		2		
Vaccination site pruritus	6	16	4	13	2	3
Vaccination site pustule	1	1	1	1		
Vaccination site rash	2	5	1	2	1	3
Vaccination site reaction		6		4		2
Vaccination site swelling	10	33	5	19	5	14
Vaccination site urticaria	2	3			2	3
Vaccination site warmth	1	11	1	7		4
Vascular pain		1				1
Vertigo	10	37	3	24	7	13
Vestibular neuronitis		1				1
Viral infection		2		1		1
Vision blurred	6	14	1	5	5	9
Visual field defect	1	2			1	2
Visual impairment		3		1		2
Vomiting	9	49	7	35	2	14
Wheezing		1		1		
White coat hypertension	1	1	1	1		
Yellow skin	1	1			1	1
	1,028	3,763	507	2220	521	1543

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\* AE=Adverse Event  
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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal pain	1	2	1	1		1
Abdominal pain upper	1	2	1	2		
Abnormal dreams		1		1		
Acute myocardial infarction	1	1			1	1
Altered state of consciousness		1				1
Amnesia		1				1
Anal incontinence		1		1		
Anaphylactic reaction		2				2
Anaphylactoid reaction	1	1			1	1
Angina pectoris	1	3			1	3
Angioedema	1	1			1	1
Anosmia	2	2	1	1	1	1
Aortic arteriosclerosis		1				1
Apathy	1	2			1	2
Aphasia	2	3		1	2	2
Application site erythema		1				1
Arrhythmia		1				1
Arteriosclerosis		1				1
Arthralgia	11	29	10	22	1	7
Asthenia	8	22	7	17	1	5
Atrial fibrillation	2	3			2	3
Atrial flutter		1				1
Back pain	3	4	2	3	1	1
Bacterial test positive	1	1	1	1		
Basal ganglia haemorrhage		1				1
Blister	1	1			1	1
Blood pressure increased	1	3			1	3
Blood pressure systolic increased		2		2		
Blood urine present	1	1	1	1		
Body temperature increased		1		1		
Bone pain	1	1			1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Bradycardia		4
Brain oedema	1	1
Bundle branch block right	1	1
Cardiac arrest	1	2
Cardiac disorder	1	1
Cardiac failure	2	3
Carpal tunnel syndrome	1	1
Cerebral ischaemia		1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	6	7
Chest discomfort	1	3
Chest pain	1	3
Chills	10	30
Circulatory collapse		1
Cold sweat		1
Condition aggravated		1
Confusional state	2	3
Constipation	1	3
Cough	5	9
COVID-19	7	11
COVID-19 pneumonia		3
C-reactive protein increased		2
Deafness		1
Deafness neurosensory	1	1
Death	1	1
Decreased appetite	7	13
Decreased interest		1
Deep vein thrombosis	2	2
Delirium		2
Dementia	1	1
Dermatitis allergic	2	2
Diarrhoea	5	10

Spontaneous			
Nonserious		Serious	
I	C	I	C
			4
		1	1
		1	1
		1	2
		1	1
		2	3
		1	1
			1
		1	1
		6	7
1	2		1
1	2		1
8	24	2	6
			1
	1		
			1
1	2	1	1
	2	1	1
3	7	2	2
1	1	6	10
			3
			2
			1
		1	1
		1	1
6	10	1	3
	1		
		2	2
			2
		1	1
		2	2
3	7	2	3

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
		1	1
		1	2
	2	2	2
		1	1
		1	1
		4	6
			1
	1		
	1	1	1
			1
1	6	7	12
1	1		
		1	1
		1	1
	1	1	1
			1
			1
1		1	1
1	2		
1		1	1
1		1	1
1		1	3
1		1	2
8	31	6	10
	2		1
		2	3
	1	1	1
1	1		
		1	1
1	2		

Disease recurrence 2 2  
 Disorganised speech 1 1  
 Disorientation 1 2  
 Disturbance in attention 1 2  
 Dizziness 2 4  
 Drug eruption 1 1  
 Drug hypersensitivity 1 1  
 Drug ineffective 4 6  
 Duodenal ulcer 1 1  
 Dysarthria 1 1  
 Dyspepsia 1 2  
 Dysphagia 1 1  
 Dyspnoea 8 18  
 Ear pain 1 1  
 Electrocardiogram abnormal 1 1  
 Epilepsy 1 1  
 Epistaxis 1 2  
 Erythema 1 1  
 Escherichia infection 1 1  
 Eye haemorrhage 1 1  
 Eye pain 1 2  
 Eye swelling 1 1  
 Face oedema 1 1  
 Facial paralysis 1 3  
 Fall 1 2  
 Fatigue 14 41  
 Feeling hot 3 3  
 Gait disturbance 2 3  
 Gait inability 1 2  
 Gal bladder disorder 1 1  
 Gastric ulcer 1 1  
 Gastrointestinal disorder 1 2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal necrosis		1				1
Gaze palsy		1				1
General physical health deterioration	1	1			1	1
Glaucoma	1	1			1	1
Grunting		1				1
Guillain-Barre syndrome	1	1			1	1
Haematochezia		1				1
Haemoptysis	1	1			1	1
Haemorrhage		1				1
Hallucination		1				1
Headache	6	21	5	16	1	5
Heart rate increased	2	3			2	3
Hemiparesis	1	1			1	1
Hemiplegia		1				1
Herpes zoster	4	4			4	4
Hordeolum	1	1			1	1
Hyperacusis	1	1			1	1
Hyperglycaemia	3	4			3	4
Hyperhidrosis	3	5	3	5		
Hyperpyrexia	1	1			1	1
Hypersensitivity	3	4			3	4
Hypersomnia		1				1
Hypertension	1	3		1	1	2
Hypoacusis		1		1		
Hypoaesthesia	1	5		2	1	3
Hypoglycaemia	1	2		1	1	1
Hypokalaemia		1				1
Hypokinesia		1		1		
Hypotension		7		3		4
Hypoxia		2				2
Immunoglobulins increased		1		1		
Impaired work ability		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Inflammation		1		1			
Influenza like illness	11	19	9	16	2	3	
Insomnia	5	7	3	4	2	3	
Intestinal infarction		1				1	
Ischaemic stroke	1	2			1	2	
Jaundice		1		1			
Joint effusion		1				1	
Joint swelling	1	1	1	1			
Klebsiella infection		1				1	
Laboratory test abnormal	1	1	1	1			
Lacrimation increased	1	1	1	1			
Leukocytosis	1	1	1	1			
Leukopenia	1	1			1	1	
Limb discomfort	2	2	1	1	1	1	
Lip swelling	1	1			1	1	
Localised oedema	1	1			1	1	
Loss of consciousness	3	7			3	7	
Lymphadenopathy	3	5	1	1	2	4	
Lymph node pain		1		1			
Lymphoedema		1		1			
Malaise	2	5		2	2	3	
Mass	1	1			1	1	
Mesenteric arterial occlusion		1				1	
Mesenteric vascular insufficiency		1				1	
Monoplegia		2				2	
Mucosal dryness		1		1			
Multiple organ dysfunction syndrome		1				1	
Multiple sclerosis		1				1	
Muscle spasms		1				1	
Muscle spasticity		1		1			
Muscular weakness	1	2			1	2	
Musculoskeletal stiffness	1	1	1	1			

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	16	1	6
			1
			1
		2	3
			1
			1
		1	1
		2	2
6	9	1	1
	1		
			1
			2
	2		
1	1		
	1	1	1
2	4		2
3	8	2	3
1	3	1	1
	1	1	1
	3	1	3
			1
	1		
		2	2
			1
		1	1
		2	5
		1	1
			1
	23		
	1	1	4
	1		
		1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation error		23		23		
Product use issue		2		2		
Prostate cancer		1				1
Pruritus	2	6	2	2		4
Psychomotor hyperactivity	1	1			1	1
Pulmonary embolism	1	1			1	1
Purpura	1	1			1	1
Pyrexia	22	54	12	34	10	20
Rash	1	5		1	1	4
Rash macular		3		1		2
Rash maculo-papular		1				1
Rash pruritic		3		1		2
Rash vesicular	1	1	1	1		
Renal failure		1				1
Renal impairment	1	1			1	1
Renal transplant failure	1	1			1	1
Respiratory acidosis		1		1		
Respiratory depression		1				1
Respiratory failure	1	3			1	3
Respiratory tract oedema	1	2			1	2
Restlessness		1		1		
Retching	1	1	1	1		
Rheumatoid arthritis	1	1			1	1
Rhinitis	1	1	1	1		
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive	1	2			1	2
Seizure	1	3			1	3
Sepsis		2				2
Shock		2				2
Skin disorder	1	1			1	1
Sleep disorder		1		1		
Somnolence	3	7		3	3	4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sopor		1				1
Speech disorder		1				1
Splenic infection		1				1
Sputum discoloured	1	1			1	1
Sudden death		2				2
Suspected COVID-19	1	1			1	1
Swelling face	1	2			1	2
Syncope	3	6			3	6
Tachycardia	1	3		1	1	2
Tenderness	1	1	1	1		
Tension headache		1		1		
Throat irritation		1				1
Tinnitus	3	4	1	1	2	3
Tongue oedema	1	2			1	2
Toothache		1		1		
Transient ischaemic attack	1	1			1	1
Transverse sinus thrombosis	1	1			1	1
Tremor		3		2		1
Troponin I increased		1				1
Urinary tract infection	1	1			1	1
Urticaria	2	2			2	2
Vaccination failure	3	4			3	4
Vaccination site anaesthesia		1				1
Vaccination site discomfort		1		1		
Vaccination site erythema		4				4
Vaccination site hypersensitivity		1				1
Vaccination site joint movement impairment		1				1
Vaccination site mass		1				1
Vaccination site oedema		4		2		2
Vaccination site pain	2	15	2	10		5
Vaccination site pruritus		2				2
Vaccination site swelling		2		1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth		1				1
Vena cava thrombosis		1				1
Venous thrombosis limb	1	1			1	1
Ventricular tachycardia		1				1
Vertigo	1	7	1	5		2
Vision blurred	3	4		1	3	3
Vomiting	5	8	4	4	1	4
Wheezing		1		1		
	334	847	133	413	201	434

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess of salivary gland		1				1
Arthralgia	1	2		1	1	1
Asthenia		1		1		
COVID-19		2				2
Decreased appetite		1		1		
Drug ineffective		1				1
Dry mouth		1		1		
Dysphagia		1		1		
Exposure via breast milk		1		1		
Fatigue		2		1		1
Headache		2		2		
Hyperhidrosis		1		1		
Ligament pain	1	1	1	1		
Lymphadenopathy		1				1
Oral pruritus		1		1		
Poor quality sleep		1		1		
Pyrexia		2		2		
Rash maculo-papular		1				1
Spinal pain		1		1		
Tachycardia		1		1		
Taste disorder		1		1		
Throat tightness		1		1		
Vaccination failure		1				1
Vertigo		1		1		
Vomiting		1				1
	2	30	1	20	1	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**DENMARK**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension		1		1		
Abdominal pain	4	15	1	8	3	7
Abdominal pain lower		1				1
Abdominal pain upper		7		4		3
Abdominal tenderness		1				1
Abdominal wall abscess		1				1
Abortion missed	1	2			1	2
Accidental exposure to product		1		1		
Acute kidney injury	1	3			1	3
Acute leukaemia		1				1
Acute myocardial infarction	3	4			3	4
Acute respiratory failure		1				1
Adrenal insufficiency		1				1
Ageusia		1		1		
Alanine aminotransferase increased		1		1		
Allergy to vaccine		1				1
Altered state of consciousness	1	3			1	3
Amnesia	3	3			3	3
Anaemia		1		1		
Anaphylactic reaction	2	19			2	19
Anaphylactic shock	1	6			1	6
Angina pectoris		1				1
Angioedema		6				6
Anosmia		1		1		
Anti-glomerular basement membrane disease	1	1			1	1
Anxiety	1	4		1	1	3
Aphasia	1	1			1	1
Appendicitis		3				3
Arthralgia	6	50	1	30	5	20
Arthritis		1		1		
Arthritis reactive		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	18	1	5	3	13
Asthma	1	5		1	1	4
Atrial fibrillation	3	6			3	6
Atrial flutter		2				2
Auricular swelling		1		1		
Axillary pain		5		5		
Back pain		7		6		1
Bacterial infection		1				1
Balance disorder		1				1
Blood bilirubin decreased		1		1		
Blood count abnormal		1		1		
Blood creatine phosphokinase increased		1				1
Blood glucose increased		1		1		
Blood lactate dehydrogenase abnormal		1		1		
Blood lactic acid increased		1		1		
Blood potassium decreased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased		3		1		2
Blood pressure fluctuation		1		1		
Blood pressure increased	1	9		3	1	6
Blood pressure systolic increased		1				1
Blood sodium decreased		1		1		
Blood urea decreased		1				1
Blood uric acid abnormal		1		1		
Body temperature increased	1	5		4	1	1
Bradycardia	2	4			2	4
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchospasm	1	2			1	2
Burning sensation	1	6	1	4		2
Bursitis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carbon monoxide poisoning	1	1			1	1
Cardiac arrest	2	2			2	2
Cardiogenic shock		1				1
Cardiovascular disorder	1	1			1	1
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis	1	2			1	2
Cerebrovascular accident	7	11			7	11
Chest discomfort	2	22		8	2	14
Chest pain	7	17		4	7	13
Chills	2	57		40	2	17
Choking sensation		1				1
Chorioretinitis		1				1
Chronic obstructive pulmonary disease	2	3			2	3
Cold sweat	1	6		4	1	2
Colitis	1	1			1	1
Condition aggravated	1	8			1	8
Confusional state	2	7			2	7
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1		1		
Contusion		1		1		
Coordination abnormal		3				3
Coronary artery thrombosis	2	2			2	2
Cough	3	22	1	13	2	9
COVID-19	4	12	3	3	1	9
C-reactive protein increased	3	13	1	4	2	9
Crying		1				1
Cystitis		1		1		
Death	5	10			5	10
Decreased appetite		1		1		
Deep vein thrombosis	4	5			4	5
Delirium		2				2
Delusion		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dementia	1	1			1	1
Depressed level of consciousness	1	7			1	7
Derealisation	1	5		4	1	1
Dermatitis allergic		2				2
Diarrhoea	7	31	4	20	3	11
Diplopia	2	3			2	3
Discomfort	2	13	1	4	1	9
Disease recurrence		1		1		
Disorientation		1				1
Disseminated intravascular coagulation	1	1			1	1
Disturbance in attention	2	4		1	2	3
Dizziness	10	130	6	71	4	59
Dizziness exertional		1		1		
Dizziness postural		2				2
Drug ineffective		4				4
Dry eye		1		1		
Dry mouth		5		4		1
Dry skin		1		1		
Dry throat	1	1	1	1		
Dysaesthesia		2		1		1
Dysarthria	1	2			1	2
Dysgeusia	1	4		2	1	2
Dyspepsia		1				1
Dysphagia	2	8	1	2	1	6
Dysphonia		7		5		2
Dyspnoea	17	79	2	23	15	56
Dyspnoea at rest		1				1
Dyspnoea exertional	2	5	1	4	1	1
Dysstasia		1				1
Ear discomfort		2		2		
Ear pruritus		1				1
Eating disorder		1		1		

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 \* AE=Adverse Event  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eczema	1	1	1	1		
Electrocardiogram QT prolonged		1				1
Electrocardiogram ST segment depression		1				1
Epistaxis	1	4		1	1	3
Erythema	2	38	1	23	1	15
Exposure via skin contact		1		1		
Eye irritation		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		2				2
Eye pain		6		6		
Eye pruritus		5		4		1
Eye swelling		1		1		
Face oedema		2				2
Facial paralysis	3	3			3	3
Facial paresis	2	2			2	2
Faeces soft		1		1		
Fall	1	5			1	5
Fatigue	20	153	7	104	13	49
Feeling abnormal	1	6		4	1	2
Feeling cold		11		7		4
Feeling hot	1	24	1	11		13
Feeling of body temperature change		3				3
Femur fracture		1				1
Fibrin D dimer increased	1	1			1	1
Flatulence		1		1		
Fluid intake reduced		1		1		
Flushing	1	8	1	3		5
Foaming at mouth		2		1		1
Gait disturbance	1	2		1	1	1
Gastric ulcer	1	1			1	1
Gastrointestinal disorder		1		1		
Gastrointestinal necrosis	1	1			1	1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	1	1
1	2	2	10
	1		
1	1		
			1
		1	1
		1	1
		1	1
	1		
1	1		
1	1		
		1	1
			3
			1
	1		
20	188	14	77
	2		1
			1
	1		
	3		
3	9	3	5
		1	1
		3	4
		1	1
1	2		
	1		
	4		
	2		1
	1		
			1
	7	2	6
1	6		16
	1	2	3

Gastroesophageal reflux disease	1	2
General physical health deterioration	3	12
Glossodynia		1
Groin pain	1	1
Guillain-Barre syndrome		1
Haematemesis	1	1
Haematochezia	1	1
Haematology test abnormal	1	1
Haematoma		1
Haematuria	1	1
Haemodynamic instability	1	1
Haemoglobin decreased		3
Hallucination, visual		1
Hand dermatitis		1
Headache	34	265
Head discomfort		3
Head injury		1
Heart rate abnormal		1
Heart rate decreased		3
Heart rate increased	6	14
Heart rate irregular	1	1
Hemiparesis	3	4
Hemiplegia	1	1
Hepatic enzyme increased	1	2
Herpes zoster		1
Hot flush		4
Hyperacusis		2
Hyperchlorhydria		1
Hyperglycaemia		1
Hyperhidrosis	2	13
Hypersensitivity	1	22
Hypersomnia	2	4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	3	19	1	7	2	12
Hypertonia		1				1
Hyperventilation		5				5
Hypoacusis	1	3		1	1	2
Hypoaesthesia	2	5	2	3		2
Hypoaesthesia oral		2				2
Hypoglycaemia		2		1		1
Hypokalaemia		2				2
Hypophagia		1		1		
Hypotension	1	7			1	7
Hypothermia		2				2
Hypotonia	1	1	1	1		
Hypoxia		1				1
Idiopathic intracranial hypertension	1	1			1	1
Idiopathic pulmonary fibrosis	1	1			1	1
Illrd nerve paresis		1				1
Illness		1		1		
Immune-mediated adverse reaction		1				1
Immunisation reaction		1		1		
Inappropriate schedule of product administration	2	4	2	4		
Incorrect route of product administration		3		2		1
Infarction	1	1			1	1
Infection	1	3	1	2		1
Influenza		9		5		4
Influenza like illness	3	18		9	3	9
Initial insomnia		1		1		
Injected limb mobility decreased		1		1		
Injection site erythema		1		1		
Injection site pain		2		2		
Injection site swelling		1		1		
Insomnia	1	3	1	3		
Intestinal ischaemia	1	1			1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	7	2	12
			1
			5
	1	1	2
2	3		2
			2
	1		1
			2
	1		
		1	7
			2
1	1		
			1
		1	1
		1	1
			1
	1		
			1
	1		
2	4		
	2		1
		1	1
1	2		1
	5		4
	9	3	9
	1		
	1		
	1		
	2		
	1		
1	3		
		1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Joint stiffness		2		1			1
Joint swelling		5		2			3
Joint warmth		1		1			
Ketoacidosis		1					1
Lacrimation increased		2		2			
Lethargy		3		3			
Leukocytosis		1		1			
Leukopenia		1					1
Limb discomfort	1	9		4	1		5
Lip pruritus		1					1
Lip swelling		2					2
Livedo reticularis		1					1
Loss of consciousness	1	7			1		7
Loss of control of legs		1					1
Lung disorder	2	2			2		2
Lymphadenitis		2		1			1
Lymphadenopathy	1	25	1	17			8
Lymph node pain		4		4			
Lymphopenia	1	3	1	1			2
Malaise	14	121	4	67	10		54
Maternal exposure during pregnancy	1	3	1	2			1
Melaena	1	1			1		1
Memory impairment	1	1			1		1
Meniere's disease		1					1
Mesenteric artery thrombosis	1	1			1		1
Metabolic acidosis	1	1			1		1
Metabolic alkalosis		1		1			
Migraine	1	6	1	4			2
Mobility decreased	1	3	1	3			
Monoparesis	1	2			1		2
Monoplegia		2					2
Motor dysfunction		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multimorbidity	1	1			1	1
Muscle discomfort		1				1
Muscle fatigue	2	4	2	4		
Muscle spasms	1	6		3	1	3
Muscle tightness		2		1		1
Muscle twitching		1		1		
Muscular weakness	2	10	2	4		6
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness		1				1
Myalgia	6	103	1	77	5	26
Mydriasis		1		1		
Myelitis		1				1
Myelosuppression		1				1
Myocardial infarction	1	1			1	1
Nasal congestion		5		5		
Nasal discomfort		1				1
Nasal pruritus	1	3	1	1		2
Nasopharyngitis		3		3		
Nausea	14	136	10	87	4	49
Neck pain	2	8	1	6	1	2
Nervous system disorder		1				1
Neuralgia		1				1
Night sweats		1		1		
Obliterative bronchiolitis		1				1
Obstructive airways disorder		2				2
Ocular hyperaemia		1		1		
Odynophagia		2		1		1
Oedema	1	2			1	2
Oedema peripheral	2	5	1	3	1	2
Oesophageal spasm		1		1		
Off label use	2	6	2	6		
Oral discomfort		2		1		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
2	4		
	3	1	3
	1		1
	1		
2	4		6
			1
			1
1	77	5	26
	1		
			1
			1
		1	1
	5		
			1
1	1		2
	3		
10	87	4	49
1	6	1	2
			1
			1
	1		
			1
			2
		1	2
	1		
	1		
		1	
1	3	1	2
	1		
2	6		
	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oral fungal infection		1		1			
Oral mucosal blistering		1		1			
Oral mucosal eruption		1		1			
Oral pruritus		2		2			
Oropharyngeal discomfort		3		2			1
Oropharyngeal pain	2	15	1	13	1		2
Oxygen saturation decreased	2	6	1	1	1		5
Pain	4	22	3	16	1		6
Painful respiration		2		2			
Pain in extremity	5	41	2	35	3		6
Pain of skin		4		2			2
Pallor	1	11		3	1		8
Palpitations	1	27	1	15			12
Pancreatitis acute		1					1
Pancytopenia	1	1			1		1
Panic attack		1					1
Paraesthesia	2	37		22	2		15
Paraesthesia mucosal		1					1
Paraesthesia oral	3	13	2	7	1		6
Paresis		1					1
Parkinson's disease		1					1
Periarthritis		1		1			
Pericarditis	1	1			1		1
Periorbital swelling		1		1			
Peripheral coldness	1	1			1		1
Peripheral swelling	2	8	1	5	1		3
Pharyngeal oedema		1					1
Pharyngeal paraesthesia		1		1			
Pharyngeal swelling		10		2			8
Photophobia	2	5		1	2		4
Photopsia		3		1			2
Photosensitivity reaction	1	1	1	1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pleural effusion		2				2	
Pleuritic pain	1	1	1	1			
Pneumonia	4	8			4	8	
Pneumonia bacterial		1				1	
Poor quality sleep		1		1			
Postmenopausal haemorrhage		1				1	
Presyncope	3	23	3	8		15	
Productive cough		1		1			
Product use issue		5		5			
Prolonged expiration		1				1	
Pruritus	3	41	3	29		12	
Pulmonary arterial hypertension		1				1	
Pulmonary arterial pressure increased	1	1	1	1			
Pulmonary embolism	11	14			11	14	
Pulmonary fibrosis		1				1	
Pulmonary oedema	1	4			1	4	
Pulmonary pain		1		1			
Pulse abnormal	1	1			1	1	
Pyrexia	18	190	6	125	12	65	
Rash	2	33	2	20		13	
Rash erythematous	1	18		11	1	7	
Rash macular		2		2			
Rash morbilliform		1		1			
Rash papular		1		1			
Rash pruritic	1	9		7	1	2	
Rash vesicular		1		1			
Renal colic		1		1			
Renal failure		3				3	
Renal pain		1				1	
Respiration abnormal	1	2			1	2	
Respiratory acidosis	2	4			2	4	
Respiratory disorder		1		1			

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Respiratory distress	1	1
Respiratory failure	3	7
Respiratory tract infection bacterial		1
Restlessness	1	9
Rhabdomyolysis		1
Rheumatoid arthritis	1	1
Rhinalgia		1
Rhinorrhoea	1	7
Salivary gland enlargement		1
Salivary gland pain		1
Salivary hypersecretion		1
SARS-CoV-2 test positive		1
Scratch		1
Seizure		2
Sensation of foreign body	2	4
Sensory disturbance	2	9
Sensory loss		2
Sepsis	1	1
Severe acute respiratory syndrome		1
Sinus tachycardia		2
Skin burning sensation		1
Skin lesion		1
Sleep disorder	2	3
Sneezing		5
Somnolence	2	7
Speech disorder	1	2
Splenic infarction	1	1
Staphylococcal infection		1
Stomatitis		1
Stress cardiomyopathy		1
Stridor		1
Sudden cardiac death		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		3	7
			1
	6	1	3
			1
		1	1
	1		
	5	1	2
	1		
	1		
			1
			1
			2
		2	4
1	7	1	2
			2
		1	1
			1
	2		
			1
	1		
2	3		
	5		
1	4	1	3
		1	2
		1	1
			1
	1		
			1
			1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death		3				3
Swelling	1	7	1	6		1
Swelling face	1	19	1	7		12
Swelling of eyelid		2		1		1
Swollen tongue		10		2		8
Syncope	3	14			3	14
Systemic immune activation	1	1			1	1
Systemic inflammatory response syndrome		1				1
Tachycardia	1	8		2	1	6
Tachypnoea		1				1
Taste disorder		3		2		1
Tenderness	3	12	1	7	2	5
Therapeutic response unexpected		1		1		
Throat irritation	2	8	1	3	1	5
Throat tightness		5		2		3
Thrombocytopenia	2	3			2	3
Thrombophlebitis superficial	1	1			1	1
Thrombosis	5	6			5	6
Tinnitus	1	5		3	1	2
Tongue discomfort		1		1		
Tongue pruritus		2				2
Tonic convulsion		1				1
Tonsillar hypertrophy		1		1		
Toxicity to various agents		1				1
Transient ischaemic attack	1	2			1	2
Tremor	4	18		5	4	13
Troponin I increased		2		1		1
Troponin increased	1	2			1	2
Tunnel vision		2				2
Type I hypersensitivity		1				1
Underdose		2		2		
Upper respiratory tract infection		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infection	1	3			1	3
Urinary tract infection bacterial		1				1
Urine odour abnormal	1	1			1	1
Urosepsis	1	1			1	1
Urticaria	6	34	3	21	3	13
Vaccination complication		2		1		1
Vaccination site abscess		1				1
Vaccination site discolouration		1				1
Vaccination site discomfort	1	3	1	3		
Vaccination site erythema	6	35	6	32		3
Vaccination site haematoma		3		3		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		2		
Vaccination site inflammation		4		4		
Vaccination site irritation		2		1		1
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1		1		
Vaccination site necrosis		1				1
Vaccination site nodule		1		1		
Vaccination site pain	18	168	16	152	2	16
Vaccination site paraesthesia		3		3		
Vaccination site pruritus	2	10	2	9		1
Vaccination site rash		5		2		3
Vaccination site reaction		1		1		
Vaccination site swelling	4	47	4	42		5
Vaccination site thrombosis		1				1
Vaccination site warmth	2	17	2	16		1
Vaginal discharge		1		1		
Vaginal haemorrhage	1	2		1	1	1
Vasodilatation		1				1
Ventricular tachycardia	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo		3		1		2
Viral infection		1		1		
Vision blurred		4		1		3
Visual impairment		2		1		1
Vlith nerve paralysis	1	1			1	1
Vomiting	4	40	2	21	2	19
Vulvovaginal pain		1		1		
Vulvovaginal pruritus		1		1		
Weight increased	1	1	1	1		
Wheezing		1				1
White matter lesion		1		1		
Wound		1				1
	495	3,320	174	1863	321	1457

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3		1	1	2
Abdominal pain upper	1	2			1	2
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Acute respiratory distress syndrome		1				1
Aggression	1	2			1	2
Altered state of consciousness	1	1			1	1
Amnesia		2				2
Anaemia		1				1
Anaphylactic reaction	1	1			1	1
Angioedema		1				1
Anxiety		1		1		
Aphasia	1	1			1	1
Arthralgia	1	3		2	1	1
Aspiration		1				1
Asthenia		5		1		4
Atrial fibrillation	2	3			2	3
Back pain		3		2		1
Bacteraemia		1				1
Balance disorder	1	1			1	1
Basilar artery occlusion	1	1			1	1
Blood albumin decreased		1		1		
Blood chloride increased		1		1		
Blood creatinine increased		1				1
Blood glucose increased		1		1		
Blood pressure decreased		1		1		
Blood pressure systolic increased	1	2		1	1	1
Body temperature increased		1		1		
Bronchitis		1				1
Bronchospasm	1	1			1	1
Calcium ionised increased		1		1		
Cardiac arrest	5	6			5	6

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiac failure	1	1
Cardiovascular disorder	1	1
Cerebral thrombosis	1	1
Cerebrovascular accident	5	6
Chest discomfort		1
Chills	1	7
Chronic obstructive pulmonary disease	1	4
Circulatory collapse		1
Clonic convulsion		1
Cognitive disorder	1	1
Colitis	1	1
Coma		1
Condition aggravated		3
Confusional state	3	5
Contusion	1	1
Cough	2	4
COVID-19		9
C-reactive protein increased	2	4
Death	3	6
Decreased appetite	1	6
Deep vein thrombosis	4	4
Dehydration	1	2
Delirium	3	6
Depressed level of consciousness	2	4
Diarrhoea	2	6
Discomfort	1	1
Disease recurrence		1
Disturbance in attention	1	2
Dizziness	2	8
Drug ineffective		4
Drug interaction		1
Dysarthria	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
		5	6
			1
1	6		1
		1	4
			1
			1
		1	1
1	1		
			1
			3
	1	3	4
		1	1
	1	2	3
	1		8
1	1	1	3
		3	6
	1	1	5
		4	4
		1	2
		3	6
		2	4
	2	2	4
		1	1
	1		
	1	1	1
	4	2	4
			4
			1
		1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1	8	19
	1		1
		1	1
		2	2
			1
	1		
	1		
	1		
			1
	1		1
	2		
	3	3	4
2	18	2	8
	1	1	1
	1		
	3		
1	1	1	1
		1	2
	2		1
		1	1
	1		
			1
			1
			1
	1	1	1
3	19	2	7
			1

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\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparesis	1	2			1	2
Hemiplegia	1	1			1	1
Herpes zoster		1				1
Hot flush		2		2		
Hyperhidrosis	1	2		1	1	1
Hypersensitivity	1	2	1	1		1
Hypoacusis		1		1		
Hypoaesthesia		2				2
Hypophagia		1		1		
Hypotension	2	4		1	2	3
Ileus paralytic		1				1
Immune-mediated hepatitis	1	1			1	1
Immune thrombocytopenia		1				1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration		1		1		
Influenza	1	2		1	1	1
Influenza like illness		7		7		
Insomnia		2		2		
Lacrimation increased		1		1		
Limb discomfort		1		1		
Lip swelling	1	2			1	2
Livedo reticularis	1	1			1	1
Loss of control of legs		1				1
Lung infiltration	1	1			1	1
Lymphadenopathy		4		3		1
Lymphangitis	1	1			1	1
Malaise	3	15		5	3	10
Micturition urgency		1				1
Migraine	1	1			1	1
Mobility decreased	1	3			1	3
Muscle discomfort		1		1		
Muscle twitching		1				1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
			1
	10	2	7
			1
	1		
	6	1	5
		1	1
	1		
		1	1
		2	2
	4		
	4	1	2
		1	2
	4	1	3
	3	2	2
			1
1	1		
	1		
	1	1	1
		1	1
		1	1
		1	2
			1
		1	2
	1		
		1	1
			1
	1	1	1
	4	4	12

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\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia aspiration		1				1
Pneumonitis		1				1
Presyncope	1	2			1	2
Productive cough	2	2			2	2
Product use issue		2		2		
Pruritus		4		3		1
Pulmonary embolism	7	9			7	9
Pulmonary fibrosis	1	1			1	1
Pulmonary oedema	1	2			1	2
Pyrexia	4	35	2	22	2	13
Rales		1				1
Rash	2	7	2	7		
Rash erythematous		1		1		
Rash pruritic	2	3		1	2	2
Renal failure	1	1			1	1
Respiratory arrest	2	3			2	3
Respiratory failure	1	7			1	7
Respiratory rate decreased		1				1
Restlessness		1		1		
Retinal vascular thrombosis	1	1			1	1
Rheumatoid factor increased	1	1			1	1
Rhinitis		1		1		
Seasonal allergy		1		1		
Seizure	1	2			1	2
Sepsis		1				1
Septic shock		1				1
Skin abrasion	1	1			1	1
Skin haemorrhage	1	1			1	1
Sneezing		1		1		
Somnolence		5		4		1
Speech disorder		1		1		
Splenic haemorrhage	1	1			1	1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sputum discoloured	1	1			1	1
Sudden death	1	1			1	1
Swelling		1		1		
Swollen tongue	1	1			1	1
Syncope	2	4			2	4
Systemic immune activation	1	1			1	1
Tachypnoea		1				1
Taste disorder		1		1		
Temporomandibular joint syndrome		1				1
Thinking abnormal		1				1
Throat irritation		2		2		
Thrombocytopenia	1	1			1	1
Thrombocytosis	1	1			1	1
Thrombosis	4	5			4	5
Tinnitus		1		1		
Tracheal stenosis	1	1			1	1
Transplant failure		1				1
Tremor		2		2		
Unresponsive to stimuli	1	1			1	1
Urinary incontinence		1				1
Urticaria	2	6	1	4	1	2
Vaccination site erythema	1	1	1	1		
Vaccination site movement impairment		1		1		
Vaccination site pain	2	27	2	26		1
Vaccination site rash		1		1		
Vaccination site swelling		3		2		1
Vasculitis	1	1	1	1		
Vomiting	3	8	2	4	1	4
Wound complication		1		1		
Wound infection	1	1			1	1
	187	623	20	252	167	371

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 \* AE=Adverse Event  
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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	3	3			3	3
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Exposure via breast milk		1		1		
Fatigue		2		2		
Headache		2		2		
Hypoaesthesia		1		1		
Influenza like illness		2		2		
Myalgia		2		2		
Product administration error		1		1		
Product preparation issue		1		1		
Reaction to excipient	2	2			2	2
	7	19		12	7	7

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Country Where Event Occurred

**ECUADOR**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Blood pressure increased		1		1		
COVID-19		3				3
Depressed mood		1		1		
Diarrhoea		3		3		
Discomfort	2	3	2	3		
Dizziness		2		2		
Drug ineffective		2				2
Face oedema		1		1		
Fatigue	1	1	1	1		
Lip oedema		1		1		
Lymphadenitis	1	1	1	1		
Myalgia	1	1	1	1		
Oropharyngeal pain		1		1		
Pain	1	1	1	1		
Pyrexia	3	4	3	4		
SARS-CoV-2 test positive		1		1		
Suspected COVID-19		1				1
Vaccination site pain	1	1	1	1		
Vomiting		1		1		
	11	31	10	24	1	7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Blood pressure increased	1	1	1	1		
Chills	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	3		2	1	1
Diarrhoea	1	1	1	1		
Discomfort	1	1	1	1		
Drug ineffective	1	1			1	1
Eye pain		1		1		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Laryngitis		1		1		
Limb discomfort	1	1	1	1		
Lung infiltration	1	1	1	1		
Pyrexia	2	2	2	2		
Thrombotic stroke	1	1			1	1
Vaccination site pain	3	4	3	4		
	18	23	15	20	3	3

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Drug ineffective		1				1
Laryngitis		1		1		
Musculoskeletal disorder		1		1		
Tracheitis		1		1		
Vaccination site pain		1		1		
		6		4		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**EGYPT**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ESTONIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Abdominal pain upper		1				1
Acute disseminated encephalomyelitis		1				1
Ageusia	1	2	1	2		
Anxiety		1				1
Aphonia	1	1			1	1
Arthralgia	6	14	6	14		
Asthenia	8	22	8	17		5
Asymptomatic COVID-19		1				1
Back pain		3		1		2
Balance disorder	1	2	1	2		
Blood creatine phosphokinase increased		1		1		
Blood pressure increased		1				1
Body temperature decreased	1	1	1	1		
Bone contusion		1				1
Bone pain		2		1		1
Bradycardia		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain	3	5	3	3		2
Chills	8	21	8	20		1
Cognitive disorder		1		1		
Cold sweat		1				1
Condition aggravated	1	1	1	1		
Contusion		1				1
Cough	1	3	1	3		
COVID-19	21	24		1	21	23
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased	1	1	1	1		
Decreased appetite	1	2	1	2		
Demyelination		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	3	1	3		
Disease recurrence	1	1	1	1		
Dizziness	6	13	6	9		4
Drug hypersensitivity		1				1
Drug ineffective	3	5			3	5
Dysgeusia		6		4		2
Dyspepsia	1	1	1	1		
Dysphagia	1	1			1	1
Dyspnoea	6	12	5	10	1	2
Dysuria		1				1
Ear disorder	1	1	1	1		
Ear pain	1	1	1	1		
Exposure during pregnancy	2	4	2	4		
Extensive swelling of vaccinated limb		1		1		
Facial nerve disorder		1		1		
Facial pain	1	2	1	2		
Facial paralysis		1				1
Fall		2		2		
Fatigue	3	14	3	13		1
Feeling hot	1	2	1	2		
Flushing		1		1		
Fracture		1				1
Haematoma		1		1		
Headache	8	36	8	32		4
Heart rate increased		1				1
Hyperhidrosis	3	3	3	3		
Hypersensitivity		4		1		3
Hypertension		4		3		1
Hypoaesthesia		4		4		
Hypoaesthesia oral		1		1		
Hypopnoea		1				1
Hypotension		2				2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothermia	3	5			3	5
Immunisation anxiety related reaction		9		8		1
Immunisation reaction		1				1
Increased appetite		1		1		
Influenza like illness	1	1	1	1		
Insomnia	4	5	4	5		
Intranasal paraesthesia		1		1		
Joint range of motion decreased	1	1	1	1		
Joint stiffness	1	1	1	1		
Joint swelling	1	1	1	1		
Laryngeal oedema	1	2			1	2
Lip swelling		1				1
Loss of consciousness		1				1
Lymphadenopathy	1	4	1	4		
Malaise		8		6		2
Maternal exposure during pregnancy		3		3		
Migraine with aura		1		1		
Mouth swelling		1				1
Muscle spasms		1		1		
Muscular weakness	1	3	1	3		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness		1				1
Myalgia	6	14	6	13		1
Myelitis transverse		1				1
Nasal congestion		1		1		
Nausea	4	14	4	10		4
Neck pain		2				2
Nervousness		1				1
Ocular discomfort	1	1	1	1		
Off label use		1		1		
Oral herpes		2		2		
Oropharyngeal discomfort		1				1

\* I=Interval, C=Cumulative  
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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
1	1		1
2	8		
			1
	3		
	1		
1	13		3
	3		
1	1		
	1		
	1		
1	1		
			1
			1
	1		
1	1		
			1
12	32		1
			1
1		1	1
	1		
	3		
			1
1	1		
3	3		
	1		
1	8		1
			1
			1
1	1		
		5	10
	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	3	1	3		
Tendon pain	1	1	1	1		
Throat tightness		1				1
Thrombophlebitis	1	1	1	1		
Tinnitus	1	2	1	1		1
Tremor	1	2	1	2		
Type I hypersensitivity		1				1
Type IV hypersensitivity reaction	1	1			1	1
Underdose		1		1		
Urinary retention		1				1
Vaccination failure	17	18			17	18
Vaccination site erythema	1	5	1	5		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	1	2	1	2		
Vaccination site oedema	2	6	2	6		
Vaccination site pain	4	28	4	28		
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash	1	2	1	2		
Vaccination site swelling	1	4	1	4		
Vaccine breakthrough infection	1	1			1	1
Ventricular extrasystoles		1				1
Vision blurred	1	2	1	2		
Visual impairment		1				1
Vomiting	1	2	1	2		
Wound		1				1
	191	549	134	393	57	156

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Asthenia		1				1
Blindness unilateral	1	1			1	1
Cardiac failure congestive	1	1			1	1
Cerebral infarction	1	1			1	1
Chills		1		1		
Chronic obstructive pulmonary disease	1	1			1	1
COVID-19	3	3			3	3
Death	2	2			2	2
Deep vein thrombosis	1	1			1	1
Diplopia	1	1	1	1		
Disease recurrence		1				1
Dizziness		1		1		
Drug ineffective	1	1			1	1
Dysphagia		1		1		
Headache	1	2	1	2		
Hypertensive heart disease	1	1			1	1
Hypoaesthesia oral		1		1		
Hypoglycaemia	1	1			1	1
Illrd nerve disorder	1	1			1	1
Immunisation anxiety related reaction		1		1		
Lymphadenopathy		1		1		
Malaise		2		1		1
Nausea		2		2		
Paraesthesia	1	2	1	2		
Peripheral sensory neuropathy		1				1
Pharyngeal hypoaesthesia		1		1		
Psoriasis		1				1
Pulmonary embolism	1	2			1	2
Pulmonary oedema	1	1			1	1
Pyrexia	1	4	1	3		1
Respiratory failure	2	2			2	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal vascular thrombosis	1	1			1	1
Seizure		1				1
Suspected COVID-19	1	1			1	1
Syncope		1				1
Trigeminal nerve disorder	1	1			1	1
Vaccination failure	3	3			3	3
Vaccination site erythema		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		6		6		
	29	60	4	26	25	34

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Myalgia		1		1
Pyrexia		1		1
Vaccination site erythema		1		1
Vaccination site pain		1		1
		5		5

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Country Where Event Occurred

**FINLAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2				2
Abdominal distension	1	3		2	1	1
Abdominal pain	2	11		3	2	8
Abdominal pain lower		3		1		2
Abdominal pain upper		5				5
Abdominal symptom		2		1		1
Abortion spontaneous	1	1			1	1
Acute myocardial infarction		1				1
Ageusia		1				1
Alanine aminotransferase increased		1				1
Allergy to vaccine		2				2
Amaurosis fugax	1	1			1	1
Amnesia		1				1
Anaesthesia		1		1		
Anaphylactic reaction	4	16			4	16
Anaphylactic shock		3				3
Anuria	2	2			2	2
Anxiety		1				1
Aortitis	1	1			1	1
Aphasia	1	1			1	1
Aphonia		3		1		2
Apnoea		2				2
Appendicitis		1				1
Arrhythmia	2	19			2	19
Arthralgia	9	60	1	21	8	39
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	8	49		8	8	41
Asthenopia		2				2
Asthma		1				1
Atrial fibrillation	4	5			4	5
Axillary pain		14		6		8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	1	14		7	1	7
Bacterial test positive	2	3			2	3
Balance disorder		2				2
Bedridden		1				1
Blepharitis		1				1
Blister	1	2		1	1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood glucose increased		1				1
Blood lactic acid decreased		1		1		
Blood pressure decreased	2	7		1	2	6
Blood pressure diastolic decreased		1				1
Blood pressure diastolic increased		2				2
Blood pressure fluctuation		1				1
Blood pressure increased	3	21		3	3	18
Blood pressure systolic decreased		1				1
Blood uric acid increased		1				1
Body temperature decreased		2				2
Body temperature fluctuation		1				1
Body temperature increased		2		1		1
Bone pain		3		1		2
Breast cyst		1				1
Breast pain		1				1
Breast swelling		1				1
Breast tenderness		1				1
Breath sounds abnormal		2		1		1
Bronchitis		2				2
Burning sensation	1	9		3	1	6
Cardiac arrest	1	1			1	1
Cardiac failure	1	1			1	1
Cardiac flutter	1	1			1	1
Cardiac hypertrophy	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system inflammation	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral infarction	5	10			5	10
Cerebrovascular accident		1				1
Cervical spinal stenosis		1				1
Cheilitis		1		1		
Chest discomfort	3	15		4	3	11
Chest pain	1	9		2	1	7
Chest X-ray abnormal	1	1			1	1
Chills	3	39		17	3	22
Choking sensation		1				1
Cholelithiasis		1				1
Circulatory collapse	2	2			2	2
Clumsiness		1		1		
Cognitive disorder		3		1		2
Cold sweat		3		1		2
Coma scale abnormal		2				2
Condition aggravated		3				3
Confusional state	1	4			1	4
Congestive cardiomyopathy		1				1
Conjunctival hyperaemia	1	1			1	1
Contusion	1	2		1	1	1
Coordination abnormal	1	1	1	1		
Corneal infection	1	1			1	1
Cough	4	18	1	1	3	17
COVID-19	2	2			2	2
C-reactive protein increased		11		2		9
CREST syndrome		1				1
Crohn's disease		1				1
CSF immunoglobulin increased	1	1			1	1
CSF protein increased		1				1
Cyanosis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cystitis	1	1			1	1
Deafness unilateral	2	2			2	2
Death		7				7
Decreased appetite	6	9			6	9
Deep vein thrombosis	2	3			2	3
Dehydration	1	1			1	1
Delusion		2		2		
Dementia Alzheimer's type		2				2
Demyelination	1	1			1	1
Depressed level of consciousness		5				5
Derealisation		1		1		
Diarrhoea	4	19		8	4	11
Diplopia	2	2	2	2		
Discomfort		3		1		2
Disease recurrence	2	5			2	5
Disturbance in attention		1				1
Diverticulitis	1	2			1	2
Dizziness	8	49	1	14	7	35
Dry eye		1				1
Dry mouth		2				2
Dysarthria	5	7	1	1	4	6
Dysgeusia	1	3		1	1	2
Dyskinesia		1		1		
Dysmetria	1	1			1	1
Dyspepsia	1	1			1	1
Dysphagia		7		2		5
Dysphonia	1	5		2	1	3
Dyspnoea	12	67		7	12	60
Dyspnoea exertional	1	4			1	4
Dysstasia		2				2
Dysuria		2		1		1
Ear discomfort		2		2		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		1
	1		
1	1		
			1
		1	1
		1	1
			1
			2
	1	1	2
			2
1	11	2	26
			1
		1	2
		1	2
	2		
	3		2
			1
	1		
			1
	1		4
	1		
	3	1	5
	1	2	10
	2		2
		2	11
			2
	1	4	10
	36	15	71
	1		
			1
	2	3	12
	4	1	10

Ear pain		4
Ear pruritus		1
Eating disorder	1	1
Eczema		1
Electrocardiogram ST segment depression	1	1
Electrocardiogram T wave inversion	1	1
Encephalitis		1
Epilepsy		2
Epistaxis	1	3
Erysipelas		2
Erythema	3	37
Erythema multiforme		1
Erythema of eyelid	1	2
Exercise tolerance decreased	1	2
Extensive swelling of vaccinated limb		2
Extrasystoles		5
Eye disorder		1
Eye irritation		1
Eyelid irritation		1
Eyelid oedema		5
Eye movement disorder		1
Eye pain	1	8
Face oedema	2	11
Facial pain		4
Facial paralysis	2	11
Facial paresis		2
Fall	4	11
Fatigue	15	107
Fear		1
Feeding disorder		1
Feeling abnormal	3	14
Feeling cold	1	14

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling drunk	1	1			1	1
Feeling hot	1	25		9	1	16
Female genital tract fistula		1				1
Fibrin D dimer increased	1	1	1	1		
Fixed eruption		2		2		
Flank pain		1				1
Flatulence		1		1		
Flushing		8		2		6
Food allergy		2				2
Food aversion		1				1
Gait disturbance		5		1		4
Gait inability		1				1
Gastric disorder		1		1		
Gastrointestinal necrosis	1	1			1	1
Gaze palsy		2				2
General physical health deterioration	5	18		2	5	16
Giant cell arteritis	1	1			1	1
Gingival swelling		1		1		
Glossodynia		1				1
Grip strength decreased		1				1
Groin pain		1				1
Haematochezia		1				1
Haematoma	1	3		2	1	1
Haematuria	1	1			1	1
Haemodynamic instability	1	1			1	1
Haemoglobin decreased	1	1			1	1
Hallucination		1				1
Hallucination, auditory		2				2
Headache	12	125	2	37	10	88
Head discomfort	2	8	1	3	1	5
Head injury		2		1		1
Heart rate decreased		2		1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	2	20		1	2	19
Heart rate irregular	1	3		1	1	2
Helplessness		1		1		
Hemianaesthesia	1	19			1	19
Hemihyperaesthesia		1				1
Hemiparaesthesia		3				3
Hemiparesis	3	4			3	4
Hemiplegia	1	1			1	1
Herpes ophthalmic	1	1			1	1
Herpes zoster	3	11		6	3	5
Herpes zoster oticus		1				1
Hip fracture	1	1			1	1
Hot flush		2				2
Hyperaesthesia		4				4
Hyperhidrosis	1	11		3	1	8
Hyperlactacidaemia	1	1			1	1
Hypersensitivity	3	17		1	3	16
Hypersomnia		2		1		1
Hypertension		6		1		5
Hypoacusis	2	3	2	3		
Hypoaesthesia	9	35	2	12	7	23
Hypoaesthesia oral	1	13	1	5		8
Hypoaesthesia teeth		1		1		
Hypokalaemia		5				5
Hyponatraemia	1	1			1	1
Hyposmia	1	1	1	1		
Hypotension	1	2			1	2
Hypothermia		3				3
Hypotonia		2				2
Illness		1				1
Immune thrombocytopenia	1	1			1	1
Impaired reasoning		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability	3	13			3	13
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	1	10	1	10		
Increased tendency to bruise	1	1			1	1
Increased upper airway secretion		5				5
Infection	1	2			1	2
Inflammation	1	1			1	1
Inflammatory marker increased		1				1
Influenza	2	3	1	1	1	2
Influenza like illness	1	2			1	2
Initial insomnia		1				1
Insomnia	2	10		2	2	8
International normalised ratio decreased	3	3	1	1	2	2
Intestinal ischaemia	1	1			1	1
Iritis		1				1
Irritability		2				2
Jaundice		1				1
Joint effusion		1				1
Joint injury	1	1			1	1
Joint range of motion decreased		3		2		1
Joint stiffness		1		1		
Joint swelling	1	1	1	1		
Keratitis	1	1			1	1
Laryngeal pain		1				1
Limb discomfort	1	1	1	1		
Limb injury	1	1			1	1
Lip oedema	3	4	2	3	1	1
Lip pain		2		2		
Lip pruritus		1				1
Lip swelling		2		1		1
Localised oedema		4		2		2
Loss of consciousness	1	6			1	6

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Loss of control of legs		2
Loss of personal independence in daily activities		2
Lung disorder	1	2
Lymphadenopathy	4	48
Lymph node pain	1	8
Lymph nodes scan abnormal		1
Malaise	9	53
Malignant lymphoid neoplasm		1
Maternal exposure during pregnancy		1
Memory impairment	1	2
Menstrual disorder		1
Mental impairment	1	2
Mesenteric artery thrombosis	1	1
Middle insomnia	1	5
Migraine	3	12
Migraine with aura	1	1
Mobility decreased		3
Monoparesis		1
Mouth haemorrhage	1	1
Mouth swelling		2
Movement disorder		1
Muscle disorder	1	1
Muscle fatigue		2
Muscle spasms		6
Muscle spasticity		2
Muscle strain		1
Muscle tightness		2
Muscle twitching		8
Muscular weakness	6	21
Musculoskeletal discomfort		1
Musculoskeletal disorder		2
Musculoskeletal pain		3

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
			2
		1	2
1	22	3	26
1	3		5
			1
2	14	7	39
			1
	1		
	1	1	1
			1
		1	2
		1	1
	2	1	3
	1	3	11
		1	1
	1		2
			1
		1	1
			2
			1
		1	1
			2
	1		5
			2
			1
	1		1
1	3	5	18
			1
	1		1
	1		2

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	6	13	2	6	4	7
Myalgia	9	92	1	24	8	68
Mydriasis		1		1		
Myocardial infarction		2				2
Myocarditis		1				1
Narcolepsy	1	1			1	1
Nasal congestion	1	4		2	1	2
Nasal pruritus		1		1		
Nasopharyngitis	2	8		1	2	7
Nausea	12	69	3	22	9	47
Neck pain	2	12		1	2	11
Neuralgia	1	11	1	2		9
Neurological symptom	1	2			1	2
Night sweats		1		1		
Nodule	1	2	1	2		
Noninfective sialoadenitis		1				1
Nuchal rigidity		2		2		
Obstruction		1				1
Ocular discomfort		1		1		
Ocular hyperaemia		2				2
Oedema peripheral	2	7	1	2	1	5
Off label use		1		1		
Opisthotonus		1				1
Oral discomfort		2		2		
Oral mucosal blistering		2		2		
Oral pruritus		4				4
Oropharyngeal discomfort		5		1		4
Oropharyngeal oedema		2		1		1
Oropharyngeal pain	1	14		7	1	7
Oxygen saturation decreased	1	3			1	3
Pain	5	27		2	5	25
Pain in extremity	13	80	5	27	8	53

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain of skin		4		1		3
Pallor		4		1		3
Palpitations	3	19		6	3	13
Papule		1		1		
Paraesthesia	7	35	1	11	6	24
Paraesthesia oral	1	18	1	9		9
Paraparesis		1				1
Peak expiratory flow rate decreased		3				3
Perichondritis		1		1		
Peripheral coldness		1				1
Peripheral swelling	1	1	1	1		
Pharyngeal hypoaesthesia		4		1		3
Pharyngeal oedema	1	7		1	1	6
Pharyngeal paraesthesia		3		1		2
Pharyngeal swelling	2	6			2	6
Photophobia		4		1		3
Photopsia	1	2			1	2
Photosensitivity reaction		1				1
Platelet disorder	1	1			1	1
Pneumonia	1	4			1	4
Polymyalgia rheumatica	1	1			1	1
Porphyria	1	1			1	1
Post procedural haemorrhage	1	1			1	1
Presyncope	1	5		1	1	4
Productive cough		2				2
Product use issue		1		1		
Pruritus	2	15		9	2	6
Pulmonary embolism	6	6			6	6
Pulmonary haemorrhage	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	5			1	5
Pyelonephritis		2				2

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	39	14	97
			1
1	3	1	8
	2	1	2
	1		2
1	3	1	1
		1	1
			1
		1	1
		1	1
1	1		
		1	1
			1
		1	1
		1	1
			1
		1	1
			1
		1	1
			1
			2
	2		1
		2	2
			1
			1
	1	1	2
	1	1	1
			1
			1
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body	2	8		1	2	7
Sensory disturbance		1		1		
Sensory loss		1				1
Sialoadenitis		1				1
Sinus tachycardia		2				2
Skin reaction	1	1	1	1		
Skin sensitisation	1	1			1	1
Skin striae	1	1			1	1
Skin warm	1	2		1	1	1
Sneezing	1	1			1	1
Snoring		1				1
Somnolence	2	4		1	2	3
Speech disorder	1	2			1	2
Spinal pain		2		1		1
Sputum discoloured	1	1			1	1
Stiff tongue		1				1
Strabismus		1				1
Stridor		2				2
Stupor		1				1
Sudden death		1				1
Sudden hearing loss		1				1
Suffocation feeling	1	2			1	2
Swelling		6		3		3
Swelling face		3		1		2
Swelling of eyelid		2				2
Swollen tongue	1	2			1	2
Syncope	4	15			4	15
Synovial fluid white blood cells positive		1				1
Tachycardia	2	9		1	2	8
Throat irritation		11		3		8
Throat tightness	1	6			1	6
Thrombocytosis		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombophlebitis superficial		1				1
Thrombosis	3	3			3	3
Thrombotic cerebral infarction	1	1			1	1
Tinnitus	1	5		4	1	1
Tongue discolouration	1	1			1	1
Tongue discomfort	1	3		1	1	2
Tongue disorder		1				1
Tongue erythema	1	1			1	1
Tongue oedema	1	4			1	4
Toothache		1		1		
Transient aphasia	1	2			1	2
Transient ischaemic attack	1	2			1	2
Tremor	1	10		1	1	9
Trigeminal palsy	1	1			1	1
Trismus	1	1	1	1		
Troponin I increased	1	1			1	1
Type IV hypersensitivity reaction		1		1		
Ulcerative keratitis		1				1
Unresponsive to stimuli		2				2
Urinary retention	1	1			1	1
Urinary tract infection	3	6	1	1	2	5
Urine porphobilinogen increased	1	1			1	1
Urogenital haemorrhage	1	1			1	1
Urticaria	3	23		7	3	16
Vaccination failure	2	2			2	2
Vaccination site abscess		1				1
Vaccination site bruising		2				2
Vaccination site erythema	1	30	1	21		9
Vaccination site haematoma		5		5		
Vaccination site hyperaesthesia		5		1		4
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		5		4		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint movement impairment		1		1		
Vaccination site macule		1		1		
Vaccination site mass		5		1		4
Vaccination site movement impairment		7		2		5
Vaccination site oedema		16		15		1
Vaccination site pain	4	57	1	31	3	26
Vaccination site plaque		1		1		
Vaccination site pruritus		7		5		2
Vaccination site rash		1		1		
Vaccination site reaction	1	4		2	1	2
Vaccination site swelling		7		2		5
Vaccination site urticaria		1		1		
Vaccination site warmth	1	15		9	1	6
Vaginal infection		1				1
Venous thrombosis	2	2			2	2
Ventricular fibrillation	1	1			1	1
Vertigo		3		1		2
Vestibular neuronitis		1				1
Viral infection		2				2
Vision blurred		4		1		3
Visual impairment	2	4		1	2	3
Vomiting	7	31	2	8	5	23
Vulvovaginal inflammation		1				1
Wheezing	1	5		1	1	4
White blood cell count increased	1	2			1	2
White blood cells urine	1	1			1	1
White blood cells urine positive	1	1			1	1
Wrong technique in product usage process		1		1		
	479	2,744	60	755	419	1989

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		1				1
Abdominal pain lower	1	1	1	1		
Accommodation disorder		1		1		
Ankylosing spondylitis		1				1
Aphasia		1				1
Apnoea		1				1
Areflexia		1				1
Arrhythmia	2	2			2	2
Arthralgia	2	8		3	2	5
Arthritis reactive	1	1			1	1
Asthenia	2	6	1	3	1	3
Atrial f brillation		1				1
Autoimmune arthritis	1	1			1	1
Back pain	1	5	1	3		2
Blister		1		1		
Blood creatine increased	1	1			1	1
Blood creatinine increased		1				1
Blood glucose decreased	1	1			1	1
Blood pressure decreased	1	2			1	2
Blood pressure increased	2	3			2	3
Borrelia infection		1				1
Cardiac failure	1	5			1	5
Cerebral haemorrhage		1				1
Cerebral infarction	1	1			1	1
Cerebrovascular accident		1				1
Cerebrovascular disorder	1	1			1	1
Chest discomfort		2		1		1
Chest pain		1				1
Chills	3	6			3	6
Chronic obstructive pulmonary disease		1				1
Clumsiness		1		1		

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Gender

**MALE**

*Preferred Term*

Condition aggravated  
Confusional state  
Coronary artery thrombosis  
Cough  
C-reactive protein increased  
Deafness unilateral  
Death  
Deep vein thrombosis  
Delirium  
Dementia Alzheimer's type  
Depressed level of consciousness  
Diarrhoea  
Discomfort  
Dizziness  
Dry mouth  
Dysarthria  
Dysphagia  
Dyspnoea  
Ear canal erythema  
Ear discomfort  
Ear pain  
Eczema  
Encephalitis  
Eosinophil count increased  
Epilepsy  
Epistaxis  
Erythema  
Extrasystoles  
Eye haematoma  
Eye infection  
Eyelid ptosis  
Eye pain

*Interval Total # Spontaneous AE*

*Cumulative Total # Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	2		
		1	1
	2		1
			2
			1
1		1	5
			1
1		1	1
			2
			1
	1		
			1
5	2	5	14
			1
2		2	4
			2
2	2	2	12
	1		
1	1	1	1
	3		
			1
			1
			1
			2
			1
	1		
			1
		1	1
			1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Face oedema		1					1
Facial paralysis		3					3
Fall		1					1
Fatigue	1	14		2	1		12
Feeling cold	1	2			1		2
Feeling hot	1	1			1		1
Flank pain		1					1
Fluid intake reduced		1					1
Foaming at mouth		1					1
Gait disturbance	1	3		1	1		2
Gastrointestinal viral infection	1	1			1		1
General physical health deterioration	2	10			2		10
Haemoglobin decreased		1					1
Headache	1	10		4	1		6
Head discomfort		1					1
Heart rate increased		2		1			1
Heart rate irregular		1					1
Hemiparesis		1					1
Hemiplegia	1	1			1		1
Herpes virus infection		1		1			
Herpes zoster		1					1
Herpes zoster cutaneous disseminated		1					1
Hyperacusis	1	1			1		1
Hypernatraemia		1					1
Hypertension	1	1			1		1
Hyperventilation		1					1
Hypoacusis	1	1			1		1
Hypoaesthesia	1	4		2	1		2
Hypophagia		1					1
Hypopnoea		1					1
Hyporeflexia		1					1
Hypotension	1	1			1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothermia		1				1
Hypotonia	1	1			1	1
Impaired work ability	2	3		1	2	2
Incorrect route of product administration		1		1		
Increased upper airway secretion		1				1
Influenza like illness	1	1			1	1
Insomnia		1		1		
Intervertebral disc disorder		1		1		
Irritability postvaccinal		1		1		
Lethargy	1	1			1	1
Limb discomfort		1		1		
Limb injury	1	1			1	1
Loss of consciousness		1				1
Loss of control of legs		1				1
Lymphadenopathy		2				2
Lymph node pain		1				1
Macular oedema	1	1			1	1
Malaise	2	5		2	2	3
Meniere's disease		1				1
Middle insomnia		2		1		1
Mobility decreased	1	1			1	1
Muscle twitching		1		1		
Muscular weakness	2	6			2	6
Musculoskeletal stiffness		2		2		
Myalgia	3	10		3	3	7
Nasal congestion		1				1
Nasal oedema		2				2
Nasopharyngitis		1				1
Nausea	2	10		4	2	6
Neck pain	1	2	1	2		
Neuralgia		2		2		
Neuritis	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutropenia		1				1
Nodule	1	1			1	1
Obstruction		1				1
Oedema peripheral		1				1
Ophthalmic vein thrombosis	1	1			1	1
Oral disorder		1				1
Oral herpes		1		1		
Oropharyngeal pain		2		2		
Osteoarthritis		1		1		
Pain	2	3		1	2	2
Painful respiration		1				1
Pain in extremity	1	9	1	5		4
Pain of skin		1				1
Pallor		2				2
Paraesthesia		1				1
Paranasal sinus discomfort		1				1
Paresis	1	1			1	1
Pelvic venous thrombosis		1				1
Peripheral embolism	1	1			1	1
Petit mal epilepsy	1	1			1	1
Pigmentary glaucoma	1	1			1	1
Pneumonia	2	7			2	7
Pneumonia aspiration		1				1
Polyarthritis	1	1			1	1
Poor quality sleep	1	1			1	1
Productive cough		1				1
Pseudomonal sepsis	1	1			1	1
Pulmonary embolism	2	4			2	4
Pulmonary infarction		1				1
Pulmonary pain		1		1		
Pyrexia	3	18		5	3	13
Rash	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous		1				1
Rash macular		1				1
Respiratory arrest		1				1
Respiratory tract infection		1				1
Retinal vascular occlusion	1	1			1	1
Retinal vascular thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Rhonchi		1				1
Rinne tuning fork test abnormal		1		1		
SARS-CoV-2 test negative	1	1			1	1
Secretion discharge		1		1		
Seizure	1	3			1	3
Sensation of foreign body		1		1		
Sinus disorder		1				1
Skull fractured base		1				1
Slow speech		1				1
Somnolence		2				2
Speech disorder		1				1
Stress	1	1			1	1
Subcutaneous abscess		1				1
Sudden death		2				2
Swelling	1	2		1	1	1
Swelling face		1				1
Tendon pain	1	2			1	2
Thrombosis		1				1
Tinnitus		1				1
Tremor	1	5		1	1	4
Tympanic membrane hyperaemia		1		1		
Urticaria		2				2
Vaccination site erythema		3				3
Vaccination site hyperaesthesia		1				1
Vaccination site hypoaesthesia		1				1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		2				2
Vaccination site oedema		3		2		1
Vaccination site pain		10		4		6
Vertigo	1	2			1	2
Visual acuity reduced	1	1			1	1
Visual impairment		2				2
Vomiting	1	5		2	1	3
Weber tuning fork test abnormal		1		1		
Weight decreased		1		1		
Wheezing		1				1
White blood cell count increased		1				1
	100	422	5	95	95	327

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Cerebral infarction	1	1			1	1
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Hemiparesis	1	1			1	1
Myalgia		1		1		
Off label use	1	2	1	2		
Poor quality product administered		12		12		
Product preparation error		12		12		
Product quality issue	1	1	1	1		
Pyrexia		1		1		
Vaccination site mass		1		1		
Vomiting		1		1		
	6	36	2	32	4	4

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**FRANCE**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	6	1	3		3
Abdominal pain	14	75	5	30	9	45
Abdominal pain lower	1	1			1	1
Abdominal pain upper	8	28		6	8	22
Abdominal rigidity		1				1
Abnormal behaviour	1	1	1	1		
Abnormal faeces		1		1		
Abnormal sensation in eye	1	1	1	1		
Abortion spontaneous	6	9			6	9
Accidental overdose		2		2		
Accommodation disorder		1				1
Acne		1		1		
Acquired haemophilia	1	1			1	1
Activated partial thromboplastin time prolonged		1				1
Activated partial thromboplastin time shortened	1	1			1	1
Acute coronary syndrome	5	11			5	11
Acute febrile neutrophilic dermatosis		1				1
Acute kidney injury	5	12			5	12
Acute myeloid leukaemia	1	2			1	2
Acute myocardial infarction	2	4			2	4
Acute pulmonary oedema	5	19			5	19
Acute respiratory distress syndrome	3	12			3	12
Acute respiratory failure	1	12			1	12
Acute sinusitis	1	1	1	1		
Acute vestibular syndrome	1	3			1	3
Adrenal insufficiency	1	1			1	1
Adrenal mass	1	1	1	1		
Adrenocortical insufficiency acute		1				1
Adverse event	1	1	1	1		
Aerococcus urinae infection		1				1
Aerophagia	1	1			1	1
Affective disorder	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
2	2		2
		2	4
1	4	2	8
	3		
			1
			1
	2		3
		1	9
			1
			2
1		1	1
3		3	5
			2
2	1	2	5
1		1	1
			1
	2		2
10		10	34
4		4	13
			1
3		3	9
1		1	1
17	1	17	47
1		1	5
1	1		3
			1
			1
			2
4	6	3	12
	1		
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Aortic bruit		1		1			
Aortic dissection		1					1
Aortic stenosis	1	1			1		1
Aortic valve calcification	1	1			1		1
Aortic valve incompetence	2	3			2		3
Apathy	2	3	1	1	1		2
Aphasia	5	17	1	5	4		12
Aphonia		2					2
Aphthous ulcer		3		2			1
Aplastic anaemia	1	1			1		1
Apnoea		2					2
Appendicitis		1					1
Application site warmth		1		1			
Arrhythmia	11	34			11		34
Arrhythmia supraventricular		3					3
Arterial disorder	1	1			1		1
Arteriosclerosis		1					1
Arthralgia	33	160	11	59	22		101
Arthritis	1	6		1	1		5
Arthritis reactive	1	2			1		2
Aspartate aminotransferase increased		4		4			
Asphyxia		1					1
Aspiration	1	2			1		2
Asthenia	103	517	36	182	67		335
Asthma	5	13	1	1	4		12
Asthmatic crisis	2	6			2		6
Asymptomatic COVID-19	12	13			12		13
Ataxia	4	5	2	2	2		3
Atrial fibrillation	29	65			29		65
Atrial flutter	2	3	1	1	1		2
Atrioventricular block		2		1			1
Atrioventricular block complete		2					2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Auditory disorder		1					1
Aura		2					2
Autoimmune hepatitis	1	1			1		1
Autoimmune thyroiditis	1	1			1		1
Axillary pain		12		7			5
Back pain	12	39	4	13	8		26
Bacterial pyelonephritis		1					1
Bacterial sepsis	1	1			1		1
Bacterial test positive	1	2		1	1		1
Balance disorder	2	16	1	3	1		13
Basedow's disease	1	1			1		1
Bed rest	1	1			1		1
Behaviour disorder	1	6		1	1		5
Benign breast neoplasm		1		1			
Bipolar disorder		1					1
Bladder dilatation	1	1			1		1
Blastocystis infection		1					1
Blindness	1	1			1		1
Blindness unilateral	1	1			1		1
Blister	1	2			1		2
Blood albumin decreased	1	1	1	1			
Blood alkaline phosphatase increased		1		1			
Blood calcium decreased	1	1	1	1			
Blood creatinine abnormal		1					1
Blood creatinine decreased		1					1
Blood creatinine increased		1		1			
Blood culture positive	1	1			1		1
Blood folate decreased	1	1			1		1
Blood glucose fluctuation		1		1			
Blood glucose increased	2	4	2	4			
Blood loss anaemia	1	1			1		1
Blood pressure abnormal	1	3	1	1			2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	19		4	1	15
Blood pressure diastolic decreased	1	2		1	1	1
Blood pressure fluctuation	2	4	2	3		1
Blood pressure inadequately controlled		1				1
Blood pressure increased	2	16	1	4	1	12
Blood pressure systolic decreased		2		1		1
Blood pressure systolic increased	3	5	1	1	2	4
Blood sodium decreased	1	1	1	1		
Blood thyroid stimulating hormone decreased	1	1	1	1		
Blood thyroid stimulating hormone increased	2	4		2	2	2
Blood urine present		1		1		
Blue toe syndrome		1		1		
Body temperature decreased		2		1		1
Body temperature increased	2	8			2	8
Bone abscess		1				1
Bone pain	1	5	1	1		4
Bone swelling		1		1		
Bradycardia	6	30			6	30
Brain contusion	1	1			1	1
Brain natriuretic peptide increased	1	2	1	1		1
Brain scan abnormal		1				1
Breast abscess		1				1
Breast induration	1	1			1	1
Breast mass	1	1			1	1
Breast pain	1	4	1	1		3
Breast swelling		1		1		
Breath sounds abnormal	1	1			1	1
Bronchial obstruction		1				1
Bronchial secretion retention		1		1		
Bronchiolitis		1				1
Bronchitis		2				2
Bronchopneumopathy	1	2	1	1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm		7				7
Bundle branch block		1				1
Bundle branch block left		3				3
Bundle branch block right		5		2		3
Burning sensation	2	15	2	5		10
Burn oral cavity	1	2			1	2
Bursitis	1	3		1	1	2
Carcinoembryonic antigen increased		1				1
Cardiac arrest	3	10			3	10
Cardiac discomfort	1	1			1	1
Cardiac disorder	1	2			1	2
Cardiac failure	18	48			18	48
Cardiac failure acute		4				4
Cardiac failure congestive	2	3			2	3
Cardiac fibrillation		1				1
Cardiac flutter		2				2
Cardiac tamponade	1	1			1	1
Cardiogenic shock	1	5			1	5
Cardiomegaly		1				1
Cardiopulmonary failure	1	2			1	2
Cardio-respiratory arrest	8	19			8	19
Cardio-respiratory distress	1	1			1	1
Cardiovascular disorder	1	4			1	4
Carotid artery thrombosis	2	2			2	2
Cell death	4	4			4	4
Cellulitis		1				1
Central nervous system lesion		1				1
Cerebellar infarction		1				1
Cerebellar stroke		1				1
Cerebral artery stenosis		1				1
Cerebral atrophy		1				1
Cerebral haematoma	2	5			2	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cerebral haemorrhage		1					1
Cerebral hyperperfusion syndrome		1					1
Cerebral infarction	2	3			2		3
Cerebral ischaemia		1					1
Cerebral thrombosis	1	2			1		2
Cerebral venous thrombosis	2	2			2		2
Cerebrovascular accident	9	28			9		28
Cervical radiculopathy	1	2		1	1		1
Cervicobrachial syndrome		1		1			
Chest discomfort	10	49	3	19	7		30
Chest injury		1					1
Chest pain	17	85	4	16	13		69
Chest X-ray abnormal	1	2			1		2
Chillblains		3		2			1
Chills	38	219	13	79	25		140
Choking	1	4			1		4
Choking sensation		1		1			
Cholecystitis	1	2			1		2
Cholestasis	2	4			2		4
Cholestatic liver injury		1					1
Chondrocalcinosis	1	1			1		1
Chromaturia		1					1
Chronic obstructive pulmonary disease		7					7
Circadian rhythm sleep disorder	1	1	1	1			
Circulatory collapse	1	5			1		5
Claudication of jaw muscles	1	1			1		1
Clinomania	1	1	1	1			
Clonus		2		1			1
Clumsiness		1					1
Cognitive disorder	1	4		2	1		2
Cold sweat	2	5	1	2	1		3
Colitis	1	1			1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma	3	9			3	9
Coma scale abnormal	1	1			1	1
Condition aggravated	15	46	1	9	14	37
Conduction disorder		1				1
Confusional state	14	28	3	3	11	25
Conjunctival haemorrhage	2	11			2	11
Conjunctival oedema	1	1	1	1		
Conjunctivitis	2	6	1	3	1	3
Conjunctivitis bacterial	1	1			1	1
Constipation	1	5	1	4		1
Contraindicated product administered	1	1			1	1
Contusion	1	1	1	1		
Coordination abnormal		1		1		
Coronary artery insufficiency	1	1			1	1
Coronary artery stenosis	2	2			2	2
Coronavirus infection		3		2		1
Costovertebral angle tenderness		1				1
Cough	19	63	9	23	10	40
COVID-19	95	203	14	47	81	156
COVID-19 pneumonia	3	9			3	9
C-reactive protein increased	10	28	4	16	6	12
Creatinine renal clearance decreased		1				1
Crepitations		2		1		1
Culture urine positive	1	1	1	1		
Cutaneous lupus erythematosus	1	1			1	1
Cutaneous vasculitis		1				1
Cyanosis	2	9	1	2	1	7
Cystitis	1	1			1	1
Cystitis klebsiella		1				1
Cytomegalovirus test positive		1		1		
Daydreaming	2	2			2	2
Deafness	1	5			1	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral	2	6			2	6
Death	10	57			10	57
Decreased appetite	10	46	5	21	5	25
Decreased interest		1				1
Decubitus ulcer		1				1
Deep vein thrombosis	19	29			19	29
Dehydration	7	15	3	4	4	11
Delirium		3				3
Delusion	1	3		1	1	2
Dementia	1	3			1	3
Demyelination		1				1
Dependent rubor	1	1			1	1
Depressed level of consciousness	2	14			2	14
Depression		1				1
Dermal cyst		1				1
Dermatitis bullous		1				1
Dermatomyositis	1	2			1	2
Dermo-hypodermitis	1	3			1	3
Diabetes insipidus		1				1
Diabetes mellitus	3	4			3	4
Diabetes mellitus inadequate control	4	7			4	7
Diabetic coma		1				1
Diabetic hyperosmolar coma	1	1			1	1
Diabetic ketoacidosis		1				1
Diabetic ketosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	26	135	8	45	18	90
Diarrhoea haemorrhagic	3	4			3	4
Diplegia		1				1
Diplopia	4	8	1	1	3	7
Discomfort	11	43	3	13	8	30
Disease recurrence	11	43		2	11	41

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Disinhibition		1					1
Disorientation	7	16	1	3	6	13	
Disturbance in attention	3	9	1	2	2	7	
Diverticulitis	1	2			1	2	
Dizziness	42	147	12	43	30	104	
Dizziness postural		3				3	
Droling		1		1			
Dropped head syndrome		1				1	
Drug hypersensitivity	1	2			1	2	
Drug ineffective	36	82	1	1	35	81	
Dry eye	1	3	1	2		1	
Dry mouth	1	6		3	1	3	
Dry skin	1	1	1	1			
Dry throat		2		1		1	
Dysaesthesia	3	9		4	3	5	
Dysarthria	2	12		2	2	10	
Dysgeusia	5	23	1	11	4	12	
Dysgraphia	1	1			1	1	
Dyshidrotic eczema		2		2			
Dyskinesia	1	2		1	1	1	
Dyslipidaemia		1		1			
Dyspepsia		5				5	
Dysphagia	6	20	4	7	2	13	
Dysphemia		2				2	
Dysphonia	2	8		3	2	5	
Dyspnoea	33	137	8	23	25	114	
Dyspnoea at rest	2	4			2	4	
Dyspnoea exertional	6	12	2	4	4	8	
Dysstasia	1	7		2	1	5	
Dysuria	1	2		1	1	1	
Ear discomfort		1		1			
Ear disorder		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain	6	14	2	5	4	9
Ear swelling	2	3		1	2	2
Eating disorder		2		1		1
Eczema		2		1		1
Ejection fraction decreased		1				1
Electrocardiogram abnormal		1				1
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment depression		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T segment abnormal		1				1
Electrocardiogram T wave inversion		2				2
Embolic stroke	2	2			2	2
Embolism		1				1
Embolism venous		1				1
Emphysema		1				1
Encephalitis	1	2			1	2
Encephalitis viral		1				1
Endocrine ophthalmopathy	1	1			1	1
Enlarged uvula		1				1
Enterococcal infection		1				1
Eosinophil count increased		1		1		
Eosinophilia	1	2			1	2
Eosinophilic bronchitis	1	1			1	1
Epilepsy	7	15			7	15
Epistaxis	4	10		2	4	8
Epstein-Barr virus infection		1				1
Epstein-Barr virus infection reactivation		1				1
Epstein-Barr virus test positive		1		1		
Erectile dysfunction		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Eructation		3					3
Erysipelas	1	2			1		2
Erythema	16	75	4	31	12		44
Erythema multiforme		2					2
Erythema nodosum	2	2			2		2
Erythema of eyelid		1					1
Erythrosis		1		1			
Escherichia infection	1	1			1		1
Escherichia test positive	1	2	1	2			
Escherichia urinary tract infection	1	2			1		2
Euphoric mood		1		1			
Exophthalmos	1	1			1		1
Exposure via breast milk	1	2		1	1		1
Exposure via skin contact		1		1			
Extensive swelling of vaccinated limb	2	11	2	9			2
Extensor plantar response		1					1
Extradural haematoma		1					1
Extrapyramidal disorder	1	1			1		1
Extrasystoles	10	15	3	4	7		11
Extremity necrosis	1	1	1	1			
Eye discharge	1	1			1		1
Eye disorder		1					1
Eye haemorrhage	1	3			1		3
Eye injury	1	2			1		2
Eye irritation	1	2		1	1		1
Eyelid disorder		1					1
Eyelid irritation		1		1			
Eyelid myoclonus	1	1			1		1
Eyelid oedema	2	13		3	2		10
Eyelid ptosis		2					2
Eye movement disorder	1	1	1	1			
Eye oedema		2		1			1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	5		3
		2	2
		2	2
1	2	11	29
			1
		1	1
	1		2
		29	71
1	3		1
1	1		
		1	2
			2
	1		
			1
4	11	17	48
			1
28	116	42	155
1	1		1
			1
3	8	1	9
	7	2	12
	3	2	5
	7	6	14
	2	2	2
		1	3
		1	5
	1		
1	1		
		1	1
		1	1
			1
1	3	3	9

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Foaming at mouth		1				1
Focal dyscognitive seizures		1				1
Food aversion	1	2		1	1	1
Food craving	1	1			1	1
Formication	2	10		4	2	6
Frostbite		1		1		
Functional gastrointestinal disorder		3				3
Gait disturbance	3	13	2	6	1	7
Gait inability	5	8		1	5	7
Gamma-glutamyltransferase increased	1	4		3	1	1
Gangrene	1	1			1	1
Gastric pH decreased	1	1	1	1		
Gastric volvulus		1				1
Gastritis		1				1
Gastrointestinal disorder	1	8		2	1	6
Gastrointestinal haemorrhage		1				1
Gastrointestinal hypermotility		1		1		
Gastrointestinal inflammation		1				1
Gastrointestinal motility disorder	1	2	1	1		1
Gastrointestinal pain	2	5	1	3	1	2
Gastrooesophageal reflux disease		2				2
Gaze palsy	1	1			1	1
Generalised anxiety disorder		1				1
Generalised oedema		1				1
Generalised onset non-motor seizure		1				1
Generalised tonic-clonic seizure	4	6			4	6
General physical health deterioration	13	35	4	5	9	30
Genital haemorrhage	1	1			1	1
Genital herpes	2	2			2	2
Genital herpes zoster	1	1			1	1
Giant cell arteritis	5	7			5	7
Gingival bleeding	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival discomfort	1	2	1	1		1
Glaucoma	1	1			1	1
Glomerular filtration rate decreased	1	5	1	1		4
Glossitis	1	2	1	1		1
Glossodynia	1	1	1	1		
Goitre		1		1		
Gout		2		1		1
Groin pain		1		1		
Guillain-Barre syndrome	1	2			1	2
Haemarthrosis	1	2			1	2
Haematemesis	1	3			1	3
Haematochezia	1	5			1	5
Haematoma	6	13	1	2	5	11
Haematoma muscle	1	1			1	1
Haematuria	1	3			1	3
Haemodynamic instability		1		1		
Haemoglobin decreased	1	3		2	1	1
Haemoglobinuria		1				1
Haemolytic anaemia	1	1			1	1
Haemophagocytic lymphohistiocytosis	1	1			1	1
Haemoptysis		2				2
Haemorrhagic disorder	1	1			1	1
Haemorrhagic stroke	6	14			6	14
Haemorrhagic transformation stroke		1				1
Haemorrhoids thrombosed		1				1
Haemothorax		1				1
Hair colour changes		1		1		
Hallucination	2	12			2	12
Hallucination, auditory	2	4			2	4
Hallucination, olfactory		1				1
Hallucinations, mixed		2				2
Hallucination, visual	5	7			5	7

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	123	571	34	202	89	369
Head discomfort		4		3		1
Head injury	3	12	1	1	2	11
Heart rate decreased	4	6	2	4	2	2
Heart rate increased	2	11	2	5		6
Heart rate irregular	1	3			1	3
Heart sounds abnormal		2		1		1
Hemianaesthesia		1				1
Hemianopia		1				1
Hemianopia homonymous		1				1
Hemiapraxia	1	1			1	1
Hemiparaesthesia		2				2
Hemiparesis	5	11			5	11
Hemiplegia	7	12			7	12
Hepatic cyst	1	1			1	1
Hepatic enzyme increased		1				1
Hepatic function abnormal	1	2	1	2		
Hepatic haematoma		1				1
Hepatic infarction	1	1			1	1
Hepatic lesion		1		1		
Hepatic pain		1		1		
Hepatitis		1				1
Hepatitis acute	2	2			2	2
Hepatitis cholestatic		1				1
Hepatitis infectious mononucleosis		1				1
Hepatitis viral		1				1
Hepatocellular injury	6	13			6	13
Hepatomegaly	1	1			1	1
Herpangina	1	1	1	1		
Herpes ophthalmic	1	1			1	1
Herpes pharyngitis	1	1			1	1
Herpes simplex		2		1		1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
1	20	17	41
		1	1
		2	2
	1		
	1		
			1
1	1	1	1
1	1	1	1
6	42	4	24
1	1		
1	5		4
	1		
			2
	1		1
	1		
2	4	1	2
10	49	8	38
	3		3
5	12	5	12
	4		2
9	60	8	41
	1		1
2	4	1	3
125	359	116	317
39	106	39	106
	1		1
8	45	4	30
1	5	1	5
	1		1
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperventilation		2		1			1
Hypoacusis	1	5		1	1		4
Hypoesthesia	14	31	6	13	8		18
Hypoesthesia oral	1	6		1	1		5
Hypoalbuminaemia	1	1			1		1
Hypocalcaemia		1					1
Hypoglycaemia	2	11		1	2		10
Hypokalaemia		4					4
Hypokinesia	1	5		1	1		4
Hyponatraemia	1	1	1	1			
Hypoperfusion		2		1			1
Hypotension	22	97	6	20	16		77
Hypothermia	1	13			1		13
Hypothyroidism	1	1			1		1
Hypotonia	2	5		1	2		4
Hypoventilation		1					1
Hypoxia	1	16			1		16
Illrd nerve paralysis		1					1
Ill-defined disorder		1					1
Illness	1	4	1	1			3
Illusion	1	1			1		1
Immune thrombocytopenia	3	4			3		4
Immunodeficiency	1	1			1		1
Immunoglobulins increased	1	1	1	1			
Impaired driving ability	1	1			1		1
Impaired work ability	3	18	1	3	2		15
Inappropriate schedule of product administration	5	15	4	13	1		2
Incoherent	3	3	3	3			
Incorrect dose administered		3		3			
Incorrect route of product administration	2	10	1	9	1		1
Increased bronchial secretion	1	3			1		3
Induration	1	2			1		2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Infarction		2					2
Infection	2	5	1	1	1		4
Infectious mononucleosis		1					1
Inflammation	10	20	5	9	5		11
Inflammatory pain	1	2			1		2
Influenza	10	43	4	11	6		32
Influenza like illness	90	367	11	51	79		316
Initial insomnia		1					1
Injected limb mobility decreased	7	27	1	6	6		21
Injection site erythema		2		2			
Injection site hyperaesthesia		1		1			
Injection site pain		5		5			
Injection site paraesthesia		1		1			
Injection site pruritus		2		2			
Injection site rash		1					1
Injection site reaction		2		1			1
Injection site swelling		1		1			
Inner ear disorder		2		1			1
Insomnia	13	42	4	15	9		27
Insulin-requiring type 2 diabetes mellitus		1					1
Intercostal neuralgia		1					1
International normalised ratio abnormal		2		1			1
International normalised ratio increased	1	3			1		3
Interstitial lung disease	2	5			2		5
Intervertebral disc compression		1					1
Intestinal ischaemia	2	2			2		2
Intestinal obstruction		2					2
Intracardiac thrombus	1	2			1		2
Intracranial haematoma		1					1
Intracranial pressure increased		1					1
Iridocyclitis		1					1
Iron deficiency anaemia		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Irritability		1					1
Ischaemic cardiomyopathy		1					1
Ischaemic stroke	22	45			22		45
Jaundice		2					2
Joint ankylosis		1					1
Joint dislocation	1	1			1		1
Joint effusion	2	4		2	2		2
Joint injury		1					1
Joint range of motion decreased	1	2			1		2
Joint stiffness	1	4		1	1		3
Joint swelling	5	7	1	2	4		5
Joint warmth	1	1			1		1
Jugular vein distension		1					1
Jugular vein thrombosis		1					1
Klebsiella infection		2					2
Labile blood pressure		1					1
Lacrimation increased	1	6	1	3			3
Lactic acidosis		1					1
Lactobacillus infection		1					1
Lacunar infarction		1					1
Lacunar stroke	2	2			2		2
Language disorder	1	3			1		3
Large intestine infection	1	2			1		2
Laryngeal discomfort	2	5		1	2		4
Laryngeal dyspnoea		2					2
Laryngeal oedema	4	11			4		11
Laryngitis		2					2
Laryngitis allergic		1					1
Left atrial dilatation	1	1			1		1
Left ventricular end-diastolic pressure increased		1					1
Left ventricular failure		1					1
Left ventricular hypertrophy		2					2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukocytosis	1	3	1	2		1
Leukocyturia		2		1		1
Leukoencephalopathy	1	1			1	1
Leukopenia	3	4			3	4
Lichen planus		1				1
Ligament sprain		1				1
Limb discomfort	6	12	2	8	4	4
Lipase increased		2		2		
Lip oedema	2	15		3	2	12
Lipoma		2				2
Lip pain	1	2			1	2
Lip pruritus		1				1
Lip swelling	1	6			1	6
Listless		1				1
Livedo reticularis	1	6	1	1		5
Liver injury		1				1
Lividity		1				1
Localised oedema	2	7	1	3	1	4
Local reaction	2	3	2	3		
Logorrhoea		1				1
Loss of consciousness	18	68		1	18	67
Loss of personal independence in daily activities	5	7	2	2	3	5
Low density lipoprotein increased		1				1
Lower respiratory tract congestion	2	2			2	2
Lower respiratory tract infection		1				1
Lung disorder	4	22		2	4	20
Lung opacity		2				2
Lymphadenitis	2	9	2	7		2
Lymphadenopathy	16	96	6	43	10	53
Lymphangitis	1	1			1	1
Lymph node pain	1	6	1	2		4
Lymphocyte count decreased	1	2	1	1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphoedema		1		1		
Lymphopenia	4	9	3	5	1	4
Macroglossia	1	2			1	2
Macule		1		1		
Major depression	1	1			1	1
Malaise	60	250	19	67	41	183
Malnutrition	1	2			1	2
Maternal exposure during pregnancy		3		2		1
Maternal exposure timing unspecified		1		1		
Mean cell volume decreased	1	2		1	1	1
Melaena		1				1
Memory impairment	3	7		1	3	6
Meniere's disease	1	1			1	1
Meningitis	1	2			1	2
Meningitis aseptic		2				2
Meningoencephalitis herpetic	2	2			2	2
Meningoradiculitis	1	1			1	1
Meningorrhagia	1	1			1	1
Menorrhagia		1				1
Menstruation delayed		1				1
Mental fatigue		1				1
Mental impairment		2				2
Metamorphopsia		1		1		
Metastases to peritoneum		1				1
Metrorrhagia		2				2
Microembolism		1				1
Middle insomnia	2	5		3	2	2
Migraine	5	24	2	9	3	15
Migraine with aura	2	6	1	3	1	3
Miosis		1				1
Mitral valve calcification	1	2			1	2
Mitral valve disease		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mitral valve incompetence	2	3			2	3
Mitral valve stenosis	1	1			1	1
Mobility decreased	6	12	3	5	3	7
Monoclonal immunoglobulin increased		1				1
Monocytosis	2	2	1	1	1	1
Mononeuropathy multiplex	1	1			1	1
Mononucleosis syndrome		1				1
Monoparesis		2		1		1
Monoplegia	2	3			2	3
Morning sickness		1		1		
Motor dysfunction	4	10		2	4	8
Mouth haemorrhage	1	1			1	1
Mouth ulceration	1	2	1	2		
Movement disorder	1	3	1	1		2
Mucosal discolouration	1	1			1	1
Mucosal pain		1		1		
Multiple organ dysfunction syndrome	2	4			2	4
Muscle contractions involuntary		1		1		
Muscle contracture	1	6		2	1	4
Muscle disorder		1		1		
Muscle fatigue	1	3		1	1	2
Muscle rigidity		1		1		
Muscle spasms	1	14		5	1	9
Muscle tightness		2		2		
Muscular weakness	12	27	3	9	9	18
Musculoskeletal chest pain		6		1		5
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder		2		1		1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	15	74	4	18	11	56
Myalgia	50	277	16	106	34	171
Myalgia intercostal		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myasthenia gravis	1	1			1	1
Myasthenia gravis crisis	1	1			1	1
Mydriasis	1	2	1	1		1
Myocardial infarction	3	18			3	18
Myocardial ischaemia		1				1
Myocardial necrosis		1				1
Myocarditis	1	4			1	4
Myoclonus		1				1
Myokymia		1		1		
Myositis		2		1		1
Nasal congestion		1		1		
Nasopharyngitis		5		3		2
Nausea	67	310	19	109	48	201
Near death experience	1	1			1	1
Neck pain	6	19	3	6	3	13
Necrosis	1	1			1	1
Necrotising colitis	1	1			1	1
Needle issue	1	2	1	2		
Nephropathy	1	1			1	1
Nerve compression	1	1	1	1		
Nerve injury		1				1
Nervousness		1				1
Nervous system disorder	3	4	1	1	2	3
Neuralgia	5	32		8	5	24
Neuritis	1	2		1	1	1
Neurological examination abnormal		1				1
Neurological symptom		1				1
Neuromuscular pain		2		1		1
Neuromyopathy		2				2
Neuropathy peripheral	3	4			3	4
Neutropenia	3	6			3	6
Neutrophil count abnormal		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neutrophil count decreased		2		1			1
Neutrophil count increased	1	4	1	3			1
Neutrophilia		2		2			
Neutrophilic dermatosis		1					1
Nightmare		1		1			
Night sweats	1	4	1	1			3
Nitrite urine present	1	1	1	1			
Nocturia	1	1	1	1			
Nocturnal dyspnoea	1	1			1		1
Noninfective gingivitis		2		1			1
Normal pressure hydrocephalus	1	1			1		1
Normochromic anaemia	1	1			1		1
Normochromic normocytic anaemia	1	1	1	1			
Normocytic anaemia		1					1
N-terminal prohormone brain natriuretic peptide increased	1	4		1	1		3
Nystagmus		3		1			2
Obstructive airways disorder		1		1			
Occipital neuralgia	1	3			1		3
Occupational exposure to product		2		2			
Ocular discomfort		4		3			1
Ocular hyperaemia	1	3			1		3
Ocular myasthenia		1					1
Ocular vascular disorder	1	1			1		1
Odynophagia		2		1			1
Oedema	2	10		3	2		7
Oedema mouth		1					1
Oedema peripheral	11	29	1	4	10		25
Oesophageal pain		1					1
Oesophageal spasm		1					1
Off label use	5	20	4	19	1		1
Oliguria		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ophthalmic herpes zoster	7	17			7	17
Optic ischaemic neuropathy		1				1
Oral blood blister	1	1			1	1
Oral discomfort	1	1	1	1		
Oral disorder		1		1		
Oral dysaesthesia	2	3	1	2	1	1
Oral fungal infection	1	1	1	1		
Oral herpes		1				1
Oral pain		4		4		
Oral pruritus		3		1		2
Orbital haematoma		1				1
Oropharyngeal discomfort	1	3	1	2		1
Oropharyngeal pain	2	12	1	10	1	2
Oropharyngeal swelling		1				1
Orthopnoea		1				1
Orthostatic hypotension		3				3
Osteoarthritis	1	1	1	1		
Otitis externa	1	1	1	1		
Otolithiasis		1				1
Overdose	2	6	2	6		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	19	82	3	5	16	77
Oxygen saturation increased	1	1			1	1
Pain	27	132	11	54	16	78
Pain in extremity	27	107	6	38	21	69
Pain in jaw	4	8		2	4	6
Pain of skin		3		1		2
Palatal oedema		3				3
Pallor	4	17		1	4	16
Palpitations	11	46	4	21	7	25
Pancreatitis acute	2	4			2	4
Pancytopenia		3				3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Panic attack	1	2
Papule		2
Paraesthesia	36	118
Paraesthesia ear	1	1
Paraesthesia oral	2	19
Paralysis	3	6
Paresis		1
Parkinsonism	1	1
Parophthalmia	1	1
Parosmia		2
Parotitis	1	1
Partial seizures	1	3
Peau d'orange		1
Pelvic pain	1	4
Pemphigoid	2	3
Peptic ulcer		1
Periarthritis		4
Pericardial effusion	3	4
Pericardial haemorrhage	1	1
Pericarditis	3	15
Periorbital haematoma	1	1
Periorbital pain	1	2
Periorbital swelling	1	1
Peripheral artery thrombosis	2	2
Peripheral coldness	2	7
Peripheral ischaemia	4	6
Peripheral swelling	6	15
Peripheral venous disease	1	1
Pernio-like erythema		1
Persecutory delusion	1	2
Persistent depressive disorder		1
Persistent postural-perceptual dizziness	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	1	1
	1		1
6	36	30	82
		1	1
	8	2	11
		3	6
			1
		1	1
		1	1
	2		
		1	1
		1	3
	1		
		1	4
		2	3
			1
			4
		3	4
		1	1
		3	15
		1	1
1	1		1
		1	1
		2	2
2	4		3
	1	4	5
1	3	5	12
		1	1
	1		
	1	1	1
			1
		1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	3	6	1	4	2	2
Petit mal epilepsy	2	7			2	7
Phaeochromocytoma		1				1
Pharyngeal disorder		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		5		1		4
Pharyngeal swelling		1		1		
Pharyngitis	1	1	1	1		
Phlebitis	6	8	2	2	4	6
Phlebitis superficial	2	2	2	2		
Phonophobia		2		1		1
Photophobia	1	7	1	2		5
Photopsia		3		1		2
Photosensitivity reaction		1		1		
Piloerection		1				1
Platelet count decreased	1	2	1	2		
Platelet count increased		1				1
Pleural effusion	3	3			3	3
Pleurisy	1	1			1	1
Pneumonia	6	16			6	16
Pneumonia aspiration	5	19			5	19
Pneumonitis		4		1		3
Pneumoperitoneum		1				1
Pneumothorax	1	1			1	1
Pollakiuria	1	1	1	1		
Polyarthrits	1	2			1	2
Polychondritis	1	1			1	1
Polydipsia		1				1
Polyneuropathy	1	3			1	3
Polyserositis	1	1			1	1
Poor quality product administered		81		81		
Posterior revers ble encephalopathy syndrome	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Prerenal failure		1				1
Presyncope	7	32	2	13	5	19
Proctitis	1	1	1	1		
Product administered at inappropriate site		1				1
Product administration error		1				1
Productive cough	1	6		3	1	3
Product preparation error		3		3		
Product preparation issue	1	6	1	6		
Product temperature excursion issue		81		81		
Product use issue	1	11	1	11		
Progressive supranuclear palsy	1	1			1	1
Proteinuria		3		1		2
Prothrombin time shortened	2	2	1	1	1	1
Pruritus	9	58	2	22	7	36
Psoriasis	1	1			1	1
Psychomotor hyperactivity		1				1
Psychomotor retardation		1				1
Psychomotor skills impaired	1	3		1	1	2
Pulmonary alveolar haemorrhage	1	1			1	1
Pulmonary arterial hypertension	1	2			1	2
Pulmonary arterial pressure increased	1	2			1	2
Pulmonary artery dilatation	1	1			1	1
Pulmonary congestion		2				2
Pulmonary embolism	43	73			43	73
Pulmonary infarction	2	3			2	3
Pulmonary oedema	4	6			4	6
Pulmonary pain		1		1		
Pulmonary sepsis		1				1
Pulpitis dental		1				1
Pulse absent	1	2	1	1		1
Purpura	4	5	1	1	3	4
Pyelonephritis	4	5			4	5

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
26	159	51	297
		1	1
		1	2
1	1	3	6
1	19	4	22
1	3	3	12
	1	1	4
	3	3	5
	1	1	1
1	5	3	5
		1	1
		1	2
	1		
			1
3	6	3	6
	2		
			1
1	1	1	1
			1
3	11	3	11
	2		2
1	1	1	1
1	2	1	2
			1
1	3	1	3
1	2	1	2
	3		3
1	8	1	7
6	28	6	28
1	6	1	6
	1		1
1	1	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Respiratory tract congestion		1					1
Respiratory tract infection		1					1
Restlessness	2	9	1	4	1		5
Retinal artery occlusion		1					1
Retinal vein occlusion	2	2			2		2
Rheumatic disorder	1	2		1	1		1
Rheumatic fever	1	1			1		1
Rheumatoid arthritis	4	12			4		12
Rhinalgia	1	1			1		1
Rhinitis	3	8	2	5	1		3
Rhinorrhoea	1	9		2	1		7
Rhonchi		1					1
Rib fracture		2					2
Right ventricular dilatation	1	1			1		1
Road traffic accident		1					1
Salivary gland disorder		1		1			
Salivary hypersecretion		4		2			2
SARS-CoV-2 ant body test negative	2	6	2	6			
SARS-CoV-2 ant body test positive		3		3			
SARS-CoV-2 test positive	12	19	3	5	9		14
Sciatica	1	3	1	1			2
Scleritis		1					1
Sedation	1	1	1	1			
Seizure	4	13			4		13
Seizure anoxic		1					1
Sense of oppression	1	2			1		2
Sensorimotor disorder	1	4	1	1			3
Sensory disturbance	2	4	1	2	1		2
Sensory loss	3	8	1	4	2		4
Sepsis		3					3
Septic shock		2					2
Serum ferritin increased		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock		4				4
Shoulder injury related to vaccine administration	1	1			1	1
Sialoadenitis		1				1
Sinusitis	1	3			1	3
Sinus pain		1				1
Sinus tachycardia	5	14	1	2	4	12
Sjogren's syndrome	3	3			3	3
Skin discolouration	1	2	1	1		1
Skin disorder		1		1		
Skin exfoliation		1		1		
Skin fissures		1				1
Skin hyperpigmentation	1	1			1	1
Skin lesion	3	5	2	2	1	3
Skin necrosis	1	1			1	1
Skin plaque	1	4	1	3		1
Skin reaction	2	5	2	3		2
Skin ulcer	1	1			1	1
Skin warm		2		2		
SLE arthritis		1				1
Sleep apnoea syndrome	1	1			1	1
Sleep disorder	4	10	2	3	2	7
Sleep disorder due to general medical condition, insomnia type	1	2	1	2		
Sleep talking		1		1		
Sluggishness		2		2		
Snoring		1		1		
Somnolence	11	28	3	11	8	17
Speech disorder	3	11			3	11
Spinal compression fracture		2				2
Spinal osteoarthritis		1		1		
Spinal pain		2				2
Splenic infarction	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Spondylitis		1					1
Staphylococcal bacteraemia	1	1			1		1
Status epilepticus	3	5			3		5
Status migrainosus		1					1
Stereotypy		1					1
Stertor		1					1
Stomatitis	1	2	1	1			1
Stress		5		4			1
Stress cardiomyopathy	1	3			1		3
Subarachnoid haemorrhage	2	2			2		2
Subdural haematoma	1	1			1		1
Subileus		1					1
Sudden death	8	36			8		36
Sudden hearing loss	4	5			4		5
Sudden onset of sleep	1	2			1		2
Suffocation feeling		4					4
Suicidal ideation		1					1
Sunburn		1					1
Supraventricular extrasystoles	1	2			1		2
Supraventricular tachyarrhythmia		1					1
Supraventricular tachycardia	1	8			1		8
Suspected COVID-19	1	3	1	1			2
Swelling		6		4			2
Swelling face	2	5		1	2		4
Swelling of eyelid	1	1			1		1
Swollen tongue		6		2			4
Syncope	5	25			5		25
Synovial cyst		2					2
Systemic inflammatory response syndrome	1	1			1		1
Systemic lupus erythematosus		1					1
Systolic hypertension		1					1
Tachyarrhythmia	1	3		1	1		2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	41	186	12	46	29	140
Tachycardia paroxysmal	1	1			1	1
Tachypnoea	2	11	1	2	1	9
Temporal lobe epilepsy	1	1			1	1
Tendon disorder		1				1
Tendonitis	1	6		2	1	4
Tendon pain		2		2		
Tenosynovitis		1		1		
Tension		4		2		2
Tension headache		1				1
Tetany		1				1
Therapeutic response unexpected		1		1		
Thermal burns of eye		1				1
Thermohypoaesthesia		1		1		
Thirst	1	6		3	1	3
Throat irritation	2	9	1	5	1	4
Throat tightness	2	5			2	5
Thrombocytopenia	5	9			5	9
Thrombolysis	1	1			1	1
Thrombophlebitis	3	3			3	3
Thrombophlebitis superficial	4	5	2	3	2	2
Thrombosed varicose vein	1	1			1	1
Thrombosis	6	7			6	7
Thyroid mass		1		1		
Thyroxine free decreased	1	1	1	1		
Tinnitus	11	32	4	9	7	23
Tongue coated	1	2			1	2
Tongue discolouration		1				1
Tongue discomfort		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue movement disturbance		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema	2	7	1	2	1	5
Tonic clonic movements	1	4			1	4
Tonsillitis	1	2			1	2
Tooth abscess		2		1		1
Toothache		2		1		1
Tooth infection		1		1		
Torticollis		1				1
Toxicity to various agents	1	1			1	1
Toxic skin eruption		1				1
Transcription medication error		1		1		
Transient global amnesia		2				2
Transient ischaemic attack	10	26			10	26
Tremor	10	45	2	14	8	31
Trigeminal neuralgia	1	2			1	2
Tri-iodothyronine free decreased	1	1	1	1		
Trismus		2		2		
Troponin increased	4	9	1	2	3	7
Tumour perforation		1				1
Type 1 diabetes mellitus	1	1			1	1
Type I hypersensitivity	1	2			1	2
Type II hypersensitivity		1				1
Type III immune complex mediated reaction	1	1			1	1
Underdose	1	8	1	8		
Unresponsive to stimuli		2				2
Urinary incontinence	3	4			3	4
Urinary retention	3	3			3	3
Urinary tract candidiasis		1				1
Urinary tract discomfort	1	1	1	1		
Urinary tract infection	1	5		1	1	4
Urinary tract infection bacterial	2	3			2	3
Urine odour abnormal	1	1	1	1		
Urosepsis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	12	56	5	24	7	32
Urticaria chronic		1				1
Uvulitis		1				1
Vaccination complication	1	6		2	1	4
Vaccination failure	70	76			70	76
Vaccination site abscess		2		1		1
Vaccination site bruising		1		1		
Vaccination site cellulitis		1				1
Vaccination site coldness		1		1		
Vaccination site discharge		1				1
Vaccination site discolouration		1				1
Vaccination site discomfort		1				1
Vaccination site dysaesthesia	1	1			1	1
Vaccination site erythema	7	44	5	28	2	16
Vaccination site exfoliation		1				1
Vaccination site granuloma	1	1			1	1
Vaccination site haematoma	3	11	1	5	2	6
Vaccination site haemorrhage		2		1		1
Vaccination site hypersensitivity		10		10		
Vaccination site hypoaesthesia		1				1
Vaccination site induration	6	17	4	13	2	4
Vaccination site inflammation	3	25	1	11	2	14
Vaccination site joint movement impairment		1				1
Vaccination site joint pain		2		1		1
Vaccination site lymphadenopathy		1				1
Vaccination site mass	2	3	2	2		1
Vaccination site movement impairment	3	14		6	3	8
Vaccination site nodule		3		1		2
Vaccination site oedema	2	14	1	4	1	10
Vaccination site pain	51	298	15	140	36	158
Vaccination site papule		1		1		
Vaccination site paraesthesia		10		5		5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site plaque		1					1
Vaccination site pruritus	4	23	3	12	1		11
Vaccination site rash	1	4		2	1		2
Vaccination site reaction	4	13	1	8	3		5
Vaccination site recall reaction		1		1			
Vaccination site swelling	3	18	1	10	2		8
Vaccination site thrombosis		1					1
Vaccination site urticaria		3		3			
Vaccination site warmth	3	16	1	7	2		9
Vagus nerve disorder		1					1
Varicella virus test positive	1	1			1		1
Vascular encephalopathy		1					1
Vascular purpura	1	5		2	1		3
Vascular stenosis	1	1			1		1
Vasculitis		2		1			1
Vasodilatation		1		1			
Vasoplegia syndrome	1	1			1		1
Vein rupture	1	1			1		1
Vena cava thrombosis	1	1			1		1
Venous oxygen saturation decreased	1	2			1		2
Venous thrombosis		1					1
Venous thrombosis limb	2	2			2		2
Ventricular arrhythmia	1	1			1		1
Ventricular extrasystoles	2	9		2	2		7
Ventricular failure	1	1			1		1
Ventricular fibrillation	2	2			2		2
Ventricular hypokinesia	1	1			1		1
Ventricular tachycardia		1					1
Vertigo	22	87	8	26	14		61
Vertigo positional	3	11			3		11
Vestibular disorder	1	4	1	2			2
Vestibular neuronitis	2	5			2		5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Viral infection		3		2		1	
Vision blurred	5	14		4	5	10	
Visual acuity reduced		1				1	
Visual acuity reduced transiently	1	1			1	1	
Visual field defect	2	3			2	3	
Visual impairment	3	16	1	3	2	13	
Vitamin D deficiency	1	1	1	1			
Vlth nerve paralysis		1				1	
Vomiting	48	170	10	41	38	129	
Von Willebrand's factor activity decreased		1				1	
Walking disability		2				2	
Weight decreased	2	6		1	2	5	
Weight increased	2	3	1	1	1	2	
Wheezing	2	4	1	1	1	3	
White blood cell count decreased	1	2	1	2			
White blood cell count increased		1		1			
Withdrawal hypertension		1		1			
Wrong patient received product		1		1			
Wrong technique in product usage process		3		3			
	1	1	1	1			
	3,343	12,301	720	3470	2623	8831	

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3	1	2		1
Abdominal distension	1	2	1	2		
Abdominal mass	1	1	1	1		
Abdominal pain	3	19	2	6	1	13
Abdominal pain lower	2	2	2	2		
Abdominal pain upper	1	7		5	1	2
Abdominal rigidity		1				1
Abnormal behaviour	1	2	1	1		1
Acidosis hyperchloraemic		1				1
Acne	1	1	1	1		
Acquired haemophilia	1	1			1	1
Activated partial thromboplastin time abnormal	1	1			1	1
Acute abdomen		1				1
Acute coronary syndrome	4	9			4	9
Acute kidney injury	2	11			2	11
Acute myocardial infarction		1				1
Acute pulmonary oedema	1	4			1	4
Acute respiratory distress syndrome	2	5			2	5
Acute respiratory failure	1	4			1	4
Acute vestibular syndrome	1	2			1	2
Adult failure to thrive		1				1
Ageusia	3	6	2	5	1	1
Aggression	2	2	1	1	1	1
Agitation	3	7		2	3	5
Agnosia	1	1			1	1
Agranulocytosis	1	2			1	2
Air embolism	1	1			1	1
Alanine aminotransferase increased		2		1		1
Altered state of consciousness	2	5			2	5
Amaurosis	1	1			1	1
Amnesia	1	2	1	1		1
Amyotrophy	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	2	6		1	2	5
Anaphylactic reaction		5				5
Aneurysm ruptured		1				1
Angina pectoris	1	4			1	4
Angina unstable		1				1
Angioedema	4	11			4	11
Anosmia	1	2	1	2		
Anterograde amnesia	1	1			1	1
Anticoagulation drug level below therapeutic	2	2	1	1	1	1
Anti-neutrophil cytoplasmic antibody positive vasculitis		1				1
Anxiety	1	3		1	1	2
Aortic dissection		1				1
Aortic valve incompetence	1	1			1	1
Apathy	1	4	1	3		1
Aphasia	2	8		1	2	7
Aphonia		1				1
Aphthous ulcer	1	3		1	1	2
Aplasia		1				1
Appendicitis		1				1
Appendicitis perforated	1	1			1	1
Arrhythmia	14	35			14	35
Arrhythmia supraventricular	1	2			1	2
Arterial thrombosis	2	2			2	2
Arteriosclerosis	1	1			1	1
Arteriosclerosis coronary artery	1	1			1	1
Arteriovenous fistula thrombosis		1				1
Arthralgia	10	43	3	20	7	23
Arthritis	2	3	1	1	1	2
Arthritis reactive	2	2			2	2
Arthrodesis	1	1	1	1		
Arthropathy		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aspartate aminotransferase increased		1				1
Aspiration	1	2			1	2
Asthenia	40	148	13	46	27	102
Asthma	1	1			1	1
Asthmatic crisis		2				2
Asymptomatic COVID-19	7	10	2	3	5	7
Ataxia	4	5	3	3	1	2
Atelectasis		1				1
Atrial fibrillation	17	40			17	40
Atrial flutter	1	3			1	3
Atrial thrombosis	1	1			1	1
Atrioventricular block	3	5			3	5
Atrioventricular block complete		1				1
Atrioventricular block second degree	1	1			1	1
Atypical pneumonia		1				1
Autoimmune haemolytic anaemia		1				1
Autoimmune thyroiditis		2				2
Axillary pain		2		2		
Axillary vein thrombosis	1	1	1	1		
Back pain	2	9	2	5		4
Bacterial infection		1				1
Bacterial sepsis	1	1			1	1
Balance disorder	3	8	1	1	2	7
B-cell lymphoma	1	1			1	1
Bedridden		1		1		
Behaviour disorder	4	4			4	4
Benign prostatic hyperplasia	2	2	1	1	1	1
Beta 2 microglobulin increased		1		1		
Bilirubin conjugated increased		1		1		
Blindness	1	1			1	1
Blindness transient	1	1			1	1
Blindness unilateral	1	3			1	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blister		1					1
Blood alkaline phosphatase increased	2	3	2	3			
Blood bicarbonate decreased		1					1
Blood bilirubin abnormal	1	1	1	1			
Blood bilirubin increased		1		1			
Blood bilirubin unconjugated increased		1		1			
Blood creatine phosphokinase increased		1					1
Blood creatinine increased	1	1	1	1			
Blood glucose increased	1	4	1	2			2
Blood lactate dehydrogenase increased	1	2	1	2			
Blood parathyroid hormone increased	1	1	1	1			
Blood potassium increased	1	1	1	1			
Blood pressure decreased	3	4		1	3		3
Blood pressure diastolic decreased		1		1			
Blood pressure fluctuation	1	2			1		2
Blood pressure increased	1	13	1	3			10
Blood pressure systolic decreased	1	1	1	1			
Blood pressure systolic increased		2					2
Blood sodium increased	1	3		1	1		2
Blood thyroid stimulating hormone increased	1	1	1	1			
Blood uric acid increased		1		1			
Body temperature decreased		1					1
Body temperature increased	1	3	1	2			1
Bone pain	1	1			1		1
Bone swelling		1		1			
Bradycardia	10	19			10		19
Bradyphrenia	1	2			1		2
Brain hypoxia	1	1			1		1
Brain natriuretic peptide increased	2	2	1	1	1		1
Brain neoplasm	1	1			1		1
Brain stem haemorrhage		1					1
Bronchiolitis	1	1			1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		8		2		6
Bronchopneumopathy		2				2
Bundle branch block left		1				1
Bundle branch block right	1	2	1	1		1
Burning sensation	2	6	1	5	1	1
Bursal fluid accumulation		1		1		
Bursal haematoma		1				1
Bursitis		1				1
Cardiac arrest	4	13			4	13
Cardiac discomfort		1				1
Cardiac disorder	1	1	1	1		
Cardiac failure	16	39			16	39
Cardiac failure acute	1	1			1	1
Cardiac fibrillation	1	1			1	1
Cardiomyopathy	1	1			1	1
Cardiopulmonary failure	1	1			1	1
Cardio-respiratory arrest	4	19			4	19
Carotid artery occlusion	3	3			3	3
Carotid artery stenosis	1	1			1	1
Carotid artery thrombosis	1	1			1	1
Cataract	1	1			1	1
Cerebellar ataxia	1	1	1	1		
Cerebellar haematoma	1	1			1	1
Cerebellar infarction		1				1
Cerebellar syndrome	1	3			1	3
Cerebral amyloid angiopathy		1				1
Cerebral arteriosclerosis	1	1			1	1
Cerebral atrophy	1	1			1	1
Cerebral disorder		1				1
Cerebral haematoma	1	2			1	2
Cerebral haemorrhage	5	8			5	8
Cerebral infarction	4	6			4	6

\* I=Interval, C=Cumulative

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	13	20			13	20
Cervical cord compression	1	1			1	1
Cervical radiculopathy		1		1		
Cervicobrachial syndrome		2				2
Chest discomfort	1	8		4	1	4
Chest pain	14	41	3	7	11	34
Chills	9	54	4	25	5	29
Choking	1	1			1	1
Cholecystitis		1				1
Cholestasis		1				1
Chromaturia		1		1		
Chronic kidney disease	1	1			1	1
Chronic obstructive pulmonary disease	1	8		2	1	6
Circulatory collapse	1	1			1	1
Citrobacter infection	1	1			1	1
Cluster headache	1	1			1	1
Cold sweat	2	4	2	3		1
Colitis		2		1		1
Colitis ulcerative	1	1			1	1
Coma	3	6			3	6
Complex regional pain syndrome		1		1		
Condition aggravated	8	16	1	2	7	14
Confusional state	10	16	2	4	8	12
Congestive cardiomyopathy		1				1
Conjunctival haemorrhage	2	4			2	4
Conjunctival hyperaemia	1	1	1	1		
Conjunctival irritation		1		1		
Conjunctivitis		1				1
Constipation	3	4	3	4		
Contusion		1		1		
Coordination abnormal	1	1			1	1
Coronary artery disease	1	2			1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Coronary artery occlusion	1	1
Coronary artery stenosis		2
Cough	11	28
COVID-19	45	127
COVID-19 pneumonia	9	13
C-reactive protein increased	8	22
Crepitations	1	1
Crohn's disease	1	1
Cyanosis		1
Cystic lymphangioma		1
Cytomegalovirus infection	1	2
Deafness	1	2
Deafness neurosensory		1
Deafness unilateral	1	4
Death	12	44
Decreased appetite	9	24
Decubitus ulcer	2	2
Deep vein thrombosis	15	16
Defect conduction intraventricular	1	1
Dehydration	6	11
Delirium	1	5
Delusion		1
Depressed level of consciousness	1	2
Depression		1
Dermabrasion		1
Dermatitis bullous	1	2
Dermatitis exfoliative generalised	1	2
Dermo-hypodermatitis	2	3
Diabetes mellitus	3	5
Diabetes mellitus inadequate control	3	5
Diabetic ketoacidosis	1	3
Diabetic metabolic decompensation		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			2
5	10	6	18
8	16	37	111
		9	13
4	9	4	13
1	1		
		1	1
			1
			1
		1	2
		1	2
			1
		1	4
		12	44
5	11	4	13
1	1	1	1
		15	16
		1	1
2	4	4	7
		1	5
	1		
		1	2
	1		
		1	2
		2	3
		3	5
		3	5
		1	3
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	14	53	4	17	10	36
Diarrhoea haemorrhagic		1				1
Diarrhoea infectious	2	2			2	2
Diplopia	2	7			2	7
Discomfort	5	15	3	4	2	11
Disease progression		1				1
Disease recurrence	10	27		1	10	26
Disorientation	5	7	3	3	2	4
Disseminated intravascular coagulation	1	1			1	1
Disturbance in attention	1	2		1	1	1
Diverticulum intestinal	2	2	1	1	1	1
Dizziness	9	42	4	17	5	25
Drooling		1		1		
Drop attacks		1				1
Drug eruption	1	1	1	1		
Drug ineffective	13	55			13	55
Drug interaction	2	2	1	1	1	1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry eye		1		1		
Dry mouth	1	2	1	1		1
Dysaesthesia	1	4	1	2		2
Dysarthria	6	8	1	1	5	7
Dysgeusia	2	5		2	2	3
Dysgraphia	1	1			1	1
Dyskinesia	1	2	1	1		1
Dyslipidaemia		1		1		
Dysmetria	1	1			1	1
Dyspepsia		2		1		1
Dysphagia	1	6		2	1	4
Dysphemia		1				1
Dysphonia	1	5		3	1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	14	56	2	8	12	48
Dyspnoea at rest		3				3
Dyspnoea exertional	5	11	1	2	4	9
Dysstasia		2				2
Dysuria	1	5	1	2		3
Ear discomfort		1				1
Ear disorder	1	1	1	1		
Ear haemorrhage	1	1	1	1		
Ear infection		2				2
Ear pain	3	7	2	3	1	4
Eczema	1	3		1	1	2
Eczema nummular	1	1			1	1
Electric shock		1				1
Electrocardiogram QRS complex prolonged	1	1			1	1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram T wave abnormal		1		1		
Electroencephalogram abnormal		1				1
Embolic stroke	2	2			2	2
Enterocolitis haemorrhagic	1	1			1	1
Enuresis		1				1
Eosinophilia	1	3			1	3
Epilepsy	4	13			4	13
Epistaxis	8	16	3	7	5	9
Erectile dysfunction	1	2			1	2
Eructation		1				1
Erysipelas	4	8			4	8
Erythema	3	19		9	3	10
Erythema multiforme	1	1			1	1
Erythema nodosum		1		1		
Escherichia bacteraemia		1				1
Escherichia urinary tract infection	1	1			1	1
Exposure to SARS-CoV-2		1				1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	8	12	48
			3
1	2	4	9
			2
1	2		3
			1
1	1		
1	1		
			2
2	3	1	4
	1	1	2
		1	1
			1
	1		
			1
		2	2
		1	1
			1
			1
		2	2
		1	1
			1
		1	3
		4	13
3	7	5	9
		1	2
			1
		4	8
	9	3	10
		1	1
	1		
			1
		1	1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extensive swelling of vaccinated limb		1		1		
Extrapyramidal disorder	2	2	1	1	1	1
Extrasystoles	1	4			1	4
Extremity necrosis	1	1			1	1
Eye contusion		1		1		
Eye haemorrhage		3				3
Eye irritation		1		1		
Eyelid disorder		1		1		
Eyelid function disorder		1				1
Eyelid haematoma		1		1		
Eyelid oedema	1	3		1	1	2
Eye pain		2				2
Eye swelling		2		1		1
Face oedema	1	8		1	1	7
Facial asymmetry	1	1			1	1
Facial bones fracture	1	1			1	1
Facial pain		4		1		3
Facial paralysis	19	42			19	42
Facial paresis		2				2
Faeces discoloured		1		1		
Faeces soft		2		2		
Fall	13	30	4	6	9	24
Fatigue	21	84	10	49	11	35
Fat tissue increased		1		1		
Febrile convulsion		1				1
Feeling abnormal	1	4		2	1	2
Feeling cold	2	5	1	3	1	2
Feeling drunk		1				1
Feeling hot		5		2		3
Femoral neck fracture		1				1
Femur fracture		1				1
Fibrin D dimer increased	1	1			1	1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	1		
	2	1	2
		1	1
		1	1
		1	1
2	4	3	8
	1		1
4	5		1
			2
2	2		2
		1	2
	1		
	1		
1	1		
	2		
	1		1
	2	2	5
2	5	5	12
		1	1
			1
			1
	1		
1	1		1
			1
		2	3
	1		
	3	3	3
2	3	2	2
1	1	1	1
2	3	2	3
1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased	3	5	2	2	1	3
Haemolytic anaemia	1	1			1	1
Haemophagocytic lymphohistiocytosis	2	3			2	3
Haemoptysis	2	3			2	3
Haemorrhage		1				1
Haemorrhagic diathesis	1	1			1	1
Haemorrhagic stroke	3	5			3	5
Haemorrhoids		1				1
Hallucination	1	1			1	1
Hallucination, auditory	1	1			1	1
Hallucination, visual	4	4			4	4
Headache	26	110	13	47	13	63
Head discomfort		2		1		1
Head injury	4	7			4	7
Heart rate decreased		2		1		1
Heart rate increased		6		3		3
Heart rate irregular	1	2			1	2
Heart sounds abnormal		2				2
Hemianopia	1	2			1	2
Hemianopia homonymous	1	2			1	2
Hemiparaesthesia		1				1
Hemiparesis	2	5			2	5
Hemiplegia	2	7			2	7
Henoch-Schonlein purpura		1		1		
Hepatic cyst infection		1				1
Hepatic enzyme increased	1	2	1	1		1
Hepatic steatosis	2	2	1	1	1	1
Hepatitis B	1	1			1	1
Hepatitis cholestatic	1	1			1	1
Hepatocellular injury	1	4			1	4
Hepatojugular reflux	1	1	1	1		
Hepatomegaly		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes ophthalmic		2				2
Herpes simplex		2		1		1
Herpes zoster	15	45		15	15	30
Hoffmann's sign		1		1		
Horner's syndrome		1				1
Hot flush	2	7	1	5	1	2
Humerus fracture	1	1			1	1
Hyperaesthesia	1	4	1	3		1
Hyperbilirubinaemia	2	2			2	2
Hypercalcaemia	1	1	1	1		
Hypercapnia	1	1			1	1
Hyperchloraemia	1	1			1	1
Hyperferritinaemia	1	1			1	1
Hyperglycaemia	3	8	1	3	2	5
Hyperglycinaemia		1				1
Hyperhidrosis	4	22	2	9	2	13
Hyperkalaemia	3	4			3	4
Hyperlactacidaemia	1	1			1	1
Hyperleukocytosis	2	6			2	6
Hypnatraemia	3	3	1	1	2	2
Hypersensitivity	1	13		6	1	7
Hypersensitivity vasculitis	1	1			1	1
Hypersomnia	1	2	1	2		
Hypertension	37	108	3	10	34	98
Hypertensive crisis	13	44			13	44
Hypertensive urgency		1				1
Hyperthermia	4	16	1	3	3	13
Hypertonia	1	1			1	1
Hypertrophic cardiomyopathy	1	2			1	2
Hyperventilation		1		1		
Hypervitaminosis B12		1				1
Hypoacusis	2	4		1	2	3

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoaesthesia	6	11
Hypoaesthesia oral		1
Hypogammaglobulinaemia	1	1
Hypokalaemia	2	3
Hypophagia		1
Hypotension	12	43
Hypotensive crisis		1
Hypothermia		3
Hypotonia	2	3
Hypovolaemic shock	1	2
Hypoxia	3	7
Illrd nerve paralysis		1
Immune thrombocytopenia	2	4
Impaired work ability	1	3
Inappropriate schedule of product administration	2	4
Incoherent	3	3
Incontinence	1	1
Incorrect dose administered		2
Incorrect route of product administration	2	5
Induration		1
Infarction	2	2
Infection	1	3
Inflammation	7	12
Influenza	3	12
Influenza like illness	20	96
Injected limb mobility decreased		3
Injection site erythema		1
Injection site pain		1
Injection site pruritus	1	1
Injection site swelling		1
Insomnia	4	16
International normalised ratio abnormal		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	5	3	6
			1
		1	1
		2	3
	1		
3	9	9	34
			1
			3
1	1	1	2
		1	2
		3	7
			1
		2	4
		1	3
2	4		
		3	3
		1	1
	2		
2	5		
	1		
		2	2
1	2		1
3	4	4	8
2	3	1	9
7	22	13	74
	1		2
	1		
	1		
1	1		
	1		
3	10	1	6
			1

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Gender

**MALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	3
		1	1
1	1		
1	1		
		3	3
	1		
			1
		1	1
19	36	19	36
			2
1	1	1	1
			1
			1
	1		
1	1	1	1
			1
	1		
			1
			1
			1
1	2		
1	1	1	1
1	2	1	2
2	2		
1	4	1	4
1	1		
			1
			1
1	1	1	1
1	1	1	1
			2
	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lithiasis		1		1		
Livedo reticularis	2	4	1	2	1	2
Liver function test increased	1	1			1	1
Localised oedema		1				1
Loss of consciousness	16	34			16	34
Loss of libido	1	1	1	1		
Loss of personal independence in daily activities	2	2			2	2
Lower respiratory tract congestion		3				3
Lung abscess		1				1
Lung disorder	6	12	4	4	2	8
Lyme disease	1	2			1	2
Lymphadenitis	1	2			1	2
Lymphadenopathy	7	25	3	15	4	10
Lymphadenopathy mediastinal	1	1	1	1		
Lymphangitis	1	1			1	1
Lymphoedema	2	3	1	2	1	1
Lymphopenia	5	9	2	2	3	7
Macroglossia		1				1
Macular oedema	1	1			1	1
Madarosis		1				1
Malaise	22	90	9	28	13	62
Malignant hypertension		1				1
Malnutrition		1		1		
Mass		1				1
Medication error		1		1		
Memory impairment		1				1
Meningeal disorder		1				1
Mental impairment	1	1			1	1
Mesenteric vein thrombosis	1	1			1	1
Metamorphopsia	1	1			1	1
Middle insomnia	2	3			2	3
Migraine		3		1		2

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
			1
			2
2		2	2
1		1	3
			1
			1
7		7	9
	1		
2	1	2	2
	1		
2		2	2
			2
	1		
1	2		
	1		
2	2	1	2
			1
5	2	3	6
	1		
1	2		
6	4	6	16
1	1		1
10	26	8	37
1		1	1
1		1	1
	1		2
			1
			1
1		1	1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	5	18			5	18
Myocardial ischaemia		3				3
Myocardial necrosis marker increased		2				2
Myocarditis		4				4
Myoclonus	2	4			2	4
Myositis	1	1			1	1
Nasal congestion		3		2		1
Nasal herpes		1				1
Nasopharyngitis	2	4	2	4		
Nausea	12	58	6	23	6	35
Near death experience		2				2
Neck injury	1	1			1	1
Neck pain	3	9	2	5	1	4
Needle issue		1		1		
Neoplasm		1				1
Nephrotic syndrome	1	1			1	1
Nerve conduction studies abnormal	1	1	1	1		
Nervous system disorder		2				2
Neuralgia	4	8	2	4	2	4
Neuralgic amyotrophy	1	1			1	1
Neuritis		1		1		
Neurological decompensation	1	2	1	1		1
Neutropenia	1	3			1	3
Neutrophil count decreased		1				1
Neutrophil count increased	1	1	1	1		
Neutrophilia	1	1	1	1		
Nightmare	1	1			1	1
Night sweats	1	3	1	2		1
Noninfective chorioretinitis		1				1
N-terminal prohormone brain natriuretic peptide increased	1	1			1	1
Obstruction gastric		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort	1	2	1	2		
Ocular hyperaemia	1	3			1	3
Odynophagia	2	2	2	2		
Oedema	1	2	1	2		
Oedema genital	1	1			1	1
Oedema mucosal		1		1		
Oedema peripheral	6	14	3	4	3	10
Off label use		6		6		
Ophthalmic herpes zoster	3	6			3	6
Optic ischaemic neuropathy	1	1			1	1
Optic neuritis	1	1			1	1
Oropharyngeal candidiasis	1	1			1	1
Oropharyngeal discomfort		1		1		
Oropharyngeal oedema		1				1
Oropharyngeal pain	2	6	2	5		1
Orthopnoea	1	2			1	2
Osteoarthritis	2	3	2	2		1
Otitis externa		2		1		1
Overdose		5		5		
Oxygen saturation decreased	6	31	2	7	4	24
Pain	8	50	2	22	6	28
Painful respiration		1				1
Pain in extremity	11	28	6	16	5	12
Pain in jaw	1	3			1	3
Pain of skin	1	2			1	2
Palatal oedema		2				2
Pallor	1	8		1	1	7
Palpitations	7	19	2	5	5	14
Pancreatitis	1	2			1	2
Pancreatitis acute	2	3			2	3
Pancytopenia	1	1			1	1
Paraesthesia	9	29	1	6	8	23

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia oral	1	2		1	1	1
Paresis		2				2
Parkinsonism		1				1
Parkinson's disease	1	1			1	1
Parosmia		1		1		
Partial seizures		3				3
Pelvic fracture		1				1
Pemphigoid	1	1			1	1
Pericardial effusion	2	4			2	4
Pericarditis	7	10			7	10
Periorbital oedema		1				1
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness		3		3		
Peripheral embolism	1	1			1	1
Peripheral ischaemia	3	4			3	4
Peripheral sensory neuropathy	1	1			1	1
Peripheral swelling	2	6	1	3	1	3
Peripheral venous disease	1	1	1	1		
Pernio-like erythema		1		1		
Petechiae	2	3	1	2	1	1
Petit mal epilepsy	1	1			1	1
Pharyngitis	1	1	1	1		
Phlebitis	6	7	3	4	3	3
Photophobia		5				5
Photopsia	1	1			1	1
Platelet count decreased	1	2			1	2
Pleural effusion	3	4	2	2	1	2
Pneumococcal sepsis		1				1
Pneumonia	7	18			7	18
Pneumonia aspiration	2	8			2	8
Pneumonia bacterial	3	4			3	4
Pneumonia moraxella		1				1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	2
	1		
		1	1
	1		
	2	2	2
	1	1	2
1	1		
	38		
		1	1
	1		
	1		
	4	8	
		1	1
	1		
	4	3	6
			1
	1	1	2
	1		
	7		
	35		
	5		
	3	2	2
	1		1
	1	1	1
	4	22	12
			1
	1		1
			1
		1	
	29	29	38
	1	1	1
	1	1	1
	1	1	7
	1	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulse abnormal		1		1		
Pulse absent		1		1		
Pupils unequal		1		1		
Purpura	2	4	1	1	1	3
Pyrexia	33	152	12	51	21	101
Radial nerve palsy	1	1			1	1
Rales	2	6			2	6
Rash	5	18	1	7	4	11
Rash erythematous	2	4	1	3	1	1
Rash macular	1	2			1	2
Rash maculo-papular	1	7		3	1	4
Rash papular		5		2		3
Rash pruritic	1	3		1	1	2
Rash vesicular		1		1		
Raynaud's phenomenon	1	2		1	1	1
Recalled product administered	1	1	1	1		
Rectal haemorrhage		2				2
Renal artery stenosis		1				1
Renal colic	1	1			1	1
Renal cyst	1	1			1	1
Renal failure	4	8			4	8
Renal impairment		1				1
Respiration abnormal	1	1			1	1
Respiratory acidosis	1	1			1	1
Respiratory depression		1				1
Respiratory disorder	1	6			1	6
Respiratory distress	3	10			3	10
Respiratory failure	1	7			1	7
Respiratory rate increased	1	3	1	2		1
Respiratory tract infection		2				2
Respiratory tract infection bacterial	1	1			1	1
Respiratory tract oedema		1				1

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\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restlessness		2		1		1
Retinal artery occlusion	3	4			3	4
Retinal fovea disorder	1	1			1	1
Retinal vein occlusion	3	5			3	5
Retrograde amnesia	1	1			1	1
Rhabdomyolysis	4	5			4	5
Rheumatoid factor increased	1	1			1	1
Rhinitis		1		1		
Rhinorrhoea	1	6	1	3		3
Rhonchi		2		1		1
Rib fracture	1	1			1	1
Road traffic accident	3	5	1	1	2	4
Romberg test positive		1		1		
Rotator cuff syndrome		2		1		1
SARS-CoV-2 ant body test negative	1	7	1	7		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test false positive	1	1	1	1		
SARS-CoV-2 test positive	5	12	3	4	2	8
Scleral disorder	1	1			1	1
Seizure	3	12			3	12
Sensory disturbance	1	3			1	3
Sensory loss	1	3			1	3
Sepsis	4	7			4	7
Septic shock	1	4			1	4
Serum sickness	1	1			1	1
Shock		1				1
Shock haemorrhagic	2	2			2	2
Sinus arrest		1				1
Sinus bradycardia		2				2
Sinus disorder		1				1
Sinus tachycardia	2	5	1	2	1	3
Skin discolouration		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin exfoliation		1
Skin induration	1	1
Skin lesion		2
Skin mass		2
Skin ulcer		1
Skin warm		1
Sleep apnoea syndrome		1
Sleep disorder		2
Sleep disorder due to general medical condition, insomnia type		1
Somnolence	4	15
Speech disorder	3	8
Spinal cord infarction	2	2
Spinal cord ischaemia	1	1
Spinal pain	1	2
Staphylococcal bacteraemia	1	2
Staphylococcal sepsis	1	1
Staring		1
Status epilepticus		3
Stereotypy		1
Sternal fracture	1	1
Stress		1
Subarachnoid haemorrhage	1	1
Subclavian vein thrombosis	1	1
Subdural haematoma	1	2
Subileus		1
Sudden death	7	21
Sudden hearing loss	1	1
Suffocation feeling		3
Superinfection	2	2
Superinfection bacterial	1	1
Superior vena cava syndrome		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
	1		1
	1		1
	1		
	1		
	1		
	1		1
2	8	2	7
	1	3	7
		2	2
		1	1
1	1		1
		1	2
		1	1
			1
			3
			1
		1	1
	1		
		1	1
		1	1
		1	2
			1
		7	21
		1	1
	2		1
		2	2
		1	1
			1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular extrasystoles		3				3
Supraventricular tachycardia	1	2			1	2
Suspected COVID-19	1	4			1	4
Swelling face		2		1		1
Syncope	3	14			3	14
Systemic inflammatory response syndrome	1	1			1	1
Tachyarrhythmia		3		1		2
Tachycardia	13	54	5	14	8	40
Tachypnoea	1	5			1	5
Target skin lesion		1				1
Taste disorder		1		1		
Tenderness		1		1		
Tendon disorder		1				1
Tendonitis		2				2
Tendon rupture	1	1			1	1
Tension		1		1		
Terminal state		1				1
Testicular pain	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Thirst	1	2	1	1		1
Throat irritation		1		1		
Thrombocytopenia	11	20	1	1	10	19
Thrombocytopenic purpura		1				1
Thrombocytosis	1	1	1	1		
Thrombophlebitis	6	6	1	1	5	5
Thrombophlebitis superficial	7	9	2	2	5	7
Thrombosis	3	5			3	5
Thrombosis mesenteric vessel	1	1			1	1
Thyroid disorder		1		1		
Tinnitus	4	14	2	4	2	10
Tongue biting	2	3	1	1	1	2
Tongue haematoma		2		2		

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	1
			3
		1	2
	1		
1	1		1
			1
		1	1
		1	1
1	1		
			1
		8	10
1	4	2	12
			1
1	2		3
		1	1
			1
		1	1
1			
	8		
			1
1	1	2	2
			1
		1	3
1	1		
	4	2	12
			1
	1		
		39	47
	1		
			1
1	8		2

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\* AE=Adverse Event

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site haematoma		1
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity		9
Vaccination site induration		4
Vaccination site infection	1	1
Vaccination site inflammation	1	5
Vaccination site joint inflammation		1
Vaccination site joint pain		1
Vaccination site lymphadenopathy		1
Vaccination site movement impairment		4
Vaccination site oedema	1	5
Vaccination site pain	11	89
Vaccination site paraesthesia		1
Vaccination site pruritus		3
Vaccination site rash		1
Vaccination site reaction		4
Vaccination site swelling	1	4
Vaccination site urticaria		1
Vaccination site warmth		2
Vaginal haemorrhage		1
Varicose vein	1	1
Vascular purpura	1	3
Vascular stent thrombosis	1	1
Vein rupture		1
Vena cava thrombosis	1	1
Venous thrombosis	1	3
Venous thrombosis limb	5	5
Ventricular extrasystoles	3	5
Ventricular fibrillation		3
Ventricular hypokinesia	1	1
Ventricular tachycardia	1	6
Vertigo	7	31

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
	9		
	3		1
		1	1
1	2		3
			1
	1		
	1		3
1	3		2
6	60	5	29
	1		
	1		2
			1
	1		3
	3	1	1
			1
	2		
			1
1	1		
		1	3
		1	1
			1
		1	1
		1	3
1	1	4	4
1	1	2	4
			3
		1	1
		1	6
3	9	4	22

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vestibular disorder		1				1	
Vestibular neuronitis		3				3	
Vestibulitis		1				1	
Viral infection		1		1			
Vision blurred	3	7		1	3	6	
Visual acuity reduced	1	4			1	4	
Visual brightness		1				1	
Visual impairment		4		1		3	
Vitamin D deficiency		1				1	
Vlth nerve paralysis	1	2			1	2	
Vitreous floaters		1				1	
Vomiting	10	49	4	14	6	35	
Weight decreased	5	8	1	1	4	7	
Weight increased	1	1			1	1	
Wheezing	2	3			2	3	
White blood cell count decreased	2	3			2	3	
White blood cell count increased	1	3		1	1	2	
White matter lesion		1				1	
Withdrawal hypertension		1				1	
Wound	1	1			1	1	
Yellow skin		1		1			
	1,664	4,906	385	1362	1279	3544	

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome		1		1		
Ageusia	1	1			1	1
Allergy to vaccine	1	1	1	1		
Anaphylactoid reaction		1				1
Anosmia	1	1			1	1
Arthralgia		1		1		
Asthenia	2	2			2	2
Asymptomatic COVID-19	1	8			1	8
Autoimmune thyroiditis		1				1
Bronchospasm		1				1
Cerebral haematoma		1				1
Circumstance or information capable of leading to medication error	1	1	1	1		
COVID-19	17	77		2	17	75
Death		5				5
Deformity		1		1		
Diplopia	1	1	1	1		
Disease recurrence		1				1
Drug ineffective	8	72			8	72
Dyspnoea exertional		1				1
Exposure during pregnancy	1	1			1	1
Exposure via breast milk		2		2		
Eyelid ptosis		1		1		
Fall		3				3
General physical health deterioration		2				2
Haematemesis		1				1
Headache	1	2		1	1	1
Herpes zoster		2		2		
Hypertension		4		4		
Hyperthermia		1		1		
Immune thrombocytopenia	1	2			1	2
Inappropriate schedule of product administration		2		2		

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\* AE=Adverse Event

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	2	4		2	2	2
Insomnia	1	1			1	1
Intercepted product preparation error		1		1		
Lymphadenopathy		2				2
Musculoskeletal stiffness		2		2		
Myalgia	1	1			1	1
Myocardial ischaemia		1				1
No adverse event	2	2	2	2		
Off label use		2		2		
Pain in extremity		2		2		
Pancreatitis acute		1				1
Pneumonia aspiration		1				1
Poor quality product administered	2	69	2	69		
Product administered at inappropriate site		1		1		
Product complaint		15		15		
Product contamination physical		1		1		
Product label confusion	1	1	1	1		
Product packaging quantity issue		1		1		
Product physical issue		1		1		
Product preparation error		6		6		
Product preparation issue	1	6	1	6		
Product quality issue	1	1	1	1		
Product storage error	1	1	1	1		
Product temperature excursion issue		48		48		
Pulmonary embolism	1	1			1	1
Pyrexia		3		3		
Rash		1				1
Respiratory distress		1				1
Rhinitis		1		1		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 test positive	2	2			2	2
Serology negative	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Small for dates baby	1	1			1	1
Speech disorder		1		1		
Tachycardia		1				1
Underdose		11		11		
Vaccination failure	11	12			11	12
Vaccination site dysaesthesia		1		1		
Vaccination site erythema		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site pain		1		1		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vertigo		1		1		
Wrong technique in product usage process		1		1		
	64	417	12	209	52	208

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Country Where Event Occurred

**FRENCH POLYNESIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Arthralgia		1		1
Asthenia		1		1
Confusional state		1		1
Dysstasia		1		1
Hyperaesthesia		1		1
Hyperthermia		1		1
Memory impairment		1		1
Movement disorder		1		1
Oxygen saturation decreased		1		1
		9		9

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Asthenia		1		1
Cardiopulmonary failure		1		1
Dermatitis bullous		1		1
Dermatosis		1		1
Dyspnoea		1		1
Haemoptysis		1		1
Pulmonary embolism		1		1
Staphylococcal sepsis		1		1
Toxic epidermal necrolysis		1		1
		10		10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**FRENCH SOUTHERN TERRITORIES**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	1	1	1	1
	1	1	1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**GEORGIA**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sepsis	1	1	1	1
	1	1	1	1

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pneumonia	1	1	1	1
	1	1	1	1

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 \* AE=Adverse Event  
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Country Where Event Occurred

**GERMANY**



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	2	4			2	4		
Abdominal distension		1				1		
Abdominal pain	4	19		1	3	12	1	7
Abdominal pain lower		5				4		1
Abdominal pain upper	5	16			3	10	2	6
Abnormal faeces	1	7			1	6		1
Abortion missed		1						1
Abortion spontaneous	1	4					1	4
Abscess		1						1
Abscess limb	1	1					1	1
Accidental exposure to product		1				1		
Accidental overdose		11				9		2
Acidosis		1						1
Acute coronary syndrome	2	5					2	5
Acute febrile neutrophilic dermatosis	1	2					1	2
Acute kidney injury		9						9
Acute myocardial infarction	2	10					2	10
Acute phase reaction	1	1			1	1		
Acute respiratory distress syndrome		2						2
Acute respiratory failure		2						2
Acute stress disorder	1	1					1	1
Adverse event	1	1					1	1
Ageusia	2	9			2	9		
Aggression		1						1
Agitation		4				1		3
Agranulocytosis		1						1
Alanine aminotransferase increased	1	2					1	2
Allergic oedema		2				1		1
Allergy to vaccine		3				1		2
Allodynia	1	1			1	1		
Alopecia	1	3				1	1	2
Altered state of consciousness		4		1				4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Amino acid level decreased		1
Amnesia		4
Amnesic disorder	1	1
Anaemia		1
Anaesthesia		1
Anaphylactic reaction	6	76
Anaphylactic shock	3	14
Anaphylactoid reaction		2
Angina pectoris	2	15
Angioedema	8	27
Anorectal disorder	1	1
Anosmia	1	4
Anxiety	2	4
Aortic aneurysm	1	2
Aortic dissection		1
Apathy		4
Aphasia	2	14
Appendicitis	1	1
Application site vesicles		1
Arrhythmia	5	27
Arterial occlusive disease		1
Arterial thrombosis		2
Arteriosclerosis		2
Arthralgia	33	88
Arthritis	1	1
Arthropathy		1
Ascites		1
Aspartate aminotransferase increased	1	2
Aspiration		2
Asthenia	49	125
Asthenopia		1
Asthma	6	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		3
				1	1
			1		
					1
				6	76
	1			3	14
					2
				2	15
				8	27
				1	1
		1	4		
		2	3		1
				1	2
					1
			1		3
			5	2	9
	1			1	1
					1
	1			5	27
					1
					2
			1		1
	17	32	77	1	11
				1	1
					1
					1
		1	1		1
					2
		43	103	6	22
			1		
		6	11		7

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asymptomatic COVID-19	1	5
Ataxia		5
Atrial fibrillation	2	14
Atrial flutter		1
Atrial tachycardia		1
Atrioventricular block complete	1	3
Atrioventricular block first degree		1
Autoimmune disorder		1
Autoimmune thyroiditis	1	1
Autonomic nervous system imbalance	1	2
Axillary pain	3	10
Back pain	9	20
Balance disorder		1
Basal ganglia infarction		1
Basilar artery thrombosis	1	2
Bedridden		2
Bladder discomfort		1
Bladder dysfunction	1	1
Bladder pain		1
Blepharitis		1
Blister	2	5
Blood calcium decreased	1	2
Blood creatinine increased		1
Blood disorder		1
Blood glucose abnormal		1
Blood glucose decreased	2	4
Blood glucose fluctuation	1	2
Blood glucose increased		2
Blood immunoglobulin M increased		1
Blood lactate dehydrogenase increased		2
Blood methaemoglobin present		1
Blood potassium decreased		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	4
					5
				2	14
			1		
					1
				1	3
			1		
					1
				1	1
		1	1		1
		3	9		1
		8	18	1	2
			1		
					1
				1	2
			1		1
			1		
				1	1
			1		
		1	3	1	2
			1	1	1
					1
			1		
			2	2	2
		1	2		
			2		
			1		
					2
			1		
					3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood pressure abnormal		1
Blood pressure decreased	2	10
Blood pressure fluctuation	1	3
Blood pressure immeasurable		1
Blood pressure increased	10	30
Blood sodium decreased	1	2
Blood test abnormal	1	1
Blood thyroid stimulating hormone increased		1
Blood urine present	1	2
Bloody discharge	1	1
Body temperature decreased	2	2
Body temperature increased	11	46
Bone pain	9	22
Booster dose missed		2
Bradycardia		3
Brain death		1
Brain injury		1
Brain oedema	1	3
Brain stem infarction	1	1
Breast pain	2	2
Bronchial disorder		1
Bronchial obstruction	1	2
Bronchitis		2
Bronchitis bacterial		1
Bronchospasm		5
Burning sensation	7	16
Bursitis	1	1
Capillary nail refill test abnormal		2
Carbon dioxide decreased	1	1
Cardiac aneurysm		1
Cardiac arrest	2	10
Cardiac death	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	1		3	2	7
		1	3		
					1
	2	6	16	4	14
			1	1	1
		1	1		
			1		
				1	2
		1	1		
		2	2		
		11	37		9
		9	20		2
			2		
					3
					1
					1
				1	3
				1	1
	1	2	2		
			1		
				1	2
			1		1
			1		4
		4	7	3	9
	1			1	1
			1		1
				1	1
				2	10
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac discomfort	1	2
Cardiac failure	4	25
Cardiac failure acute		1
Cardiac failure congestive		3
Cardiogenic shock		4
Cardiomyopathy		1
Cardio-respiratory arrest		1
Cardiovascular disorder	6	33
Cardiovascular insufficiency	2	5
Carotid artery occlusion	1	1
Cerebellar ataxia		1
Cerebellar syndrome		1
Cerebral haemorrhage		7
Cerebral infarction	3	10
Cerebral ischaemia		2
Cerebral thrombosis	2	2
Cerebral venous sinus thrombosis	1	3
Cerebral venous thrombosis	1	2
Cerebral ventricle collapse		1
Cerebrovascular accident	11	31
Cerebrovascular disorder		1
Cervix haematoma uterine	1	1
Chest discomfort	3	13
Chest pain	9	26
Chills	76	188
Chronic kidney disease		1
Chronic obstructive pulmonary disease	1	5
Circulatory collapse	8	34
Circumoral oedema	1	1
Coagulation time prolonged		1
Coagulopathy		1
Cold sweat	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
				4	25
					1
					3
					4
					1
					1
		6	24		9
				2	5
				1	1
					1
					1
					7
				3	10
					2
				2	2
				1	3
				1	2
					1
				11	31
					1
				1	1
		3	8		5
		9	18		8
	20	68	164	8	24
					1
				1	5
	1			8	34
		1	1		
			1		
					1
		2	3	1	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Colitis ulcerative		4
Coma		1
Complement factor C3 increased		1
Condition aggravated		7
Confusional state	2	11
Conjunctival haemorrhage		2
Conjunctival hyperaemia	1	1
Conjunctivitis	1	4
Constipation		2
Contusion		1
Coordination abnormal		1
Coronary artery dissection	1	1
Coronary artery stenosis	1	1
Coronary artery thrombosis		1
Coronavirus infection		1
Coronavirus test positive		2
Cor pulmonale		1
Cough	10	43
COVID-19	48	187
COVID-19 pneumonia	3	9
Cranial nerve decompression		1
Cranial nerve disorder		1
C-reactive protein increased	4	8
Crepitations		1
Creutzfeldt-Jakob disease	2	2
Cyanosis	2	6
Cystitis		1
Cystitis haemorrhagic	1	1
Dark circles under eyes	1	1
Deafness	4	6
Deafness transitory		1
Deafness unilateral		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
			1		
			4		3
		1	4	1	7
					2
				1	1
		1	3		1
			2		
					1
					1
				1	1
				1	1
					1
			1		
			1		1
					1
	1	8	32	2	11
	1	20	53	28	134
				3	9
					1
			1		
		4	5		3
					1
				2	2
		2	3		3
			1		
				1	1
		1	1		
				4	6
					1
					2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Death	26	109
Decreased appetite	7	18
Deep vein thrombosis	10	14
Dehydration		3
Delirium	1	4
Delusion		1
Dementia	1	6
Depressed level of consciousness	1	5
Depressed mood		1
Depression	2	3
Dermatitis allergic	3	9
Diabetes mellitus		1
Diaphragmalgia		1
Diarrhoea	31	89
Diet refusal		3
Digestive enzyme abnormal	1	1
Diplopia	3	3
Discomfort		3
Disease progression	1	1
Disease recurrence	3	7
Disorientation		5
Disseminated intravascular coagulation		1
Disturbance in attention	2	25
Diverticulitis		1
Dizziness	57	213
Drug eruption	1	1
Drug ineffective	25	113
Drug interaction	1	1
Dry age-related macular degeneration	1	1
Dry eye		1
Dry mouth	4	11
Dry skin		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				26	109
		6	15	1	3
				10	14
					3
				1	4
					1
				1	6
				1	5
					1
		2	3		
		2	5	1	4
					1
			1		
	10	29	72	2	17
					3
		1	1		
		1	1	2	2
	1		2		1
				1	1
		2	5	1	2
			1		4
					1
		2	17		8
					1
	36	44	150	13	63
		1	1		
				25	113
				1	1
			1	1	1
		2	6	2	5
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry throat		1
Dysaesthesia	1	9
Dysarthria		3
Dysgeusia	6	10
Dysgraphia		1
Dyskinesia		1
Dyslalia		1
Dyspepsia	1	2
Dysphagia	5	15
Dysphonia	2	12
Dyspnoea	31	125
Dyspnoea at rest		2
Dyspnoea exertional	3	11
Dysstasia	1	2
Dysuria	1	2
Ear discomfort		4
Ear pain	2	5
Eczema	2	5
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment depression		1
Electrocardiogram T wave inversion		1
Electrolyte depletion		1
Electrolyte imbalance		1
Embedded device	1	1
Embolic cerebral infarction	1	1
Embolic stroke	1	1
Embolism	1	1
Embolism arterial		1
Emotional disorder		1
Enanthema		1
Encephalitis		1
Enteritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	5		4
					3
		5	8	1	2
			1		
					1
					1
		1	2		
		2	7	3	8
		2	9		3
	2	18	54	13	71
					2
		1	4	2	7
		1	2		
				1	2
			2		2
		2	5		
		2	4		1
					1
					1
			1		
					1
				1	1
				1	1
				1	1
					1
					1
					1
					1
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Epilepsy	2	25
Epistaxis	2	5
Epstein-Barr virus infection reactivation		3
Erysipelas	2	3
Erythema	15	55
Erythema multiforme		1
Evans syndrome		1
Exposure during pregnancy		3
Exposure via breast milk		2
Extrapyramidal disorder	1	1
Extrasystoles	1	2
Eye haemorrhage		3
Eye irritation	2	5
Eyelid oedema	1	3
Eye pain	2	4
Eye pruritus	1	8
Eye swelling		4
Face oedema	1	1
Facial nerve disorder		1
Facial pain	2	3
Facial paralysis	8	25
Facial paresis	8	24
Factor VIII inhibition		1
Fall	2	10
Fatigue	86	318
Fear		1
Febrile infection		1
Feeling abnormal	6	14
Feeling cold	8	30
Feeling drunk	1	1
Feeling hot	10	27
Feeling of body temperature change	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	25
		1	4	1	1
					3
				2	3
		13	40	2	15
					1
					1
			3		
			2		
				1	1
			1	1	1
					3
		2	4		1
		1	1		2
		2	4		
			3	1	5
			3		1
		1	1		
					1
		2	3		
		4	13	4	11
					1
			2	2	8
	43	80	293	6	25
					1
					1
		6	14		
		7	24	1	6
		1	1		
		7	18	3	9
		1	9		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Femoral artery embolism		1
Fibrin D dimer increased	2	2
Fistula		1
Flank pain		1
Flatulence	1	2
Fluid retention	1	1
Flushing	10	39
Food refusal		3
Formication		1
Fracture		1
Frequent bowel movements		1
Gait disturbance	1	9
Gait inability		2
Gamma-glutamyltransferase increased	1	1
Gastrointestinal disorder		1
Gastrointestinal motility disorder		1
Gastrointestinal necrosis		2
Gastrointestinal pain		3
Generalised tonic-clonic seizure		3
General physical condition abnormal	1	6
General physical health deterioration	6	36
Genital haemorrhage	1	1
Giant cell arteritis		1
Gingival bleeding	1	2
Gingival swelling		2
Gingivitis	2	2
Glomerular filtration rate decreased		1
Gout		1
Groin pain		2
Guillain-Barre syndrome		1
Haematemesis		1
Haematochezia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	2		
					1
			1		
		1	2		
		1	1		
		9	17	1	22
			1		2
			1		
					1
			1		
			6	1	3
			1		1
				1	1
					1
			1		
					2
					3
					3
				1	6
		2	11	4	25
				1	1
					1
				1	2
			1		1
				2	2
			1		
			1		
			2		
					1
					1
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematocrit decreased		1
Haematoma	1	10
Haematoma infection		1
Haematuria		1
Haemoglobin decreased		2
Haemoptysis	2	3
Haemorrhage	1	3
Haemothorax		1
Hallucination		3
Headache	131	453
Head discomfort	6	10
Head injury	1	1
Heart rate increased	1	10
Hemiparaesthesia	1	2
Hemiparesis	3	12
Hemiplegia		1
Hepatic enzyme increased	2	4
Hepatic failure		3
Herpes dermatitis		1
Herpes simplex	1	3
Herpes virus infection		1
Herpes zoster	3	38
Herpes zoster infection neurological		1
Herpes zoster meningitis		1
Herpes zoster oticus		2
Herpes zoster reactivation		1
Hordeolum		1
Hot flush	5	12
Huntington's disease		3
Hyperaesthesia	2	3
Hypercalcaemia		2
Hyperglycaemia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			4	1	6
			1		1
			1		
			1		1
		1	2	1	1
				1	3
					1
					3
	46	115	386	16	67
		6	8		2
				1	1
			6	1	4
				1	2
				3	12
					1
		2	2		2
			1		
		1	2		1
			1		
		1	31	2	7
					1
					1
					2
			1		
			1		
		3	10	2	2
					3
		1	2	1	1
					2
					2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperhidrosis	7	26
Hyperkalaemia		1
Hypersensitivity	21	74
Hypersensitivity vasculitis	2	4
Hypersomnia	1	4
Hypertension	10	58
Hypertensive crisis	3	13
Hypertensive emergency		1
Hyperthermia		1
Hyperventilation	1	9
Hypoacusis		2
Hypoaesthesia	9	34
Hypoaesthesia oral	3	12
Hypoglycaemia	1	1
Hypokinesia		1
Hyponatraemia		3
Hypophagia	1	2
Hyporesponsive to stimuli		1
Hypotension	9	32
Hypothermia	2	3
Hypothyroidism	1	1
Hypotonia	7	14
Hypoventilation		1
Hypoxia	1	2
Idiopathic intracranial hypertension	1	2
Illrd nerve paresis	1	1
Ileus		1
Ileus paralytic		2
Illness	2	2
Immune thrombocytopenia	3	5
Impaired healing	1	1
Impaired work ability		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	22		4
					1
	3	15	29	6	45
				2	4
		1	2		2
	2	5	20	5	38
				3	13
					1
					1
		1	4		5
			1		1
	2	7	26	2	8
		3	9		3
		1	1		
			1		
			2		1
				1	2
					1
		8	15	1	17
				2	3
				1	1
		5	9	2	5
					1
				1	2
				1	2
				1	1
					1
		1	1	1	1
				3	5
				1	1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Inadequate aseptic technique in use of product	1	1
Inappropriate schedule of product administration	4	16
Incorrect route of product administration	17	54
Increased upper airway secretion		1
Infarction		1
Infection	1	5
Infective exacerbation of chronic obstructive airways disease		1
Inflammation		1
Inflammatory marker increased		1
Influenza	4	5
Influenza like illness	19	59
Injected limb mobility decreased		1
Injection site erythema		1
Injection site pain	2	5
Injection site pruritus		1
Injection site rash		1
Injection site swelling		1
Insomnia	3	10
Intentional product misuse	1	1
International normalised ratio decreased		1
Intestinal gangrene		1
Intestinal infarction		1
Intestinal ischaemia	1	1
Intestinal obstruction		1
Iridocyclitis	2	2
Irregular breathing		2
Ischaemia		1
Ischaemic cerebral infarction		2
Ischaemic stroke	1	2
Jaundice		1
Jaw clicking		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	16		
		17	53		1
			1		
					1
	1		2	1	3
					1
					1
		4	5		
		19	56		3
			1		
			1		
		2	5		
			1		
			1		
			1		
		3	9		1
		1	1		
			1		
					1
					1
				1	1
					1
				2	2
					2
					1
					2
				1	2
			1		
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint range of motion decreased	1	4
Joint swelling		2
Lacrimation increased	1	8
Language disorder		1
Laryngeal oedema		5
Laryngospasm		1
Leukocytosis		1
Leukopenia		1
Lhermitte's sign	1	1
Limb discomfort	8	25
Lipase increased		1
Lipid metabolism disorder		1
Lip oedema		2
Lip pain		1
Lip swelling		8
Listless	1	1
Livedo reticularis		1
Liver function test increased		2
Localised infection		1
Local reaction	5	13
Loss of consciousness	4	19
Lower respiratory tract congestion		1
Lung disorder	1	2
Lymphadenitis	3	6
Lymphadenopathy	21	60
Lymphangitis		1
Lymph node pain	2	18
Lymphocytic infiltration		1
Lymphoedema	1	2
Lymphopenia		2
Malaise	25	78
Marasmus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
					2
			5	1	3
					1
					5
					1
					1
					1
		1	1		
		5	19	3	6
					1
			1		
			1		1
			1		
			1		7
		1	1		
			1		
					2
			1		
		4	10	1	3
				4	19
			1		
		1	2		
		3	4		2
	1	21	57		3
					1
		2	18		
					1
		1	2		
			1		1
	37	23	58	2	20
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Maternal exposure during pregnancy	2	35
Maternal exposure timing unspecified		2
Memory impairment	1	5
Meningism	1	3
Meningitis		1
Meningitis aseptic		1
Meningitis viral		1
Menorrhagia		1
Menstrual disorder		5
Menstruation irregular		1
Mental disorder	1	3
Mental impairment		1
Metabolic acidosis		1
Microcytic anaemia		2
Microembolism		1
Micturition disorder	1	1
Micturition urgency	1	1
Middle insomnia		2
Migraine	3	11
Mobility decreased	5	13
Monocytosis		1
Monoplegia	1	2
Mouth haemorrhage	1	1
Mouth swelling		3
Movement disorder	1	6
Multimorbidity		1
Multiple organ dysfunction syndrome		4
Multiple sclerosis		1
Multiple sclerosis relapse	2	4
Muscle contractions involuntary		1
Muscle discomfort		1
Muscle mass	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	34		1
			2		
			2	1	3
		1	1		2
					1
					1
			1		
			5		
			1		
		1	2		1
					1
					1
		1	1		
		1	1		
			2		
		3	9		2
		4	11	1	2
					1
				1	2
		1	1		
			1		2
		1	4		2
					1
					4
					1
				2	4
					1
			1		
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle spasms	5	9
Muscle spasticity		1
Muscle strain		
Muscle swelling		2
Muscle tightness	2	2
Muscle twitching	4	7
Muscular weakness	1	14
Musculoskeletal chest pain	1	5
Musculoskeletal disorder	1	1
Musculoskeletal pain	2	4
Musculoskeletal stiffness	1	4
Myalgia	45	150
Myasthenia gravis		1
Myelitis	1	1
Myocardial infarction		6
Myocardial ischaemia	1	1
Myocarditis	2	5
Myoclonus		2
Myosclerosis		2
Myositis	1	1
Nasal congestion	1	6
Nasopharyngitis	6	26
Nausea	54	168
Neck pain	6	17
Neoplasm	1	1
Nervousness		1
Nervous system disorder		4
Neuralgia	3	6
Neuralgic amyotrophy		2
Neuritis		3
Neurodermatitis	1	3
Neuropathy peripheral	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	6	1	3
					1
	1				
			2		
	1	2	2		
		4	5		2
			8	1	6
		1	2		3
		1	1		
		1	2	1	2
		1	4		
	28	44	136	1	14
					1
				1	1
					6
				1	1
				2	5
			1		1
					2
		1	1		
		1	5		1
	1	6	22		4
	29	49	134	5	34
		6	16		1
				1	1
			1		
					4
		3	6		
					2
			3		
		1	3		
				1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neutropenia	1	2
Night sweats	1	6
Nodule		1
Nuchal rigidity	1	2
Nystagmus		1
Obstructive airways disorder	1	1
Obstructive pancreatitis	1	1
Occipital neuralgia		1
Occupational exposure to product		1
Ocular discomfort	1	4
Ocular hyperaemia		5
Ocular icterus	1	1
Odynophagia		
Oedema		1
Oedema peripheral		3
Oesophageal irritation		1
Off label use	4	21
Oligoarthritis		1
Oliguria		1
Onychoclasia		1
Ophthalmic herpes zoster		2
Ophthalmic vein thrombosis	2	2
Optic neuritis		2
Optic neuropathy		1
Oral discomfort		2
Oral herpes		4
Oral mucosa erosion		1
Oral mucosal blistering		1
Oral pain		1
Organ failure		1
Oropharyngeal blistering		2
Oropharyngeal discomfort		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	6		
			1		
		1	1		1
				1	1
				1	1
			1		
			1		
			3	1	1
			4		1
		1	1		
	1				
					1
			2		1
					1
		4	21		
					1
					1
			1		
					2
				2	2
					2
					1
			2		
			3		1
			1		
			1		
					1
					1
					2
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oropharyngeal pain	5	21
Oropharyngeal swelling	1	1
Orthopnoea		2
Orthostatic hypotension	1	1
Orthostatic intolerance	1	2
Otitis media		1
Overdose		1
Oxygen saturation decreased		12
Pain	12	43
Painful respiration	2	2
Pain in extremity	66	239
Pain in jaw		2
Pain of skin	1	2
Pallor	1	3
Palpitations	14	54
Pancreatitis acute		1
Panic attack	1	4
Panic disorder	1	1
Panic reaction	1	3
Papilloedema	1	1
Paraesthesia	24	82
Paraesthesia oral	9	18
Paralysis	2	4
Paranoia		1
Paresis	1	3
Parkinsonian rest tremor		1
Parkinson's disease		2
Parosmia	2	3
Partial seizures	1	2
Pathogen resistance		1
Pelvic fracture	1	1
Pelvic pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	5	18		3
				1	1
					2
		1	1		
		1	1		1
			1		
					1
			2		10
		11	32	1	11
		2	2		
		59	217	7	22
			2		
		1	2		
				1	3
	1	9	36	5	18
					1
		1	1		3
		1	1		
			2	1	1
				1	1
	3	18	48	6	34
		9	14		4
				2	4
					1
		1	2		1
			1		
					2
		2	2		1
				1	2
					1
				1	1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pemphigus	2	2
Performance status decreased		2
Pericardial effusion	1	1
Perioral dermatitis		1
Peripheral circulatory failure	3	5
Peripheral coldness	1	2
Peripheral embolism	1	2
Peripheral swelling	4	17
Peripheral vascular disorder	6	26
Peritonitis		1
Personality change		6
Petechiae	5	10
Petit mal epilepsy		1
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngeal swelling	2	10
Pharyngitis	1	2
Phlebitis	1	1
Photopsia		2
Photosensitivity reaction		1
Platelet count decreased		1
Pleocytosis		1
Pleural effusion		2
Pleuritic pain	1	1
Pneumonia	2	20
Pneumonia aspiration		3
Pneumonia bacterial		1
Pneumonia viral	1	1
Polyarthritits		1
Polydipsia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
			2		
			1	1	1
		3	3		2
		1	2		
			1	1	1
		2	10	2	7
	1	5	11	1	15
					1
			1		5
		3	5	2	5
					1
			2		
			1		
					1
			1		
	1		3	2	7
		1	2		
		1	1		
			2		
			1		
					1
					2
		1	1		
				2	20
					3
					1
				1	1
					1
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Polymyalgia rheumatica	1	2
Polyneuropathy	1	2
Polyuria	1	1
Poor quality product administered	5	27
Poor quality sleep	1	6
Postictal state		1
Pregnancy		1
Pregnancy with contraceptive device	1	1
Presyncope	4	14
Product administered at inappropriate site		1
Product dose omission issue	1	3
Product preparation issue		2
Product storage error	1	2
Product supply issue		1
Product temperature excursion issue	5	27
Product use issue	1	15
Protein urine present		1
Pruritus	22	62
Pruritus allergic		2
Psoriasis		2
Psychological factor affecting medical condition		1
Psychomotor hyperactivity		2
Psychomotor retardation	1	1
Pulmonary artery thrombosis		1
Pulmonary embolism	21	31
Pulmonary hypertension	1	1
Pulmonary infarction	1	1
Pulmonary oedema	1	3
Pulmonary pain		2
Pulmonary vasculitis		1
Pulse waveform abnormal		1
Pupillary disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	2
				1	1
		5	25		2
			4	1	2
					1
			1		
				1	1
		3	9	1	5
			1		
		1	2		1
			2		
		1	2		
			1		
		5	25		2
		1	15		
			1		
	1	16	39	6	23
			1		1
			1		1
					1
					2
				1	1
					1
				21	31
				1	1
				1	1
				1	3
			1		1
					1
			1		
		1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pustule	2	6
Pyrexia	74	244
Quadriplegia		2
Radiculopathy		2
Rash	15	64
Rash erythematous	1	3
Rash macular	1	5
Rash maculo-papular		2
Rash papular	1	2
Rash pruritic	5	12
Rash pustular	1	1
Rash vesicular		3
Raynaud's phenomenon		1
Reaction to excipient		1
Rectal haemorrhage		1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased	1	1
Renal failure		9
Renal impairment	1	1
Renal pain		3
Respiration abnormal	1	3
Respiratory distress	16	73
Respiratory failure		7
Respiratory fume inhalation disorder	1	1
Respiratory rate decreased	1	1
Respiratory rate increased		1
Respiratory symptom		1
Respiratory tract infection		4
Respiratory tract infection viral	1	1
Respiratory tract oedema		1
Resting tremor		1
Restlessness	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		2
	19	65	198	9	46
					2
			1		1
	4	10	33	5	31
		1	3		
		1	5		
			2		
		1	2		
		5	10		2
		1	1		
			3		
			1		
			1		
					1
			1		
		1	1		
					9
				1	1
			1		2
		1	3		
				16	73
					7
				1	1
		1	1		
			1		
			1		
					4
		1	1		
					1
					1
		3	7	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Resuscitation		1
Retching	2	4
Retinal artery occlusion	1	1
Retinal disorder		1
Retinal tear		2
Retinopathy		1
Retrograde amnesia	1	2
Reversible cerebral vasoconstriction syndrome		1
Rheumatic disorder	1	2
Rheumatoid arthritis		2
Rhinalgia		2
Rhinitis		1
Rhinitis allergic		1
Rhinorrhoea	4	21
Rhonchi		2
Rosacea		1
Salivary gland enlargement		2
SARS-CoV-2 ant body test	1	1
SARS-CoV-2 ant body test negative	1	10
SARS-CoV-2 ant body test positive	4	22
SARS-CoV-2 sepsis		1
SARS-CoV-2 test positive	3	18
Scratch	1	2
Seasonal allergy	1	1
Secondary hypertension	1	1
Seizure	3	20
Sensation of blood flow		1
Sensation of foreign body	3	17
Sense of oppression		1
Sensitive skin		1
Sensory disturbance	10	21
Sensory level abnormal		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	4		
				1	1
					1
					2
					1
		1	1		1
					1
		1	1		1
					2
			2		
			1		
			1		
		4	20		1
					2
					1
			2		
		1	1		
		1	10		
		4	22		
					1
		3	11		7
		1	2		
		1	1		
		1	1		
				3	20
			1		
		2	3	1	14
			1		
			1		
		8	17	2	4
			3		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensory loss		1
Sepsis		3
Septic arthritis staphylococcal	1	1
Septic shock		1
Shock	1	2
Sialoadenitis		1
Sinus congestion		2
Sinusitis		1
Sinus tachycardia	1	6
Skin abrasion		1
Skin burning sensation	2	4
Skin discolouration	1	4
Skin disorder		1
Skin exfoliation	1	3
Skin irritation	1	1
Skin lesion		1
Skin necrosis	1	1
Skin reaction	1	2
Skin swelling	1	2
Skin warm	1	1
Sleep disorder	1	5
Sneezing		5
Snoring	2	2
Soft tissue infection		1
Somatic symptom disorder		1
Somnolence	8	25
Sopor		1
Speech disorder	2	4
Spinal cord ischaemia	1	1
Spinal pain	1	3
Staphylococcal sepsis		1
Status epilepticus		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
				1	1
					1
				1	2
					1
			2		
			1		
		1	1		5
					1
		2	3		1
		1	3		1
					1
		1	3		
		1	1		
					1
				1	1
		1	2		
		1	2		
		1	1		
		1	5		
			5		
		2	2		
					1
					1
		6	14	2	11
					1
			1	2	3
				1	1
			1	1	2
					1
					4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Stomatitis	2	3
Stress		3
Stridor		4
Stupor		1
Subarachnoid haemorrhage	2	3
Subclavian vein thrombosis	1	1
Subileus	1	2
Sudden cardiac death	1	2
Sudden death	1	17
Sudden visual loss		1
Superinfection bacterial	2	2
Superior sagittal sinus thrombosis		1
Supraventricular extrasystoles	1	3
Supraventricular tachycardia		2
Suspected counterfeit product		1
Suspected COVID-19		2
Swelling	8	20
Swelling face	8	23
Swelling of eyelid		3
Swollen tongue	7	19
Syncope	10	47
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	1	1
Tachyarrhythmia		2
Tachycardia	20	83
Tachycardia induced cardiomyopathy		1
Tachypnoea		3
Taste disorder	3	6
Temporomandibular joint syndrome		1
Tenderness	1	1
Tendonitis	1	1
Tendon pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
			3		
					4
					1
				2	3
				1	1
		1	1		1
				1	2
				1	17
					1
				2	2
					1
			2	1	1
			1		1
			1		
					2
		7	16	1	4
	3	5	11	3	12
			2		1
		6	9	1	10
	1			10	47
					1
				1	1
			1		1
	5	20	45		38
					1
			1		2
		3	4		2
			1		
		1	1		
				1	1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tension headache	1	2
Therapeutic response unexpected	4	4
Thirst	1	2
Throat irritation	5	12
Throat tightness	6	23
Thrombocytopenia	1	6
Thrombophlebitis	3	3
Thrombophlebitis superficial	3	3
Thrombosis	5	7
Thyroiditis acute		1
Tinnitus	2	6
Tongue coated	1	1
Tongue discomfort		1
Tongue disorder		1
Tongue oedema		1
Tongue pruritus		1
Tonsillar hypertrophy	1	1
Tonsillitis bacterial		1
Toothache		1
Transaminases increased		1
Transient global amnesia		1
Transient ischaemic attack	1	2
Tremor	9	33
Trichoglossia		1
Trigeminal neuralgia		1
Tryptase increased		1
Type 1 diabetes mellitus	1	2
Underdose		5
Unresponsive to stimuli	2	7
Upper respiratory tract infection	1	5
Urinary tract infection	1	2
Urinary tract inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		4	4		
	1	1	2		
	1	5	11		1
		5	11	1	12
				1	6
		2	2	1	1
		2	2	1	1
				5	7
					1
		1	4	1	2
		1	1		
			1		
			1		
					1
					1
		1	1		
					1
			1		
					1
					1
				1	2
		6	16	3	17
			1		
			1		
					1
				1	2
			5		
				2	7
		1	1		4
			1	1	1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Urine odour abnormal	1	1
Urticaria	12	31
Vaccination complication		2
Vaccination failure	5	16
Vaccination site bruising		1
Vaccination site dermatitis		1
Vaccination site discolouration		1
Vaccination site discomfort		5
Vaccination site erythema	14	37
Vaccination site granuloma	1	1
Vaccination site haematoma	1	6
Vaccination site haemorrhage		2
Vaccination site hyperaesthesia		3
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia		1
Vaccination site induration	2	6
Vaccination site inflammation		
Vaccination site irritation		1
Vaccination site joint movement impairment		3
Vaccination site joint pain		1
Vaccination site lymphadenopathy	2	3
Vaccination site movement impairment	2	10
Vaccination site oedema	1	1
Vaccination site pain	88	358
Vaccination site papule	1	1
Vaccination site paraesthesia	2	6
Vaccination site pruritus	3	13
Vaccination site rash	1	4
Vaccination site reaction	3	10
Vaccination site swelling	21	55
Vaccination site urticaria	1	3
Vaccination site warmth	5	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		10	20	2	11
					2
				5	16
			1		
			1		
			1		
			5		
	1	13	34	1	3
		1	1		
		1	5		1
			2		
			3		
		1	1		
					1
		2	6		
	1				
			1		
			2		1
			1		
		2	3		
		2	10		
		1	1		
	41	87	347	1	11
		1	1		
		2	6		
		3	12		1
		1	3		1
		2	8	1	2
	8	21	51		4
		1	3		
	1	4	19	1	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Varicella		1
Varicella zoster virus infection		1
Varicose vein	1	1
Vascular dementia		1
Vascular occlusion	1	1
Vasculitis		2
Venous occlusion	1	1
Venous thrombosis	1	2
Venous thrombosis in pregnancy	1	1
Venous thrombosis limb	1	2
Ventricular extrasystoles	1	1
Ventricular fibrillation		2
Vertigo		7
Viral rash		1
Visceral venous thrombosis		1
Vision blurred	1	9
Visual field defect		3
Visual impairment	6	23
Vlth nerve paralysis	1	1
Vitreous disorder		1
Vomiting	20	77
Vulvitis	1	1
Vulvovaginal discomfort	1	1
Vulvovaginal mycotic infection	1	1
Vulvovaginal pain	1	1
Vulvovaginal swelling	1	1
Weight decreased	1	1
Weight increased	1	1
Wheezing		5
White blood cell count decreased		2
White blood cell count increased	1	2
Wrong technique in product usage process		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	1		
					1
				1	1
			1		1
				1	1
				1	2
				1	1
				1	2
				1	1
					2
			7		
			1		
					1
			5	1	4
			1		2
		3	8	3	15
				1	1
					1
	6	15	46	5	31
				1	1
				1	1
				1	1
		1	1		
				1	1
		1	1		
			1		4
			2		
		1	1		1
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	2,196	7,951		395	1555	4868	641	3083

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	6	11			3	7	3	4
Abdominal pain lower	1	1					1	1
Abdominal pain upper		3				3		
Abnormal faeces	1	7			1	7		
Abscess neck	1	1					1	1
Accidental overdose	1	3			1	2		1
Acne		1				1		
Acute abdomen	1	3					1	3
Acute generalised exanthematous pustulosis	1	1					1	1
Acute kidney injury	1	6					1	6
Acute myeloid leukaemia	1	1					1	1
Acute myocardial infarction	4	10					4	10
Acute respiratory distress syndrome	1	3					1	3
Acute respiratory failure	1	2					1	2
Acute right ventricular failure	1	1					1	1
Adverse event	1	1			1	1		
Ageusia		4				3		1
Aggression	1	2					1	2
Agitation		1						1
Allergy to vaccine		1						1
Alopecia areata		1				1		
Altered state of consciousness	1	2					1	2
Amaurosis fugax		1						1
Amnesia	1	3					1	3
Anaemia	2	2					2	2
Anaphylactic reaction	1	11					1	11
Anaphylactic shock		2						2
Angina pectoris		1						1
Angioedema	1	6					1	6
Anosmia		4				3		1
Antibody test abnormal		3				3		
Anxiety		1				1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aortic aneurysm		1
Aortic dissection	1	1
Apathy	1	5
Aphasia	1	3
Aphthous ulcer		1
Arrhythmia	4	13
Arthralgia	12	30
Arthritis reactive		1
Aspiration		2
Asthenia	11	42
Asthma		2
Asymptomatic COVID-19	1	1
Ataxia		2
Atrial f brillation	1	8
Atrioventricular block complete	1	2
Atypical pneumonia		1
Autoimmune thyroiditis	1	1
Automatism		1
Back pain	2	6
Balance disorder	1	1
Basal ganglia haemorrhage	1	1
Basedow's disease	1	1
Basilar artery occlusion		1
Bladder discomfort	1	1
Blindness unilateral	1	1
Blister		2
Blister infected		1
Blood calcium decreased		1
Blood cholesterol increased		1
Blood count abnormal	1	1
Blood creatine phosphokinase increased		2
Blood creatine phosphokinase MB increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		1	4		1
				1	3
					1
				4	13
	5	12	27		3
					1
					2
		10	33	1	9
			1		1
				1	1
					2
				1	8
				1	2
					1
				1	1
					1
		2	5		1
				1	1
				1	1
				1	1
		1	1		
				1	1
			2		
			1		
			1		
				1	1
			1		1
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood glucose fluctuation		1				1		
Blood potassium decreased		1				1		
Blood pressure decreased	4	5			3	3	1	2
Blood pressure fluctuation		2				2		
Blood pressure increased		2				1		1
Blood pressure systolic increased	1	1					1	1
Body temperature increased	1	12			1	11		1
Bone pain		1				1		
Bowel movement irregularity		1				1		
Bradyarrhythmia	1	1					1	1
Bradycardia	1	3					1	3
Brain death	1	1					1	1
Bronchitis		2				1		1
Bronchitis bacterial		1						1
Bronchitis chronic	1	1			1	1		
Bundle branch block right	1	2					1	2
Burning sensation	1	2			1	2		
Bursitis	1	1			1	1		
Cardiac arrest	4	9					4	9
Cardiac failure	5	14					5	14
Cardiac failure congestive		1						1
Cardiac fibrillation		2						2
Cardiogenic shock	1	3					1	3
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		1						1
Cardiovascular disorder		5				2		3
Cardiovascular insufficiency	1	2					1	2
Cellulitis		1						1
Cerebellar syndrome		1						1
Cerebral atrophy		1						1
Cerebral haemorrhage	4	8					4	8
Cerebral infarction	3	4					3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		3	3	1	2
			2		
			1		1
				1	1
		1	11		1
			1		
			1		
				1	1
				1	3
				1	1
			1		1
					1
		1	1		
				1	2
		1	2		
		1	1		
				4	9
				5	14
					1
					2
				1	3
					1
					1
			2		3
				1	2
					1
					1
				4	8
				3	4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral ischaemia	2	4
Cerebral venous sinus thrombosis	3	4
Cerebrovascular accident	6	17
Chest discomfort		3
Chest pain	3	3
Chest X-ray abnormal		1
Chills	22	67
Cholelithiasis		1
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Chronic kidney disease		1
Chronic obstructive pulmonary disease	1	3
Circulatory collapse	3	14
Clonus	1	1
Coagulopathy	1	1
Cognitive disorder		2
Cold sweat	1	4
Coma		1
Communication disorder		1
Condition aggravated	3	5
Confusional state	1	5
Conjunctivitis		1
Contusion		3
Coronary artery disease	1	1
Cough	3	13
COVID-19	32	135
COVID-19 pneumonia		12
Cranial nerve disorder		1
Craniocerebral injury	1	1
C-reactive protein increased	2	3
Cyanosis		3
Deafness bilateral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
				3	4
				6	17
			2		1
		2	2	1	1
					1
	5	22	62		5
			1		
					1
			1	1	2
				3	14
				1	1
				1	1
			1		1
		1	2		2
					1
			1		
				3	5
			1	1	4
					1
			1		2
				1	1
		3	8		5
		15	35	17	100
					12
			1		
				1	1
		1	2	1	1
					3
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Death	20	79
Decreased appetite	3	6
Deep vein thrombosis	12	16
Dehydration		2
Delirium		2
Delusion		1
Dementia of the Alzheimer's type, with delirium		1
Depressed level of consciousness	1	3
Depression	2	2
Dermatitis allergic	1	1
Dermatitis atopic		1
Dermatitis bullous	1	1
Diabetes mellitus		1
Diabetes mellitus inadequate control		1
Diarrhoea	12	30
Diet refusal		2
Diplopia	1	3
Discomfort		
Disease recurrence	2	6
Disorientation	1	3
Disturbance in attention	4	12
Diverticulitis	1	1
Dizziness	9	38
Dizziness postural		2
Drug eruption		1
Drug ineffective	11	78
Drug interaction	1	3
Dry eye	1	1
Dysaesthesia		1
Dysarthria		1
Dysgeusia		3
Dyspepsia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				20	79
		2	4	1	2
				12	16
			1		1
					2
					1
					1
				1	3
		2	2		
		1	1		
			1		
				1	1
					1
					1
	1	9	25	3	5
					2
		1	2		1
	2				
				2	6
		1	3		
		4	8		4
				1	1
	5	9	28		10
			1		1
					1
				11	78
			2	1	1
		1	1		
					1
					1
			2		1
			2		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysphagia	1	3
Dyspnoea	10	39
Dyspnoea exertional	2	2
Ear pain		2
Eastern Cooperative Oncology Group performance status worsened	1	1
Eating disorder		2
Eczema	1	2
Effusion	1	1
Emphysema	1	1
Encephalitis	1	2
Encephalitis autoimmune	1	1
Enteritis		1
Eosinophilia	1	1
Epilepsy	2	6
Episcleritis		1
Epistaxis	1	2
Erysipelas		1
Erythema	3	13
Escherichia infection		1
Essential tremor		1
Exercise tolerance decreased		
Extrapyramidal disorder		1
Extrasystoles		1
Eye haemorrhage		1
Eye irritation		1
Eyelid oedema	1	1
Eye pain		2
Eye swelling		1
Face oedema	1	2
Facial nerve disorder		1
Facial paralysis	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		2
		4	13	6	26
		1	1	1	1
			2		
		1	1		
			2		
		1	2		
				1	1
				1	1
				1	2
				1	1
					1
				1	1
				2	6
			1		
	1	1	1		1
					1
			1		
					1
	1				
			1		
					1
					1
			1		
			1		
		1	1		1
				2	13

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Facial paresis	1	8
Faeces discoloured		1
Fall		9
Fatigue	24	130
Febrile infection		2
Feeling abnormal	1	2
Feeling cold	1	8
Feeling hot	3	11
Feeling jittery		
Feeling of body temperature change	1	2
Femoral neck fracture		1
Femur fracture		1
Fibrin D dimer increased		1
Flatulence	1	3
Flushing		2
Functional gastrointestinal disorder		1
Gait disturbance		3
Gastrointestinal disorder	1	1
Gastrointestinal necrosis	1	1
Gastrointestinal pain		
General physical condition abnormal		3
General physical health deterioration	2	25
Genital herpes		1
Glomerular filtration rate decreased		1
Glomerulonephritis minimal lesion		1
Guillain-Barre syndrome		1
Haematemesis		3
Haematochezia	1	3
Haematocrit decreased		1
Haematoma	1	1
Haemoglobin decreased	1	3
Haemolytic uraemic syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		5
			1		
					9
	12	21	122	3	8
			1	1	1
		1	8		
		1	7	2	4
	1				
		1	2		
					1
					1
					1
	1		2	1	1
			2		
			1		
					3
		1	1		
				1	1
	1				
					3
		2	6		19
			1		
			1		
					1
					1
					3
				1	3
			1		
		1	1		
			1	1	2
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemorrhage	4	4
Hallucination	1	1
Hallucination, auditory		1
Hallucinations, mixed		1
Headache	31	142
Head discomfort		1
Head injury	1	2
Heart rate decreased	1	2
Heart rate increased	2	3
Hemiparaesthesia		1
Hemiparesis	2	8
Hemiplegia	2	3
Hepatic cirrhosis	1	1
Hepatic failure		1
Hepatic pain		1
Hepatitis cholestatic		2
Herpes simplex encephalitis		1
Herpes zoster	4	9
Herpes zoster infection neurological		1
Herpes zoster meningitis	1	1
Herpes zoster oticus		1
HIV test positive	1	1
Hot flush	1	2
Hunger		1
Hyperacusis	1	1
Hyperaesthesia	1	2
Hyperhidrosis	3	10
Hyperpyrexia		1
Hypersensitivity	3	15
Hypersensitivity vasculitis	1	2
Hypersomnia		1
Hypertension	5	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	4
				1	1
					1
					1
	10	31	134		8
			1		
				1	2
				1	2
		1	1	1	2
					1
				2	8
				2	3
				1	1
					1
			1		
					2
					1
		2	5	2	4
					1
				1	1
					1
		1	2		
			1		
		1	1		
		1	2		
	1	2	9	1	1
					1
	1	2	5	1	10
				1	2
			1		
	1	3	6	2	8

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertensive crisis		5
Hyperthyroidism	1	2
Hypertonia		2
Hyperventilation		2
Hypoaesthesia	4	13
Hypoaesthesia oral		1
Hypoglycaemia		1
Hyponatraemia		2
Hypotension	3	10
Hypotonia	1	1
Hypoxia	1	1
Ileectomy	1	1
Illness		3
Immune thrombocytopenia	1	4
Impaired work ability		1
Inappropriate schedule of product administration	5	12
Incontinence		1
Incorrect dose administered		2
Incorrect route of product administration	9	20
Induration		1
Infection	2	3
Infective exacerbation of chronic obstructive airways disease		1
Inflammation	1	2
Influenza	2	3
Influenza like illness	4	25
Initial insomnia		2
Injected limb mobility decreased	1	1
Injection site discomfort		1
Injection site pain		2
Insomnia	1	2
Intentional product misuse		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
				1	2
			1		1
					2
		3	11	1	2
			1		
			1		
					2
		2	5	1	5
		1	1		
				1	1
				1	1
			3		
				1	4
					1
		5	12		
					1
			2		
		9	20		
			1		
		1	1	1	2
					1
				1	2
		1	1	1	2
		4	23		2
			2		
		1	1		
			1		
			2		
		1	2		
			1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Internal haemorrhage	1	1
International normalised ratio increased		1
Intestinal haemorrhage	1	1
Intestinal ischaemia		1
Intestinal obstruction	1	1
Intracranial aneurysm		1
Ischaemia	1	1
Ischaemic cardiomyopathy	1	1
Ischaemic cerebral infarction	1	2
Ischaemic stroke	1	3
IVth nerve disorder		1
IVth nerve paresis		1
Jaundice		1
Joint swelling		1
Keratoconus	1	1
Lacrimation increased		1
Language disorder		1
Laryngeal obstruction	1	1
Laryngeal oedema	1	1
Left ventricular failure		1
Leukaemia	1	1
Limb discomfort	2	10
Lip swelling		2
Listless		1
Local reaction	3	3
Loss of consciousness	2	6
Loss of personal independence in daily activities		2
Low density lipoprotein increased		1
Lung infiltration		1
Lymphadenopathy	6	17
Lymph node pain	2	5
Lymphopenia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
				1	1
					1
				1	1
					1
				1	1
				1	1
				1	2
				1	3
					1
					1
					1
			1		
				1	1
			1		
					1
				1	1
					1
					1
				1	1
		2	9		1
					2
					1
		2	2	1	1
				2	6
			2		
			1		
					1
		6	16		1
		2	5		
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Malaise	7	27
Malignant melanoma		1
Malignant pleural effusion	1	1
Medication error	1	1
Mental disorder	1	1
Mesenteric vein thrombosis	2	4
Metabolic disorder		1
Microscopic polyangiitis	1	2
Middle insomnia		1
Mobility decreased		4
Monoparesis	2	3
Monoplegia		2
Motor dysfunction		1
Mouth swelling		1
Movement disorder	2	6
Multi-organ disorder		1
Multiple organ dysfunction syndrome	1	5
Multiple sclerosis		1
Muscle spasms	1	3
Muscle strength abnormal		1
Muscle tightness		1
Muscle twitching	2	5
Muscular weakness	1	4
Musculoskeletal chest pain		1
Musculoskeletal discomfort	1	1
Myalgia	14	60
Myelitis		1
Myocardial infarction	2	4
Myocarditis	1	7
Myocarditis infectious		1
Myocarditis septic		1
Myoglobin blood increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	13	5	19	2	8
					1
				1	1
		1	1		
				1	1
				2	4
					1
				1	2
			1		
			2		2
		1	1	1	2
					2
					1
		1	2	1	4
					1
				1	5
					1
			1	1	2
			1		
			1		
		2	4		1
			3	1	1
					1
		1	1		
	7	14	59		1
					1
				2	4
				1	7
					1
					1
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myositis		1
Nasal congestion		1
Nasopharyngitis		8
Nausea	8	36
Neck pain	1	10
Nephrolithiasis	1	1
Nephrotic syndrome		1
Nervous system disorder		1
Neuralgia		3
Neuralgic amyotrophy		3
Neuritis		1
Neurodermatitis		1
Obstructive airways disorder	1	2
Odynophagia	1	1
Oedema		2
Off label use	4	8
Ophthalmic vein thrombosis	2	2
Optic ischaemic neuropathy	1	1
Oral candidiasis	1	1
Oral fungal infection		1
Oral mucosal eruption	1	1
Oropharyngeal pain	1	5
Orthostatic hypotension	1	1
Osteoporosis	1	1
Overdose	1	1
Oxygen saturation decreased		3
Pain	6	21
Pain in extremity	17	90
Pain of skin		1
Palatal swelling		1
Pallor	2	4
Palpitations	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			6		2
	6	8	28		8
		1	9		1
				1	1
					1
			1		
			3		
			1		2
					1
			1		
				1	2
		1	1		
					2
		4	8		
				2	2
				1	1
				1	1
					1
		1	1		
		1	5		
		1	1		
		1	1		
				1	1
					3
		5	15	1	6
		16	85	1	5
			1		
					1
		1	2	1	2
	3		4	1	4

\* I=Interval, C=Cumulative  
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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pancytopenia	2	2
Paraesthesia	2	7
Paraesthesia oral		1
Paresis	1	4
Parkinsonism		1
Pelvic venous thrombosis	2	2
Performance status decreased		2
Pericarditis		1
Peripheral circulatory failure	3	4
Peripheral coldness		1
Peripheral swelling	3	5
Peripheral vascular disorder		7
Peroneal nerve injury		1
Personality change	1	2
Petechiae		2
Pharyngeal swelling		2
Platelet count decreased		1
Pleocytosis	1	2
Pleurisy		1
Pneumonia	4	18
Pneumonia bacterial		1
PO2 decreased	1	1
Poisoning	1	1
Pollakiuria	1	2
Polyneuropathy	1	2
Poor quality product administered		7
Poor quality sleep		1
Presbycusis		1
Presyncope		3
Product complaint	1	1
Product preparation error		1
Product storage error	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		2	6		1
			1		
			1	1	3
					1
				2	2
					2
					1
		1	1	2	3
			1		
		3	5		
			1		6
					1
				1	2
					2
					2
					1
				1	2
					1
				4	18
					1
				1	1
				1	1
		1	2		
				1	2
			7		
			1		
					1
			2		1
		1	1		
			1		
		1	1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product supply issue		1
Product temperature excursion issue		7
Product use issue		1
Proteinuria		1
Prurigo		1
Pruritus	5	11
Pseudoallergic reaction	2	2
Pulmonary embolism	22	33
Pulmonary fibrosis		1
Pulmonary haemorrhage	1	1
Pulmonary infarction	1	1
Pulmonary oedema		1
Pulmonary sarcoidosis	1	1
Pulmonary sepsis		2
Pupils unequal		1
Purpura		1
Pustule		1
Pyramidal tract syndrome		1
Pyrexia	19	126
Rash	7	20
Rash erythematous	1	2
Rash macular	1	1
Rash maculo-papular	1	3
Rash pruritic	1	2
Rash vesicular	1	1
Rectal polyp		1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased		1
Renal disorder		2
Renal failure	2	4
Renal pain		1
Respiratory distress	6	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			7		
			1		1
			1		
	1	4	8	1	3
		1	1	1	1
				22	33
					1
				1	1
				1	1
					1
				1	1
					2
					1
					1
	1				
					1
	7	19	85		41
		4	9	3	11
		1	2		
		1	1		
		1	3		
		1	2		
		1	1		
			1		
			1		
					2
				2	4
			1		
				6	21

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory failure		14
Respiratory rate increased	1	1
Respiratory tract infection		2
Respiratory tract inflammation		1
Restlessness	1	5
Retching		2
Retinal vein thrombosis	1	1
Rhabdomyolysis		3
Rhinitis		1
Rhinorrhoea	1	3
SARS-CoV-2 ant body test negative	3	8
SARS-CoV-2 ant body test positive		10
SARS-CoV-2 test positive	3	15
Seizure	1	14
Sensation of foreign body		1
Sensory disturbance	2	6
Sensory loss		1
Septic shock		2
Shock		1
Sinusitis		1
Skin burning sensation		1
Skin haemorrhage		1
Skin laceration	1	1
Skin ulcer	1	1
Sleep disorder		6
Sneezing		2
Somnolence	3	9
Speech disorder	1	3
Staphylococcal sepsis		1
Status epilepticus		3
Stress		1
Stridor		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					14
		1	1		
					2
					1
		1	3		2
			1		1
				1	1
					3
			1		
		1	3		
		3	7		1
			9		1
		3	9		6
				1	14
			1		
		2	6		
			1		
					2
					1
			1		
					1
					1
		1	1		
			6		
			2		
		2	6	1	3
		1	2		1
					1
					3
					1
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Subclavian artery thrombosis		1						1
Subclavian vein thrombosis	1	1					1	1
Subcutaneous abscess	1	1					1	1
Subdural haematoma		1						1
Sudden cardiac death		1						1
Sudden death	2	11					2	11
Sudden hearing loss	1	8					1	8
Sudden onset of sleep		1						1
Superinfection bacterial		1						1
Suspected COVID-19		2						2
Swelling		2				2		
Swelling face		2				1		1
Syncope	10	16					10	16
Tachyarrhythmia		2						2
Tachycardia	3	19		1	2	8	1	11
Tachypnoea		1						1
Taste disorder		1				1		
Tendon rupture	1	1					1	1
Tenosynovitis		1				1		
Tension		1				1		
Tetany		1						1
Thalamic infarction		1						1
Therapeutic response unexpected	1	5			1	5		
Thirst		1				1		
Throat irritation	1	5			1	5		
Throat tightness		3				2		1
Thrombectomy	1	1					1	1
Thrombocytopenia	1	2					1	2
Thrombosis	7	9					7	9
Tinnitus		3				1		2
Tongue discomfort		1				1		
Tongue oedema		1						1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonic convulsion		1
Tonsillitis bacterial		1
Toxicity to various agents		1
Transaminases increased		2
Transient aphasia	1	1
Transient global amnesia		1
Transient ischaemic attack	2	3
Tremor	1	2
Trigeminal neuralgia	1	1
Underdose		1
Unresponsive to stimuli		3
Upper gastrointestinal haemorrhage		2
Urinary retention		1
Urinary tract infection		1
Urosepsis		1
Urticaria	7	11
Vaccination complication	1	2
Vaccination failure	6	17
Vaccination site bruising		3
Vaccination site discomfort	1	3
Vaccination site dysaesthesia		1
Vaccination site erythema	3	4
Vaccination site haematoma		1
Vaccination site hypersensitivity	1	1
Vaccination site induration	1	1
Vaccination site joint pain		1
Vaccination site lymphadenopathy		1
Vaccination site movement impairment	1	1
Vaccination site pain	33	156
Vaccination site pruritus	1	1
Vaccination site reaction	2	3
Vaccination site swelling	3	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
			2		
				1	1
			1		
				2	3
			1	1	1
		1	1		
			1		
					3
					2
					1
					1
	1	5	8	2	3
				1	2
				6	17
			3		
		1	3		
			1		
		2	3	1	1
			1		
		1	1		
		1	1		
			1		
		1	1		
	12	33	154		2
		1	1		
		2	3		
	4	2	8	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site warmth		2			2			
Vascular encephalopathy		1						1
Vasculitis		2						2
Venous thrombosis	2	2					2	2
Venous thrombosis limb	1	1					1	1
Ventricular extrasystoles	1	1			1	1		
Ventricular fibrillation		2						2
Ventricular tachycardia	1	2					1	2
Vertebral wedging		1						1
Vertigo		3				2		1
Vestibular neuronitis	1	1			1	1		
Viral rash	1	1			1	1		
Vision blurred		2				1		1
Visual acuity reduced		1						1
Visual impairment	3	6					3	6
Vomiting	5	21		2	3	16	2	5
Weight bearing difficulty		1						1
Weight decreased	1	1					1	1
Wheezing		1				1		
White blood cell count decreased	1	1			1	1		
White blood cell count increased		2				1		1
Wrong technique in product usage process		1				1		
	788	2,965		108	422	1581	366	1384

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower		1		1		
Ageusia		1		1		
Allergic oedema		1				1
Allergy to vaccine		1		1		
Anaphylactic reaction		2				2
Angioedema		1				1
Anxiety		1				1
Aphasia	1	1			1	1
Asthenia	1	1	1	1		
Asthma	1	1			1	1
Blood pressure decreased		1				1
Body temperature increased		1		1		
Cardiovascular disorder		2				2
Chills		22		22		
Circulatory collapse		1				1
Circumstance or information capable of leading to medication error		2		2		
Coronavirus infection	7	10	7	7		3
Cough	2	3	2	3		
COVID-19	17	126	14	33	3	93
Deafness		1				1
Death		20				20
Decreased appetite		1				1
Deep vein thrombosis	2	2			2	2
Dehydration	1	1			1	1
Diarrhoea	2	4	2	3		1
Diet refusal		1				1
Disturbance in attention	2	2	1	1	1	1
Dizziness		3		2		1
Drug ineffective	3	91		2	3	89
Dysarthria	1	1	1	1		
Dysphagia	1	4	1	4		

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\* AE=Adverse Event

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dyspnoea	1	3
Eczema		4
Erythema		3
Exposure via breast milk		3
Facial paralysis		1
Facial paresis		1
Fall	1	1
Fatigue	2	16
Feeling cold	1	1
Femur fracture	1	1
Headache	2	27
Herpes zoster		2
Hyperaesthesia	1	1
Hypersensitivity		2
Hypertensive crisis	1	1
Hypoaesthesia		1
Hypotension		1
Hypothermia		1
Hypotonia	1	1
Inappropriate schedule of product administration		1
Incorrect dose administered		1
Incorrect route of product administration	1	2
Influenza like illness		1
Ischaemia	1	1
Lip swelling		1
Listless	1	1
Local reaction		1
Lymphadenopathy		2
Malaise		12
Myalgia		12
Nasopharyngitis		1
Nausea	1	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		2
	4		
	3		
	3		
			1
	1		
		1	1
2	16		
1	1		
		1	1
2	26		1
	2		
1	1		
	1		1
		1	1
	1		
			1
			1
		1	1
	1		
	1		
1	2		
	1		
		1	1
	1		
1	1		
	1		
	2		
	12		
	11		1
	1		
1	4		

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 \* AE=Adverse Event  
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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neck pain		1		1			
Necrosis		1					1
Neuralgia		1		1			
No adverse event		4		4			
Oculogyric crisis		1					1
Off label use		5		5			
Pain	1	1	1	1			
Pain in extremity	1	12	1	12			
Paraesthesia	1	3	1	2			1
Paraesthesia oral		3		3			
Peripheral embolism	1	1			1		1
Peripheral ischaemia	1	1			1		1
Peripheral swelling		1		1			
Polyneuropathy	1	1			1		1
Poor quality product administered		7		7			
Product administered to patient of inappropriate age		1		1			
Product complaint		5		5			
Product leakage		1		1			
Product preparation error		2		2			
Product preparation issue		7		7			
Product quality issue		1		1			
Product temperature excursion issue		1		1			
Product use issue		2		2			
Pyrexia		18		15			3
Rales		1					1
Rash		1		1			
Raynaud's phenomenon	1	1	1	1			
SARS-CoV-2 ant body test negative		3		3			
SARS-CoV-2 ant body test positive		3		3			
SARS-CoV-2 test false positive		4		4			
SARS-CoV-2 test positive	2	18	2	14			4

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stridor		1				1
Sudden hearing loss		1				1
Swelling		1		1		
Syncope		1				1
Thrombosis	1	1			1	1
Tremor		1		1		
Type IV hypersensitivity reaction		4		4		
Underdose		15		15		
Vaccination site hyperaesthesia		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling		1		1		
Visual impairment		1		1		
Vomiting		4		2		2
Wound		1		1		
Wrong technique in product usage process	1	1	1	1		
	68	574	47	316	21	258

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Country Where Event Occurred

**GREECE**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain	1	9		4	1	5
Abdominal pain upper		5		4		1
Abortion spontaneous	1	1			1	1
Acne	1	1	1	1		
Acute respiratory failure		1				1
Ageusia		1				1
Alanine aminotransferase increased		2		2		
Allergy to vaccine		4		1		3
Alopecia		1		1		
Anaemia	2	2	1	1	1	1
Anaphylactic reaction	2	10			2	10
Anaphylactic shock	1	7			1	7
Anaphylactoid reaction		2				2
Angioedema	3	13			3	13
Ankylosing spondylitis	1	1			1	1
Anosmia		2		1		1
Anxiety	1	2	1	2		
Aphasia	1	1			1	1
Arrhythmia	4	8	1	1	3	7
Arteriovenous graft thrombosis	1	1			1	1
Arthralgia	7	55	5	27	2	28
Arthritis		1		1		
Arthritis enteropathic		1				1
Aspartate aminotransferase increased		1		1		
Aspiration	1	1			1	1
Asthenia	3	23	1	12	2	11
Asthmatic crisis		1				1
Asymptomatic COVID-19	2	4			2	4
Atrial fibrillation	2	3			2	3
Auscultation		1		1		
Autonomic nervous system imbalance	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back injury	1	1			1	1
Back pain	3	7	2	5	1	2
Balance disorder		2		1		1
Blepharospasm		1		1		
Blister		2		2		
Blood gases abnormal	1	1			1	1
Blood glucose abnormal		2		1		1
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	1	5		1	1	4
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation		1		1		
Blood pressure increased	12	41	2	18	10	23
Blood pressure systolic		1				1
Blood pressure systolic increased	1	4		1	1	3
Blood triglycerides increased	1	1			1	1
Body dysmorphic disorder		1				1
Bone pain	1	4		1	1	3
Breast pain		1		1		
Bronchial hyperreactivity	1	1			1	1
Bronchospasm		8				8
Burning sensation	7	27	5	18	2	9
Burning sensation mucosal		1				1
Bursitis	1	1			1	1
Cachexia		2				2
Cardiac arrest		3				3
Cardiac discomfort		1				1
Cerebrovascular accident	1	1			1	1
Cervix erythema		1				1
Chest discomfort	1	6		2	1	4
Chest pain	5	15	2	5	3	10
Chills	4	56	1	25	3	31
Choking sensation	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cholelithiasis		1					1
Cholinergic syndrome	1	4			1		4
Circumoral oedema		1					1
Clonus	1	1			1		1
Cold sweat	1	1			1		1
Coma	1	1			1		1
Complex regional pain syndrome	1	4		1	1		3
Condition aggravated	1	3			1		3
Confusional state	2	6		1	2		5
Conjunctival hyperaemia		2		2			
Contusion	1	1			1		1
Cough	3	20	2	6	1		14
COVID-19	3	17		5	3		12
C-reactive protein increased		2		2			
CSF polymorphonuclear cell count increased	1	1			1		1
Cyanosis		1					1
Deafness		1					1
Deafness unilateral		1					1
Death	1	2			1		2
Decreased appetite	1	1			1		1
Deep vein thrombosis	1	1			1		1
Defaecation urgency		1					1
Dehydration	1	1			1		1
Dermatitis allergic		3					3
Dermatomyositis	1	1			1		1
Diabetes mellitus inadequate control	1	1			1		1
Diarrhoea	2	20	2	12			8
Diastolic hypertension		1					1
Diplegia	1	2			1		2
Diplopia		2					2
Discomfort	1	4		2	1		2
Disease recurrence	2	4			2		4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disorientation	1	1	1	1		
Diverticulitis	1	1			1	1
Dizziness	13	61	6	36	7	25
Drowning		1				1
Drug ineffective	2	12			2	12
Drug interaction		1				1
Dry eye	1	1	1	1		
Dry mouth	2	5	2	4		1
Dry throat	2	11	1	2	1	9
Dysarthria		2				2
Dysgeusia	1	11		5	1	6
Dyskinesia		4		3		1
Dyspepsia	1	3		1	1	2
Dysphagia	2	17	1	3	1	14
Dysphonia	2	13	1	2	1	11
Dysphoria	1	3			1	3
Dyspnoea	8	31		9	8	22
Dysstasia	2	2			2	2
Ear pain		3		2		1
Eating disorder	2	2	1	1	1	1
Eating disorder symptom	1	1	1	1		
Electrocardiogram repolarisation abnormality	1	1			1	1
Electromyogram abnormal	1	1	1	1		
Enlarged uvula	2	3			2	3
Epigastric discomfort		1				1
Epilepsy	1	1			1	1
Episcleritis		1				1
Eructation	1	3		2	1	1
Erythema	4	50	2	34	2	16
Extrasystoles	1	4		2	1	2
Eye disorder	1	1	1	1		
Eye haemorrhage	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Eyelid irritation		1					1
Eyelid oedema	1	4	1	3			1
Eyelid ptosis		2					2
Eyelids pruritus	1	2	1	1			1
Eye oedema		1					1
Eye pain	1	1			1		1
Eye pruritus		1		1			
Face oedema	1	4	1	1			3
Facial paralysis	1	1			1		1
Facial paresis	4	5	3	3	1		2
Fall	1	1			1		1
Fatigue	14	76	10	41	4		35
Feeling abnormal		1					1
Feeling cold	1	2	1	2			
Feeling drunk		1					1
Feeling hot		3		2			1
Femur fracture	1	1			1		1
Fibrin D dimer increased		2		1			1
Fibromyalgia		1		1			
Flatulence		2					2
Flushing	3	26		10	3		16
Gait disturbance	2	6		3	2		3
Gait inability	1	1			1		1
Gamma-glutamyltransferase increased		1					1
Gastroenteritis		1					1
Gastrointestinal disorder	1	6		5	1		1
Gastrointestinal hypermotility		1					1
Genital herpes zoster		1					1
Glossodynia	2	2			2		2
Goitre	1	1			1		1
Granuloma annulare	1	1	1	1			
Guillain-Barre syndrome	1	3			1		3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematochezia	1	1			1	1
Haematocrit decreased	1	1	1	1		
Haemoptysis	2	2			2	2
Headache	8	99	5	62	3	37
Head discomfort		2		2		
Heart rate abnormal	1	1			1	1
Heart rate decreased	2	3			2	3
Heart rate increased	2	19	1	13	1	6
Hemiparesis	1	1			1	1
Hepatitis		1				1
Herpes dermatitis		1				1
Herpes simplex reactivation	1	1	1	1		
Herpes zoster	1	11		4	1	7
Hordeolum	1	1	1	1		
Hyperhidrosis	3	15		7	3	8
Hypersensitivity	3	30		11	3	19
Hypersensitivity vasculitis	1	1			1	1
Hypertension	3	25		12	3	13
Hypertensive crisis		12				12
Hypertensive emergency		1				1
Hypoacusis		1				1
Hypoaesthesia	17	68	8	37	9	31
Hypoaesthesia oral		21		6		15
Hypoalbuminaemia		1		1		
Hypokalaemia	1	1			1	1
Hyponatraemia	1	2		1	1	1
Hyporeflexia	1	1			1	1
Hypotension		16		5		11
Hypothermia	1	2			1	2
Hypotonia		3		1		2
Immunoglobulins increased	1	1			1	1
Impaired gastric emptying	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incomplete course of vaccination		1		1		
Incorrect route of product administration		2		2		
Infection	1	1	1	1		
Inflammation		3				3
Influenza like illness		1		1		
Injection site hypoaesthesia		1		1		
Injury		1		1		
Insomnia		1				1
Intercostal neuralgia	1	1	1	1		
Intervertebral disc degeneration	1	1	1	1		
Intervertebral disc protrusion	1	1	1	1		
Iridocyclitis	1	1			1	1
Irritability		1		1		
Ischaemic cerebral infarction	1	1			1	1
Joint range of motion decreased		1		1		
Joint stiffness		1				1
Joint swelling		1		1		
Lacrimation increased		1		1		
Laryngeal oedema		5				5
Laryngeal pain		1				1
Laryngospasm	1	5			1	5
Lethargy	1	4		3	1	1
Leukaemia	1	1			1	1
Leukocytosis	1	1	1	1		
Lichenoid keratosis	1	1	1	1		
Limb discomfort		2		1		1
Limb injury		1		1		
Lip oedema	1	8		2	1	6
Lip pain	2	2			2	2
Lip swelling		3		2		1
Liquid product physical issue		1		1		
Livedo reticularis		1		1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
1	1		
			3
	1		
	1		
	1		
			1
1	1		
1	1		
1	1		
		1	1
	1		
		1	1
	1		
	1		
			5
			1
		1	5
		3	1
		1	1
1	1		
1	1		
	1		1
	2	1	6
		2	2
	2		1
	1		
	1		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
	2		
			2
2	5	3	14
6	16	2	14
	3		1
			1
	1		
3	13	2	10
3	4		
		1	1
	1		
			1
			1
	1		
	1		1
1	2		
1	7		2
1	1		1
1	1		
			1
			1
	1		
	1		3
	1		
	2	1	3
1	1		
1	1		
		1	1
	1		

Localised oedema		2
Local reaction		2
Loss of consciousness		2
Lymphadenitis	5	19
Lymphadenopathy	8	30
Lymph node pain		4
Lymphoedema		1
Lymphopenia		1
Malaise	5	23
Maternal exposure during pregnancy	3	4
Memory impairment	1	1
Meningism		1
Meningomyelitis herpes		1
Menorrhagia		1
Menstruation delayed		1
Menstruation irregular		2
Metrorrhagia	1	2
Migraine	1	7
Monoparesis	1	1
Mouth injury	1	1
Mucosal dryness		1
Muscle discomfort		1
Muscle fatigue		1
Muscle spasms		4
Muscle tightness		1
Muscular weakness	1	5
Musculoskeletal chest pain	1	1
Musculoskeletal stiffness	1	1
Myalgia	8	90
Myelitis	1	2
Myocardial infarction	1	1
Nail discolouration		1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
	1		
	26	2	12
1	3	1	1
			1
			1
		1	1
	1		
		2	3
	1		2
	2	1	1
1	4		
1	3		1
	1		
1	5	2	6
	1		
	1	4	7
1	10		12
9	25	1	4
	1		1
	11	4	10
			1
			1
	2	2	2
			1
		1	1
		1	1
	1	1	1
1	1		
1	1	1	6
1	2		
		1	1

Nasal congestion	1	2
Nasal pruritus		1
Nausea	2	38
Neck pain	2	4
Nervousness		1
Neuralgia		1
Neuropathy peripheral	1	1
Nystagmus		1
Ocular hyperaemia	2	3
Oedema		3
Oedema peripheral	1	3
Off label use	1	4
Oral herpes	1	4
Oral mucosal erythema		1
Oropharyngeal pain	3	11
Orthostatic hypotension		1
Oxygen saturation decreased	4	8
Pain	1	22
Pain in extremity	10	29
Pain in jaw		2
Palpitations	4	21
Pancreatitis		1
Panic reaction		1
Paraesthesia	2	4
Paralysis		1
Paratracheal lymphadenopathy	1	1
Parosmia	1	1
Parotid gland enlargement	1	2
Periorbital swelling	1	1
Peripheral coldness	2	7
Peripheral swelling	1	2
Peripheral venous disease	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	1	1			1	1
Pharyngeal oedema		1		1		
Pharyngitis		1		1		
Photophobia	1	1			1	1
Platelet count increased		1		1		
Polyarthritits	1	1			1	1
Polydipsia		1		1		
Polymenorrhoea		2		2		
Polyneuropathy	1	2			1	2
Polyuria		1		1		
Poor quality product administered		1		1		
Post herpetic neuralgia		1				1
Presyncope	1	9	1	5		4
Product use issue	1	3	1	3		
Pruritus	6	54	1	29	5	25
Pruritus allergic		1				1
Pulmonary embolism	1	2			1	2
Pulmonary mass	1	1			1	1
Pulmonary thrombosis		2				2
Pulse abnormal		1		1		
Pulse absent		1				1
Purpura	1	1			1	1
Pyrexia	23	121	16	72	7	49
Rash	11	58	5	24	6	34
Rash erythematous		2		2		
Rash macular		1		1		
Rash maculo-papular	1	3		1	1	2
Rash papular	1	1			1	1
Rash pruritic	1	10	1	6		4
Raynaud's phenomenon	1	1			1	1
Reflexes abnormal	1	1			1	1
Renal failure	1	1			1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Respiratory failure	1	1
Respiratory tract infection	1	2
Rheumatoid arthritis		2
Rhinitis	1	1
Rhinitis allergic		1
Rhinorrhoea	1	2
Salivary gland enlargement	1	1
Salivary gland pain	1	2
Sarcoidosis	1	1
Seizure		1
Sensation of foreign body		1
Sensory loss	1	1
Sjogren's syndrome	1	1
Skin burning sensation	1	3
Skin reaction		1
Soft tissue swelling		1
Somnolence	2	18
Speech disorder	2	3
Spinal pain	2	4
Stress		1
Sudden death		1
Suspected COVID-19		2
Swelling	3	3
Swelling face	1	3
Syncope		4
Tachycardia	7	47
Tachypnoea		2
Taste disorder	1	3
Teething		1
Temporomandibular joint syndrome	1	2
Tension		1
Terminal state	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	2
			2
1	1		
	1		
	1	1	1
		1	1
1	2		
		1	1
			1
		1	1
	2	1	1
			1
	1		
2	13		5
1	1	1	2
		2	4
	1		
			1
	1		1
1	1	2	2
1	1		2
			4
2	20	5	27
	2		
		1	3
			1
1	2		
	1		
		1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Therapeutic response unexpected		1		1			
Throat irritation	3	12	1	8	2	4	
Throat tightness		1				1	
Thrombosis	1	2			1	2	
Thyroid cyst		1				1	
Thyroiditis	1	2		1	1	1	
Thyroiditis acute		1				1	
Tinnitus		5		3		2	
Tongue discomfort		1				1	
Tongue oedema	2	4			2	4	
Tongue ulceration		1		1			
Tonsillitis	1	1	1	1			
Tremor	4	15	3	10	1	5	
Trigeminal neuralgia		1				1	
Trismus		1		1			
Urinary tract infection		2		1		1	
Urticaria	1	5	1	3		2	
Uveitis	2	3			2	3	
Vaccination failure		1				1	
Vaccination site discomfort	1	2	1	2			
Vaccination site erythema	1	3		1	1	2	
Vaccination site haemorrhage		1		1			
Vaccination site hypoaesthesia	1	2		1	1	1	
Vaccination site induration		1		1			
Vaccination site inflammation		1		1			
Vaccination site irritation		1				1	
Vaccination site movement impairment		1		1			
Vaccination site oedema		4		4			
Vaccination site pain	3	72	2	62	1	10	
Vaccination site pruritus		2		1		1	
Vaccination site rash	1	3	1	3			
Vaccination site reaction		1		1			

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		1		1		
Vaccination site warmth	1	3		2	1	1
Vascular pain	1	1			1	1
Vasculitis	1	1			1	1
Vasoconstriction	1	1			1	1
Venous thrombosis limb	1	1			1	1
Ventricular arrhythmia		1				1
Vertigo	2	11	1	8	1	3
Viral infection		2		2		
Vision blurred		2		2		
Visual impairment	1	1			1	1
Vomiting	6	19	3	9	3	10
Walking disability	1	1			1	1
Water pollution	1	1			1	1
White blood cell count decreased		1		1		
	473	2,303	179	1117	294	1186

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		2		1
Abdominal pain upper		2		2		
Acute myocardial infarction	1	3			1	3
Acute respiratory distress syndrome		1				1
Aggression		1				1
Agitation		1				1
Anaphylactic reaction	2	4			2	4
Angina pectoris	1	1			1	1
Angioedema		2				2
Arrhythmia	1	4			1	4
Arteriosclerosis		1				1
Arthralgia	2	13	1	5	1	8
Asthenia	1	18	1	13		5
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation	1	3			1	3
Audiogram abnormal	1	1	1	1		
Axillary pain	1	2		1	1	1
Back pain	1	3	1	3		
Blepharitis		1		1		
Blister		2		2		
Blood calcium decreased		1		1		
Blood creatine phosphokinase increased		1		1		
Blood glucose abnormal		1		1		
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood potassium decreased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased		2		2		
Blood pressure diastolic increased		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased	3	12		6	3	6
Blood pressure systolic abnormal	1	1			1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood pressure systolic increased	1	1
Blood urea increased		1
Body temperature increased		1
Bradycardia		2
Brain death	1	2
Bronchospasm		1
Burning sensation		2
Bursitis		1
Cachexia		2
Capillary disorder		1
Carbohydrate antigen 125 increased		1
Carcinoembryonic antigen increased		1
Cardiac arrest	3	5
Cardiac failure	1	1
Cardiac valve disease		1
Carotid artery occlusion		1
Catarrh		1
Central nervous system stimulation		1
Cerebral haemorrhage		1
Cerebral ischaemia	1	1
Cerebral venous thrombosis	1	1
Cerebrovascular accident	1	3
Cervical radiculopathy		1
Chest discomfort	1	2
Chest pain		3
Chills	5	32
Communication disorder	1	1
Complex regional pain syndrome	1	1
Condition aggravated		1
Confusional state		4
Conjunctivitis		1
Constipation		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
	1		
			2
		1	2
			1
	2		
	1		
			2
	1		
	1		
			1
		3	5
		1	1
			1
	1		
			1
			1
		1	1
		1	1
		1	3
			1
		1	2
	2		1
5	17		15
1	1		
		1	1
			1
	1		3
	1		
	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronary artery stenosis		1				1
Cough		6		4		2
COVID-19	2	17		5	2	12
Cyanosis		2		2		
Deafness unilateral		1				1
Death	1	4			1	4
Decreased appetite		3		3		
Deep vein thrombosis	2	3			2	3
Depression		1		1		
Diabetes mellitus inadequate control	1	3			1	3
Diarrhoea	1	7	1	5		2
Diplegia		1				1
Discomfort		3		2		1
Disorientation		1				1
Disturbance in attention		1				1
Dizziness	1	21	1	14		7
Drug ineffective	1	9			1	9
Dry mouth		3		2		1
Dry throat		1		1		
Dysarthria	1	1			1	1
Dysgeusia		2		2		
Dyskinesia		1		1		
Dysphagia	2	6		3	2	3
Dysphonia	1	3	1	2		1
Dysphoria	1	1			1	1
Dyspnoea	3	15	1	5	2	10
Dysstasia		2		1		1
Ear, nose and throat examination abnormal	1	1	1	1		
Ear pain		1				1
Eczema		1		1		
Epistaxis	1	1	1	1		
Eructation		2		1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	4	13	2	8	2	5
Extrasystoles		1		1		
Eye irritation		1		1		
Eyelid oedema	1	1	1	1		
Eye pruritus		1				1
Eye swelling		1				1
Face oedema		1		1		
Facial paralysis	2	5			2	5
Facial paresis	5	7			5	7
Fall		5		2		3
Fatigue	9	30	6	19	3	11
Feeding disorder	1	1	1	1		
Feeling cold		1		1		
Feeling hot		2		1		1
Fine motor skill dysfunction		1				1
Flushing		4		3		1
Foot deformity	1	1			1	1
Gait disturbance	1	2		1	1	1
Gait inability		1				1
Gastrointestinal disorder		4		4		
Gastrointestinal haemorrhage	1	1			1	1
Glycosylated haemoglobin decreased		1		1		
Guillain-Barre syndrome	2	3			2	3
Haematocrit decreased	1	1			1	1
Haematoma		1				1
Haematuria		1				1
Haemoglobin decreased		1		1		
Haemoptysis		1		1		
Headache	10	34	8	22	2	12
Head discomfort	1	2		1	1	1
Heart rate decreased	1	2			1	2
Heart rate increased		4		2		2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Heart rate irregular		1					1
Hemiparesis		2					2
Herpes ophthalmic	1	2			1		2
Herpes zoster	1	6	1	5			1
Hot flush	1	2			1		2
Hyperhidrosis	2	10	1	4	1		6
Hypersensitivity		4		2			2
Hypertension	1	9		3	1		6
Hypertensive crisis		3					3
Hypertrophic cardiomyopathy		1					1
Hypoaesthesia	2	17		8	2		9
Hypoaesthesia oral		2		2			
Hypoglycaemia	1	4		3	1		1
Hypokalaemia	1	1			1		1
Hyponatraemia	1	1			1		1
Hypotension	1	4		1	1		3
Hypotonia	1	3		2	1		1
Illness	1	2	1	1			1
Impaired self-care		1					1
Impaired work ability		1					1
Incorrect route of product administration	1	1	1	1			
Inflammation	1	1	1	1			
Injection site pain		2		2			
Insomnia	2	5	1	4	1		1
Insulin resistance		1					1
Ischaemic stroke		1					1
Joint effusion	1	1			1		1
Laryngeal oedema		1					1
Left ventricular hypertrophy		1					1
Lethargy		1					1
Leukocytosis		1					1
Limb discomfort		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
			1
		3	7
	1		
		1	1
	1	2	3
2	5	2	4
2	7		2
	1		
			1
	1		
	1		
1	1		
	1		
		1	1
		1	1
	1	3	5
	1		
1	1		1
4	15	1	11
			2
			1
	1		
	1		
2	6		3
1	1		1
			1
			1
	1		
1	1		
	1		

Lip oedema 1  
Liquid product physical issue 1  
Localised oedema 1  
Loss of consciousness 3 7  
Loss of personal independence in daily activities 1  
Lower respiratory tract infection 1 1  
Lymphadenitis 2 4  
Lymphadenopathy 4 9  
Malaise 2 9  
Mechanical urticaria 1  
Memory impairment 1  
Middle insomnia 1  
Migraine 1  
Movement disorder 1 1  
Muscle injury 1  
Muscle spasms 1 1  
Muscle tightness 1 1  
Muscular weakness 3 6  
Musculoskeletal discomfort 1  
Musculoskeletal stiffness 1 2  
Myalgia 5 26  
Myocardial infarction 2  
Myocarditis 1  
Nail discolouration 1  
Nasopharyngitis 1  
Nausea 2 9  
Neck pain 1 2  
Neuritis 1  
Neuropathy peripheral 1  
No adverse event 1  
Occupational exposure to product 1 1  
Ocular hyperaemia 1

\* I=Interval, C=Cumulative  
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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral	1	1			1	1
Off label use		1		1		
Onycholysis		1		1		
Ophthalmic artery thrombosis	1	1			1	1
Oropharyngeal pain		2		2		
Orthostatic hypotension		1				1
Overdose		1		1		
Oxygen saturation abnormal	1	1			1	1
Pain		6		4		2
Pain in extremity	3	10	2	8	1	2
Pallor	1	3		2	1	1
Palpitations	1	7		2	1	5
Pancreatitis		1				1
Papilloedema		1				1
Paralysis		1				1
Paraparesis	1	1			1	1
Paresis	1	1			1	1
Parotitis		1		1		
Periorbital oedema		1		1		
Peripheral coldness		1				1
Petechiae		1		1		
Petit mal epilepsy		1				1
Pneumonia		1				1
Pollakiuria		1		1		
Polyneuropathy	1	1			1	1
Poor quality product administered		1		1		
Poor quality sleep		1		1		
Presyncope	1	4			1	4
Product preparation error		1		1		
Product use issue		1		1		
Protein total decreased		1		1		
Prothrombin time prolonged		1		1		

\* I=Interval, C=Cumulative  
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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	6	1	3
	1		
			1
			1
		1	1
12	33	3	20
	6		7
			1
1	2		
		1	1
			1
1	2		
	1		
			1
		1	1
			1
	1		
			1
	2		1
	2	1	1
		1	1
			1
	1		1
		1	9
1	6	2	6
	1		
	2		
1	1		
		1	1

Pruritus 3 9  
 Psoriasis 1  
 Psoriatic arthropathy 1  
 Pulmonary oedema 1  
 Pulse abnormal 1 1  
 Pyrexia 15 53  
 Rash 13  
 Rash maculo-papular 1  
 Rash pruritic 1 2  
 Renal impairment 1 1  
 Respiratory tract infection 1  
 SARS-CoV-2 ant body test positive 1 2  
 SARS-CoV-2 test positive 1  
 Sciatica 1  
 Scleritis 1 1  
 Shock 1  
 Skin irritation 1  
 Skin lesion 1  
 Soft tissue swelling 1  
 Somnolence 3  
 Speech disorder 1 3  
 Sputum increased 1 1  
 Sputum purulent 1  
 Sudden death 2  
 Swelling 2  
 Swelling face 1  
 Syncope 1 9  
 Tachycardia 3 12  
 Tension 1  
 Therapeutic response unexpected 2  
 Thirst 1 1  
 Thrombosis 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	2	4	1	3	1	1
Tongue oedema		1				1
Tonsillar hypertrophy		1				1
Transient ischaemic attack		1				1
Tremor		3		2		1
Urinary incontinence	1	2	1	1		1
Urinary tract infection	1	1			1	1
Uveitis	2	2			2	2
Vaccination failure	1	3			1	3
Vaccination site discomfort	1	3	1	3		
Vaccination site erythema		2		2		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypoaesthesia		2		2		
Vaccination site lymphadenopathy		1				1
Vaccination site oedema		4		3		1
Vaccination site pain	6	28	5	25	1	3
Vertigo		1				1
Visual impairment	1	1	1	1		
Vomiting		5		2		3
Wheezing		1		1		
	198	878	83	440	115	438

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Anaphylactic reaction		1				1
Asthenia		1		1		
Blood pressure increased	1	2	1	2		
Bronchospasm		1				1
Burning sensation	1	2	1	2		
Chills	1	1	1	1		
Circumstance or information capable of leading to medication error		2		2		
Cough		4		3		1
COVID-19		1				1
Crying		1		1		
Dizziness		3		2		1
Drug ineffective		1				1
Dysgeusia		2		1		1
Dyspepsia		2		2		
Dysphagia		2		1		1
Erythema		2		1		1
Expired product administered		1		1		
Exposure via breast milk		1		1		
Eye irritation	1	1	1	1		
Headache	1	3	1	2		1
Heart rate increased	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity		2		2		
Hypertension		2		1		1
Hypoaesthesia oral	1	5	1	4		1
Incorrect route of product administration		1		1		
Liquid product physical issue		2		2		
No adverse event		9		9		
Oedema		1		1		
Oral discomfort	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal discomfort		2		2		
Pain in extremity		1		1		
Palpitations		1		1		
Periorbital oedema	1	1	1	1		
Poor quality product administered		3		3		
Product quality issue		1		1		
Product temperature excursion issue		1		1		
Pruritus		1				1
Rash		2		1		1
Rash macular	1	1	1	1		
Reaction to excipient		1				1
Restlessness		1		1		
Tachycardia	1	3	1	3		
Therapeutic response unexpected		1		1		
Urticaria		1		1		
Vaccination site bruising	1	1	1	1		
Vomiting		1		1		
Wrong technique in product usage process		2		2		
	13	85	13	70		15

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**GUINEA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headache	1	1	1	1
Hypertension	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**HOLY SEE (VATICAN CITY STATE)**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Extensive swelling of vaccinated limb		1		1
Injected limb mobility decreased		1		1
Oedema peripheral		2		2
Pain in extremity		1		1
Periorbital oedema		1		1
Vaccination site pain		1		1
		8		8

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Country Where Event Occurred

**HONG KONG**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Abortion spontaneous	1	1			1	1
Allergy to vaccine	2	2	1	1	1	1
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	1	2		1	1	1
Blood pressure increased	3	4	1	2	2	2
Burning sensation	1	1	1	1		
Chest discomfort	4	5	2	3	2	2
Chest pain	4	5			4	5
Dizziness	13	14	4	4	9	10
Drug hypersensitivity	1	1	1	1		
Dyspnoea	2	4	1	2	1	2
Essential hypertension	1	1			1	1
Fatigue		1		1		
Headache	3	3	1	1	2	2
Hyperhidrosis	1	1	1	1		
Hypertension	9	9	1	1	8	8
Hyperventilation	2	2			2	2
Hypoaesthesia	5	5			5	5
Loss of consciousness	3	3			3	3
Malaise		1		1		
Muscle twitching	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Nausea	3	3	1	1	2	2
Neuralgia		1		1		
Palpitations	6	7			6	7
Pharyngeal swelling	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	2	2	1	1	1	1
Rash	11	13	7	7	4	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	2	2			2	2
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	3	2	2	1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1			1	1
	94	108	33	40	61	68

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Back pain	1	1			1	1
Blood pressure increased	1	1	1	1		
Cerebrovascular accident		1				1
Chest discomfort	2	2	1	1	1	1
Chest pain	1	1			1	1
Contusion	1	1			1	1
Coronary artery disease	1	2			1	2
Dizziness	7	8	3	3	4	5
Dyspnoea		1				1
Facial paralysis	2	2			2	2
Fall	2	2			2	2
Headache	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	2	3	1	1	1	2
Hypertension	4	4	1	1	3	3
Hypoaesthesia	4	5	2	2	2	3
Injury	1	1			1	1
Ischaemic stroke	1	1			1	1
Lip injury	1	1			1	1
Loss of consciousness	7	7			7	7
Muscular weakness	1	1			1	1
Myocardial ischaemia		1				1
Palpitations	4	5	2	2	2	3
Paresis		1				1
Presyncope	1	1			1	1
Rash	1	1			1	1
Seizure	5	5			5	5
Syncope	4	5			4	5
Urticaria	1	1			1	1
Vomiting	1	1	1	1		
	59	69	14	14	45	55

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\* AE=Adverse Event

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Decreased appetite	1	1	1	1		
Dizziness	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Injection site pain	1	1	1	1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	2	2	2	2		
Migraine	1	1	1	1		
Movement disorder	1	1	1	1		
Paraesthesia	1	1	1	1		
Paralysis	1	1			1	1
Seizure	1	1			1	1
Syncope	1	1			1	1
Tremor	1	1	1	1		
	19	19	14	14	5	5

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Country Where Event Occurred

**HUNGARY**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		3		
Abdominal distension		3		3		
Abdominal pain		7		7		
Abdominal pain upper		1		1		
Abortion	1	1			1	1
Abortion missed	1	2			1	2
Adnexa uteri pain		1		1		
Adverse event following immunisation		1		1		
Ageusia		2		2		
Aggression	1	1			1	1
Alanine aminotransferase increased	1	1	1	1		
Allergy to vaccine		1				1
Alopecia		1		1		
Anaemia	1	1	1	1		
Anaphylactic reaction		2				2
Angina pectoris	2	4			2	4
Angioedema		2				2
Anosmia		3		3		
Antibody test normal	1	1	1	1		
Aphthous ulcer		1		1		
Arrhythmia		1				1
Arteriosclerosis		1				1
Arthralgia	5	17	3	13	2	4
Arthritis reactive		1				1
Aspartate aminotransferase increased	1	1	1	1		
Asphyxia		3				3
Asthenia	9	55	5	45	4	10
Asthenopia	1	1	1	1		
Atrial fibrillation		2				2
Autoimmune thyroiditis	1	1			1	1
Axillary mass		1		1		
Axillary pain	1	4	1	4		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	2	9	2	9		
Bezold-Jarisch reflex		1		1		
Biliary tract disorder		1				1
Blepharospasm	1	1	1	1		
Blindness		1				1
Blister		1		1		
Blood glucose decreased	1	1	1	1		
Blood glucose increased		3		3		
Blood pressure decreased		2		2		
Blood pressure fluctuation	1	3	1	1		2
Blood pressure increased	5	15	1	8	4	7
Blood pressure systolic increased		1				1
Blood urine present	1	1			1	1
Body temperature increased		2		2		
Bone pain	1	2	1	2		
Bradycardia		1				1
Bradyphrenia		1		1		
Breast mass	1	1			1	1
Bronchitis	1	1			1	1
Burning sensation	2	8	1	7	1	1
Capillaritis		1		1		
Cardiac disorder	1	1			1	1
Cardiac failure	1	3			1	3
Cardiomegaly	1	1			1	1
Cardiopulmonary failure	1	1			1	1
Cartilage injury		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	1	1			1	1
Cervical neuritis		1		1		
Chest discomfort	1	3		2	1	1
Chest pain	3	12	1	10	2	2
Chills	12	50	12	49		1

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis	1	1			1	1
Chromaturia		1		1		
Chronic obstructive pulmonary disease		1		1		
Circulatory collapse		1				1
Cold sweat		1		1		
Condition aggravated	1	4	1	2		2
Confusional state	1	2		1	1	1
Cough	2	7	1	6	1	1
COVID-19	7	17		4	7	13
Craniofacial fracture		1				1
C-reactive protein increased	1	1	1	1		
Cutaneous symptom		1				1
Death	1	3			1	3
Decreased appetite	2	5	2	5		
Deep vein thrombosis	1	2			1	2
Defaecation urgency		1		1		
Dehydration	1	1			1	1
Dementia	1	1			1	1
Depressed mood		1		1		
Depression		1		1		
Diarrhoea	2	19	1	18	1	1
Discomfort	1	1	1	1		
Disease recurrence	1	1			1	1
Disturbance in attention	2	2	1	1	1	1
Dizziness	7	39	5	33	2	6
Drug hypersensitivity		2		2		
Drug ineffective	8	15			8	15
Drug interaction	1	1	1	1		
Dry eye		2		2		
Dry mouth	1	3	1	2		1
Dysgeusia		6		5		1
Dysphagia	2	9	1	3	1	6

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1	1	2
1	8		2
		1	1
1	2	1	1
	3		
	2		
1		1	1
	1		
			1
1		1	1
	11		1
			1
	1		
	2		
			1
			1
1		1	1
	1		
1	1		
			2
1	2		
1	1		2
	1		
			2
	2		1
	1		3
8	30		
	1		
			1
	7		2
	2		

Dysphemia 1 1  
 Dysphonia 1 3  
 Dyspnoea 1 10  
 Dyspnoea exertional 1 1  
 Ear discomfort 2 3  
 Ear pain 3  
 Ear pruritus 2  
 Ear swelling 1 1  
 Eczema 1  
 Emphysema 1  
 Enteritis 1 1  
 Erythema 12  
 Erythema multiforme 1  
 Exposure during pregnancy 1  
 Exposure via breast milk 2  
 Extrasystoles 1  
 Eye haemorrhage 1  
 Eye inflammation 1 2  
 Eye irritation 1  
 Eyelid oedema 1 1  
 Eye oedema 2  
 Eye pain 1 2  
 Face oedema 1 3  
 Facial pain 1  
 Facial paralysis 2  
 Facial paresis 3  
 Fall 4  
 Fatigue 8 30  
 Fear of death 1  
 Feeding disorder 1  
 Feeling abnormal 9  
 Feeling cold 2

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling hot	1	6
Feeling of body temperature change		1
Femoral neck fracture		1
Flushing		4
Foaming at mouth		1
Gait disturbance		2
Gamma-glutamyltransferase increased	1	1
Glossitis		1
Glossodynia		1
Haematoma	2	2
Haematuria	1	2
Haemorrhage		2
Headache	16	76
Head discomfort	1	1
Heart rate decreased		1
Heart rate increased	2	8
Heart rate irregular	1	1
Hemiparesis		1
Hepatic enzyme increased	1	1
Herpes virus infection		1
Herpes zoster		3
Hot flush	2	3
Hyperaemia		1
Hyperaesthesia		2
Hyperhidrosis	1	8
Hypersensitivity	3	7
Hypertension	1	3
Hypertensive crisis		1
Hypoaesthesia	6	17
Hypoaesthesia oral	3	6
Hypoglycaemia		1
Hypokinesia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	4	1	2
	1		
			1
	3		1
			1
	2		
1	1		
	1		
	1		
		2	2
1	1		1
			2
15	70	1	6
1	1		
	1		
2	6		2
1	1		
			1
1	1		
	1		
	3		
1	2	1	1
	1		
	2		
1	8		
1	4	2	3
1	2		1
			1
5	14	1	3
2	5	1	1
	1		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyporeflexia		2		2		
Hypotension		4		2		2
Illness	1	3	1	3		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	1	2	1	2		
Induration		1		1		
Influenza		1		1		
Influenza like illness	1	3	1	3		
Injection site discolouration		1		1		
Injection site erythema		1		1		
Injection site pain		1		1		
Injection site swelling		1		1		
Injection site urticaria	1	1	1	1		
Insomnia	2	5	2	5		
Ischaemic stroke		1				1
Joint range of motion decreased		1		1		
Lacrimation increased		3		3		
Lactation disorder	1	1	1	1		
Left ventricular failure		1				1
Lethargy	1	2		1	1	1
Limb discomfort		1		1		
Lip oedema		1				1
Lip swelling	1	3	1	1		2
Listless		1				1
Localised oedema		1		1		
Local reaction		2		2		
Loss of consciousness		2				2
Lower limb fracture		1				1
Lymphadenitis		3		3		
Lymphadenopathy	4	31	2	24	2	7
Lymph node pain		9		8		1
Macular oedema		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	6	37	6	34		3
Mastication disorder	1	1	1	1		
Maternal exposure during breast feeding		1		1		
Maternal exposure during pregnancy		2		1		1
Memory impairment	1	2		1	1	1
Menstruation delayed		1		1		
Menstruation irregular		1		1		
Micturition urgency		1		1		
Migraine		5		4		1
Monoplegia		2				2
Mood altered		2		2		
Mouth swelling		1				1
Mucosal inflammation	1	1			1	1
Muscle fatigue		1		1		
Muscle strain		1		1		
Muscle twitching	1	1			1	1
Muscular weakness		4		4		
Musculoskeletal chest pain		2		2		
Musculoskeletal stiffness		3		2		1
Myalgia	9	37	9	36		1
Nasal congestion		2		2		
Nasopharyngitis		2		2		
Nausea	7	38	7	34		4
Neck pain	1	3	1	3		
Neoplasm progression		1				1
Neuralgia	1	2	1	2		
Night sweats		1		1		
Nipple pain		1		1		
Noninfective gingivitis		1		1		
Odynophagia		1		1		
Oedema blister	1	1			1	1
Oedema peripheral		2		1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	3	1	3		
Oral herpes		2		2		
Oropharyngeal pain	3	10	2	9	1	1
Overdose	1	1	1	1		
Oxygen consumption increased		1		1		
Oxygen saturation decreased		2		1		1
Pain	1	6	1	6		
Painful respiration		1		1		
Pain in extremity	7	51	7	49		2
Pain of skin	1	3	1	3		
Pallor	1	4	1	4		
Palpitations	2	7	1	5	1	2
Panic attack		1		1		
Paraesthesia		4		2		2
Paralysis		1				1
Periarthritis		1		1		
Pericarditis	1	1			1	1
Periorbital disorder	1	1			1	1
Peripheral coldness		1		1		
Peripheral nerve paresis		1				1
Peripheral swelling	3	8	1	6	2	2
Peripheral venous disease	1	1			1	1
Petechiae	1	1			1	1
Pharyngeal oedema		1		1		
Pharyngeal swelling	2	3	1	2	1	1
Pharyngitis		1		1		
Photopsia		1		1		
Pneumonia	1	2			1	2
Pollakiuria	1	1			1	1
Polyarthritis		2				2
Polyneuropathy		1				1
Poor quality sleep		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Potentiating drug interaction	1	1	1	1		
Product administered at inappropriate site		1		1		
Productive cough		1		1		
Product use issue		3		3		
Pruritus	1	13	1	12		1
Psychiatric symptom		1				1
Pulmonary arterial pressure increased	1	1			1	1
Pulpitis dental		1		1		
Pyrexia	15	74	14	71	1	3
Rash	1	8	1	5		3
Rash erythematous	2	6	1	5	1	1
Rash macular	1	2	1	2		
Rash maculo-papular		2		2		
Rash pruritic	2	6	1	5	1	1
Red blood cell sedimentation rate increased	1	1	1	1		
Renal pain		1		1		
Respiratory distress		2		1		1
Restlessness		1		1		
Retching		2		2		
Rhinorrhoea		4		4		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	2	5		1	2	4
Sensation of foreign body		3				3
Sensitive skin		3		3		
Sensory loss		1		1		
Skin burning sensation		5		4		1
Skin discolouration	2	2	1	1	1	1
Skin disorder		1		1		
Skin haemorrhage	1	1			1	1
Skin hypertrophy		1		1		
Skin ulcer	1	1			1	1
Skin warm		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder	1	2	1	2		
Somnolence	3	7	2	6	1	1
Stress		1		1		
Suspected COVID-19		1				1
Swelling	1	3	1	3		
Swelling face		1		1		
Swelling of eyelid	1	2	1	2		
Swollen tongue	1	1	1	1		
Syncope	1	4			1	4
Tachycardia		7		4		3
Taste disorder		1		1		
Thirst		2		1		1
Throat irritation		1		1		
Throat tightness		2				2
Thrombocytopenia	1	1			1	1
Thrombophlebitis	1	1	1	1		
Thrombophlebitis superficial	1	1			1	1
Thrombotic stroke		1				1
Tinnitus	1	1	1	1		
Toothache	1	1	1	1		
Tremor	2	9	1	6	1	3
Tricuspid valve incompetence	1	1			1	1
Type IV hypersensitivity reaction		1				1
Upper respiratory tract infection		1		1		
Urinary tract pain		1		1		
Urticaria	2	8	1	6	1	2
Uveitis		1				1
Vaccination failure	1	2			1	2
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site erythema	8	30	8	30		
Vaccination site haematoma		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site induration	1	2	1	2		
Vaccination site inflammation		1		1		
Vaccination site macule	1	1	1	1		
Vaccination site mass		1		1		
Vaccination site movement impairment	2	6	2	6		
Vaccination site nodule	1	4	1	4		
Vaccination site oedema		2		2		
Vaccination site pain	11	53	11	52		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		4		4		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	6	21	6	21		
Vaccination site warmth		5		5		
Vaginal discharge		1		1		
Varicose vein		2		2		
Vasculitis		1		1		
Vasoconstriction	1	1			1	1
Vision blurred		2		2		
Visual impairment		2		1		1
Vomiting	1	13	1	11		2
White coat hypertension		1		1		
Wound	2	3	2	3		
	326	1,450	218	1149	108	301

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Acute respiratory failure	1	2			1	2
Anaemia	1	1			1	1
Anal incontinence		1				1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Anosmia		1		1		
Antibody test negative		1		1		
Anuria	1	1			1	1
Anxiety		1		1		
Arthralgia		3		3		
Asphyxia	1	1			1	1
Asthenia		13		7		6
Ataxia		1		1		
Atrial fibrillation	2	2			2	2
Back pain		1		1		
Blister		1		1		
Blood glucose increased		1				1
Blood pressure decreased	1	1			1	1
Blood pressure fluctuation		1		1		
Blood pressure increased		9		6		3
Blood thyroid stimulating hormone decreased		1		1		
Bronchitis	1	1	1	1		
Burning sensation		1		1		
Bursitis		1		1		
Cardiac disorder	1	1			1	1
Cardiac failure		2				2
Cardiomegaly	1	1	1	1		
Cellulitis	1	1			1	1
Cerebral infarction		1				1
Cerebrovascular accident		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	1	3	1	3		
Chest pain		1		1		
Chills	1	9	1	9		
Choking	1	1			1	1
Chromaturia		1		1		
Circulatory collapse	1	2			1	2
Cold sweat		1		1		
Condition aggravated	2	3			2	3
Confusional state	1	2	1	1		1
Constipation		1		1		
Coordination abnormal	1	1	1	1		
Cough	4	5	3	4	1	1
COVID-19	8	16	1	1	7	15
COVID-19 pneumonia		1				1
Cyanosis		1				1
Death	1	3			1	3
Decreased appetite	1	3	1	2		1
Decubitus ulcer		1				1
Dermal cyst		1		1		
Dermatitis herpetiformis		1		1		
Diarrhoea	2	5	1	4	1	1
Diarrhoea haemorrhagic		1				1
Dizziness	1	6	1	6		
Drug ineffective	5	11			5	11
Dysgeusia	1	1	1	1		
Dysphagia		3				3
Dysphonia	1	1			1	1
Dyspnoea	2	9	1	2	1	7
Dysuria		1		1		
Ear discomfort		1		1		
Ear pruritus		1		1		
Epistaxis		1		1		

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
2	3		
	2		
			1
			1
1	1	1	1
1	13		1
			1
1	2		
	2		
	1		
1	1	1	1
	1		
	1		
	1		
1	1	1	1
1	1	1	1
1	1		
	1		
1	1		
			1
			1
	1		1
1	17		1
	2		
	1		
	4		
1	1		
	1		
			1
	4		

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\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	1	5	1	5		
Hypoaesthesia oral	1	2	1	1		1
Hypotension		3				3
Hypotonia	1	1			1	1
Incorrect product formulation administered	1	1	1	1		
Inflammation	1	1	1	1		
Influenza like illness		1		1		
Insomnia		3		3		
Intervertebral disc protrusion		1		1		
Iodine uptake decreased		1		1		
Irritability		1		1		
Laryngeal oedema		1				1
Lethargy		3		3		
Lhermitte's sign		1		1		
Liquid product physical issue	1	1	1	1		
Loss of consciousness	1	3			1	3
Lymphadenopathy		6		6		
Lymph node pain		1		1		
Lymphocyte count decreased		1		1		
Malaise	3	10	3	10		
Megacolon		1				1
Melaena	1	1			1	1
Metabolic acidosis		1				1
Micturition urgency		1		1		
Mobility decreased		1		1		
Monocyte count increased		1		1		
Monocytosis	1	1			1	1
Muscle spasms	1	1	1	1		
Muscle strain		1		1		
Muscle tightness		1		1		
Muscular weakness	1	3	1	3		
Myalgia		10		10		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Myelopathy		1					1
Nausea	2	6	2	6			
Neuralgia		1					1
Oedema peripheral		1					1
Oropharyngeal pain	2	3		1	2		2
Pain	1	2	1	2			
Pain in extremity	1	8	1	8			
Pain of skin		2		2			
Pallor		1					1
Palpitations		1		1			
Paranasal sinus discomfort		1		1			
Peripheral coldness		1		1			
Peripheral swelling		1		1			
Petechiae		1		1			
Pharyngeal oedema		1		1			
Pityriasis rosea		1		1			
Pneumonia	2	2			2		2
Poor quality product administered	1	1	1	1			
Product complaint	1	1	1	1			
Productive cough	1	2	1	2			
Pruritus		1		1			
Psychiatric symptom	1	1			1		1
Pulmonary embolism	1	1			1		1
Pulseless electrical activity		1					1
Pyrexia	5	27	3	21	2		6
Radiculopathy		1		1			
Rash		3		3			
Rash erythematous		2		2			
Rash maculo-papular		1					1
Rash pruritic		1		1			
Rash vesicular		1		1			
Red blood cell sedimentation rate increased		1		1			

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal impairment	1	1			1	1
Renal pain		1		1		
Respiratory disorder	1	1	1	1		
Respiratory failure	1	1			1	1
Rhinorrhoea	1	5	1	5		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	4		2	1	2
Sciatica		1				1
Sensation of foreign body		2				2
Serum ferritin increased		1		1		
Sinusitis		1		1		
Skin lesion		1		1		
Skin sensitisation	1	1	1	1		
Somnolence	1	4		2	1	2
Speech disorder	1	1	1	1		
Spinal osteoarthritis		1		1		
Stress		1		1		
Stridor		1				1
Swelling		1		1		
Swelling face		1		1		
Syncope	2	3			2	3
Tachycardia		1				1
Tachypnoea		1				1
Tension	1	2	1	2		
Tension headache	1	1	1	1		
Therapeutic response unexpected		1		1		
Throat irritation		1		1		
Thrombophlebitis	1	1			1	1
Thyroiditis subacute		1		1		
Thyroxine free increased		1		1		
Tinnitus		3		3		

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
1	1		
		1	1
1	5		
	1		
	1		
	2	1	2
			1
			2
	1		
	1		
	1		
1	1		
	2	1	2
1	1		
	1		
			1
	1		
		2	3
			1
			1
1	2		
1	1		
	1		
		1	1
	1		
	1		
	3		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tooth disorder		1				1
Transient ischaemic attack		1				1
Tremor		1		1		
Tri-iodothyronine free increased		1		1		
Urinary incontinence	1	1	1	1		
Urticaria		2		2		
Vaccination failure	1	2			1	2
Vaccination site coldness		1		1		
Vaccination site pain		10		10		
Vomiting	1	2	1	1		1
Weight decreased	1	1			1	1
Wheezing	1	1			1	1
White matter lesion		1		1		
	110	452	51	300	59	152

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Dermatitis allergic		1		1		
Drug ineffective		1				1
Exposure via breast milk		1		1		
Full blood count abnormal	1	1			1	1
Headache	1	1	1	1		
Herpes zoster		4		4		
Lymphadenopathy		1		1		
Lymphoedema		1		1		
Pain in extremity	1	1	1	1		
Pyrexia		2		2		
	3	15	2	12	1	3

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Country Where Event Occurred  
**ICELAND**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal incontinence		1		1		
Aortic aneurysm		1				1
Aphasia		2		1		1
Arthralgia		3		3		
Asthenia		5		5		
Asthma		1				1
Axillary pain		3		3		
Back pain	1	3	1	3		
Balance disorder	1	1			1	1
Blood pressure increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Breast inflammation		1		1		
Breath sounds abnormal		1				1
Cardiac failure		1				1
Chest discomfort		2		2		
Chest pain		2		2		
Chills		10		10		
Cold sweat		1		1		
Confusional state	1	1			1	1
Contusion		1				1
Cough		5		4		1
Death		4				4
Decreased appetite		4		4		
Deep vein thrombosis	1	1			1	1
Delirium	1	1			1	1
Disease progression		1				1
Disease recurrence		1		1		
Dizziness	1	10	1	10		
Dry mouth		1		1		
Dry throat		1		1		
Dysgeusia		1		1		

\* I=Interval, C=Cumulative  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea		6		4		2
Ear pain		1		1		
Erythema		4		4		
Fall	1	1	1	1		
Fatigue	1	15		14	1	1
Feeling abnormal	1	3	1	3		
Feeling cold		1		1		
Feeling hot		1		1		
Fibrin D dimer increased	1	1			1	1
Fluid overload		1				1
Gastrointestinal pain		1		1		
Headache	1	33	1	33		
Head discomfort		1		1		
Heart rate increased		2		2		
Hepatic enzyme increased		2		1		1
Hot flush		1		1		
Hypercapnia		1				1
Hyperhidrosis		2		2		
Hypersomnia		1		1		
Hypertension		1		1		
Hypoaesthesia		5		5		
Hypoperfusion		1				1
Hypoxia		1				1
Influenza like illness	1	1	1	1		
Insomnia	1	2	1	2		
Joint stiffness		1		1		
Limb discomfort		1		1		
Loss of consciousness	1	2			1	2
Lung infiltration		1				1
Lymphadenopathy	1	5	1	5		
Malaise	1	22	1	18		4
Maternal exposure during pregnancy	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Memory impairment	1	1	1	1		
Migraine		1		1		
Motor dysfunction	1	1			1	1
Muscle twitching		2		2		
Muscular weakness	1	1	1	1		
Myalgia		23		23		
Nasopharyngitis		5		5		
Nausea	2	10	2	10		
Noninfective sialoadenitis		1		1		
Ocular discomfort		1		1		
Off label use		2		2		
Oropharyngeal pain		5		5		
Oxygen saturation decreased		1				1
Pain		1		1		
Painful respiration		1		1		
Pain in extremity	3	8	1	6	2	2
Pallor		2		2		
Periorbital swelling		1		1		
Peripheral artery thrombosis		1				1
Peripheral embolism	1	1			1	1
Peripheral swelling	1	1			1	1
Personality change		1				1
Pharyngeal swelling		1		1		
Pneumonia		3				3
Poor quality sleep		1		1		
Productive cough		1		1		
Product use issue		2		2		
Pruritus		6		6		
Pulmonary oedema		1				1
Pulmonary pain		1		1		
Pyrexia	1	34	1	32		2
Rash		4		4		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory arrest		1				1
Rhinorrhoea		2		2		
Salivary gland enlargement		1		1		
Sensitive skin		2		2		
Sensory loss		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Sleep disorder	1	1			1	1
Sluggishness		1		1		
Sudden death		1				1
Syncope	1	1			1	1
Tachycardia		2		1		1
Thirst		1		1		
Transient ischaemic attack	1	2			1	2
Tremor		1		1		
Urinary incontinence		1		1		
Urine flow decreased		1				1
Vaccination site erythema		6		6		
Vaccination site inflammation		3		3		
Vaccination site pain	2	18	2	18		
Vaccination site reaction		1		1		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth		2		2		
Vomiting		2		2		
	34	375	19	320	15	55

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Arthralgia		2		2		
Arthritis		1		1		
Asthenia		2		2		
Atrial fibrillation		1				1
Blood pressure decreased		1				1
Bone pain		1		1		
Cardiac failure		1				1
Cerebrovascular accident		1				1
Chest pain		1				1
Chills	1	3	1	3		
Chronic obstructive pulmonary disease		1				1
Death		2				2
Delirium	1	2			1	2
Depressed level of consciousness		1				1
Discomfort	1	2	1	2		
Erythema		1		1		
Fatigue		2		2		
Feeling cold		1		1		
Headache	1	3	1	3		
Hyperhidrosis		1				1
Hypoxia		1				1
Injection site pain		1		1		
Joint swelling		2		2		
Loss of consciousness		1				1
Malaise		4		3		1
Myalgia	1	3	1	3		
Myocardial infarction		1				1
Nausea	1	2	1	2		
Oedema peripheral		1		1		
Off label use		2		2		
Oropharyngeal pain		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oxygen saturation decreased		1				1	
Pain		1		1			
Pneumonia		1				1	
Pneumonia aspiration		1				1	
Product use in unapproved indication		2		2			
Product use issue		1		1			
Pyrexia	1	9	1	7		2	
Respiration abnormal		1				1	
Respiratory failure		1				1	
Sepsis		1				1	
Sudden death		1				1	
Swelling		1		1			
Syncope	1	1			1	1	
Vaccination site pain		3		3			
Vaccination site swelling		1		1			
Ventricular tachycardia	1	1			1	1	
Visual impairment	1	1	1	1			
	11	79	7	50	4	29	

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anencephaly	1	1			1	1
Maternal exposure during pregnancy	1	1	1	1		
Rhinorrhoea		1		1		
	2	3	1	2	1	1

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Country Where Event Occurred

**INDIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1			1	1
COVID-19	1	1			1	1
Dizziness	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue	1	1			1	1
Headache	1	1			1	1
Incorrect product administration duration	1	1	1	1		
Loss of consciousness	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pain	1	1			1	1
Vaccination site pain	1	1			1	1
Vomiting	1	1			1	1
	12	12	1	1	11	11

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Suspected counterfeit product		1		1
		1		1

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Country Where Event Occurred

**IRAQ**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Headache	1	1	1	1
Myalgia	1	1	1	1
Nausea	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	6	6	6	6

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
Fatigue	1	1	1	1
Insomnia	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	5	5	5	5

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Country Where Event Occurred  
**IRELAND**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	1		1
Abdominal distension	1	3	1	1		2
Abdominal infection		1				1
Abdominal pain	1	6		1	1	5
Abdominal pain upper	1	4	1	1		3
Abortion spontaneous	2	3			2	3
Accidental overdose	1	1	1	1		
Ageusia		3				3
Allergy to vaccine		1				1
Amenorrhoea		1				1
Anaemia		1				1
Anaphylactic reaction		7				7
Anaphylactic shock		1				1
Angioedema	2	3			2	3
Anxiety		5				5
Aortic aneurysm	1	1			1	1
Aphasia		1				1
Arthralgia	8	34	6	9	2	25
Aspiration		1				1
Asthenia	6	47	4	10	2	37
Asthma		1				1
Axillary mass		1				1
Axillary pain		7		1		6
Back pain	4	20	2	4	2	16
Bedridden		1				1
Blindness		1				1
Blindness transient		1				1
Blister		1				1
Blood bilirubin increased		1				1
Blood glucose fluctuation		1				1
Blood lactic acid increased		1				1
Blood pressure diastolic increased		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	2	9			2	9
Blood pressure systolic increased		1		1		
Blood urine present		1				1
Bloody discharge		1				1
Body temperature decreased		1				1
Body temperature increased	1	2	1	1		1
Bone pain	2	7		2	2	5
Bradycardia		1				1
Breast pain		3				3
Breast swelling		3				3
Breast tenderness	1	1	1	1		
Burning sensation		6		1		5
Cardiac failure	1	1			1	1
Cardiac failure congestive		1				1
Cellulitis	1	3			1	3
Cerebral infarction		1				1
Cerebrovascular accident	1	2			1	2
Cerebrovascular insufficiency	1	1			1	1
Cheilitis		1				1
Chest discomfort	2	16	1	2	1	14
Chest pain	2	15	2	2		13
Chillblains	1	1			1	1
Chills	9	46	3	5	6	41
Choking sensation		1		1		
Chromaturia	1	3	1	1		2
Cluster headache		1		1		
Cold sweat		3				3
Complicated appendicitis		1				1
Condition aggravated		1				1
Confusional state	1	5			1	5
Constipation		1				1
Contusion		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Corneal reflex decreased	1	1			1	1
Cough	3	11	1	2	2	9
COVID-19	3	8		1	3	7
Cyanosis		2		1		1
Dark circles under eyes		1				1
Deafness	1	2			1	2
Death	2	4			2	4
Decreased activity		1				1
Decreased appetite	1	9	1	1		8
Deep vein thrombosis	3	5			3	5
Dehydration		1				1
Depressed level of consciousness		1				1
Dermatitis	2	2	1	1	1	1
Dermatitis allergic		1				1
Diarrhoea	2	19	1	4	1	15
Diplopia	1	2	1	1		1
Discomfort	1	9		1	1	8
Disease recurrence		4				4
Disorientation	1	3			1	3
Disturbance in attention		4		2		2
Dizziness	10	60	5	10	5	50
Drug ineffective		2				2
Dry eye		2				2
Dry mouth		1				1
Dry throat		2				2
Dysarthria		2				2
Dysgeusia	2	6	2	2		4
Dyskinesia	1	1	1	1		
Dysphagia		2				2
Dysphonia		1				1
Dyspnoea	1	20		1	1	19
Dyspnoea at rest	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dyspnoea exertional		2					2
Dysstasia		2					2
Ear discomfort		1					1
Ear infection		1					1
Ear pain		1					1
Eczema	1	1			1		1
Emotional distress		1					1
Encephalitis		1					1
Eosinophil count increased		1					1
Epistaxis	1	2			1		2
Erythema	2	6	1	3	1		3
Erythema of eyelid		1					1
Excessive eye blinking		1					1
Exposure during pregnancy		2		2			
Extensive swelling of vaccinated limb		1		1			
Eye discharge		1					1
Eye irritation		1					1
Eyelids pruritus		1					1
Eye movement disorder		2					2
Eye pain		4					4
Eye pruritus		1					1
Eye swelling	1	2			1		2
Face injury		1					1
Facial pain		3		2			1
Facial paralysis	2	11			2		11
Facial paresis		1					1
Faeces discoloured		1					1
Faeces pale		1					1
Fatigue	15	89	9	26	6		63
Feeding disorder		1					1
Feeling abnormal	1	10	1	2			8
Feeling cold		10		2			8

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Feeling drunk		2					2
Feeling hot	2	16		2	2		14
Feeling of body temperature change		3					3
Flank pain		4					4
Flatulence		2		1			1
Flushing		6		1			5
Formication		1					1
Furuncle		1					1
Gait disturbance	1	4			1		4
Gait inability		2					2
Gastric disorder		1					1
Gastrooesophageal reflux disease		1					1
General physical condition abnormal	1	1			1		1
General physical health deterioration	1	2			1		2
Glossodynia		1		1			
Haematemesis		1					1
Haematochezia		1					1
Haemoglobin decreased		1					1
Hallucination	1	1			1		1
Hangover		1		1			
Headache	13	131	7	25	6		106
Heart rate decreased		1					1
Heart rate increased	3	11		1	3		10
Heart rate irregular	1	2			1		2
Hemiparesis	1	2			1		2
Herpes zoster		2					2
Herpes zoster reactivation		1					1
Hordeolum		1					1
Hyperaesthesia		1					1
Hyperhidrosis	1	18	1	2			16
Hyperpyrexia		1					1
Hypersensitivity	1	6	1	1			5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	1	16		2	1	14
Hyperventilation		1				1
Hypoaesthesia	8	26	5	8	3	18
Hypoaesthesia oral	1	9	1	1		8
Hypoglycaemia		1				1
Hypopnoea		1				1
Hypotension	3	9	3	3		6
Hypotonia		1				1
Illness		3		2		1
Impaired driving ability		3				3
Impaired work ability	3	17	1	2	2	15
Inappropriate schedule of product administration		4		4		
Incorrect dose administered	1	1	1	1		
Infection		1		1		
Inflammation		1				1
Influenza		1				1
Influenza like illness	4	15	3	6	1	9
Injected limb mobility decreased	1	2	1	1		1
Injection site movement impairment		1				1
Injection site pain		2				2
Injury		1				1
Injury associated with device	1	1	1	1		
Insomnia	1	14		2	1	12
Irritable bowel syndrome		1				1
IVth nerve paralysis		1				1
Jaundice		1				1
Joint range of motion decreased	1	1			1	1
Joint stiffness		4				4
Lacrimation decreased		1				1
Lacrimation increased		1				1
Lethargy		11		1		10
Limb discomfort	1	7		2	1	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lip discolouration		1					1
Lip dry		1					1
Lip swelling	2	10			2		10
Liver function test increased		1					1
Loss of consciousness	2	5			2		5
Loss of control of legs		1					1
Loss of personal independence in daily activities		5		2			3
Lower respiratory tract infection		1					1
Lymphadenopathy		18		1			17
Lymph node pain		6					6
Malaise	5	38	1	7	4		31
Mass		1					1
Mastitis	1	2			1		2
Maternal exposure during breast feeding		2		2			
Maternal exposure during pregnancy	3	8	2	6	1		2
Melaena		1					1
Memory impairment	1	2			1		2
Menorrhagia	1	1	1	1			
Menstrual disorder	1	2	1	1			1
Metabolic acidosis		1					1
Metrorrhagia	1	3			1		3
Micturition urgency		1		1			
Migraine		6		2			4
Mobility decreased		3					3
Muscle fatigue	1	1	1	1			
Muscle spasms		5		1			4
Muscle twitching	1	7	1	1			6
Muscular weakness		6					6
Musculoskeletal chest pain	1	2			1		2
Musculoskeletal discomfort		1					1
Musculoskeletal pain		1		1			
Musculoskeletal stiffness	2	7	2	3			4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	7	51	5	11	2	40
Mydriasis	1	1	1	1		
Myelitis transverse		1				1
Myocardial infarction		2				2
Nasal congestion		2		1		1
Nasopharyngitis		1		1		
Nausea	13	89	7	21	6	68
Neck pain	1	7	1	1		6
Nerve compression		1				1
Nerve injury		1				1
Nervousness		1				1
Neuralgia		3				3
Neuritis cranial		1				1
Neuropathy peripheral		1				1
Night sweats		2		1		1
Nystagmus	1	1			1	1
Off label use		9		9		
Oligomenorrhoea	1	1	1	1		
Oral herpes	3	4	2	2	1	2
Oral pruritus	1	1	1	1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		9		2		7
Oxygen saturation decreased		6				6
Pain	5	49	4	6	1	43
Pain in extremity	8	48	5	15	3	33
Pain in jaw		1		1		
Pallor	1	8	1	2		6
Palpitations	1	16	1	1		15
Pancreatitis relapsing		1				1
Panic attack	1	3			1	3
Paraesthesia	2	35	2	8		27
Paraesthesia oral	3	10	3	3		7

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	11	2	40
1	1		
			1
			2
	1		1
	1		
7	21	6	68
1	1		6
			1
			1
			1
			3
			1
	1		1
		1	1
	9		
1	1		
2	2	1	2
1	1		
			1
	2		7
			6
4	6	1	43
5	15	3	33
	1		
1	2		6
1	1		15
			1
		1	3
2	8		27
3	3		7

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Paranasal sinus discomfort		1					1
Periarthritis		1					1
Periorbital discomfort	1	1	1	1			
Periorbital oedema		1		1			
Periorbital swelling		1					1
Peripheral swelling		6					6
Pharyngeal hypoesthesia	1	1	1	1			
Pharyngeal paraesthesia	1	2	1	1			1
Pharyngeal swelling		3					3
Photophobia		1					1
Platelet count decreased		1					1
Pneumonia		1					1
Pollakiuria		1					1
Poor quality product administered	1	1	1	1			
Poor quality sleep		1		1			
Presyncope	3	6	3	4			2
Product preparation error	1	1	1	1			
Product preparation issue		3		3			
Product use issue		5		5			
Pruritus	1	17	1	4			13
Psychomotor hyperactivity		1					1
Pulmonary embolism		2					2
Pulmonary sepsis		1					1
Pulse abnormal		1					1
Pupils unequal	1	1	1	1			
Pyrexia	15	83	8	17	7		66
Quality of life decreased		1					1
Rash	5	22	2	4	3		18
Rash erythematous		6		1			5
Rash macular		1					1
Rash pruritic	2	4	2	2			2
Respiratory rate increased		1					1

\* I=Interval, C=Cumulative  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract infection		1				1
Retching		2				2
Rhinitis	1	2			1	2
Road traffic accident		1				1
Salivary hypersecretion	1	2	1	2		
SARS-CoV-2 test positive		1				1
Seizure	1	2			1	2
Sensation of foreign body		2				2
Sensitive skin		1				1
Sensory disturbance	1	1	1	1		
Sensory loss		2				2
Sinus congestion	1	1			1	1
Sinus pain		2		1		1
Skin burning sensation		2				2
Skin discolouration	1	1			1	1
Skin exfoliation		1				1
Skin laceration	1	1	1	1		
Skin papilloma		1				1
Skin tightness		1				1
Skin warm		1				1
Skin wrinkling		1				1
Sleep disorder		1				1
Somnolence		5		1		4
Speech disorder		1				1
Stridor		3				3
Sudden death		1				1
Sudden onset of sleep	1	1			1	1
Supraventricular tachycardia	2	2			2	2
Suspected product quality issue		3		3		
Swelling	1	7	1	1		6
Swelling face	1	7		1	1	6
Swelling of eyelid		2		1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swollen tongue		5				5
Syncope	3	16			3	16
Tachycardia	1	20	1	1		19
Taste disorder		2				2
Tenderness		2				2
Tension headache		1				1
Thirst		1				1
Throat irritation	1	3	1	1		2
Throat tightness		4		1		3
Thrombosis		1				1
Tinnitus	1	3	1	1		2
Tongue biting		1				1
Tongue disorder		1				1
Transient ischaemic attack	1	2			1	2
Tremor	1	9		1	1	8
Trigeminal nerve disorder		2				2
Trigeminal neuralgia		1				1
Troponin increased		1				1
Type III immune complex mediated reaction	1	1			1	1
Underdose		3		3		
Unresponsive to stimuli		2				2
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract infection	1	1	1	1		
Urinary incontinence		1				1
Urinary retention		1				1
Urinary tract infection		1		1		
Urine odour abnormal	1	1	1	1		
Urticaria	2	13	2	3		10
Urticarial vasculitis		1				1
Urticaria papular		1		1		
Vaccination error	1	1	1	1		
Vaccination failure	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site bruising		1				1
Vaccination site discolouration		1				1
Vaccination site discomfort	1	1			1	1
Vaccination site erythema		9		2		7
Vaccination site inflammation		1		1		
Vaccination site irritation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site mass		3				3
Vaccination site pain	10	26	10	14		12
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus		5		1		4
Vaccination site swelling		5		1		4
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth		5		1		4
Vaginal haemorrhage		3				3
Vertigo		2		1		1
Vision blurred		3		1		2
Visual field defect		1		1		
Visual impairment		4		1		3
Vitreous floaters		3				3
Vomiting	2	35	1	3	1	32
Weight bearing difficulty	1	1			1	1
Weight decreased		1				1
Wheezing		6				6
White blood cell count increased	1	1	1	1		
	311	2,030	164	410	147	1620

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2	1	1	1	1
Abdominal pain upper		1				1
Acute cardiac event		1				1
Ageusia		1		1		
Agitation		1				1
Alanine aminotransferase increased		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		2				2
Angioedema		1				1
Anosmia		2		1		1
Aphasia	1	1			1	1
Arthralgia	3	9	2	3	1	6
Asthenia	2	6	1	2	1	4
Asthma		1				1
Atrial fibrillation	1	1			1	1
Balance disorder		1		1		
Blepharospasm		1				1
Blood pH decreased	1	1			1	1
Blood pressure increased		1				1
Breath odour	1	1			1	1
Carbon dioxide increased	1	1			1	1
Cardiac arrest	3	3			3	3
Cellulitis		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort		2				2
Chest pain	3	4			3	4
Chills	1	6		1	1	5
Cold sweat		2		1		1
Confusional state	1	3			1	3
Conjunctivitis	1	1	1	1		
Coronary artery occlusion	1	1			1	1
Coronary artery thrombosis	1	1			1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cough		1
COVID-19	2	3
C-reactive protein increased		2
Cyanosis		1
Death	2	5
Decreased appetite	2	2
Deep vein thrombosis	1	1
Dehydration	1	1
Depressed level of consciousness		1
Depressed mood	1	1
Diarrhoea	1	2
Diplopia	1	1
Discomfort		1
Dizziness	1	4
Drug ineffective		1
Dysarthria		2
Dyspnoea	1	3
Dyspnoea at rest		1
Ear pain		1
Emotional distress		1
Erythema		1
Exposure via breast milk		1
Eye irritation	1	1
Eye movement disorder		1
Eye swelling	1	1
Facial nerve disorder		1
Facial paralysis		4
Fall	1	1
Fatigue	6	13
Feeling abnormal		2
Feeling hot	1	3
Flushing		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		2	3
			2
			1
		2	5
		2	2
		1	1
1	1		
			1
		1	1
		1	2
		1	1
			1
	2	1	2
			1
			2
		1	3
			1
			1
			1
1	1		
			1
1	1		
	1		
			4
		1	1
4	6	2	7
	1		1
	1	1	2
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait inability	1	1	1	1		
General physical health deterioration	2	2			2	2
Headache	3	15	1	2	2	13
Heart rate irregular		1				1
Hemiparesis		1				1
Hyperhidrosis		3				3
Hypersensitivity		1				1
Hypertension		2				2
Hypoaesthesia		3		1		2
Hypoglycaemia		1				1
Hypopnoea		1				1
Hypotension		1				1
Hypotonia		1				1
Hypoxia		1				1
Impaired work ability		3				3
Inappropriate schedule of product administration	1	1	1	1		
Inflammation		1				1
Insomnia	1	3			1	3
Irritability	1	1			1	1
Joint stiffness	1	1	1	1		
Joint swelling		2				2
Lip swelling		1				1
Loss of consciousness	1	5			1	5
Lymphadenopathy		4				4
Lymph node pain		1				1
Malaise	3	7	1	2	2	5
Migraine	1	1			1	1
Migraine with aura	1	1			1	1
Mood swings	1	1			1	1
Muscle tightness		1				1
Musculoskeletal stiffness	3	3	3	3		
Myalgia		5		1		4

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Gender

**MALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
			1
			1
1	1	2	6
			1
		1	2
		1	1
	1		
		1	1
			1
			1
1	1		
			1
		1	1
		1	3
1	1	1	7
3	4		1
	1		2
	1		
2	3		3
	1		
			1
1	2		1
			1
1		1	1
			1
			1
			2
	2		
	1		1
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pyrexia	2	14
Rales		1
Rash		4
Rash erythematous		2
Rash macular		1
Respiration abnormal		1
Respiratory distress	1	1
Respiratory failure	1	1
Respiratory rate decreased	1	3
Respiratory rate increased		1
Respiratory tract infection	2	2
Retching	1	2
Seizure		1
Sinusitis		1
Skin discolouration		1
Somnolence		1
Stress		1
Sudden death	1	2
Supraventricular tachycardia		1
Suspected COVID-19		1
Suspected product quality issue		2
Swelling face		1
Swollen tongue		1
Syncope	3	5
Tachycardia		1
Tardive dyskinesia		1
Tidal volume decreased	1	1
Tinnitus	1	1
Tongue movement disturbance		1
Tonic clonic movements		1
Transient ischaemic attack	1	1
Type IV hypersensitivity reaction		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		12
			1
	2		2
			2
			1
			1
		1	1
		1	1
		1	3
			1
		2	2
		1	2
			1
			1
	1		
			1
	1		
		1	2
			1
			1
			1
		3	5
			1
			1
		1	1
1	1		
			1
			1
		1	1
			1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose		3		3		
Unresponsive to stimuli		2				2
Urticaria		4		1		3
Vaccination site discomfort	1	1	1	1		
Vaccination site pain	6	9	5	5	1	4
Vertigo	1	2		1	1	1
Vomiting	1	3			1	3
Wheezing		1				1
	111	351	38	78	73	273

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product	1	3	1	3		
Arthralgia	1	1	1	1		
Chills	1	1	1	1		
Circumstance or information capable of leading to medication error	1	1	1	1		
COVID-19		1				1
Dizziness	1	1	1	1		
Drug ineffective		2				2
Expired product administered	1	1	1	1		
Exposure via breast milk	1	5	1	5		
Exposure via skin contact	1	2	1	2		
Facial paralysis		1				1
Fatigue	1	1	1	1		
Headache	3	3	3	3		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Injury associated with device		1		1		
Lymphadenopathy		1		1		
Malaise	1	1	1	1		
No adverse event	1	3	1	3		
Pain	2	2	2	2		
Poor quality product administered	11	11	11	11		
Product preparation issue		1		1		
Product temperature excursion issue	1	1	1	1		
Pyrexia	1	1	1	1		
Suspected COVID-19		1				1
Underdose		4		4		
Vaccination site discharge		1		1		
Vomiting		3		3		
Wound		1		1		
Wrong technique in product usage process	11	11	11	11		
	40	68	40	61		7

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**ISRAEL**

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\* I=Interval, C=Cumulative  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain		7			6		1	
Abdominal pain upper	1	3			1	3		
Abortion spontaneous	1	2					1	2
Activated partial thromboplastin time shortened	1	1					1	1
Adnexa uteri pain		1				1		
Ageusia		2				2		
Allergy to vaccine		4				2		2
Anaemia		1				1		
Anal haemorrhage	1	2			1	2		
Anaphylactic reaction	1	6					1	6
Anaphylactic shock		1						1
Anger		1				1		
Angina pectoris		2						2
Angioedema		1						1
Anorectal discomfort		1				1		
Anosmia		2				2		
Antinuclear antibody positive	1	1			1	1		
Antiphospholipid antibodies positive	1	1					1	1
Anxiety	2	3				1	2	2
Aphasia	2	2			1	1	1	1
Aphonia		1						1
Arrhythmia		4						4
Arthralgia	1	20			1	18		2
Arthritis	1	1			1	1		
Arthropathy		1				1		
Aspiration		1						1
Asthenia	10	86			7	77	3	9
Asthenopia		1				1		
Asthma		1				1		
Asymptomatic COVID-19	3	3					3	3
Atrial fibrillation	1	2					1	2
Axillary pain		1				1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Back pain	2	13
Blindness transient	1	1
Blister	1	1
Blood chloride increased		1
Blood glucose increased		2
Blood immunoglobulin M increased		1
Blood iron decreased	1	1
Blood pressure abnormal	1	1
Blood pressure decreased		1
Blood pressure fluctuation	1	1
Blood pressure increased		8
Body temperature decreased		1
Bone pain		6
Brain death		1
Brain injury		1
Brain oedema		1
Breast inflammation		1
Breast tenderness		1
Burning sensation		1
Cardiac arrest		5
Cardiac death		1
Cardiac disorder		1
Cardiac failure	1	2
Cardiac failure chronic	1	1
Cardiogenic shock	1	1
Cerebellar haemorrhage		1
Cerebral ischaemia		1
Cerebrovascular accident	3	5
Cheilitis	1	1
Chest discomfort	1	3
Chest pain	10	19
Chills	5	55

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	12	1	1
				1	1
				1	1
					1
					2
			1		
				1	1
				1	1
			1		
				1	1
			6		2
			1		
			6		
					1
					1
					1
			1		
			1		
					1
					5
					1
					1
				1	2
				1	1
				1	1
					1
					1
				3	5
		1	1		
			2	1	1
		3	11	7	8
		3	51	2	4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Choking		3
Cold sweat	1	4
Condition aggravated		1
Confusional state	1	1
Contusion	1	2
Coronavirus infection	1	3
Cough	3	7
COVID-19	9	24
C-reactive protein increased		1
Crying		2
Deafness neurosensory	2	2
Deafness unilateral	2	2
Death	1	13
Decreased activity		1
Decreased appetite	1	7
Deep vein thrombosis	2	2
Depressed level of consciousness		1
Depressed mood		4
Depression		1
Diabetic ketoacidosis		1
Diarrhoea	3	10
Discomfort		3
Disease recurrence		4
Dizziness	3	28
Drug exposure before pregnancy		1
Drug hypersensitivity		2
Drug-induced liver injury		1
Drug ineffective	9	20
Dry mouth		1
Dysaesthesia		1
Dysgeusia		8
Dyskinesia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	4		
			1		
		1	1		
		1	1		1
				1	3
		1	5	2	2
	1	1	4	8	20
			1		
			1		1
				2	2
				2	2
				1	13
			1		
		1	7		
				2	2
					1
			4		
			1		
					1
		3	9		1
			3		
			3		1
		1	22	2	6
			1		
			1		1
					1
	1			9	20
			1		
			1		
			8		
		1	1	1	1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysmenorrhoea		1
Dyspepsia		6
Dysphagia		5
Dysphemia	1	1
Dyspnoea	8	33
Dyspnoea exertional		2
Dysstasia		1
Ear discomfort		2
Ear infection		1
Ear pain		3
Endocarditis		1
Eosinophilic oesophagitis		1
Epistaxis	1	1
Erythema	1	8
Exposure during pregnancy	2	6
Exposure to SARS-CoV-2		
Exposure via breast milk		1
Extensive swelling of vaccinated limb		2
Eye disorder		1
Eyelid oedema		1
Eye pain		3
Eye swelling		4
Face injury		1
Facial asymmetry		1
Facial nerve disorder		1
Facial pain		2
Facial paralysis	5	15
Facial paresis	1	1
Fall	1	5
Fatigue	6	52
Feeling abnormal	1	10
Feeling cold		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			6		
			3		2
				1	1
		4	13	4	20
			2		
					1
			2		
			1		
			3		
					1
			1		
				1	1
		1	8		
		1	5	1	1
	1				
			1		
			2		
			1		
			1		
			2		1
			2		2
					1
			1		
			1		
			1		
			1		1
				5	15
				1	1
		1	2		3
		5	50	1	2
			7	1	3
			8		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling hot	1	6
Feeling of body temperature change		1
Foetal death	1	1
Food craving		1
Formication		2
Gait disturbance	2	4
Gastric haemorrhage		1
Gastrointestinal necrosis		1
General physical health deterioration	1	3
Gingival bleeding	1	1
Glomerular filtration rate decreased		1
Guillain-Barre syndrome	1	2
Haematochezia		1
Haemorrhage		2
Hallucination		1
Hallucination, auditory		1
Hangover		1
Headache	5	84
Head discomfort		1
Heart rate increased		6
Hemiparaesthesia	1	1
Hemiplegia		1
Hepatic failure	1	1
Hepatic function abnormal		1
Hepatitis		1
Hepatitis acute		1
Herpes simplex		1
Herpes virus infection	1	1
Herpes zoster	7	13
Hip fracture		1
Hormone level abnormal		1
Hot flush		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6		
			1		
			1	1	1
			1		
			2		
			1	2	3
					1
					1
				1	3
				1	1
					1
				1	2
					1
					2
					1
					1
			1		
		5	81		3
			1		
			5		1
				1	1
					1
				1	1
					1
					1
			1		
		1	1		
		6	11	1	2
					1
			1		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperbilirubinaemia		1
Hyperhidrosis		7
Hypersensitivity	6	13
Hypersomnia		1
Hypertension		2
Hypoaesthesia	6	28
Hypoaesthesia oral	1	10
Hypotension	1	3
Illrd nerve paralysis	1	1
Illness		1
Impaired quality of life		1
Inappropriate schedule of product administration		5
Inflammation of wound	1	1
Influenza		3
Influenza like illness		8
Injection site pain		4
Insomnia		7
International normalised ratio decreased	1	1
International normalised ratio increased		1
Joint noise		1
Joint swelling		2
Leukocytosis		3
Leukopenia		1
Limb discomfort		1
Limb injury	1	1
Lip pruritus		1
Lip swelling	1	3
Liver function test increased		1
Loss of consciousness	3	6
Loss of personal independence in daily activities		1
Lung disorder	1	1
Lymphadenopathy	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			7		
		2	3	4	10
			1		
			1		1
		4	25	2	3
		1	8		2
		1	1		2
				1	1
			1		
			1		
			5		
		1	1		
			3		
			8		
			4		
			7		
				1	1
					1
			1		
			2		
					3
					1
			1		
		1	1		
			1		
		1	2		1
			1		
				3	6
			1		
				1	1
		1	11	2	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lymphopenia		1
Malaise		20
Maternal exposure during pregnancy	1	6
Maternal exposure timing unspecified		1
Mean cell haemoglobin decreased		2
Mean platelet volume increased		1
Mechanical urticaria		1
Menorrhagia		3
Menstrual disorder		2
Menstruation irregular	1	3
Mental disorder		2
Metrorrhagia		1
Migraine		3
Miliaria		1
Mobility decreased		3
Mood altered		1
Motor dysfunction		1
Movement disorder	1	2
Multiple sclerosis	1	2
Multiple sclerosis relapse		2
Muscle contractions involuntary		4
Muscle disorder		1
Muscle rigidity		1
Muscular weakness	2	6
Musculoskeletal stiffness		1
Myalgia	3	47
Myasthenia gravis		1
Myocardial infarction	2	6
Myocarditis	6	7
Nasopharyngitis		2
Nausea	2	40
Neck pain		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			18		2
			5	1	1
			1		
			1		1
			1		
			1		
			3		
			2		
		1	3		
			2		
			1		
			3		
			1		
			2		1
			1		
					1
		1	2		
				1	2
					2
			4		
			1		
			1		
		1	4	1	2
			1		
		2	44	1	3
					1
				2	6
				6	7
			2		
		2	38		2
			4		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervous system disorder	1	1
Neuralgia		1
Neuralgic amyotrophy		1
Neuritis		1
Neutrophil count decreased		1
Neutrophil count increased		1
Night sweats		1
Ocular hyperaemia		1
Odynophagia		1
Oedema mouth		1
Oedema peripheral	1	1
Off label use		6
Ophthalmic herpes zoster	1	2
Oral discomfort	1	1
Oral herpes	1	4
Oropharyngeal discomfort		1
Oropharyngeal pain		4
Overdose		1
Oxygen saturation decreased		2
Pain	7	24
Pain in extremity	5	39
Pallor	1	2
Palmar erythema		1
Palpitations	2	10
Paraesthesia	5	35
Paraesthesia oral		12
Paralysis		1
Paraplegia		1
Parosmia		4
Pelvic fracture		1
Pelvic pain		1
Pericardial effusion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
			1		
			1		
			1		
					1
			1		
			1		
			1		
		1	1		
			6		
				1	2
		1	1		
		1	3		1
			1		
			1		
			1		1
		4	19	3	5
		4	37	1	2
		1	2		
			1		
			8	2	2
		4	30	1	5
			10		2
					1
					1
			4		
					1
			1		
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pericarditis	11	13
Peripheral artery occlusion	1	1
Peripheral coldness	1	3
Peripheral ischaemia	1	1
Peripheral swelling	1	5
Personality change		1
Pharyngeal swelling	1	4
Pleural effusion	1	1
Pleuritic pain	1	1
Pneumonia aspiration	1	2
Polyneuropathy		1
Poor quality product administered	1	3
Poor quality sleep		1
Premature labour	1	1
Premenstrual syndrome		1
Presyncope	1	4
Product administered at inappropriate site	1	2
Product administered to patient of inappropriate age		2
Product colour issue		1
Product packaging quantity issue		1
Product preparation error		1
Product preparation issue	1	2
Product use issue		4
Pruritus		10
Psoriatic arthropathy	1	1
Pulmonary embolism	4	5
Pulmonary oedema		2
Pulse abnormal		1
Pulseless electrical activity		1
Pupil fixed		1
Purpura	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				11	13
				1	1
		1	3		
			4	1	1
			1		
			2	1	2
				1	1
		1	1		
				1	2
					1
		1	3		
			1		
				1	1
			1		
			3	1	1
		1	2		
			2		
			1		
			1		
		1	2		
			4		
			6		4
				1	1
				4	5
					2
					1
					1
					1
		1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pyrexia	7	71
Rash	3	15
Rash macular		1
Rash maculo-papular	1	1
Rash pruritic		1
Rash vesicular	1	1
Reduced facial expression		1
Respiratory arrest		1
Respiratory disorder	2	3
Respiratory rate increased		1
Restlessness		1
Rhinalgia		1
Rhinorrhoea		1
Rib fracture		1
Right ventricular enlargement		1
SARS-CoV-2 ant body test negative	1	2
Schizophrenia		1
Seizure	6	7
Sensory disturbance		3
Sensory loss	1	3
Skin burning sensation		2
Skin discolouration	1	2
Skin disorder		1
Sleep disorder		1
Somnolence	1	2
Speech disorder		5
Stillbirth	1	1
Stress		1
Sudden hearing loss	3	3
Suffocation feeling	1	1
Swelling		2
Swelling face		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	64	2	7
		2	10	1	5
			1		
		1	1		
			1		
				1	1
			1		
					1
		1	1	1	2
					1
			1		
			1		
			1		
					1
			1		
		1	2		
					1
				6	7
			2		1
			1	1	2
			2		
		1	2		
			3		2
				1	1
			1		
		1	2		
			2		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swollen tongue		4
Syncope	1	4
Systemic inflammatory response syndrome		1
Tachycardia		5
Taste disorder		1
Tenderness		1
Therapeutic response unexpected	2	3
Thinking abnormal		1
Thirst		2
Throat irritation	1	1
Throat tightness		1
Thrombosis		2
Tic		2
Tinnitus	5	7
Tongue oedema		1
Tonic convulsion	1	1
Tracheal oedema		1
Transient ischaemic attack	3	3
Tremor		4
Troponin increased	1	1
Twin pregnancy		1
Underdose		2
Unresponsive to stimuli	1	1
Urinary tract infection		1
Urticaria	1	5
Uterine contractions abnormal		1
Uterine haemorrhage		1
Uterine pain		1
Vaccination failure	3	3
Vaccination site bruising		1
Vaccination site cellulitis		2
Vaccination site erythema	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
				1	4
					1
			4		1
			1		
			1		
		2	3		
			1		
			1		1
				1	1
					1
					2
			2		
		1	2	4	5
					1
				1	1
					1
				3	3
			4		
				1	1
			2		
				1	1
			1		
			2	1	3
			1		
					1
			1		
				3	3
			1		
			1		1
		1	8		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vaccination site hypersensitivity		1				1			
Vaccination site inflammation		1				1			
Vaccination site joint movement impairment		1				1			
Vaccination site lymphadenopathy		2				2			
Vaccination site movement impairment		2				2			
Vaccination site pain	3	71			3	71			
Vaccination site paraesthesia		1				1			
Vaccination site pruritus		1				1			
Vaccination site reaction		1				1			
Vaccination site swelling		9				8			1
Vaccination site vesicles	1	1			1	1			
Vaginal haemorrhage	4	10			1	5	3		5
Vein discolouration	1	1			1	1			
Vertigo	2	2					2		2
Vision blurred		2				2			
Vitamin B12 decreased	1	1					1		1
Vomiting	2	10			2	10			
Weight decreased		1							1
Wheezing	1	2				1	1		1
Wrong technique in product usage process		1				1			
	312	1,681		3	123	1207	189		474

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Abdominal pain upper		1		1		
Acute kidney injury	1	2			1	2
Acute myocardial infarction	2	4			2	4
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Adverse event	1	2	1	2		
Agitation		1		1		
Alcohol intolerance		1		1		
Alopecia		1		1		
Anaemia	1	1			1	1
Anaesthesia oral		1		1		
Angina pectoris		2				2
Angioedema	2	3			2	3
Anxiety	1	4	1	4		
Aphthous ulcer		1		1		
Arterial thrombosis		1				1
Arthralgia	2	14	2	11		3
Arthritis reactive		1				1
Asthenia	8	45	6	39	2	6
Asthma		1				1
Asymptomatic COVID-19	2	2			2	2
Atelectasis		1				1
Atrial fibrillation	2	6			2	6
Autoimmune haemolytic anaemia		1				1
Back pain	1	6	1	5		1
Blood chloride increased		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal	1	1	1	1		
Blood glucose increased		1		1		
Blood lactate dehydrogenase increased		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Blood pressure increased		5		1		4
Blood pressure systolic increased		1		1		
Body temperature decreased		2		2		
Bone pain		1		1		
Cardiac arrest		7				7
Cardiac disorder		1				1
Cardiac failure	3	5			3	5
Cardiac flutter		1				1
Cardiac tamponade	1	1			1	1
Cartilage injury		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident	3	7			3	7
Chest discomfort	2	4	2	3		1
Chest pain	11	15	8	10	3	5
Chills	5	20	4	19	1	1
Choking		1				1
Cholelithiasis		1		1		
Chronic lymphocytic leukaemia		1				1
Chronic obstructive pulmonary disease	1	2			1	2
Circulatory collapse		1				1
Condition aggravated		1		1		
Confusional state	1	3		1	1	2
Conjunctival disorder		1				1
Coronavirus infection	1	3			1	3
Cough	1	5		4	1	1
COVID-19	10	30	1	4	9	26
C-reactive protein increased	1	3		1	1	2
Deafness	1	3			1	3
Deafness neurosensory	2	2			2	2
Deafness unilateral	1	1			1	1
Death	1	18			1	18

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	4	1	3		1
Deep vein thrombosis	1	1			1	1
Depressed mood		1				1
Depression		1				1
Diarrhoea	5	11	5	10		1
Discomfort	2	3	2	3		
Disease recurrence		1				1
Disseminated intravascular coagulation	1	1			1	1
Diverticulitis		1				1
Dizziness	2	18	2	14		4
Drug hypersensitivity		1				1
Drug ineffective	9	30			9	30
Dysarthria		1				1
Dyschromatopsia		1		1		
Dysgeusia		2		2		
Dyskinesia	1	4	1	3		1
Dyspepsia		1		1		
Dysphagia		1		1		
Dyspnoea	5	19	2	8	3	11
Dyspnoea exertional		1		1		
Dysstasia	1	3	1	2		1
Ear discomfort	3	4	1	2	2	2
Ear pain		2		2		
Electrocardiogram abnormal	1	2	1	1		1
Electrocardiogram T wave inversion	1	1			1	1
Encephalitis	1	1			1	1
Epilepsy		1				1
Erythema	4	8	3	5	1	3
Exposure to contaminated water	1	1	1	1		
Eye infection		2		1		1
Eye irritation		2		1		1
Eyelid function disorder		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Eye pain		2		2			
Eye swelling		1					1
Facial paralysis	8	23			8		23
Facial paresis	1	1			1		1
Fall		2		1			1
Fatigue	2	23	2	21			2
Feeling abnormal	2	9	1	5	1		4
Feeling cold	1	5	1	5			
Food refusal		1					1
Formication		1		1			
Gait disturbance	1	3	1	1			2
Gastroenteritis viral		1		1			
General physical health deterioration	1	1			1		1
Gingival pain		1		1			
Gingivitis		1		1			
Guillain-Barre syndrome	2	2			2		2
Haematemesis		1					1
Haemolytic anaemia		1					1
Headache	10	41	7	35	3		6
Head injury		1					1
Heart rate increased		4		4			
Hepatic enzyme increased	1	1			1		1
Hepatic function abnormal	1	1			1		1
Herpes zoster	2	6	1	4	1		2
Hyperhidrosis	3	4	3	4			
Hypersensitivity		1		1			
Hypertension		4		2			2
Hyperventilation	1	1	1	1			
Hypoacusis	2	2	1	1	1		1
Hypoaesthesia	2	13	2	12			1
Hypoaesthesia oral		3		3			
Hypoaesthesia teeth		1		1			

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyponatraemia	1	1			1	1
Hypotension	1	2		1	1	1
Hypothermia		1				1
Hypoventilation		1				1
Illness		1		1		
Immune thrombocytopenia	1	2			1	2
Inappropriate schedule of product administration		2		2		
Incorrect dose administered	1	2	1	2		
Infection		1		1		
Inflammation	1	4	1	2		2
Inflammatory marker increased		1				1
Influenza like illness		5		5		
Injection site erythema		1		1		
Intentional dose omission		1		1		
International normalised ratio increased		1		1		
Ischaemic stroke		1				1
Jaundice		1		1		
Joint swelling		1				1
Lacrimation increased		2		1		1
Laryngeal inflammation		1		1		
Laryngitis bacterial		1				1
Leukocytosis	3	4			3	4
Limb discomfort		1		1		
Lip disorder		1		1		
Lip pruritus		1		1		
Liquid product physical issue		1		1		
Liver injury		1				1
Localised infection	1	1			1	1
Loss of consciousness	1	6			1	6
Loss of libido		1		1		
Loss of personal independence in daily activities	1	1	1	1		
Lung disorder		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung infiltration	1	1			1	1
Lymphadenopathy	1	6		4	1	2
Lymphocyte count increased		1		1		
Lymphocytosis		1		1		
Malaise	1	11	1	8		3
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		1		1		
Mean cell volume decreased		1		1		
Mobility decreased		2		1		1
Movement disorder		3		2		1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis relapse	1	2			1	2
Muscle spasms	2	2	2	2		
Muscle twitching		1		1		
Muscular weakness	2	3		1	2	2
Musculoskeletal chest pain	1	2	1	2		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	4	23	4	21		2
Myasthenia gravis		1				1
Myocardial infarction		1				1
Myocarditis	47	63			47	63
Nasopharyngitis		3		3		
Nausea	1	11		7	1	4
Neck pain		4		4		
Nephrolithiasis	1	1			1	1
Nervousness	1	1	1	1		
Neuralgia		1				1
Neuralgic amyotrophy	1	1			1	1
Neutropenia	1	1			1	1
No adverse event		1		1		
Non-Hodgkin's lymphoma		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Odynophagia		2		1		1
Oedema		1				1
Oedema peripheral		1				1
Off label use		1		1		
Oral discomfort		1		1		
Oral herpes	1	3	1	3		
Oral pain		1		1		
Oropharyngeal pain	2	8	2	7		1
Osteomyelitis		1				1
Otitis media		1		1		
Overdose		4		4		
Pain	1	18		15	1	3
Pain in extremity		12		12		
Pain in jaw		3		3		
Palpitations		3		3		
Pancreatitis		1				1
Pancytopenia	1	1			1	1
Paraesthesia	7	15	3	11	4	4
Paraesthesia oral	1	4	1	4		
Paralysis	1	2			1	2
Pericardial effusion		1				1
Pericarditis	17	30			17	30
Peripheral coldness		1		1		
Pharyngeal paraesthesia		1		1		
Pleural effusion		1				1
Pleuritic pain		1				1
Pneumonia	1	5			1	5
Poor quality product administered		4		4		
Poor quality sleep		1		1		
Product administered at inappropriate site		1		1		
Product deposit		1		1		
Productive cough	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation error		3		3		
Pruritus	2	3	2	3		
Pseudomonas infection	1	1			1	1
Psychomotor hyperactivity		1		1		
Pulmonary embolism	1	1			1	1
Pulpitis dental		1		1		
Purpura	1	1			1	1
Pyrexia	18	37	10	24	8	13
Rash		2		1		1
Rash macular		1		1		
Recall phenomenon	2	2	2	2		
Red blood cell count increased		1		1		
Respiratory arrest		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Restlessness		1				1
Rhabdomyolysis	1	1			1	1
Rhinorrhoea		3		3		
Ruptured cerebral aneurysm		1				1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		2				2
Seizure	1	3			1	3
Sepsis		1				1
Septic shock		1				1
Shock		1				1
Sinus tachycardia		2		1		1
Skin burning sensation	1	1	1	1		
Skin discolouration	1	1	1	1		
Skin exfoliation	1	1	1	1		
Skin reaction	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sleep disorder due to general medical condition, insomnia type		1
Slow speech		1
Sneezing		3
Somnolence		2
Speech disorder	2	3
Streptococcal infection		1
Stress		1
Sudden cardiac death		1
Sudden death		1
Sudden hearing loss	1	1
Suffocation feeling		2
Suicidal ideation		1
Suspected COVID-19		1
Swelling	1	1
Swelling face	1	2
Syncope	2	6
Systemic inflammatory response syndrome	2	9
Tachycardia		3
Taste disorder		1
Testicular pain	1	1
Therapeutic response unexpected		1
Thrombocytopenia	1	1
Thrombosis		2
Tinnitus	3	4
Tongue discomfort		1
Tonsillitis	1	1
Toothache		2
Tooth injury		1
Transient ischaemic attack	3	3
Tremor	1	4
Troponin increased		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
	2		1
	2		
	1	2	2
			1
	1		
			1
			1
		1	1
			2
			1
			1
1	1		
	1	1	1
		2	6
		2	9
	1		2
	1		
1	1		
	1		
		1	1
			2
2	2	1	2
	1		
		1	1
	2		
	1		
		3	3
	3	1	1
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Underdose		1		1			
Urosepsis	1	1		1	1	1	
Urticaria		2		2			
Uveitis		1				1	
Vaccination failure	3	3			3	3	
Vaccination site discomfort		1		1			
Vaccination site erythema		2		2			
Vaccination site hypersensitivity		1		1			
Vaccination site movement impairment		1		1			
Vaccination site pain	1	25	1	25			
Vaccination site swelling		4		4			
Ventricular fibrillation		2					2
Vertigo	2	5	1	3	1	2	
Vestibular neuronitis		1					1
Vision blurred		2		2			
Vlth nerve paralysis	1	1			1	1	
Vomiting	4	9	2	5	2	4	
Weight decreased		2		1		1	
Wrong technique in product usage process		1		1			
Yawning		2		1		1	
Yellow skin		1		1			
	321	1,100	113	579	208	521	

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 \* AE=Adverse Event  
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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Adverse event		1		1		
Anosmia		1		1		
Anxiety	1	1	1	1		
Arthralgia	1	5	1	4		1
Asthenia	2	16	2	16		
Back pain		1		1		
Balance disorder		1		1		
Basedow's disease	1	1			1	1
Chest pain		1		1		
Chills		11		11		
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Condition aggravated		1				1
Coronavirus infection		1				1
Cough		2		2		
COVID-19	4	9		2	4	7
Diarrhoea		1		1		
Discomfort		1		1		
Dizziness		5		5		
Drug ineffective	2	5			2	5
Dry throat		1		1		
Dysgeusia		1		1		
Dysphonia		1		1		
Dyspnoea		2		1		1
Epistaxis		1				1
Exposure via breast milk		4		4		
Eye haemorrhage		1				1
Eye infection		1		1		
Eye pain		2				2
Facial paralysis		3				3
Fatigue		10		10		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Gender

**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		
			2
			1
			1
	9		1
	2		
	6		
			1
	1		
	1		
	1		
	1		
	18		
	1		
			1
			1
			1
	13		1
	3		
1	2		
	1		
1	1		
	1		
			1
	1		
1	1		
1	7		
	1		
			1

Feeling cold		3
Foetal death		2
Foetal exposure during pregnancy		1
Foetal heart rate abnormal		1
Foetal movement disorder		1
Headache		10
Head discomfort		2
Herpes zoster		6
Hypertension		1
Hypoaesthesia		1
Inappropriate schedule of product administration		1
Incomplete course of vaccination		1
Influenza like illness		1
Initial insomnia		1
Liquid product physical issue		18
Lymphadenopathy		1
Malaise		1
Monoplegia		1
Multiple sclerosis		1
Myalgia		14
Nausea		3
Neck pain	1	2
Neuralgic amyotrophy		1
No adverse event	1	1
Ocular discomfort		1
Off label use		1
Oral herpes		1
Oropharyngeal pain		1
Pain	1	1
Pain in extremity	1	7
Paraesthesia		1
Paralysis		1

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 \* AE=Adverse Event  
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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral swelling		1				1
Photopsia		1		1		
Poor quality product administered	2	32	2	32		
Product complaint		1		1		
Product packaging quantity issue		11		11		
Product quality issue	2	2	2	2		
Product use issue		1		1		
Pruritus	1	1	1	1		
Pyrexia	2	14	2	13		1
Rash	1	2	1	2		
Seizure		7				7
Sleep disorder	1	1	1	1		
Syncope		1				1
Syndactyly		1				1
Therapeutic response unexpected	1	4	1	4		
Throat tightness		1		1		
Tremor		3		3		
Urticaria		1				1
Vaccination failure	2	3			2	3
Vaccination site erythema		1		1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	1	16	1	16		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vision blurred		1		1		
Vomiting		2		2		
Wheezing		1				1
Wrong technique in product usage process	1	1	1	1		
	30	295	21	241	9	54

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**ITALY**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	8			1	7		1
Abdominal distension	1	11				7	1	4
Abdominal pain	23	196			12	152	11	44
Abdominal pain lower	1	2				1	1	1
Abdominal pain upper	9	95	2	2	7	70	2	25
Abdominal rigidity		3				3		
Abortion	1	2					1	2
Abortion spontaneous	1	6					1	6
Abscess		1						1
Accommodation disorder	1	1			1	1		
Acne		1				1		
Acquired macroglossia		1						1
Acute abdomen	1	1					1	1
Acute coronary syndrome	2	6					2	6
Acute kidney injury		1		1				1
Acute myocardial infarction	2	5					2	5
Acute pulmonary oedema	1	1					1	1
Acute respiratory failure		3						3
Administration site erythema		2				2		
Administration site induration		1				1		
Administration site oedema		4				4		
Administration site pain	1	26			1	26		
Administration site paraesthesia		1				1		
Administration site pruritus		2				2		
Administration site reaction		1						1
Administration site swelling		1				1		
Adrenomegaly	1	3			1	3		
Age-related macular degeneration	1	1					1	1
Ageusia	5	27	2	2	4	17	1	10
Agitation		23		1		15		8
Akathisia		1				1		
Alanine aminotransferase increased	1	3				2	1	1

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergic cough		1
Allergic reaction to excipient	1	1
Allergy to vaccine		8
Alopecia	1	3
Altered state of consciousness	1	2
Amenorrhoea		2
Amnesia	1	6
Amylase increased		1
Anaemia		2
Anaemia macrocytic	1	1
Anaesthesia	4	34
Anaesthesia oral		6
Anal erythema		1
Anal sphincter atony		1
Anaphylactic reaction	3	54
Anaphylactic shock		12
Anaphylactoid reaction		2
Aneurysm ruptured		1
Angina pectoris		5
Angioedema	8	45
Angiomyolipoma		1
Angular cheilitis		1
Anosmia	5	23
Anterograde amnesia		1
Antibody test abnormal		1
Antinuclear antibody positive		1
Anti-thyroid antibody positive		1
Anuria		3
Anxiety	2	26
Aortic dissection	1	1
Apathy		2
Aphasia	7	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			2		6
		1	1		2
				1	2
			2		
		1	4		2
					1
			2		
				1	1
		3	29	1	5
			5		1
					1
					1
	1			3	54
	1				12
					2
					1
					5
				8	45
					1
			1		
2	2	4	16	1	7
					1
			1		
					1
			1		
					3
		1	16	1	10
				1	1
					2
			2	7	12

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Aphonia	2	8
Aphthous ulcer		10
Application site coldness		1
Application site paraesthesia		1
Aptyalism		1
Arrhythmia	4	17
Arteriosclerosis		1
Arteriosclerotic retinopathy	1	1
Arteriovenous fistula	1	1
Arthralgia	88	1,115
Arthritis		3
Arthropod sting		1
Asphyxia		1
Asthenia	101	1,086
Asthenopia	1	8
Asthma	2	19
Asthma exercise induced		1
Asthmatic crisis	2	10
Asymptomatic COVID-19	5	15
Ataxia		2
Atrial f brillation	6	12
Atrial flutter	1	3
Atrioventricular block complete		1
Atrioventricular block first degree	1	1
Auditory disorder		1
Aura		3
Autoimmune thyroiditis	1	2
Axillary mass		1
Axillary pain	9	85
Azotaemia		1
Back disorder		1
Back pain	10	103

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4	2	4
1	1		8		2
			1		
			1		
				4	17
					1
				1	1
				1	1
5	9	55	870	33	245
			2		1
					1
					1
3	7	65	873	36	213
			6	1	2
			4	2	15
					1
1	2			2	10
			1	5	14
					2
				6	12
			1	1	2
					1
		1	1		
					1
			3		
				1	2
			1		
1	2	8	75	1	10
					1
					1
	2	5	74	5	29

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Balance disorder	2	15
Band sensation		6
Basedow's disease		1
Bedridden	1	1
Biliary colic	1	1
Binocular eye movement disorder	1	1
Bladder dysfunction	1	1
Blepharitis		1
Blepharospasm		2
Blindness	1	4
Blister	2	9
Blister infected		1
Blood alkaline phosphatase increased		1
Blood calcium decreased		1
Blood creatinine increased	1	1
Blood glucose abnormal	1	1
Blood glucose decreased		1
Blood glucose increased		2
Blood lactate dehydrogenase increased	1	1
Blood potassium decreased		1
Blood pressure abnormal	1	1
Blood pressure decreased		13
Blood pressure diastolic increased		1
Blood pressure fluctuation	1	4
Blood pressure increased	8	84
Blood pressure systolic increased	2	6
Blood thyroid stimulating hormone increased	1	1
Body temperature abnormal	1	1
Body temperature decreased		1
Body temperature increased	1	23
Bone marrow oedema	1	1
Bone pain	7	106

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	1	9	1	6
			4		2
					1
		1	1		
				1	1
				1	1
			1		
			1		1
				1	4
		2	7		2
			1		
					1
			1		
		1	1		
				1	1
			1		
		1	1		
	1		8		5
			1		
			1	1	3
		4	46	4	38
			2	2	4
		1	1		
		1	1		
			1		
1	1	1	21		2
				1	1
		4	74	3	32

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bradycardia	1	13
Bradykinesia	1	2
Brain stem stroke	1	1
Breast abscess		1
Breast cyst		1
Breast discomfort		3
Breast enlargement		1
Breast oedema	1	5
Breast pain	1	14
Breast swelling	1	2
Breath sounds		2
Breath sounds abnormal		3
Bronchial wall thickening		1
Bronchiectasis		1
Bronchitis		1
Bronchospasm		30
Bronchostenosis		1
Brow ptosis		1
Bundle branch block right		1
Burning mouth syndrome	1	1
Burning sensation	4	19
Burn oral cavity		1
Butterfly rash		1
Capillary fragility		1
Cardiac arrest	6	10
Cardiac failure	4	7
Cardiac failure congestive	1	1
Cardio-respiratory arrest		2
Cardiovascular disorder		1
Catarrh		2
Central cord syndrome		1
Central pain syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	13
			1	1	1
				1	1
					1
			1		
			2		1
			1		
			4	1	1
			8	1	6
				1	2
			1		1
			1		2
					1
					1
					1
	1		9		21
					1
			1		
					1
		3	11	1	8
					1
					1
				6	10
				4	7
				1	1
					2
			1		
			1		1
					1
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebellar haemorrhage		1
Cerebral artery occlusion	1	1
Cerebral artery thrombosis	1	1
Cerebral disorder		1
Cerebral haemorrhage	3	4
Cerebral infarction	1	1
Cerebral ischaemia	8	8
Cerebral venous sinus thrombosis		1
Cerebral venous thrombosis	1	1
Cerebrovascular accident	5	10
Cervical radiculopathy		2
Cervicobrachial syndrome		5
Chest discomfort	8	63
Chest expansion decreased		1
Chest pain	13	81
Chillblains	1	1
Chills	84	1,102
Choking		1
Choking sensation	2	3
Cholelithiasis	1	1
Chromaturia		1
Chronic respiratory failure		1
Circulatory collapse		3
Circumoral oedema	1	6
Circumoral swelling		2
Clonus		5
Cluster headache		2
Coagulation factor increased	1	1
Coagulopathy		1
Cognitive disorder	1	1
Cold sweat	1	23
Cold urticaria	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	1
					1
				3	4
				1	1
				8	8
					1
				1	1
1	1			5	10
			1		1
			4		1
	2	3	33	5	30
			1		
	1	3	43	10	38
		1	1		
3	7	48	862	36	240
					1
				2	3
				1	1
			1		
					1
					3
		1	6		
					2
			2		3
			2		
				1	1
					1
1	1			1	1
			16	1	7
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Colitis		1
Colitis ischaemic	1	1
Coma	1	3
Coma scale abnormal		1
Compulsions		1
Condition aggravated	4	12
Confusional state	13	79
Conjunctival haemorrhage	1	6
Conjunctival hyperaemia		3
Conjunctival irritation		2
Conjunctivitis	1	24
Conjunctivitis allergic		1
Connective tissue disorder		1
Constipation		6
Contraindicated product administered	1	1
Contusion	3	4
Convulsions local		1
Coordination abnormal		1
Corneal bleeding		1
Corneal dystrophy	1	1
Corneal opacity		1
Coronary artery disease	1	1
Coronary artery dissection	1	1
Coronary artery stenosis		1
Cough	13	150
COVID-19	38	137
COVID-19 pneumonia	2	4
Cramp-fasciculation syndrome	1	1
Cranial nerve disorder		1
Cranial nerve paralysis		1
C-reactive protein abnormal	1	1
C-reactive protein increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
				1	3
					1
			1	4	11
3	4	5	47	8	32
	1			1	6
			1		2
					2
		1	17		7
			1		
					1
			6		
				1	1
		2	3	1	1
					1
					1
				1	1
				1	1
					1
	1	6	76	7	74
1	1	5	34	33	103
1	1			2	4
				1	1
			1		
					1
				1	1
			2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Crying		2
Cyanosis	1	6
Cystitis		3
Cystitis haemorrhagic	1	5
Deafness	2	4
Deafness neurosensory		2
Death	3	3
Decreased appetite	9	62
Deep vein thrombosis	3	8
Defaecation urgency		1
Dehydration		3
Delirium		1
Delusion	1	2
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		2
Demyelination		1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness	3	33
Depressed mood		2
Dermal cyst	1	2
Dermatitis	1	8
Dermatitis allergic		4
Dermatitis atopic		1
Dermatitis bullous	2	10
Dermatitis exfoliative generalised		2
Diaphragmatic spasm		2
Diarrhoea	22	362
Diastolic hypertension		1
Diastolic hypotension		1
Dilatation atrial	1	1
Diplegia		1
Diplopia	7	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			2	1	4
			2		1
				1	5
				2	4
					2
				3	3
1	1	4	48	5	14
				3	8
			1		
					3
					1
			1	1	1
					1
					2
					1
			1		
	1			3	33
			2		
		1	2		
		1	7		1
			3		1
			1		
1	1			2	10
					2
			1		1
2	3	15	278	7	84
			1		
					1
				1	1
					1
		5	8	2	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discomfort	3	18
Disease recurrence	3	16
Disorientation	3	19
Disseminated varicella zoster virus infection	1	1
Dissociation		1
Disturbance in attention	3	21
Diverticulitis		1
Dizziness	36	291
Drooling	1	2
Drug eruption		1
Drug hypersensitivity		5
Drug ineffective	13	60
Drug interaction	1	1
Dry eye	2	6
Dry mouth	9	68
Dry skin		4
Dry throat	3	5
Dysaesthesia	3	20
Dysaesthesia pharynx		2
Dysarthria	1	6
Dysbiosis		1
Dysentery	12	151
Dysgeusia	6	94
Dysgraphia		2
Dyskinesia		3
Dyslalia		1
Dyslexia	1	1
Dysmetria	1	2
Dyspepsia	1	19
Dysphagia	9	86
Dysphemia	1	1
Dysphonia	4	41

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	15	1	3
	1		3	3	13
	2	1	10	2	9
			1	1	1
			1		
1	1	1	10	2	11
					1
	2	20	188	16	103
			1	1	1
			1		
			1		4
1	1			13	60
				1	1
		1	4	1	2
	1	5	45	4	23
					4
		2	4	1	1
		2	15	1	5
			2		
			2	1	4
					1
4	5			12	151
2	2	5	81	1	13
			1		1
			2		1
					1
				1	1
				1	2
			17	1	2
	3	3	47	6	39
				1	1
	1	1	17	3	24

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea	36	249
Dyspnoea at rest	1	3
Dyspnoea exertional		8
Dysstasia	2	4
Dysuria	1	5
Ear discomfort	1	10
Ear disorder		1
Ear haemorrhage	1	1
Ear infection	2	8
Ear pain	1	28
Ear pruritus		4
Ear swelling	1	3
Ecchymosis	2	3
Ectopic pregnancy		1
Effusion		1
Electric shock		1
Electrocardiogram abnormal	2	4
Embolism		1
Embolism venous		1
Emotional disorder	1	1
Emphysema		1
Enanthema		1
Encephalitis	1	1
Encephalopathy		1
Endometriosis	1	1
Enteritis	1	2
Enthesopathy	1	1
Eosinophil count decreased		1
Eosinophil count increased		1
Epilepsy	2	6
Episcleritis		1
Epistaxis	1	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	5	9	85	27	164
				1	3
			4		4
			2	2	2
			2	1	3
		1	7		3
			1		
		1	1		
		1	6	1	2
		1	17		11
			4		
			2	1	1
		1	2	1	1
					1
					1
					1
		1	1	1	3
					1
					1
		1	1		
					1
					1
				1	1
		1	2		
				1	1
					1
				2	6
					1
		1	10		3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erectile dysfunction		1
Eructation		2
Erysipelas	1	1
Erythema	25	293
Erythema multiforme	1	4
Erythema nodosum	3	4
Erythema of eyelid		3
Erythematotelangiectatic rosacea		1
Euphoric mood		1
Exposure during pregnancy		4
Exposure to SARS-CoV-2	1	3
Exposure via breast milk		2
Extensive swelling of vaccinated limb		5
Extraocular muscle paresis		1
Extrasystoles	3	12
Eye colour change		1
Eye disorder	1	1
Eye haematoma		1
Eye haemorrhage	1	1
Eye infection	1	1
Eye irritation	2	43
Eyelid function disorder		1
Eyelid myoclonus		2
Eyelid oedema	3	23
Eyelid pain		1
Eyelid ptosis	2	8
Eyelids pruritus		1
Eye movement disorder		2
Eye oedema		8
Eye pain	4	40
Eye paraesthesia		3
Eye pruritus	2	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		
				1	1
	1	12	196	13	97
		2	2	1	2
			2		1
			1		
			1		
			4		
		1	3		
			2		
			3		2
					1
		2	8	1	4
					1
				1	1
					1
				1	1
				1	1
	1	2	36		7
					1
					2
	1	1	11	2	12
			1		
			3	2	5
			1		
			1		1
			5		3
	1	3	30	1	10
			2		1
			10	2	8

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye swelling	1	6
Face injury	1	2
Face oedema	5	37
Facial asymmetry	1	1
Facial bones fracture		1
Facial discomfort	1	2
Facial nerve disorder		6
Facial neuralgia		3
Facial pain	2	12
Facial paralysis	6	44
Facial paresis	3	24
Facial spasm		2
Faeces soft		2
Fall	4	9
Fasciitis		1
Fatigue	79	782
Febrile convulsion		10
Feeling abnormal	4	23
Feeling cold	7	115
Feeling hot	13	139
Feeling jittery		4
Feeling of body temperature change		8
Female sexual dysfunction	1	1
Fibrin D dimer increased	1	1
Fibromuscular dysplasia	1	1
Fibromyalgia		2
Flank pain		2
Flat affect		1
Flatulence		5
Fluid retention		2
Flushing	9	91
Foaming at mouth	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		3
				1	2
			14	5	23
				1	1
					1
		1	2		
			3		3
			1		2
		1	6	1	6
1	1		1	6	43
		3	15		9
			1		1
			1		1
			1	4	8
			1		
3	4	47	597	32	185
			6		4
		2	17	2	6
	1	6	94	1	21
		8	94	5	45
			3		1
			4		4
		1	1		
				1	1
				1	1
			1		1
			2		
					1
			5		
			2		
		6	71	3	20
				2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Focal dyscognitive seizures	1	1
Foetal growth restriction		1
Folliculitis		1
Food allergy		1
Food aversion		1
Foreign body in throat		1
Foreign body sensation in eyes		1
Frequent bowel movements		3
Full blood count increased	1	1
Functional gastrointestinal disorder	1	1
Gait disturbance	6	22
Gait inability		3
Gamma-glutamyltransferase increased		1
Gastritis		1
Gastroenteritis		1
Gastrointestinal disorder	9	26
Gastrointestinal haemorrhage		1
Gastrointestinal hypermotility		1
Gastrointestinal pain	3	8
Gastrointestinal sounds abnormal	1	2
Gastrooesophageal reflux disease		2
Generalised oedema		1
Generalised tonic-clonic seizure		3
General physical health deterioration	1	3
Genital discomfort		1
Genital pain		1
Gingival bleeding		1
Gingival discolouration	1	1
Gingival discomfort		
Gingival pain		1
Gingival swelling		1
Gingivitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1		
					1
			1		
					1
			1		
			3		
		1	1		
		1	1		
		1	11	5	11
					3
					1
			1		
					1
1	1	8	22	1	4
					1
					1
		2	7	1	1
		1	2		
			2		
			1		
					3
				1	3
					1
			1		
			1		
	1			1	1
		1			
			1		
			1		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glomerulonephritis		1
Glossitis	2	4
Glossodynia	1	7
Glottal incompetence		1
Goitre		1
Grip strength decreased	1	2
Groin pain		2
Grunting		1
Guillain-Barre syndrome	1	2
Guttate psoriasis		1
Haematemesis	1	2
Haematochezia		2
Haematocrit decreased		1
Haematoma	2	10
Haematuria		5
Haemochromatosis		1
Haemoglobin decreased		2
Haemoperitoneum		1
Haemorrhage	1	2
Haemorrhage subcutaneous		1
Haemorrhagic cerebral infarction		1
Hallucination	1	5
Hallucination, auditory	1	3
Hallucination, olfactory		2
Hallucinations, mixed		1
Hallucination, visual	1	6
Hand deformity		1
Hand dermatitis		1
Haptoglobin increased		1
Headache	176	2,150
Head discomfort	1	16
Head injury	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2	2	2
			4	1	3
					1
					1
			1	1	1
2	2		2		
					1
				1	2
					1
				1	2
					2
			1		
		1	7	1	3
			3		2
			1		
			1		1
				1	2
					1
					1
				1	5
				1	3
					2
					1
				1	6
			1		
			1		
					1
7	17	110	1693	66	457
			12	1	4
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Heart rate abnormal		1
Heart rate decreased	1	4
Heart rate increased	8	20
Heart rate irregular		2
Heat stroke		2
Hemianaesthesia	1	9
Hemianopia	1	1
Hemianopia heteronymous		1
Hemianopia homonymous	1	1
Hemidysaesthesia		4
Hemihyperaesthesia		1
Hemiparaesthesia	2	23
Hemiparesis	2	15
Hemiplegia	1	4
Hepatic pain		1
Hepatitis A antibody positive		1
Hepatitis acute		2
Hepatitis B antibody positive		1
Herpes ophthalmic	1	6
Herpes simplex		5
Herpes simplex encephalitis		1
Herpes virus infection		4
Herpes zoster	3	25
Herpes zoster oticus	1	1
Herpes zoster reactivation	1	3
Hiccups	1	1
Hidradenitis		1
Hot flush	1	59
Hyperaemia	1	6
Hyperaesthesia		10
Hyperbilirubinaemia	1	1
Hyperglycaemia	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2	1	2
		4	8	4	12
					2
			1		1
				1	9
				1	1
					1
				1	1
					4
					1
				2	23
				2	15
				1	4
			1		
			1		
					2
			1		
				1	6
			4		1
					1
			4		
		1	18	2	7
				1	1
			2	1	1
		1	1		
					1
		1	45		14
		1	5		1
			9		1
				1	1
		1	1	2	4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperhidrosis	10	112
Hyperkinesia		1
Hyperpyrexia	23	188
Hypersensitivity	10	56
Hypersomnia	1	5
Hypertension	15	95
Hypertensive crisis	9	62
Hypertensive heart disease	2	2
Hyperthermia	2	30
Hyperthyroidism		1
Hypertonia		2
Hypertransaminasaemia		2
Hypertrophy of tongue papillae		3
Hyperventilation	1	6
Hypoacusis	4	6
Hypoesthesia	5	97
Hypoesthesia oral	3	41
Hypogeusia		1
Hypoglycaemia	1	3
Hypokalaemia	2	2
Hypokinesia		2
Hyponatraemia	1	1
Hyporeflexia	1	2
Hyporesponsive to stimuli		3
Hypotension	10	103
Hypotensive crisis		5
Hypothermia	4	18
Hypotonia	1	8
Hypovolaemia		1
Hypoxia	2	6
Idiopathic urticaria		1
Illness		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	3	79	7	33
			1		
	1	2	2	21	186
	2	5	23	5	33
		1	5		
		3	41	12	54
				9	62
				2	2
		1	23	1	7
					1
			2		
					2
			2		1
	1	1	2		4
		2	2	2	4
1	2	4	75	1	22
		2	33	1	8
			1		
		1	3		
				2	2
			1		1
				1	1
				1	2
			2		1
1	2	4	55	6	48
					5
				4	18
		1	4		4
					1
				2	6
			1		
			4		2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Immobile		1
Immune system disorder		1
Immunisation		2
Immunisation anxiety related reaction		1
Impaired gastric emptying		1
Impaired quality of life	1	2
Impaired work ability		1
Inappropriate schedule of product administration	4	10
Incontinence	1	2
Incorrect dosage administered		1
Incorrect dose administered	1	4
Incorrect drug administration rate		1
Incorrect route of product administration	8	25
Increased upper airway secretion		1
Increased viscosity of bronchial secretion		1
Induration		6
Infantile vomiting		1
Infected cyst		1
Infection	1	1
Inflammation		7
Inflammatory pain		1
Influenza	2	19
Influenza like illness	10	73
Infusion site pain		2
Initial insomnia	2	6
Injected limb mobility decreased	2	16
Injection related reaction		1
Injection site discomfort		3
Injection site erythema	1	36
Injection site haematoma		3
Injection site haemorrhage		1
Injection site hypersensitivity		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			2		
			1		
					1
		1	2		
					1
		3	9	1	1
				1	2
			1		
		1	4		
			1		
		8	25		
			1		
					1
			6		
			1		
					1
		1	1		
			6		1
					1
		2	16		3
1	1	8	61	2	12
			2		
		1	3	1	3
		2	15		1
			1		
			3		
		1	36		
			3		
			1		
			2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site induration		9
Injection site infection		7
Injection site inflammation		2
Injection site joint pain		2
Injection site lymphadenopathy		1
Injection site muscle weakness		1
Injection site oedema		94
Injection site pain	7	681
Injection site paraesthesia		9
Injection site pruritus	1	18
Injection site rash		1
Injection site reaction		11
Injection site swelling		19
Injection site urticaria	2	23
Injection site warmth		4
Injury		2
Insomnia	13	135
Inspiratory capacity abnormal		1
Intentional product misuse	1	1
Interstitial lung disease		2
Intestinal pseudo-obstruction		1
Intranasal hypoesthesia		1
Intranasal paraesthesia		2
Iridocyclitis		1
Irritability		9
Ischaemia		1
Ischaemic stroke	1	5
IVth nerve disorder	1	1
Jaundice	1	1
Jaw fracture		1
Joint contracture		1
Joint dislocation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			9		
			7		
			2		
			2		
			1		
			1		
			94		
		6	679	1	2
			9		
		1	18		
			1		
			11		
			19		
		2	22		1
			4		
			1		1
		6	112	7	23
			1		
		1	1		
					2
					1
			1		
			6		3
					1
				1	5
				1	1
		1	1		
					1
			1		
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint effusion	1	2
Joint hyperextension		1
Joint lock		2
Joint range of motion decreased		9
Joint stabilisation		1
Joint stiffness		2
Joint swelling	1	2
Joint warmth		2
Laboratory test abnormal		1
Labyrinthitis		4
Lacrimation disorder	1	1
Lacrimation increased	3	19
Lacunar stroke	1	1
Lagophthalmos	1	2
Laryngeal discomfort		1
Laryngeal dyspnoea	1	4
Laryngeal obstruction		1
Laryngeal oedema	9	63
Laryngeal pain		1
Laryngeal stenosis		1
Laryngospasm	3	14
Larynx irritation		1
Lateropulsion	1	1
Left ventricular hypertrophy	1	1
Lethargy		3
Leukocytosis	1	2
Leukopenia	3	4
Limb discomfort	4	47
Limb immobilisation		1
Lipase increased		2
Lip disorder	1	2
Lip dry		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
			1		
			1		1
			4		5
			1		
			2		
			1	1	1
					2
					1
			1		3
				1	1
		2	14	1	5
				1	1
		1	1		1
					1
				1	4
					1
				9	63
			1		
					1
			3	3	11
			1		
				1	1
				1	1
			3		
	1	1	2		
	1			3	4
		4	40		7
			1		
			1		1
				1	2
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip erythema		3
Lipodystrophy acquired		1
Lip oedema	5	57
Lip pain		3
Lip pruritus	1	15
Lip swelling	3	28
Localised oedema	2	22
Local reaction		3
Logorrhoea	1	1
Loss of consciousness	16	69
Loss of control of legs		1
Loss of personal independence in daily activities	1	4
Lymphadenitis	2	25
Lymphadenopathy	70	736
Lymphangitis	2	8
Lymphatic obstruction	1	1
Lymph node pain	11	75
Lymph node palpable		1
Lymphocyte count increased		1
Lymphocytosis		2
Lymphoedema		6
Lymphoma	1	1
Lymphopenia		1
Macroglossia		1
Maculopathy	1	2
Madarosis	1	1
Malaise	33	422
Mastitis	2	6
Maternal exposure before pregnancy	1	1
Maternal exposure during pregnancy	7	19
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
					1
1	1	2	28	3	29
			3		
			6	1	9
	1	1	17	2	11
		1	17	1	5
			3		
				1	1
				16	69
					1
		1	4		
			14	2	11
8	11	55	588	15	148
				2	8
				1	1
5	5	11	63		12
			1		
					1
			2		
			4		2
				1	1
					1
					1
				1	2
				1	1
	2	19	333	14	89
				2	6
		1	1		
		6	17	1	2
			1		
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mechanical urticaria		7
Medication error		1
Melaena		1
Memory impairment		4
Menorrhagia	3	6
Menstrual disorder		2
Menstruation irregular		1
Mental disorder		2
Mental impairment		2
Metrorrhagia	1	6
Micturition disorder		1
Micturition urgency		1
Middle insomnia	1	5
Migraine	8	135
Migraine with aura	1	5
Miosis		1
Mitral valve incompetence	1	2
Mobility decreased	1	6
Monocyte count decreased		1
Monoparesis		6
Monoplegia	1	6
Mood altered		2
Motor dysfunction	5	14
Mouth swelling		4
Mouth ulceration		1
Movement disorder	3	17
Mucosal dryness		2
Mucosal hyperaemia		1
Mucosal inflammation		1
Mucous stools		1
Multiple organ dysfunction syndrome	1	3
Multiple sclerosis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2		4		3
			1		
					1
			1		3
			2	3	4
			2		
			1		
			1		1
					2
		1	3		3
			1		
					1
		1	4		1
2	2	5	105	3	30
		1	4		1
			1		
				1	2
		1	5		1
					1
			5		1
				1	6
			1		1
		1	8	4	6
			2		2
					1
		1	6	2	11
			2		
					1
			1		
			1		
				1	3
					2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle contractions involuntary		6
Muscle contracture		8
Muscle disorder		1
Muscle fatigue	1	3
Muscle oedema		3
Muscle rigidity	1	16
Muscle spasms	5	35
Muscle tightness		5
Muscle twitching		6
Muscular weakness	10	65
Musculoskeletal chest pain	2	13
Musculoskeletal discomfort		1
Musculoskeletal disorder	1	2
Musculoskeletal pain	4	172
Musculoskeletal stiffness	4	28
Myalgia	114	1,289
Myalgia intercostal		2
Myasthenia gravis		3
Myasthenia gravis crisis		1
Mydriasis	1	1
Myocardial infarction	2	3
Myocardial ischaemia		1
Myocarditis	1	1
Myoclonus		4
Myositis		4
Myringitis	1	1
Narcolepsy	1	3
Nasal congestion	2	9
Nasal discomfort		2
Nasal herpes	1	2
Nasal obstruction		3
Nasal oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		1
1	1		5		3
			1		
			2	1	1
			1		2
		1	12		4
1	1	2	23	3	12
			4		1
			4		2
		5	43	5	22
		1	7	1	6
					1
		1	1		1
	1	2	123	2	49
		4	16		12
5	8	73	1034	41	255
			1		1
					3
					1
	1			1	1
				2	3
					1
	1			1	1
			1		3
					4
			1		3
				1	1
				1	3
		1	6	1	3
			2		
		1	2		
			2		1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nasal pruritus		1
Nasopharyngitis	8	36
Nausea	92	936
Neck pain	13	96
Nerve compression	1	2
Nerve injury	1	1
Nervousness		1
Nervous system disorder	2	3
Neuralgia	2	15
Neuritis	1	7
Neurodermatitis		1
Neurological symptom		2
Neurologic neglect syndrome	1	1
Neuropathy peripheral	4	13
Neurosensory hypoacusis	1	1
Neurotoxicity		1
Neutropenia		1
Neutrophil count increased	1	2
Neutrophilia	2	2
Neutrophil percentage increased		1
Nightmare		1
Night sweats		13
No adverse event	2	2
Nodule		1
Noninfective gingivitis	1	2
Non-pitting oedema		1
Nuchal rigidity	3	14
Nystagmus	1	2
Obstruction		1
Obstructive airways disorder		2
Occipital neuralgia		1
Occupational exposure to product		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		6	25	2	11
4	11	63	696	29	240
2	2	7	73	6	23
		1	2		
		1	1		
			1		
				2	3
	1	2	10		5
		1	6		1
			1		
	1		1		1
				1	1
				4	13
				1	1
					1
	1				1
		1	1		1
				2	2
					1
			1		
			1	1	1
					1
		2	6	1	8
				1	2
			1		
			1		1
					1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ocular discomfort		4
Ocular hyperaemia	3	26
Oculogyric crisis		1
Odynophagia		4
Oedema	1	20
Oedema mouth	2	5
Oedema mucosal		2
Oedema peripheral	5	30
Oedematous pancreatitis		1
Oesophageal pain		1
Oesophageal spasm		2
Off label use	5	23
Oliguria	1	2
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster		1
Optic neuritis		5
Optic neuropathy		1
Oral candidiasis		1
Oral discomfort	2	22
Oral dysaesthesia		5
Oral herpes	7	37
Oral mucosal erythema		2
Oral pain		4
Oral pruritus		12
Orbital oedema		1
Oropharyngeal discomfort	1	21
Oropharyngeal oedema		2
Oropharyngeal pain	9	81
Oropharyngeal plaque		1
Oropharyngeal spasm		1
Oropharyngeal swelling		3
Orthopnoea		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		
		1	18	2	8
					1
1	1		2		2
		1	17		3
1	1	1	3	1	2
					2
1	1	3	21	2	9
					1
					1
					2
		4	21	1	2
				1	2
					1
					1
					5
					1
			1		
	1	1	18	1	4
			5		
		3	25	4	12
			1		1
			3		1
			4		8
					1
		1	14		7
					2
	1	5	58	4	23
					1
					1
			2		1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Orthostatic hypotension	1	4
Osteoarthritis	1	1
Otitis externa		1
Overdose	4	39
Oxygen saturation decreased	8	42
Pain	33	369
Painful respiration	1	1
Pain in extremity	76	647
Pain in jaw	1	12
Pain of skin	1	3
Palatal oedema	1	15
Palatal swelling	1	5
Pallor	2	17
Palpable purpura	1	2
Palpitations	4	32
Pancreatitis acute	1	1
Panic attack		7
Panic reaction		1
Panniculitis		1
Papilloedema		2
Papule		3
Paraesthesia	46	510
Paraesthesia ear	1	1
Paraesthesia mucosal		1
Paraesthesia oral	7	204
Paralysis		3
Paraparesis	2	2
Paresis	2	5
Parosmia	1	5
Partial seizures		1
Parvovirus B19 test positive		1
Pelvic pain		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
		1	1		
			1		
		2	36	2	3
	1	1	7	7	35
1	1	14	287	19	82
		1	1		
1	2	55	535	21	112
		1	7		5
			2	1	1
		1	10		5
			3	1	2
	1	1	11	1	6
			1	1	1
		2	18	2	14
				1	1
			5		2
			1		
					1
					2
			2		1
1	3	24	350	22	160
				1	1
					1
2	3	3	127	4	77
					3
				2	2
			2	2	3
		1	3		2
					1
			1		
			2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pemphigoid		1
Pericardial effusion	4	8
Pericarditis	1	5
Perioral dermatitis		1
Periorbital oedema	3	12
Periorbital pain		2
Periorbital swelling		6
Peripheral coldness	3	15
Peripheral sensorimotor neuropathy		1
Peripheral sensory neuropathy		1
Peripheral swelling	11	67
Peripheral venous disease		1
Petechiae	3	5
Petit mal epilepsy	1	1
Pharyngeal disorder		2
Pharyngeal erythema	1	5
Pharyngeal hypoaesthesia		1
Pharyngeal mass	1	1
Pharyngeal oedema	2	8
Pharyngeal paraesthesia	2	25
Pharyngeal swelling	1	14
Pharyngitis		5
Phlebitis	5	7
Phlebitis superficial	2	2
Photophobia	1	21
Photopsia	1	6
Photosensitivity reaction		3
Piloerection		1
Pityriasis rosea		1
Pleural effusion	5	6
Plicated tongue		2
Pneumonia	5	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				4	8
				1	5
			1		
		1	7	2	5
			2		
			5		1
	1	2	11	1	4
					1
			1		
		8	51	3	16
			1		
	1	2	4	1	1
				1	1
			1		1
			2	1	3
					1
		1	1		
	1		1	2	7
			10	2	15
			5	1	9
1	1		3		2
		5	5		2
		1	1	1	1
			16	1	5
		1	3		3
			1		2
					1
			1		
		1	1	4	5
			1		1
				5	7

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pneumonia bacterial		1
Pneumonitis	1	2
PO2 decreased	1	1
Pollakiuria	2	3
Polyarthritits		2
Polymyalgia rheumatica	1	1
Polyneuropathy		1
Polyuria		3
Poor quality sleep		1
Premenstrual pain		2
Presyncope	14	99
Product administered at inappropriate site	1	5
Product administered to patient of inappropriate age		1
Productive cough	1	4
Product preparation issue		3
Product use issue	2	14
Proteinuria		1
Prurigo		1
Pruritus	23	324
Pruritus allergic		1
Pruritus genital		2
Psoriasis	1	2
Psoriatic arthropathy	1	1
Psychomotor hyperactivity	1	3
Pulmonary embolism	9	18
Pulmonary hypertension	1	1
Pulmonary hypoperfusion		1
Pulmonary mass	1	1
Pulmonary pain		3
Pulse abnormal		1
Puncture site induration		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
				1	1
		1	2	1	1
					2
				1	1
					1
			2		1
			1		
			2		
	1	7	53	7	46
		1	5		
			1		
				1	4
			3		
		2	12		2
			1		
			1		
1	2	15	244	8	80
			1		
			2		
		1	1		1
				1	1
			2	1	1
				9	18
				1	1
					1
				1	1
			2		1
					1
			2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Puncture site pain		1
Purpura		
Pustular psoriasis	1	1
Pustule	1	4
Pyrexia	200	2,454
Q fever	2	8
Quality of life decreased	1	5
Radiculitis brachial		3
Radiculopathy		3
Rales		1
Rash	18	230
Rash erythematous	2	21
Rash macular	1	9
Rash maculo-papular	1	5
Rash maculovesicular		1
Rash morbilliform		2
Rash papular		7
Rash pruritic	6	37
Rash pustular		1
Rash vesicular		8
Raynaud's phenomenon	1	1
Reaction to excipient		1
Rectal haemorrhage	1	2
Red blood cell count increased		1
Red blood cell sedimentation rate increased	2	2
Reduced facial expression		1
Regurgitation		1
Renal failure	1	3
Renal pain		5
Respiration abnormal		1
Respiratory arrest	1	3
Respiratory depression		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	1				
				1	1
		1	2		2
13	29	125	1840	75	614
				2	8
			2	1	3
			3		
			2		1
					1
	3	9	148	9	82
	1	1	13	1	8
		1	7		2
		1	5		
			1		
			2		
			6		1
		2	21	4	16
			1		
			6		2
		1	1		
					1
				1	2
			1		
				2	2
					1
					1
	1			1	3
			5		
			1		
				1	3
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Respiratory disorder	1	12
Respiratory distress		17
Respiratory failure	6	9
Respiratory fatigue		5
Respiratory rate increased		1
Respiratory tract haemorrhage		1
Respiratory tract oedema		3
Restless legs syndrome		3
Restlessness		6
Retching	6	22
Retinal artery occlusion	2	2
Retinal degeneration		1
Retinal detachment		1
Retinal disorder		1
Retinal drusen	1	1
Retinal oedema	1	1
Retinal vascular thrombosis		
Retinal vein occlusion	1	1
Retinal vein thrombosis	1	1
Retrograde amnesia		1
Rhabdomyolysis	1	1
Rheumatoid arthritis	2	5
Rhinalgia	1	2
Rhinitis	2	16
Rhinorrhoea	2	20
Root canal infection		1
Rosacea		1
Salivary hypersecretion	1	8
SARS-CoV-2 ant body test	1	1
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 ant body test positive	1	7
SARS-CoV-2 test positive	4	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	9
	1				17
			1	6	9
			1		4
					1
					1
					3
					3
			4		2
		3	13	3	9
				2	2
					1
					1
					1
				1	1
				1	1
	1				
				1	1
				1	1
			1		
				1	1
				2	5
		1	1		1
		2	13		3
			16	2	4
			1		
					1
		1	6		2
				1	1
			2		1
		1	6		1
			5	4	8

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scab		1
Scarlet fever		
Sciatica		4
Scintillating scotoma		2
Scleral discolouration		1
Scleral hyperaemia		1
Seasonal allergy		1
Seborrhoeic dermatitis		1
Sedation		3
Seizure		8
Sensation of foreign body	1	16
Sense of oppression	1	4
Sensitive skin		1
Sensory disturbance		1
Sensory loss		6
Sepsis	1	2
Septic shock	2	3
Shock	1	3
Sinus bradycardia		1
Sinus headache		1
Sinus pain		1
Sinus tachycardia	1	11
Sjogren's syndrome		1
Skin burning sensation	1	7
Skin discolouration	1	6
Skin exfoliation	1	2
Skin induration		1
Skin irritation		2
Skin laceration	2	3
Skin lesion		8
Skin mass	1	3
Skin oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
1	1				
			4		
			2		
					1
			1		
			1		1
			1		
			1		2
					8
		1	10		6
		1	1		3
			1		
			1		
			3		3
				1	2
				2	3
				1	3
			1		
			1		
					1
		1	4		7
					1
		1	6		1
			3	1	3
		1	2		
					1
			1		1
		1	2	1	1
			6		2
		1	3		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin reaction	5	19
Skin striae	1	1
Skin swelling		1
Skin tightness		2
Skin warm		5
Sleep disorder	4	9
Sluggishness		1
Sneezing		4
Soft tissue infection		1
Soliloquy		1
Somnolence	14	139
Sopor	4	6
Speech disorder	6	13
Spinal pain	2	17
Splenomegaly		1
Stertor		1
Stoma site pain		1
Stomatitis		1
Stridor	1	1
Stupor	1	8
Subcutaneous haematoma		1
Submaxillary gland enlargement		1
Sudden death	5	8
Sudden onset of sleep		2
Suffocation feeling	1	6
Superinfection bacterial		1
Supraventricular extrasystoles		1
Suspected COVID-19	2	2
Swelling	5	58
Swelling face	6	40
Swelling of eyelid		7
Swollen tongue	4	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	3	9
		1	1		
					1
			1		1
			2		3
		3	7	1	2
					1
			3		1
					1
			1		
	1	8	107	6	32
	1		1	4	5
1	1	1	5	5	8
		2	16		1
					1
					1
					1
			1		
				1	1
			3	1	5
					1
			1		
	1			5	8
					2
			3	1	3
					1
					1
				2	2
		2	45	3	13
	1	4	23	2	17
			5		2
			14	4	18

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Syncope	21	104
Systemic lupus erythematosus		1
Systolic hypertension		1
Tachyarrhythmia	1	3
Tachycardia	31	294
Tachycardia paroxysmal	1	4
Tachypnoea		15
Taste disorder	1	12
Temperature intolerance	1	1
Temperature regulation disorder		1
Temporomandibular joint syndrome		2
Tenderness	1	4
Tendonitis		1
Tenosynovitis	1	1
Tension		3
Tension headache	1	6
Terminal insomnia		1
Tetany	2	2
Therapy change		1
Thirst	1	5
Thought blocking		1
Throat irritation	6	52
Throat tightness	5	87
Thromboangiitis obliterans	1	1
Thrombocytopenia	7	11
Thrombophlebitis	2	2
Thrombophlebitis superficial	6	7
Thrombosis	5	8
Thyroglobulin increased		1
Thyroglossal cyst	1	1
Thyroid disorder		1
Thyroiditis subacute	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	4	1	1	20	103
					1
					1
		1	3		
	4	14	169	17	125
	1		1	1	3
			8		7
			6	1	6
		1	1		
			1		
			1		1
		1	3		1
			1		
		1	1		
			2		1
			4	1	2
			1		
		1	1	1	1
			1		
		1	5		
					1
		4	27	2	25
	2		36	5	51
				1	1
	1			7	11
		1	1	1	1
1	1	1	1	5	6
				5	8
					1
				1	1
			1		
		2	3		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thyroid mass		1
Thyroid pain		1
Tinnitus	4	19
Tongue blistering		1
Tongue coated		2
Tongue discolouration	1	2
Tongue discomfort	1	10
Tongue disorder		2
Tongue dry	1	4
Tongue erythema		1
Tongue geographic		1
Tongue movement disturbance	1	1
Tongue oedema	5	34
Tongue paralysis		1
Tongue pruritus		7
Tongue ulceration	1	3
Tonic clonic movements		1
Tonic convulsion		1
Tonsillar hypertrophy	1	4
Tonsillitis		1
Toothache		2
Tooth infection		1
Torticollis		6
Toxic skin eruption	1	2
Tracheal pain		2
Tracheitis		1
Transaminases increased		1
Transient ischaemic attack	2	2
Tremor	10	100
Tricuspid valve incompetence	1	1
Trigeminal nerve disorder		5
Trigeminal neuralgia	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	11	3	8
			1		
			2		
		1	1		1
			8	1	2
			1		1
		1	3		1
					1
			1		
				1	1
1	1	1	14	4	20
					1
			2		5
			2	1	1
					1
					1
		1	4		
			1		
			2		
			1		
			6		
				1	2
			1		1
					1
				2	2
	2	6	52	4	48
				1	1
			2		3
			4	1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Trigger finger		1
Trismus		1
Troponin I increased	1	1
Troponin increased	1	1
Troponin T increased	1	1
Type 1 diabetes mellitus	1	1
Type I hypersensitivity	1	8
Type IV hypersensitivity reaction	1	1
Underdose		8
Undersensing	1	1
Unresponsive to stimuli	1	2
Upper airway obstruction		2
Upper limb fracture	1	1
Upper respiratory tract inflammation		2
Urinary incontinence		2
Urinary retention	1	3
Urinary tract infection bacterial	1	1
Urine flow decreased		1
Urine odour abnormal		1
Urine output decreased	1	2
Urosepsis	1	1
Urticaria	38	262
Urticaria papular	1	1
Urticaria thermal	1	1
Urticaria vesiculosa	1	1
Use of accessory respiratory muscles		5
Uveitis		7
Vaccination complication		61
Vaccination error		1
Vaccination failure	28	55
Vaccination site bruising		4
Vaccination site cellulitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
				1	1
				1	1
				1	1
				1	1
				1	8
				1	1
			8		
				1	1
				1	2
					2
				1	1
			1		1
				1	3
				1	1
			1		
			1		
				1	2
				1	1
		24	176	14	86
		1	1		
		1	1		
		1	1		
			1		4
					7
	2		46		15
			1		
1	1			28	55
			3		1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort		1
Vaccination site eczema		1
Vaccination site erythema	16	118
Vaccination site extravasation		2
Vaccination site haematoma		6
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		9
Vaccination site induration	2	16
Vaccination site inflammation	1	8
Vaccination site irritation	1	1
Vaccination site ischaemia		1
Vaccination site joint erythema		2
Vaccination site joint movement impairment		6
Vaccination site joint pain	1	11
Vaccination site joint swelling	2	11
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	1	21
Vaccination site mass		3
Vaccination site movement impairment	1	20
Vaccination site nodule		2
Vaccination site oedema	6	83
Vaccination site pain	149	1,121
Vaccination site pallor		1
Vaccination site paraesthesia		22
Vaccination site phlebitis	1	1
Vaccination site pruritus	4	41
Vaccination site rash	1	9
Vaccination site reaction	2	27
Vaccination site swelling	15	120
Vaccination site urticaria	3	27

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
			1		
		13	83	3	35
			1		1
			6		
					1
			8		1
		1	13	1	3
			6	1	2
		1	1		
					1
			2		
			5		1
		1	11		
		2	11		
			1		
		1	16		5
			3		
		1	19		1
			2		
1	1	5	66	1	17
	3	121	930	28	191
			1		
			17		5
		1	1		
		4	32		9
		1	8		1
		1	20	1	7
	1	10	80	5	40
		3	18		9

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site vesicles		4
Vaccination site warmth		29
Vaginal haemorrhage		2
Vaginal infection	1	2
Vascular purpura	1	3
Vascular rupture		1
Vasculitic rash		1
Vasculitis	7	8
Vasculitis necrotising	1	1
Vasoconstriction	1	8
Vasodilatation		2
Vasomotor rhinitis		1
Venous thrombosis	1	1
Ventricular extrasystoles		5
Ventricular fibrillation	1	1
Vertigo	25	246
Vertigo positional		2
Vestibular neuritis	1	2
Viral corneal ulcer		1
Viral infection	1	1
Virologic failure	1	1
Vision blurred	5	34
Visual acuity reduced		2
Visual field defect		2
Visual impairment	7	21
Vitreoretinal traction syndrome		1
Vitreous detachment		3
Vitreous disorder		2
Vitreous floaters		2
Vitritis		1
Vocal cord dysfunction		1
Vocal cord paralysis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		1
			20		9
			1		1
		1	2		
		1	2		1
					1
					1
		6	6	1	2
				1	1
		1	3		5
			1		1
			1		
				1	1
			3		2
				1	1
2	2	12	179	13	67
	1		1		1
			1	1	1
					1
		1	1		
		1	1		
		2	23	3	11
	1		1		1
			1		1
	2		9	7	12
					1
					3
			1		1
					2
					1
					1
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vomiting	40	318	1	6	25	199	15	119
Vomiting projectile		3				1		2
Vulvovaginal burning sensation		1				1		
Vulvovaginal candidiasis		2				2		
Weight decreased		2				1		1
Wheezing	1	12				6	1	6
White blood cell count increased	1	3			1	1		2
Withdrawal hypertension		1				1		
Wrong technique in product usage process		1				1		
Xanthopsia		1						1
Xerophthalmia	1	2					1	2
Yellow skin	1	2						
	3,139	28,895	122	282	1596	19938	1543	8957

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1						1
Abdominal distension	2	7				4	2	3
Abdominal pain	3	40			1	30	2	10
Abdominal pain upper	2	20			1	17	1	3
Abnormal behaviour		1				1		
Accommodation disorder		1						1
Acute abdomen	1	1					1	1
Acute coronary syndrome	1	2					1	2
Acute kidney injury	2	3					2	3
Acute motor axonal neuropathy	1	1					1	1
Acute myocardial infarction	1	4					1	4
Acute polyneuropathy		1						1
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome	2	2					2	2
Acute respiratory failure	2	7					2	7
Administration site movement impairment	1	1					1	1
Administration site oedema		10				10		
Administration site pain		20				20		
Administration site swelling		1				1		
Ageusia	3	7			2	6	1	1
Agitation		6				5		1
Akinesia	1	1					1	1
Allergic respiratory symptom		1						1
Allergy to vaccine	1	1			1	1		
Allodynia		2				1		1
Alopecia		1						1
Alpha globulin increased		1				1		
Alpha tumour necrosis factor increased	1	1					1	1
Amaurosis fugax	1	1					1	1
Amnesia		2				1		1
Amylase increased		1						1
Anaemia	2	2					2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaesthesia		2
Anaesthesia oral		1
Anal incontinence		3
Anaphylactic reaction		8
Anaphylactic shock		2
Anaphylactoid reaction		2
Angioedema	1	10
Angiopathy	1	1
Anosmia	2	4
Anterograde amnesia		1
Antibody test abnormal		2
Anuria		2
Anxiety		5
Anxiety disorder due to a general medical condition		1
Aortic dilatation	1	1
Aphasia	7	8
Aphonia		3
Aphthous ulcer		2
Apnoea		1
Arrhythmia	3	12
Arteriospasm coronary		1
Arthralgia	26	287
Arthritis reactive		1
Asthenia	33	310
Asthenopia		3
Asthma		4
Asthmatic crisis	1	2
Asymptomatic COVID-19	6	10
Ataxia	1	1
Atrial fibrillation	5	12
Atrial flutter	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					1
			1		2
1	2				8
					2
					2
				1	10
				1	1
			2	2	2
					1
			2		
					2
			4		1
			1		
		1	1		
1	1			7	8
			2		1
			2		
					1
				3	12
					1
		17	230	9	57
	1				
1	3	19	250	14	60
			3		
			3		1
1	1			1	2
				6	10
				1	1
				5	12
				1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atrial tachycardia		2
Autoimmune thyroiditis		3
Axillary pain	2	19
Back pain	2	25
Balance disorder		8
Barotrauma		1
Bladder obstruction		1
Blepharospasm		1
Blindness		1
Blindness unilateral	1	1
Blister		3
Blood bilirubin increased	1	1
Blood fibrinogen increased	1	1
Blood glucose increased		1
Blood pressure decreased		2
Blood pressure increased	3	19
Blood pressure systolic increased		3
Bloody discharge	1	1
Body temperature decreased	1	2
Body temperature increased	1	11
Bone pain	5	22
Bradycardia		7
Bradykinesia	1	2
Bradyphrenia	1	1
Brain compression	1	1
Brain neoplasm		1
Brain stem haemorrhage		1
Breakthrough pain		1
Breast pain		1
Bronchitis		1
Bronchospasm		1
Burning mouth syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					3
2	3	2	16		3
	1		16	2	9
1	1		4		4
			1		
					1
			1		
					1
			3		
				1	1
		1	1		
			1		
					2
		1	11	2	8
			2		1
				1	1
			1	1	1
		1	8		3
		4	18	1	4
	1				7
				1	2
				1	1
				1	1
					1
					1
			1		
					1
					1
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Burning sensation	1	4
Bursitis infective		1
Cardiac arrest	6	9
Cardiac disorder	1	2
Cardiac failure	1	5
Cardiac failure congestive	1	2
Cardiac fibrillation	1	1
Cardiogenic shock		1
Cardiopulmonary failure	1	1
Cardio-respiratory arrest	5	6
Carotid artery dissection	1	1
Catarrh	2	2
Central nervous system lesion	1	1
Cerebellar ataxia	1	1
Cerebral artery occlusion	1	1
Cerebral haematoma		1
Cerebral haemorrhage	5	7
Cerebral infarction		1
Cerebral ischaemia	4	4
Cerebral thrombosis	1	1
Cerebral ventricle collapse	1	1
Cerebrovascular accident	6	7
Cervicobrachial syndrome		2
Chest discomfort		12
Chest pain	4	26
Chillblains	2	5
Chills	20	258
Choking		1
Choking sensation		1
Cholangitis		1
Chromaturia	1	1
Chronic obstructive pulmonary disease	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
					1
				6	9
				1	2
				1	5
				1	2
				1	1
					1
				1	1
				5	6
				1	1
		1	1	1	1
				1	1
				1	1
					1
				5	7
					1
				4	4
				1	1
				1	1
				6	7
			1		1
			9		3
			12	4	14
		2	4		1
		15	212	5	46
					1
			1		
					1
				1	1
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Circulatory collapse	1	1
Circumstance or information capable of leading to medication error		1
Clonus		1
Cluster headache		1
Cold burn		1
Cold sweat		7
Colitis		1
Coma		1
Condition aggravated	2	7
Confusional state	9	24
Conjunctival haemorrhage		3
Conjunctival hyperaemia		2
Conjunctival irritation		2
Conjunctivitis		2
Constipation		1
Contusion		1
Coordination abnormal		
Coronary artery disease		1
Coronary artery stenosis	1	1
Cough	9	36
COVID-19	22	77
COVID-19 pneumonia	6	6
Cranial nerve disorder		1
C-reactive protein abnormal		1
C-reactive protein increased	3	6
Crying	1	1
Cyanosis	1	3
Dactylitis	1	1
Deafness		1
Death	3	7
Decreased appetite	2	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
					1
			1		
			1		
			1		6
			1		
					1
			1	2	6
1	2	2	9	7	15
	1				3
			1		1
			2		
			1		1
					1
1	1		1		
					1
				1	1
		2	18	7	18
	1	1	12	21	65
	1			6	6
					1
			1		
		1	2	2	4
				1	1
				1	3
				1	1
					1
				3	7
			9	2	7

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Deep vein thrombosis	8	9
Dehydration		2
Depressed level of consciousness		12
Dermatitis acneiform		2
Dermatitis allergic		4
Dermatitis bullous	1	1
Dermatitis exfoliative		1
Dermatitis herpetiformis		3
Diaphragmalgia		1
Diarrhoea	13	99
Diarrhoea haemorrhagic		1
Diplegia		2
Diplopia	5	10
Discomfort		4
Disease recurrence	2	5
Disorientation	1	6
Disturbance in attention		3
Dizziness	12	54
Drug abuse	1	1
Drug hypersensitivity	1	2
Drug ineffective	9	43
Dry mouth		10
Dry skin		2
Dry throat		2
Dysaesthesia	1	4
Dysarthria	5	5
Dyschezia	1	1
Dysentery	2	26
Dysgeusia		21
Dyskinesia	1	1
Dyspepsia	1	3
Dysphagia	1	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			8	9
					2
					12
			2		
			1		3
				1	1
					1
			1		2
			1		
		9	77	4	22
					1
					2
		5	7		3
			2		2
				2	5
		1	1		5
			3		
	1	6	38	6	16
				1	1
				1	2
			1	9	42
			7		3
			1		1
			1		1
		1	4		
1	1			5	5
				1	1
1	1			2	26
1	1		16		5
				1	1
			1	1	2
			4	1	8

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\* AE=Adverse Event

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysphonia		5
Dyspnoea	16	70
Dyspnoea exertional	1	2
Dysstasia		1
Dysuria	3	4
Ear discomfort	1	3
Ear disorder	1	2
Ear infection		1
Ear pain		4
Ear pruritus		1
Ecchymosis	3	3
Eczema asteatotic		1
Eczema nummular		1
Electrocardiogram T wave inversion		
Electrolyte imbalance		1
Embolic stroke	1	1
Embolism	1	2
Encephalitis		1
Encephalopathy		1
Enterocolitis		1
Enthesopathy	1	1
Epicondylitis		1
Epilepsy	2	7
Epistaxis		4
Erectile dysfunction	2	3
Erysipelas	1	1
Erythema	5	48
Erythema multiforme		1
Euphoric mood		1
Exposure via breast milk	3	4
Extrasystoles		8
Extremity contracture		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		3
1	2	1	17	15	53
			1	1	1
				3	4
		1	2		1
		1	1		1
			1		
			2		2
			1		
				3	3
			1		
			1		
	1				
					1
				1	1
				1	2
					1
					1
				1	1
			1		
				2	7
			3		1
				2	3
				1	1
1	1	3	31	2	17
					1
			1		
			1	3	3
			5		3
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye allergy		1
Eye disorder		2
Eye haemorrhage		1
Eye irritation		3
Eyelid oedema		2
Eyelid pain		1
Eyelid ptosis		1
Eyelid retraction		1
Eyelids pruritus		1
Eye pain		2
Eye pruritus		1
Eye swelling	1	2
Face oedema	3	5
Facial discomfort		1
Facial paralysis	7	27
Facial paresis		10
Fall	2	6
Fatigue	12	207
Febrile convulsion	1	2
Feeding disorder		1
Feeling abnormal	1	2
Feeling cold	3	27
Feeling drunk		1
Feeling hot	6	30
Feeling jittery	1	1
Feeling of body temperature change		4
Fibrin D dimer increased	5	6
Flank pain		1
Fluid retention		2
Flushing	5	15
Frequent bowel movements		1
Furuncle		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
					1
			2		1
			1		1
					1
			1		
					1
			1		
			1		1
					1
		1	2		
		1	2	2	3
			1		
1	1			7	27
			2		8
				2	6
1	1	7	172	5	35
				1	2
					1
				1	2
		3	25		2
			1		
		5	24	1	6
				1	1
			3		1
		3	4	2	2
			1		
					2
		2	12	3	3
			1		
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait disturbance	6	15
Gait inability	1	1
Gastric dilatation		1
Gastroenteritis		3
Gastroenteritis viral	1	1
Gastrointestinal disorder		7
Gastrointestinal motility disorder		1
Gastrointestinal pain		1
Gaze palsy	1	1
Generalised tonic-clonic seizure		1
General physical health deterioration		2
Genital herpes zoster		1
Genital rash		1
Gingival bleeding	2	2
Gingival oedema		2
Gingival swelling		1
Gingivitis		1
Glossitis		1
Goitre		1
Groin pain		1
Guillain-Barre syndrome	1	2
Haematoma	2	3
Haematuria	1	2
Haemoglobin decreased		2
Haemorrhagic stroke	1	1
Hallucination		3
Hand dermatitis		1
Headache	38	535
Head discomfort		4
Head injury		1
Heart rate decreased		3
Heart rate increased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	7	5	8
				1	1
			1		
			3		
				1	1
			6		1
					1
			1		
				1	1
					1
			1		1
					1
			1		
				2	2
			1		1
					1
			1		
			1		
			1		
			1		
				1	2
			1	2	2
				1	2
			1		1
				1	1
					3
			1		
2	4	25	446	13	89
			4		
					1
			2		1
		1	3		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heat stroke		1
Hemiparaesthesia		2
Hemiparesis	5	9
Hemiplegia	4	5
Hepatic enzyme increased		
Hepatic pain		1
Herpes ophthalmic		1
Herpes simplex		1
Herpes virus infection	1	4
Herpes zoster	3	19
Herpes zoster infection neurological		1
Herpes zoster oticus		1
HIV infection		1
Hot flush	1	14
Hydrocephalus	1	1
Hyperacusis	1	2
Hyperaemia		3
Hyperaesthesia		1
Hypercapnia		1
Hypercreatininaemia	1	1
Hyperglycaemia		2
Hyperhidrosis	3	61
Hyperpyrexia	4	45
Hyperreflexia		1
Hypersensitivity	1	10
Hypersensitivity vasculitis	1	1
Hypertension	4	26
Hypertensive crisis	7	23
Hypertensive heart disease	1	1
Hyperthermia		7
Hypertonia		1
Hypertrophic cardiomyopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
				5	9
				4	5
	1				
			1		
					1
			1		
		1	1		3
1	1		6	3	13
					1
					1
					1
		1	11		3
				1	1
			1	1	1
			1		2
					1
				1	1
			1		1
		1	39	2	22
	2			4	45
					1
	1		3	1	7
				1	1
		2	10	2	16
	2			7	23
				1	1
			5		2
			1		
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperventilation		3
Hypoacusis		4
Hypoaesthesia	1	32
Hypoaesthesia oral		4
Hypoglossal nerve disorder		1
Hypoglycaemia		1
Hypokinesia	1	2
Hyposmia		3
Hypotension	6	30
Hypotensive crisis	2	2
Hypothermia		2
Hypotonia		1
Hypoxia		1
Illrd nerve paralysis		1
Illness		2
Immune thrombocytopenia		
Impaired quality of life	1	2
Inappropriate schedule of product administration	2	2
Incontinence		1
Incorrect route of product administration	3	6
Induration		3
Infarction		1
Infection		1
Inflammation	1	2
Influenza	1	12
Influenza like illness	1	23
Infusion site pain		1
Injected limb mobility decreased		1
Injection site erythema		7
Injection site induration		3
Injection site infection		1
Injection site oedema		51

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					4
			22	1	10
			2		2
					1
					1
			1	1	1
			2		1
	1		11	6	19
				2	2
					2
			1		
					1
					1
			1		1
1	1				
		1	1		1
		2	2		
			1		
		3	6		
			3		
					1
					1
				1	2
		1	12		
		1	19		4
			1		
	1		1		
			7		
			3		
			1		
			51		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site pain	1	306
Injection site paraesthesia		2
Injection site pruritus		1
Injection site reaction		1
Injection site swelling		6
Injection site urticaria		1
Injection site warmth		2
Injury	1	1
Insomnia	2	25
International normalised ratio increased	2	3
Interstitial lung disease	3	4
Intervertebral discitis		1
Intestinal ischaemia	4	4
Intestinal obstruction		1
Intraventricular haemorrhage	1	2
Irritability		1
Ischaemia	1	1
Ischaemic stroke	3	7
Jaundice		2
Jaundice cholestatic		1
Joint lock		1
Joint range of motion decreased	1	3
Joint swelling	1	3
Labyrinthitis		1
Lacrimation increased		4
Lagophthalmos	1	1
Laryngeal obstruction		1
Laryngeal oedema	2	10
Laryngospasm		2
Left ventricular dysfunction	1	1
Left ventricular failure		1
Leukaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	306		
			2		
			1		
			1		
			6		
			1		
			2		
		1	1		
			21	2	4
			1	2	2
				3	4
					1
				4	4
					1
				1	2
			1		
				1	1
				3	7
					2
					1
			1		
		1	1		2
			1	1	2
			1		
			4		
				1	1
					1
				2	10
			1		1
		1	1		
					1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Leukopenia		1
Limb discomfort	3	13
Lipase increased		1
Lip oedema	1	9
Lip pruritus		3
Lip swelling	1	3
Listeriosis		1
Livedo reticularis		1
Localised oedema	1	5
Local reaction		2
Loss of consciousness	7	27
Loss of libido	1	1
Loss of personal independence in daily activities		1
Lung disorder		1
Lung neoplasm malignant		1
Lymphadenitis		7
Lymphadenopathy	11	164
Lymphangitis	1	2
Lymph node abscess		1
Lymph node pain	3	16
Lymphocyte count decreased		1
Lymphoedema		2
Lymphopenia		2
Macroglossia		1
Macular rupture		1
Malaise	14	131
Mastication disorder	1	1
Mean cell volume increased		1
Mechanical urticaria		1
Memory impairment		1
Meningeal disorder		1
Metabolic acidosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	11	2	2
					1
		1	7		2
			3		
		1	3		
					1
	1		1		
	1		4	1	1
			2		
				7	27
		1	1		
					1
					1
			5		2
2	3	6	133	5	31
				1	2
					1
		2	12	1	4
			1		
			2		
					2
					1
					1
		8	101	6	30
				1	1
			1		
			1		
					1
			1		
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Metamorphopsia		1
Middle insomnia		3
Migraine	2	26
Migraine with aura		1
Mitral valve incompetence	2	2
Mobility decreased		2
Monocyte count increased		1
Monoparesis		1
Monoplegia		1
Motor dysfunction	1	6
Mouth haemorrhage	1	2
Mouth swelling		1
Mouth ulceration		1
Movement disorder		2
Mucosal dryness		1
Multiple organ dysfunction syndrome		
Muscle contractions involuntary		2
Muscle contracture		2
Muscle discomfort		1
Muscle fatigue	1	2
Muscle rigidity	1	2
Muscle spasms	1	9
Muscle swelling		2
Muscle tightness		2
Muscle twitching		1
Muscular weakness	1	7
Musculoskeletal chest pain	1	7
Musculoskeletal discomfort		1
Musculoskeletal pain	4	62
Musculoskeletal stiffness	2	4
Myalgia	22	366
Myasthenia gravis crisis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			3		
		1	21	1	5
			1		
				2	2
			1		1
			1		
			1		
					1
			3	1	3
			1	1	1
			1		
			1		
			2		
			1		
	1				
			1		1
			2		
			1		
			1	1	1
			1	1	1
		1	8		1
					2
			1		1
			1		
		1	6		1
		1	5		2
			1		
		2	48	2	14
			2	2	2
2	4	14	310	8	56
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myocardial infarction	2	2
Myocardial ischaemia	1	1
Myocardial necrosis marker increased		1
Myocarditis	1	5
Myoclonus		1
Myositis		1
Nasal congestion	2	4
Nasal discomfort		1
Nasal oedema		1
Nasopharyngitis	2	6
Nausea	14	165
Neck pain	1	13
Necrotising fasciitis		1
Nervousness	1	1
Neuralgia		6
Neuralgic amyotrophy		1
Neuritis		3
Neurogenic bladder		1
Neuropathy peripheral		2
Night sweats		4
No adverse event	1	2
Non-cardiac chest pain	1	1
Non-pitting oedema		1
Nuchal rigidity		1
Nystagmus		1
Obstructive airways disorder		2
Ocular discomfort		1
Ocular hyperaemia		2
Odynophagia		3
Oedema		6
Oedema mouth		3
Oedema mucosal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				1	1
					1
				1	5
			1		
	1				
		1	3	1	1
			1		
		1	4	1	2
		8	130	6	35
			9	1	4
					1
				1	1
			2		4
	1		1		
			1		2
					1
					2
			4		
		1	2		
				1	1
			1		
			1		
					1
					2
			1		
			1		1
			2		1
			5		1
			2		1
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oedema peripheral	2	8
Oesophageal oedema		1
Off label use	2	7
Oliguria		1
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster	1	2
Optic ischaemic neuropathy	1	1
Optic neuritis	1	1
Oral discomfort		1
Oral herpes		5
Oral pruritus		1
Orbital haematoma		1
Orchitis	1	1
Organic brain syndrome		1
Oropharyngeal discomfort		2
Oropharyngeal pain	1	16
Otitis media		1
Overdose	5	9
Oxygen saturation abnormal		
Oxygen saturation decreased	6	17
Pain	6	76
Pain in extremity	22	160
Palatal disorder		1
Palatal oedema	1	7
Pallor	1	7
Palpitations	2	9
Pancreatitis	2	4
Panic attack		1
Papule		1
Paraesthesia	19	100
Paraesthesia mucosal		1
Paraesthesia oral	3	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	1	6	1	2
					1
		2	7		
					1
					1
				1	2
				1	1
				1	1
					1
			2		3
			1		
					1
				1	1
					1
			2		
		1	13		3
					1
		5	8		1
1	1				
			2	6	15
		5	65	1	11
		12	138	10	22
			1		
		1	4		3
			4	1	3
		2	6		3
				2	4
					1
					1
		10	67	9	33
			1		
		3	18		7

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Paralysis	1	2
Paraparesis	1	3
Paresis		1
Paresis cranial nerve		2
Parosmia	2	4
Parotid gland enlargement		2
Paroxysmal arrhythmia		1
Partial seizures	1	1
Pericardial effusion	2	2
Pericarditis	1	6
Periorbital discomfort		1
Periorbital oedema		1
Periorbital swelling		2
Peripheral artery thrombosis	1	1
Peripheral coldness		4
Peripheral embolism	1	1
Peripheral ischaemia	2	2
Peripheral swelling	5	11
Peritonsillar abscess		1
Petechiae	1	2
Petit mal epilepsy		1
Pharyngeal erythema		3
Pharyngeal hypoaesthesia		1
Pharyngeal mass		1
Pharyngeal oedema		2
Pharyngeal paraesthesia		1
Pharyngeal swelling	1	1
Pharyngitis		6
Photophobia		5
Photopsia		1
Pityriasis rosea	1	2
Platelet count decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	3
					1
			1		1
			2	2	2
			1		1
					1
				1	1
				2	2
				1	6
					1
					1
			1		1
				1	1
			4		
				1	1
				2	2
		1	5	4	6
					1
			1	1	1
					1
			2		1
			1		
					1
					2
					1
		1	1		
			4		2
			4		1
					1
			1	1	1
		1	1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Platelet count increased	1	1
Pleural effusion	3	3
Pleurisy		1
Pleuropericarditis	1	1
Pneumatoxis	1	1
Pneumonia	3	8
Pneumonia bacterial	1	1
Pneumonia legionella		1
Pneumonitis	1	3
Pneumothorax	1	1
Pollakiuria		1
Polyarthritus	1	2
Polyuria		2
Post herpetic neuralgia		1
Presyncope	7	47
Procalcitonin increased	1	1
Product administered at inappropriate site		2
Product label confusion		1
Product preparation issue		3
Product use issue	1	5
Pruritus	5	46
Psoriatic arthropathy	2	2
Psychomotor skills impaired	1	1
Psychotic disorder	1	1
Pulmonary congestion		1
Pulmonary embolism	4	5
Pulmonary infarction	1	1
Pulmonary microemboli	1	1
Pulmonary oedema	1	2
Pulse volume decreased		1
Puncture site pain		1
Purpura		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				3	3
					1
				1	1
				1	1
				3	8
				1	1
					1
				1	3
				1	1
					1
				1	2
			1		1
					1
		3	24	4	23
		1	1		
			2		
			1		
			3		
		1	5		
		3	32	2	14
				2	2
				1	1
				1	1
					1
2	2			4	5
				1	1
				1	1
				1	2
			1		
			1		
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	77	730
Q fever		1
Quadripareisis		1
Rales	1	2
Rash	6	41
Rash erythematous	1	5
Rash macular		2
Rash maculo-papular		1
Rash papular		1
Rash pruritic	2	4
Rash vesicular		1
Raynaud's phenomenon		1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased	1	2
Red cell distribution width increased		1
Renal impairment		1
Renal pain	1	3
Respiratory disorder	1	3
Respiratory distress	2	5
Respiratory failure	6	10
Respiratory fatigue		3
Respiratory tract infection		1
Restlessness		2
Retching	1	4
Retinal detachment		1
Retinal vein thrombosis	2	2
Retrograde amnesia		1
Rheumatic disorder		1
Rhinitis	1	4
Rhinitis allergic		1
Rhinorrhoea	1	3
Rhonchi		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
6	9	35	534	42	196
					1
					1
				1	2
		3	25	3	16
			3	1	2
			1		1
			1		
					1
		1	2	1	2
			1		
			1		
					1
			1	1	1
			1		
					1
			2	1	1
				1	3
				2	5
				6	10
					3
					1
					2
		1	3		1
					1
				2	2
					1
			1	1	3
			1		
			2	1	1
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Right ventricular dilatation	1	1
Sacroiliitis	1	1
Sarcoidosis		1
SARS-CoV-2 ant body test	1	1
SARS-CoV-2 ant body test negative	1	4
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	6	13
Scab		1
Sciatica		2
Scrotal erythema	1	1
Secretion discharge	1	1
Sedation		2
Seizure	2	2
Seizure like phenomena		1
Sensation of foreign body	1	5
Sensitisation		1
Sensorimotor disorder		1
Sensory disturbance		2
Sensory loss		2
Sepsis		1
Septic shock		1
Serratia test positive		1
Severe acute respiratory syndrome	2	3
Sinusitis		2
Sinus rhythm		1
Sinus tachycardia		3
Sitting disability	1	1
Skin burning sensation		2
Skin discolouration		1
Skin exfoliation		1
Skin irritation		1
Skin laceration	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
					1
				1	1
		1	4		
			1		
			3	6	10
			1		
			1		1
				1	1
				1	1
			2		
				2	2
					1
			2	1	3
			1		
					1
					2
			1		1
					1
					1
				2	3
			1		1
			1		
1	1		3		
		1	1		
			1		1
					1
			1		
			1		
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin lesion	1	1
Skin reaction		2
Sleep disorder	1	2
Slow speech	1	1
Somnolence	3	37
Sopor		4
Speech disorder	3	5
Spider vein		1
Spinal pain		2
Status epilepticus		1
Stenotrophomonas test positive		1
Stomatitis		1
Stupor		3
Subarachnoid haemorrhage	3	3
Subcutaneous abscess		1
Subdural haematoma	1	1
Sudden death	4	10
Sudden hearing loss		1
Suffocation feeling		1
Superinfection bacterial	1	1
Supraventricular tachycardia		1
Suspected COVID-19		1
Swelling	4	16
Swelling face	2	6
Swelling of eyelid		1
Swollen tongue	1	5
Syncope	5	29
Systemic lupus erythematosus	1	1
Tachycardia	8	53
Tachycardia paroxysmal		2
Tachypnoea		5
Taste disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		
		1	2		
				1	1
1	1	2	31	1	6
1	1		2		2
			1	3	4
			1		
			2		
					1
					1
					1
			1		2
				3	3
					1
				1	1
				4	10
					1
			1		
				1	1
			1		
					1
		3	14	1	2
		1	4	1	2
			1		
		1	2		3
				5	29
				1	1
1	1	4	34	4	19
			2		
			4		1
			1	1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temporomandibular joint syndrome		1
Tenderness		2
Tendon pain		1
Tenosynovitis	1	1
Terminal insomnia		2
Testicular neoplasm	1	1
Therapeutic response unexpected		1
Thermal burns of eye		1
Throat irritation		5
Throat tightness	1	12
Thrombocytopenia	7	10
Thrombophlebitis	3	3
Thrombophlebitis superficial	2	2
Thrombosis	1	1
Thyroid hormones increased		1
Tinnitus	1	11
Tongue dry		2
Tongue eruption		1
Tongue oedema	1	4
Tongue pruritus		2
Tonic clonic movements		1
Tonsillar erythema		1
Tonsillar hypertrophy		1
Tonsillitis		1
Toothache	1	2
Torticollis		1
Transaminases increased	1	1
Transient ischaemic attack	2	3
Traumatic fracture		1
Tremor	8	33
Tricuspid valve incompetence	1	1
Trigeminal nerve disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
					1
				1	1
			2		
				1	1
			1		
					1
			2		3
		1	5		7
				7	10
		2	2	1	1
				2	2
				1	1
					1
			4	1	7
			1		1
			1		
			1	1	3
			2		
					1
			1		
			1		
					1
		1	2		
			1		
		1	1		
				2	3
					1
		2	18	6	15
				1	1
		1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Trigeminal neuritis		1
Troponin T increased	1	2
Underdose		3
Unresponsive to stimuli	1	1
Upper respiratory tract infection	1	1
Urinary incontinence	1	3
Urinary retention		1
Urinary tract infection		2
Urticaria	5	34
Vaccination complication		8
Vaccination failure	22	31
Vaccination site anaesthesia		1
Vaccination site dermatitis		1
Vaccination site discomfort		3
Vaccination site erythema		12
Vaccination site haematoma		2
Vaccination site hypoaesthesia	1	5
Vaccination site induration		3
Vaccination site inflammation		3
Vaccination site joint movement impairment		1
Vaccination site joint swelling		2
Vaccination site lymphadenopathy	1	3
Vaccination site movement impairment		5
Vaccination site oedema	1	11
Vaccination site pain	42	395
Vaccination site paraesthesia	1	7
Vaccination site pruritus		7
Vaccination site rash		4
Vaccination site reaction		7
Vaccination site swelling		21
Vaccination site urticaria		2
Vaccination site vesicles		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
			3		
				1	1
				1	1
				1	3
					1
			2		
		4	21	1	13
			8		
	1			22	31
					1
					1
			3		
			10		2
			2		
		1	4		1
			2		1
			2		1
			1		
			2		
		1	3		
			5		
		1	9		2
1	2	38	370	4	25
			5	1	2
			6		1
			2		2
			7		
1	1		16		5
			2		
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vaccination site warmth		5	1	1		4		1	1
Vasculitis	2	2			1	1	1	1	
Vasodilatation	1	1					1	1	
Venous thrombosis	2	2					2	2	
Venous thrombosis limb	2	2		1	1	1	1	1	
Ventricular arrhythmia		1							1
Ventricular extrasystoles	1	4			1	3			1
Ventricular fibrillation	1	1					1	1	
Ventricular tachycardia	1	2					1	2	
Vertigo	6	53		1	3	37	3	16	
Vestibular disorder		1							1
Vestibular neuronitis	1	2					1	2	
Vision blurred	5	16			2	9	3	7	
Visual field defect		2				2			
Visual impairment	3	4			1	1	2	3	
Vlth nerve paralysis	1	2					1	2	
Vlth nerve paresis	1	1			1	1			
Vitreous detachment		1		1					1
Vitreous disorder		1							1
Vitreous floaters		1							1
Vitreous haemorrhage	1	1					1	1	
Vocal cord paralysis		1							1
Volvulus		1							1
Vomiting	9	50	1	1	2	31	7	19	
Wandering pacemaker		1							1
Weight decreased	1	2					1	2	
Wheezing		2				2			
White blood cell count decreased		1				1			
Wound		1							1
Wrong schedule		1				1			
Xerosis		1							1
	1,109	7,774	43	83	395	5233	714	2541	

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	2	1	2		
Abdominal pain	1	2	1	2		
Abdominal pain lower		1		1		
Anaphylactic reaction		3				3
Anaphylactic shock		1				1
Arthralgia	1	17	1	14		3
Asthenia	3	19	1	14	2	5
Asthenopia		1		1		
Axillary pain	1	1	1	1		
Back pain		3		3		
Bone pain		2		2		
Bradycardia		1				1
Breakthrough pain		1		1		
Bronchospasm	1	1			1	1
Carotid artery dissection		1				1
Catarrh		1				1
Chest discomfort		1				1
Chills	1	16	1	14		2
Confusional state		3		3		
Constipation		1		1		
COVID-19		8		1		7
Cranial nerve disorder		1		1		
Deafness bilateral		1				1
Decreased appetite		2		2		
Depressed level of consciousness		1				1
Dermatitis bullous		1				1
Diarrhoea	1	1	1	1		
Diplegia		1				1
Diplopia	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness		1		1		
Drug ineffective		6				6

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth		1		1		
Dyspepsia	1	1	1	1		
Dysphagia		2		1		1
Dyspnoea		3				3
Ear pain		1		1		
Ear pruritus		1		1		
Epiglottic oedema		1				1
Erythema	1	8		5	1	3
Eyelid oedema		1		1		
Eyelid ptosis	1	1	1	1		
Eye pain	1	2	1	2		
Eye paraesthesia		1		1		
Facial paralysis		2				2
Fatigue	1	10	1	8		2
Febrile convulsion		1		1		
Feeling cold		1		1		
Feeling hot		1		1		
Flushing	1	2	1	2		
Gait inability	1	3		2	1	1
Gastrointestinal disorder	1	1	1	1		
Glossitis		1		1		
Groin pain	1	1	1	1		
Hallucination		1				1
Headache	2	24	1	19	1	5
Head discomfort		1		1		
Hemiparaesthesia		1				1
Hemiparesis		2				2
Hemiplegia		1				1
Herpes zoster		1				1
Hyperhidrosis		2		2		
Hyperpyrexia		5				5
Hypersensitivity		1				1

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypertensive crisis		1				1	
Hyperthermia		1		1			
Hypoacusis		1				1	
Hypoaesthesia	1	1			1	1	
Hypoaesthesia oral		1		1			
Hypotension		2		1		1	
Hypoxia	1	1			1	1	
Illrd nerve paralysis	1	1			1	1	
Inappropriate schedule of product administration		1		1			
Incorrect dose administered		1		1			
Influenza like illness		1		1			
Injection site infection		1		1			
Injection site joint pain		1		1			
Injection site oedema		2		2			
Injection site pain		14		14			
Insomnia	1	3	1	3			
Ischaemia		2				2	
Lacrimation increased		1		1			
Laryngeal oedema		3				3	
Lip oedema	1	3	1	3			
Lip swelling		1				1	
Lymphadenitis		1		1			
Lymphadenopathy	2	15	2	14		1	
Lymph node pain		1		1			
Malaise	1	7	1	7			
Migraine		2		1		1	
Musculoskeletal pain		3		3			
Myalgia	2	13		10	2	3	
Nausea	2	8	1	6	1	2	
Neck pain	1	1	1	1			
No adverse event		1		1			
Nuchal rigidity		1		1			

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort	1	1	1	1		
Oedema		1		1		
Oedema peripheral		1				1
Oral herpes	1	1	1	1		
Oral pain		1				1
Oropharyngeal pain		2		1		1
Pain		7		7		
Pain in extremity	1	10		8	1	2
Palatal oedema		1				1
Pallor		1		1		
Palpitations		1		1		
Papule		1		1		
Paraesthesia		7		7		
Paraesthesia oral		1		1		
Parosmia		1		1		
Perineal pain	1	1	1	1		
Periorbital pain		1		1		
Periorbital swelling		1		1		
Peripheral coldness		1		1		
Petechiae		1		1		
Photophobia		2		2		
Poor quality product administered		2		2		
Presyncope		2		2		
Product administered at inappropriate site		1		1		
Product administration error		2		2		
Product preparation issue		1		1		
Pruritus		5		4		1
Pyrexia	3	30	1	25	2	5
Radiculopathy		1		1		
Rash	1	4	1	3		1
Rhinitis		1		1		
SARS-CoV-2 ant body test negative		1		1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure		1				1
Sensory disturbance	1	1			1	1
Skin reaction		1		1		
Skin tightness		1				1
Sleep disorder		1		1		
Somnolence		2		2		
Sopor		1		1		
Swelling face		2		1		1
Syncope		1				1
Tachycardia		5		3		2
Tenderness		1		1		
Tinnitus		1		1		
Tongue oedema	1	1	1	1		
Umbilical haematoma	1	1			1	1
Underdose		1		1		
Urticaria	1	6	1	5		1
Vaccination failure		1				1
Vaccination site erythema	1	1			1	1
Vaccination site hyperaesthesia	1	1			1	1
Vaccination site lymphadenopathy		1		1		
Vaccination site oedema	1	4	1	4		
Vaccination site pain	4	19	3	17	1	2
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	1	2		1	1	1
Vaccination site reaction		1		1		
Vaccination site swelling	1	2		1	1	1
Vertigo		2		1		1
Vomiting		2		2		
Wrong technique in product usage process		1		1		
	57	443	34	327	23	116

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Country Where Event Occurred

**JAPAN**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	14	22	6	10	8	12
Abdominal distension	1	1	1	1		
Abdominal pain	28	39	14	19	14	20
Abdominal pain lower	1	3		1	1	2
Abdominal pain upper	10	10	6	6	4	4
Abdominal symptom	1	1			1	1
Abnormal sensation in eye	3	4	3	3		1
Acidosis		1				1
Acoustic neuroma	1	1			1	1
Acute febrile neutrophilic dermatosis		1				1
Administration site movement impairment	1	1	1	1		
Affective disorder		1		1		
Agitation	1	1	1	1		
Allergy to vaccine	8	10	6	8	2	2
Altered state of consciousness	3	8			3	8
Amnesia	1	1			1	1
Anaemia	3	4	3	3		1
Anal incontinence	1	1	1	1		
Anaphylactic reaction	405	639	2	2	403	637
Anaphylactic shock	11	16			11	16
Anaphylactoid reaction	4	10			4	10
Aneurysm	1	1			1	1
Angina pectoris		1				1
Angina unstable		1				1
Angioedema	1	2			1	2
Anxiety	6	7	2	3	4	4
Aphonia	1	1	1	1		
Apnoea		3				3
Apnoeic attack		1				1
Apraxia		1				1
Arrhythmia	6	7			6	7
Arthralgia	48	59	34	40	14	19

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis	2	2	1	1	1	1
Ascites	1	1			1	1
Asthenia	19	28	10	14	9	14
Asthenopia	2	2			2	2
Asthma	29	51	10	20	19	31
Atrial tachycardia	1	1			1	1
Autonomic nervous system imbalance	1	1			1	1
Autonomic neuropathy	1	1			1	1
Autophony	1	1	1	1		
Axillary pain	3	3	2	2	1	1
Back pain	10	11	8	8	2	3
Balance disorder	1	1			1	1
Bilirubinuria	1	1			1	1
Blepharospasm	3	3			3	3
Blister	1	1			1	1
Blood creatinine decreased		1		1		
Blood glucose decreased		1				1
Blood pressure abnormal	1	3	1	1		2
Blood pressure decreased	24	32	10	16	14	16
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure diastolic increased	1	2	1	1		1
Blood pressure fluctuation	1	1	1	1		
Blood pressure immeasurable	1	1	1	1		
Blood pressure increased	83	115	42	52	41	63
Blood pressure systolic increased	3	6	2	4	1	2
Body temperature abnormal		1		1		
Body temperature decreased	1	1	1	1		
Body temperature increased	6	8	6	8		
Bradycardia	6	7			6	7
Brain compression		1				1
Brain neoplasm		1				1
Breast cancer	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breath sounds abnormal	1	2			1	2
Bronchial obstruction		1				1
Bronchiectasis	1	1			1	1
Bronchospasm		1				1
Bronchostenosis	2	3			2	3
Bundle branch block right		1		1		
Burning sensation	1	2		1	1	1
Cardiac discomfort		1		1		
Cardiac failure	1	1			1	1
Cardiac failure acute	1	1			1	1
Cardio-respiratory arrest	2	3			2	3
Cardiovascular disorder	2	2	2	2		
Cellulitis	2	2			2	2
Cerebral congestion	1	1			1	1
Cerebral haemorrhage	4	5			4	5
Cerebral infarction	2	3			2	3
Cheilitis	1	1	1	1		
Chest discomfort	12	19	8	9	4	10
Chest pain	4	6	2	2	2	4
Chills	66	85	44	53	22	32
Choking	1	1			1	1
Choking sensation	1	1			1	1
Cholinergic syndrome	1	1			1	1
Chromatopsia	1	1			1	1
Circulatory collapse	3	3			3	3
Cold sweat	23	33	10	14	13	19
Colitis	1	1			1	1
Colitis ischaemic		1				1
Colitis ulcerative	1	1			1	1
Colour blindness		1		1		
Coma scale		1				1
Complex regional pain syndrome	1	2	1	1		1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	4	4
1	1		
		1	1
7	9	5	7
		1	1
46	66	73	122
	1	4	5
	2		2
2	2	1	1
			1
		1	1
		1	1
	4	7	9
		2	2
		1	1
1	1	2	3
		1	1
1	1	10	18
1	1		
3	4		1
1	1		1
23	29	15	23
1	1	1	1
8	11	4	6
1	2	1	1
		1	1
		1	1
		1	1
47	62	27	43
2	4	1	1
3	5	1	2

Condition aggravated	5	5
Confusional state	1	1
Conjunctival haemorrhage	1	1
Conjunctival hyperaemia	12	16
Convulsions local	1	1
Cough	119	188
COVID-19	4	6
Cutaneous symptom		4
Cyanosis	3	3
Daydreaming		1
Deafness neurosensory	1	1
Death	1	1
Decreased appetite	7	13
Decreased vibratory sense	2	2
Deep vein thrombosis	1	1
Dehydration	3	4
Delirium	1	1
Depressed level of consciousness	11	19
Dermatitis	1	1
Dermatitis allergic	3	5
Dermatitis atopic	1	2
Diarrhoea	38	52
Diplopia	2	2
Discomfort	12	17
Disease recurrence	2	3
Disseminated intravascular coagulation	1	1
Disturbance in attention	1	1
Diverticulitis	2	2
Diverticulum	1	1
Dizziness	74	105
Dizziness postural	3	5
Drug eruption	4	7

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug hypersensitivity	1	3			1	3
Drug ineffective	3	4			3	4
Dry mouth	2	2	1	1	1	1
Dry skin	2	2	2	2		
Dry throat	2	2	2	2		
Dysaesthesia	3	3	1	1	2	2
Dysgeusia	1	1	1	1		
Dyskinesia	1	1			1	1
Dyslalia	1	1	1	1		
Dyspepsia	3	3	1	1	2	2
Dysphagia	4	5	1	1	3	4
Dysphonia	15	23	7	8	8	15
Dysphoria	5	7	3	4	2	3
Dyspnoea	108	168	43	57	65	111
Dysstasia		2		1		1
Dysuria		1				1
Ear discomfort	5	8	4	4	1	4
Ear pruritus	1	1			1	1
Ear swelling	1	1			1	1
Eating disorder	2	2			2	2
Eczema	2	4	2	2		2
Enteritis infectious	1	1			1	1
Epigastric discomfort	2	2	1	1	1	1
Epilepsy	1	1			1	1
Epistaxis	1	2			1	2
Eructation		1		1		
Erythema	161	225	110	137	51	88
Erythema multiforme	1	1			1	1
Erythema of eyelid	1	1	1	1		
Excessive eye blinking		1				1
Exposure during pregnancy	1	1	1	1		
Eye disorder	2	5		1	2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye haemorrhage	1	1			1	1
Eyelid function disorder	1	1			1	1
Eyelid irritation	1	1			1	1
Eyelid oedema	10	18	5	8	5	10
Eyelid ptosis	1	1			1	1
Eye movement disorder	1	1			1	1
Eye oedema		1		1		
Eye pain	2	3	1	1	1	2
Eye pruritus	7	9	3	4	4	5
Eye swelling	2	3	1	1	1	2
Face oedema	2	5	1	1	1	4
Facial pain	3	4	2	2	1	2
Facial paralysis	9	11			9	11
Faeces soft	1	2		1	1	1
Fall	3	7	2	5	1	2
Fatigue	7	10	7	9		1
Feeding disorder	3	4			3	4
Feeling abnormal	99	144	54	68	45	76
Feeling cold	14	20	6	8	8	12
Feeling hot	40	54	24	31	16	23
Feeling jittery	1	1			1	1
Fibrin degradation products increased	1	1			1	1
Flushing	20	33	12	18	8	15
Foreign body in throat		2				2
Gait disturbance	8	11	1	2	7	9
Gait inability		1				1
Gastroenteritis bacterial	1	1			1	1
Gastrointestinal disorder	1	2			1	2
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal hypermotility	1	3			1	3
Gastrointestinal motility disorder	1	1	1	1		
Gastrointestinal mucosal disorder	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal oedema	1	1			1	1
Gaze palsy	2	3			2	3
Generalised oedema	2	2	1	1	1	1
Grip strength decreased	1	2	1	2		
Groin pain	1	1			1	1
Grunting	1	1			1	1
Guillain-Barre syndrome	4	4			4	4
Haemarthrosis	1	1			1	1
Haematochezia	2	4			2	4
Haemorrhage	1	1			1	1
Haemorrhage subcutaneous	7	7			7	7
Hallucination, visual	1	1			1	1
Headache	167	231	114	154	53	77
Head discomfort	17	24	9	13	8	11
Head injury		1				1
Heart rate decreased	4	4	3	3	1	1
Heart rate increased	17	29	10	18	7	11
Hemiparesis	1	1			1	1
Hemiplegia	1	1			1	1
Henoch-Schonlein purpura	1	1	1	1		
Hepatic function abnormal	5	5	1	1	4	4
Herpes zoster	2	2			2	2
Herpes zoster oticus	1	1			1	1
Hot flush	26	42	17	23	9	19
Hyperaesthesia	1	1			1	1
Hyperhidrosis	23	34	12	16	11	18
Hyperpyrexia	2	2			2	2
Hyperreflexia		1		1		
Hypersensitivity	28	41	18	20	10	21
Hypertension	17	23	5	5	12	18
Hypertensive emergency	2	2			2	2
Hypertensive urgency		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthermia	1	1			1	1
Hypertonia	1	1	1	1		
Hyperventilation	14	19	5	6	9	13
Hypoacusis	1	2	1	1		1
Hypoaesthesia	75	92	48	61	27	31
Hypoaesthesia oral	11	19	8	13	3	6
Hypokalaemia	1	3			1	3
Hypophagia	1	1			1	1
Hypothermia	2	2			2	2
Hypotonia	1	1			1	1
Hypoventilation		1				1
Hypoxia		1				1
Ileus paralytic	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	3	4	3	4		
Induration	1	1	1	1		
Inflammation		2		1		1
Injected limb mobility decreased	1	4		3	1	1
Injection site discomfort		1		1		
Injection site hypoaesthesia	1	1	1	1		
Injection site pain	2	2	2	2		
Injection site pruritus	2	2	2	2		
Injection site rash	1	1	1	1		
Injection site warmth	1	1	1	1		
Injury		1				1
Insomnia	2	2	2	2		
Internal haemorrhage	12	12			12	12
Irregular breathing	1	1			1	1
Joint range of motion decreased	4	5	1	1	3	4
Joint swelling	2	2	2	2		
Kaposi's varicelliform eruption	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased	4	6	2	4	2	2
Lacunar infarction	1	1			1	1
Laryngeal discomfort	4	7	2	4	2	3
Laryngeal obstruction		1				1
Laryngeal oedema	4	6			4	6
Laryngeal pain	1	1	1	1		
Laryngospasm	1	1			1	1
Larynx irritation	2	3	1	1	1	2
Lethargy	1	1			1	1
Leukopenia	1	1			1	1
Lid margin discharge	1	1	1	1		
Limb discomfort	4	11	3	8	1	3
Lip erythema	1	1			1	1
Lip oedema	2	2	1	1	1	1
Lip pruritus	1	3	1	1		2
Lip swelling	7	14	5	9	2	5
Listless	1	2	1	2		
Livedo reticularis	1	1	1	1		
Liver disorder	1	1			1	1
Local reaction	1	1	1	1		
Loss of consciousness	14	22			14	22
Loss of personal independence in daily activities		1				1
Lymphadenitis	1	1	1	1		
Lymphadenitis bacterial		1				1
Lymphadenopathy	10	11	8	9	2	2
Lymph node pain	2	2	1	1	1	1
Lymphocyte percentage decreased		1		1		
Lymphoedema	1	1			1	1
Lymphoma	1	1			1	1
Malaise	142	191	107	134	35	57
Marasmus	1	1			1	1
Maternal exposure during pregnancy	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Melaena	1	2			1	2
Memory impairment		1				1
Meningitis	1	1			1	1
Meningitis aseptic	3	6			3	6
Migraine		1		1		
Mobility decreased	2	3		1	2	2
Monocyte percentage increased		1		1		
Motion sickness	1	1			1	1
Mouth swelling	3	4	2	3	1	1
Movement disorder	5	6	1	2	4	4
Mucocutaneous disorder	1	1	1	1		
Mucosal disorder		1		1		
Mucosal haemorrhage	1	1	1	1		
Muscle spasms	7	10	3	4	4	6
Muscle tightness	1	1	1	1		
Muscle twitching	1	2	1	1		1
Muscular weakness	19	24	6	7	13	17
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort	2	3	1	2	1	1
Musculoskeletal stiffness	6	6	4	4	2	2
Myalgia	49	58	42	48	7	10
Mydriasis	1	1	1	1		
Myositis		1				1
Nasal congestion	2	4			2	4
Nasal obstruction	3	5	1	1	2	4
Nasal pruritus		1				1
Nasopharyngitis	2	2	2	2		
Nausea	153	217	86	111	67	106
Neck pain	6	7	3	3	3	4
Needle issue	1	1	1	1		
Nephrotic syndrome		1				1
Neuritis	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Neurological symptom		1					1
Neuropathy peripheral	18	24	1	1	17	23	
Neutrophilic dermatosis		1		1			
Night sweats		1		1			
Obstructive airways disorder	2	2			2	2	
Ocular hyperaemia	14	19	10	13	4	6	
Oculomucocutaneous syndrome	6	7			6	7	
Odynophagia		1				1	
Oedema	4	4			4	4	
Oedema mouth		1				1	
Oedema mucosal	1	1			1	1	
Oedema peripheral		1		1			
Off label use	1	1	1	1			
Opisthotonus	1	1			1	1	
Oral discomfort	7	8	7	7		1	
Oral mucosa erosion	1	1	1	1			
Oral mucosal blistering	1	1	1	1			
Oral pain	1	1	1	1			
Oral pruritus	5	5	2	2	3	3	
Oropharyngeal discomfort	98	157	49	66	49	91	
Oropharyngeal pain	13	24	10	16	3	8	
Orthostatic hypotension		1				1	
Orthostatic intolerance	1	1			1	1	
Overdose		1		1			
Oxygen saturation decreased	11	15	4	5	7	10	
Oxygen saturation increased	1	1			1	1	
Pain	21	26	15	20	6	6	
Pain in extremity	27	34	21	26	6	8	
Pallor	15	21	5	8	10	13	
Palmar erythema		1		1			
Palpitations	98	134	61	76	37	58	
Papule	1	1	1	1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	11	16	9	14	2	2
Paraesthesia oral	6	8	5	6	1	2
Paralysis	1	1			1	1
Parosmia	1	2	1	2		
Parotitis	1	2	1	2		
Periorbital oedema	1	1			1	1
Periorbital swelling	2	5		2	2	3
Peripheral circulatory failure	1	1			1	1
Peripheral coldness	19	22	14	14	5	8
Peripheral swelling	4	5	4	5		
Peritonitis	1	1			1	1
Petit mal epilepsy	1	2			1	2
Pharyngeal disorder	1	1			1	1
Pharyngeal erythema	1	1	1	1		
Pharyngeal paraesthesia	2	2	1	1	1	1
Pharyngeal stenosis	2	2			2	2
Pharyngeal swelling	5	7	3	4	2	3
Phlebitis	1	1	1	1		
Photopsia	3	4	3	3		1
Physical deconditioning	4	7	2	5	2	2
Pigmentation disorder		1		1		
Piloerection	1	2			1	2
Platelet count decreased	2	2			2	2
Pneumonia	1	1			1	1
Pneumonia viral	1	1			1	1
Pollakiuria		1				1
Poor quality sleep	1	1	1	1		
Postural tremor		1		1		
Presyncope	33	48	26	37	7	11
Product administered at inappropriate site		1		1		
Productive cough	1	3	1	2		1
Product leakage	1	2	1	2		

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			Nonserious		Serious		
			I	C	I	C	
Prolonged expiration		1		1			
Protein total decreased		1		1			
Pruritus	193	281	124	169	69	112	
Pulmonary artery thrombosis	1	1			1	1	
Pulmonary embolism	1	1			1	1	
Pulse abnormal	3	3	1	1	2	2	
Puncture site pain	1	1	1	1			
Pupils unequal	1	1	1	1			
Purpura	1	1	1	1			
Pyrexia	192	245	144	181	48	64	
Radial pulse abnormal	3	4	1	1	2	3	
Radial pulse increased		1				1	
Rash	112	161	70	92	42	69	
Rash erythematous	8	10	5	6	3	4	
Rash papular		1		1			
Rash pruritic	1	1	1	1			
Raynaud's phenomenon	1	1	1	1			
Reaction to excipient		2				2	
Rectal tenesmus	1	1			1	1	
Reduced facial expression	1	1			1	1	
Respiratory a kalosis	1	1	1	1			
Respiratory disorder	5	6	2	2	3	4	
Respiratory distress	1	9		1	1	8	
Respiratory rate decreased	1	1	1	1			
Respiratory rate increased	3	4			3	4	
Respiratory symptom	3	6	1	1	2	5	
Retinal haemorrhage	1	1			1	1	
Rhinorrhoea	14	19	10	12	4	7	
Salivary hypersecretion	1	1			1	1	
Scleritis	1	1			1	1	
Seasonal allergy	1	1	1	1			
Seizure	14	18			14	18	

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			Nonserious		Serious	
			I	C	I	C
Sensation of blood flow	1	1			1	1
Sensation of foreign body	5	5	4	4	1	1
Sensory disturbance	4	7	3	5	1	2
Serum sickness		1				1
Shock	1	2			1	2
Shock symptom		1				1
Shoulder injury related to vaccine administration		1				1
Sialoadenitis	1	1			1	1
Sinus bradycardia	1	1	1	1		
Sinus rhythm	2	2			2	2
Sinus tachycardia	3	4	2	2	1	2
Sitting disability	1	1	1	1		
Skin plaque	1	1			1	1
Sleep disorder		1				1
Slow response to stimuli	1	1			1	1
Sneezing	3	5	1	2	2	3
Soft tissue atrophy	1	1			1	1
Somatic symptom disorder		1		1		
Somnolence	8	13	6	8	2	5
Speech disorder	2	2	1	1	1	1
Speech sound disorder	1	1	1	1		
Spinal column injury	1	1	1	1		
Sputum retention	1	1	1	1		
Stenosis	2	2			2	2
Stomatitis		1		1		
Stress	3	3	2	2	1	1
Stridor	2	4	1	2	1	2
Subarachnoid haemorrhage	4	6			4	6
Submaxillary gland enlargement	1	1	1	1		
Sudden hearing loss	3	6			3	6
Suffocation feeling	1	2		1	1	1
Sunburn	1	1	1	1		

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Swelling	9	13
Swelling face	9	18
Swelling of eyelid	6	14
Sympathicotonia		1
Syncope	6	13
Tachycardia	19	32
Tachypnoea	6	10
Taste disorder	1	1
Temperature intolerance	1	1
Tenderness	1	1
Tension	1	1
Tension headache		1
Tetany	1	1
Thirst	3	4
Throat irritation	20	36
Throat tightness	16	24
Thrombocytopenic purpura	1	1
Thrombophlebitis superficial	1	1
Thrombosis	2	2
Tinnitus	3	5
Tongue disorder		1
Tonsillar disorder	1	1
Toothache	1	1
Toxic skin eruption	3	3
Tracheal obstruction	1	1
Tracheal stenosis	2	2
Tremor	13	22
Trigeminal nerve disorder	2	3
Trigeminal neuralgia	1	1
Type I hypersensitivity	7	9
Type IV hypersensitivity reaction	1	1
Underdose	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	8	4	5
5	7	4	11
5	7	1	7
			1
		6	13
8	10	11	22
4	6	2	4
1	1		
		1	1
		1	1
1	1		
			1
		1	1
2	2	1	2
14	20	6	16
9	11	7	13
		1	1
1	1		
		2	2
3	3		2
			1
1	1		
1	1		
		3	3
		1	1
		2	2
5	7	8	15
		2	3
1	1		
		7	9
1	1		
1	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Unresponsive to stimuli	1	2			1	2
Upper airway obstruction	1	1			1	1
Urinary retention		2				2
Urine abnormality	1	1			1	1
Urticaria	131	186	92	121	39	65
Vaccination complication	1	1	1	1		
Vaccination site bruising		1		1		
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema	11	20	10	14	1	6
Vaccination site haemorrhage	3	3	3	3		
Vaccination site hypoaesthesia	1	3	1	3		
Vaccination site induration	2	2	2	2		
Vaccination site joint discomfort	1	1	1	1		
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	4	6	3	5	1	1
Vaccination site necrosis	2	2			2	2
Vaccination site pain	86	103	73	88	13	15
Vaccination site paraesthesia	2	2	2	2		
Vaccination site pruritus	14	22	11	18	3	4
Vaccination site rash	4	5	4	5		
Vaccination site reaction	1	2	1	2		
Vaccination site swelling	14	16	11	12	3	4
Vaccination site urticaria	1	5	1	4		1
Vaccination site vesicles		1				1
Vaccination site warmth	1	2			1	2
Vagus nerve disorder		1				1
Vascular injury	1	1	1	1		
Vasculitis	1	1	1	1		
Vasodilatation	1	1	1	1		
Vasospasm	1	1			1	1
Ventricular extrasystoles	2	2	1	1	1	1
Vertigo	6	9	1	1	5	8

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral infection	1	1			1	1
Vision blurred	4	5	3	4	1	1
Visual impairment	3	7	2	4	1	3
Vlth nerve disorder		1				1
Vitreous floaters	1	1	1	1		
Vocal cord disorder	1	1			1	1
Vomiting	69	96	39	50	30	46
Wheezing	17	29	2	4	15	25
White blood cell count decreased	1	1			1	1
White blood cell count increased	1	1	1	1		
Yawning	4	5	2	3	2	2
	4,379	6,294	2266	2976	2113	3318

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	4	3	3		1
Abdominal pain	5	6	4	4	1	2
Abdominal pain upper		1				1
Abnormal sensation in eye	1	1			1	1
Accident	1	1			1	1
Acute coronary syndrome		2				2
Acute endocarditis	1	1			1	1
Acute lymphocytic leukaemia	1	1			1	1
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome	2	2			2	2
Allergy to vaccine	1	1			1	1
Altered state of consciousness	1	1			1	1
Amnesia	1	1			1	1
Anaemia	1	1	1	1		
Anaesthesia dolorosa	1	1			1	1
Anaphylactic reaction	45	59			45	59
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Aortic dissection	1	1			1	1
Aphasia	1	1			1	1
Arrhythmia	1	2			1	2
Arthralgia	12	12	9	9	3	3
Arthritis	1	1			1	1
Asthenia	4	5	3	3	1	2
Asthma	2	2			2	2
Atrial f brillation		1				1
Back pain	5	5	4	4	1	1
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased	5	5	4	4	1	1
Blood pressure diastolic increased	1	2		1	1	1
Blood pressure increased	5	10	3	6	2	4
Blood pressure systolic		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic abnormal	1	1			1	1
Body temperature increased	2	2	2	2		
Bradyphrenia	1	1			1	1
Brain stem haemorrhage	1	1			1	1
Brain stem infarction	1	1			1	1
Bronchostenosis	1	1			1	1
Burning sensation	1	1	1	1		
Calculus urinary		1		1		
Capillaritis	1	1	1	1		
Cardiac death	1	1			1	1
Cardiac failure	2	2			2	2
Cardiac tamponade	1	1			1	1
Cardio-respiratory arrest	4	4			4	4
Cardiovascular disorder	1	1	1	1		
Cellulitis	2	2			2	2
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebral venous sinus thrombosis	1	1			1	1
Chest discomfort	8	10	5	6	3	4
Chest pain	3	3	1	1	2	2
Chills	18	19	13	13	5	6
Circulatory collapse	1	1			1	1
Cold sweat	9	11	6	6	3	5
Complex regional pain syndrome	1	1			1	1
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia	1	2	1	1		1
Cough	14	15	8	8	6	7
C-reactive protein increased	1	1			1	1
CSF protein increased	1	1			1	1
Daydreaming	1	1	1	1		
Deafness	2	2			2	2
Decreased appetite	2	2	2	2		

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
2	2		
		1	1
		1	1
		1	1
1	1		
	1		
1	1		
		1	1
		2	2
		1	1
		4	4
1	1		
		2	2
		1	1
		2	2
		1	1
5	6	3	4
1	1	2	2
13	13	5	6
		1	1
			1
1	1		1
8	8	6	7
		1	1
		1	1
1	1		
		2	2
2	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness	2	3			2	3
Dermatitis atopic	1	1	1	1		
Diarrhoea	6	8	6	7		1
Discomfort	2	3			2	3
Dizziness	11	17	9	10	2	7
Dizziness postural	2	3	2	2		1
Drowning	1	1			1	1
Dry mouth		1				1
Dysphonia	2	2	2	2		
Dysphoria		1				1
Dyspnoea	14	18	10	10	4	8
Eczema	1	1	1	1		
Embolism venous	1	1			1	1
Enteritis		1				1
Enterocolitis	3	4			3	4
Epigastric discomfort	1	1	1	1		
Erythema	16	23	12	16	4	7
Erythema ab igne	1	1	1	1		
Extrasystoles	1	1	1	1		
Eye disorder	1	1	1	1		
Eyelid oedema	1	1			1	1
Eyelid ptosis	1	1			1	1
Eye pruritus	2	2	2	2		
Face oedema		2		1		1
Facial paralysis	4	4			4	4
Faeces soft	2	3	2	3		
Fall	3	3	1	1	2	2
Fatigue		1				1
Feeding disorder	1	1	1	1		
Feeling abnormal	13	18	10	12	3	6
Feeling cold	1	2	1	1		1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3	3	3
		2	2
1	1		
1	1		
1	1		
		1	1
1	1		
2	2	1	2
		3	3
		1	1
			1
27	29	11	17
2	3		
1	1		
		1	1
		1	1
		1	1
2	3		
		1	1
		1	1
5	6	1	2
		1	1
4	5	1	2
1	1		2
2	2		
3	6	6	8
1	2		
1	1		
1	1		
		1	1
		1	1

Feeling hot 6 6  
 Flushing 2 2  
 Fracture 1 1  
 Frequent bowel movements 1 1  
 Gastroenteritis 1 1  
 Gaze palsy 1 1  
 Glossodynia 1 1  
 Grip strength decreased 3 4  
 Guillain-Barre syndrome 3 3  
 Haematochezia 1 1  
 Haemoptysis 1 1  
 Headache 38 46  
 Head discomfort 2 3  
 Heart rate increased 1 1  
 Hemiplegia 1 1  
 Hepatic function abnormal 1 1  
 Herpes virus infection 1 1  
 Herpes zoster oticus 1 1  
 Hot flush 2 3  
 Hyperaemia 1 1  
 Hyperaesthesia 1 1  
 Hyperhidrosis 6 8  
 Hyperpyrexia 1 1  
 Hypersensitivity 5 7  
 Hypertension 1 3  
 Hyperthermia 2 2  
 Hypoaesthesia 9 14  
 Hypoaesthesia oral 1 2  
 Hypokinesia 1 1  
 Hypophagia 1 1  
 Hypoxia 1 1  
 Illrd nerve paralysis 1 1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Illusion		1				1	
Incorrect route of product administration	1	1	1	1			
Induration	1	1	1	1			
Infection	1	1	1	1			
Infective spondylitis	1	1			1	1	
Injection site muscle weakness	1	1	1	1			
Injection site swelling		1		1			
Injection site vesicles	1	1			1	1	
Internal haemorrhage	2	2			2	2	
Interstitial lung disease	1	1			1	1	
Intracranial aneurysm	1	1			1	1	
Joint range of motion decreased	1	1	1	1			
Limb discomfort	2	2	2	2			
Listless	1	1	1	1			
Loss of consciousness	8	8			8	8	
Lung infiltration		1				1	
Malaise	48	58	36	41	12	17	
Meningitis	1	1			1	1	
Migraine	1	1			1	1	
Mobility decreased	1	2	1	2			
Motion sickness	1	1	1	1			
Multiple sclerosis	1	1			1	1	
Muscle strain	1	1	1	1			
Muscle tightness		1		1			
Muscular weakness	5	7	3	4	2	3	
Musculoskeletal discomfort	1	1	1	1			
Myalgia	20	28	18	26	2	2	
Myelitis	1	1			1	1	
Myocardial infarction	2	2			2	2	
Myocarditis	4	6			4	6	
Myositis		1		1			
Nasal mucosal disorder		1				1	

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	22	31	10	12	12	19
Neck pain	1	1			1	1
Nephrotic syndrome	1	1			1	1
Neuropathy peripheral	4	4			4	4
Nystagmus		1				1
Oculomucocutaneous syndrome	1	1			1	1
Oedema peripheral	1	2			1	2
Oral discomfort	1	1			1	1
Oral mucosa haematoma	1	1	1	1		
Organising pneumonia		1				1
Oropharyngeal discomfort	11	17	7	10	4	7
Oropharyngeal pain	6	6	5	5	1	1
Oxygen saturation decreased	2	3	1	1	1	2
Pain	8	8	7	7	1	1
Pain in extremity	10	15	9	14	1	1
Pallor	2	2	1	1	1	1
Palpitations	8	11	6	7	2	4
Panic attack		1				1
Paraesthesia	2	3			2	3
Paraesthesia oral	1	1	1	1		
Paralysis		1				1
Pericarditis	2	2			2	2
Periorbital swelling	1	1	1	1		
Peripheral coldness	6	6	4	4	2	2
Peripheral nerve paresis	1	1			1	1
Peripheral swelling	2	2	2	2		
Pharyngeal paraesthesia	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Pharyngitis bacterial	1	1			1	1
Physical deconditioning		1				1
Pneumonia		2				2
Pneumothorax	2	2			2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pollakiuria	1	1			1	1
Post thrombotic syndrome	1	1			1	1
Presyncope	9	10	7	8	2	2
Productive cough	2	3	1	1	1	2
Prostatitis	1	1			1	1
Prostatomegaly	1	1			1	1
Protein urine present	1	1	1	1		
Pruritus	16	22	11	17	5	5
Pyrexia	57	65	43	47	14	18
Rash	11	18	8	14	3	4
Rash erythematous	1	1	1	1		
Respiratory disorder	4	4	1	1	3	3
Rhinorrhoea	1	3	1	2		1
Road traffic accident	1	1	1	1		
Seizure	2	2			2	2
Sensation of foreign body	1	1	1	1		
Sensory disturbance	1	1	1	1		
Sepsis	1	1			1	1
Shock	1	1			1	1
Skin abrasion	1	1			1	1
Skin fissures	1	1	1	1		
Sleep disorder due to general medical condition, insomnia type	1	1			1	1
Somatic symptom disorder	1	1	1	1		
Somnolence	1	1	1	1		
Sputum discoloured	1	1	1	1		
Sputum purulent	2	2			2	2
Stomatitis	1	1	1	1		
Streptococcal infection	1	1			1	1
Stridor	1	1			1	1
Subarachnoid haemorrhage	1	1			1	1
Sudden hearing loss	2	2			2	2

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
	1		
		2	2
2	3	1	2
1	2	1	2
2	2		
		3	3
1	1		
		1	1
			1
1	1		
2	2	1	1
			1
8	14	4	6
		1	1
1	1		
2	2	3	3
		1	1
1	1	1	1
	1		
		2	2
33	50	3	6
1	1		
1	1		
3	4	2	3
1	1	1	1
1	1		
1	1		
		1	1
		1	1
		2	2

Swelling	1	1
Swelling face	1	1
Swelling of eyelid		1
Syncope	2	2
Tachycardia	3	5
Thirst	2	4
Throat irritation	2	2
Throat tightness	3	3
Tongue oedema	1	1
Toxic skin eruption	1	1
Tracheal obstruction		1
Trance	1	1
Tremor	3	3
Upper gastrointestinal haemorrhage		1
Urticaria	12	20
Vaccination complication	1	1
Vaccination site coldness	1	1
Vaccination site erythema	5	5
Vaccination site haemorrhage	1	1
Vaccination site hypoaesthesia	2	2
Vaccination site induration		1
Vaccination site movement impairment	2	2
Vaccination site pain	36	56
Vaccination site papule	1	1
Vaccination site rash	1	1
Vaccination site swelling	5	7
Vaccination site warmth	2	2
Vasodilatation	1	1
Ventricular extrasystoles	1	1
Ventricular fibrillation	1	1
Ventricular hypokinesia	1	1
Vertebral artery dissection	2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	1	2	1	1		1
Vestibular neuronitis		1				1
Vomiting	6	9	3	3	3	6
Wheezing	2	2	1	1	1	1
White blood cell count increased		1				1
Wrong technique in product usage process	1	1			1	1
	824	1,054	472	575	352	479

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Anaphylactic reaction	16	30			16	30
Anaphylactic shock	3	4			3	4
Anxiety	1	1			1	1
Aortic dissection	1	1			1	1
Arthritis reactive	1	1			1	1
Asthma	1	2		1	1	1
Asymptomatic COVID-19	2	2			2	2
Blood pressure fluctuation		1				1
Blood pressure increased	2	3	2	2		1
Cardiac failure		1				1
Cellulitis	1	1			1	1
Cerebral infarction	1	1			1	1
Chills	2	2	2	2		
Condition aggravated	1	1			1	1
Cough	3	4	2	2	1	2
COVID-19	2	2	1	1	1	1
Death	1	1			1	1
Decreased appetite	1	1			1	1
Dermatitis allergic		1				1
Diarrhoea	1	4		3	1	1
Dizziness	3	4	2	2	1	2
Drug eruption		1		1		
Drug hypersensitivity		1		1		
Drug ineffective	3	3			3	3
Dysgeusia		1				1
Dyspnoea	2	3	1	1	1	2
Eczema	1	4	1	4		
Erythema		2		1		1
Erythema multiforme	1	1			1	1
Face oedema	1	1	1	1		

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Gender

**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
4	10		
			1
		1	1
		1	1
		1	1
4	6	2	2
1	1		
1	2		
1	1		
		1	2
		1	1
	2	1	2
		1	1
1	2		
			1
		1	1
2	2		
1	1		
1	1		
1	1		
			1
1	1		
8	9	1	1
		1	1
			1
	1		
1	1		
	1		
7	12		
		1	1
2	5		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Needle issue	1	1	1	1		
Optic atrophy	1	1			1	1
Oral discomfort		1				1
Oropharyngeal discomfort	5	7	4	4	1	3
Oropharyngeal pain	1	4	1	4		
Pain	4	6	3	5	1	1
Pallor		1				1
Palpitations	2	2	1	1	1	1
Pharyngeal swelling	1	1			1	1
Physical deconditioning	1	1			1	1
Platelet count decreased	1	1			1	1
Presyncope	1	2	1	1		1
Product preparation issue		2		2		
Pruritus	1	3	1	3		
Purpura	1	1	1	1		
Pyrexia	13	24	12	23	1	1
Rash	4	9	4	9		
Respiratory distress		1				1
Retinal haemorrhage	1	1			1	1
Seizure	1	1			1	1
Shock		1				1
Skin disorder		1		1		
Somnolence	1	1			1	1
Sudden hearing loss	1	2			1	2
Suspected COVID-19	1	1			1	1
Swelling	1	2	1	2		
Tachycardia	3	3	3	3		
Thrombosis	1	1			1	1
Tremor		1				1
Underdose		3		3		
Urticaria	6	12	5	10	1	2
Vaccination failure	1	1			1	1

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	11	19	10	18	1	1
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	2	1	2		
Vaccination site urticaria		1		1		
Vertigo	1	1	1	1		
Visual field defect	1	1	1	1		
Vomiting	3	3	2	2	1	1
	178	296	105	183	73	113

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Country Where Event Occurred

**JORDAN**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
Dysgeusia		1		1		
Erythema		1				1
Fatigue		1		1		
Gangrene		1				1
Haematemesis		1				1
Headache		1		1		
Mesenteric vein thrombosis		1				1
Muscle spasms		1		1		
Myalgia		1		1		
Obstructive airways disorder		1				1
Pain		2		2		
Pain in extremity		2		2		
Swelling		1				1
Swelling face		1		1		
Syncope		1				1
Vaccination site pain		1		1		
Weight decreased		1		1		
		20		12		8

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Anosmia		1		1		
Asthenia	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Condition aggravated		1				1
Confusional state	1	1			1	1
Cough		1		1		
COVID-19		2				2
COVID-19 pneumonia		1				1
Dizziness		1		1		
Dyspnoea		1				1
Fatigue		2		2		
Hypoxia		1				1
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1				1
Influenza		1		1		
Influenza like illness		1		1		
Injection site pain		1		1		
Loss of consciousness		1				1
Lung disorder		1				1
Myalgia		1		1		
Pain in extremity		1		1		
Respiratory failure		1				1
Sputum retention		1				1
Syncope		1				1
Tachypnoea		1				1
Tongue disorder		1		1		
Vaccination failure		1				1
Vaccination site pain		1		1		
	4	32		12	4	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1		1		
Chills		1		1		
COVID-19		1		1		
Myalgia		1		1		
Pneumonia		1				1
Pyrexia		1		1		
		6		5		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**KOREA, REPUBLIC OF (SOUTH KOREA)**

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Joint swelling	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**KUWAIT**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma		1		1
Fatigue		1		1
Headache	1	2	1	2
Lymphocyte percentage increased		1		1
Mean cell haemoglobin concentration increased		1		1
Musculoskeletal stiffness	1	1	1	1
Pain	1	1	1	1
Polyp		1		1
Pyrexia		1		1
Splenomegaly		1		1
	3	11	3	11

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
Fatigue		1		1
Lymphadenopathy		1		1
Myalgia		1		1
Neck pain		1		1
Pain in extremity		1		1
Peripheral swelling		1		1
Pyrexia		1		1
Swelling		1		1
Tenderness		2		2
Vaccination site pain		1		1
Vaccination site swelling		1		1
		13		13

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LATVIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		5		5		
Abdominal pain lower		1		1		
Abdominal pain upper		2				2
Abortion missed	1	1			1	1
Anaphylactic reaction		1				1
Anxiety		2				2
Arrhythmia		2				2
Arthralgia		40		36		4
Asthenia		20		18		2
Asthma		2		1		1
Atrial fibrillation		1				1
Bacille Calmette-Guerin scar reactivation		1		1		
Back pain		1		1		
Blood creatine phosphokinase increased		1		1		
Blood pressure increased		3		1		2
Body temperature decreased		1		1		
Body temperature increased	2	40	2	39		1
Bone pain		2		2		
Bradycardia		1				1
Bradyphrenia		1		1		
Burning sensation		4		1		3
Chest discomfort	1	1			1	1
Chest pain		2		2		
Chills		46		46		
Cold sweat		2		1		1
Condition aggravated		2		1		1
Confusional state		1		1		
Conjunctival haemorrhage		1				1
Coordination abnormal		1		1		
Costovertebral angle tenderness		1		1		
Cough	1	8	1	8		
COVID-19	1	5		2	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

*Preferred Term*

C-reactive protein increased  
Deafness  
Decreased appetite  
Depressed mood  
Depression  
Diarrhoea  
Diplopia  
Disease recurrence  
Disturbance in attention  
Dizziness  
Drug ineffective  
Dry mouth  
Dry skin  
Dysgeusia  
Dysphonia  
Dyspnoea  
Dyspnoea exertional  
Ear discomfort  
Ear pain  
Epistaxis  
Erythema  
Exposure during pregnancy  
Extrasystoles  
Eye pain  
Face oedema  
Facial paralysis  
Facial paresis  
Fatigue  
Feeling hot  
Gait disturbance  
Generalised oedema  
Generalised tonic-clonic seizure

*Interval Total # Spontaneous AE*

*Cumulative Total # Spontaneous AE*

3  
1  
7  
1  
1  
6  
1  
2  
5  
19  
2  
2  
2  
1  
4  
2  
6  
2  
1  
2  
1  
2  
2  
9  
1  
1  
2  
56  
2  
2  
1  
1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		
			1
	7		
	1		
	1		
	6		
			1
			2
	5		
	16		3
			2
	1		1
	1		
	2		2
	3		3
	2		
			1
	1		1
			1
	1		1
	1		1
	9		
			1
			1
	2		2
	53		3
	2		
	2		
			1
			1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	62		8
	1		1
			1
	2		1
	4		3
	5		
	1		1
			2
	1		
			1
	1		
			1
	2		
	1		
	1		
	3		
	2		1
	1		
			1
	2		
	1		
	1		
	3		
	2		1
	1		
			1
	2		1
			1
	21		4
	6		3
	3		
	1		1
	1		1
	2		1
	3		1
	2		
	2		1

Glomerular filtration rate decreased 1  
 Headache 70  
 Heart rate increased 2  
 Herpes zoster 1  
 Hot flush 3  
 Hyperaesthesia 7  
 Hyperhidrosis 5  
 Hypertension 2  
 Hypertensive crisis 2  
 Hypoacusis 1  
 Hypoaesthesia 1  
 Hypotension 1  
 Hypothyroidism 1  
 Illness 2  
 Inappropriate schedule of product administration 1  
 Influenza like illness 1  
 Initial insomnia 3  
 Insomnia 2  
 Joint range of motion decreased 1  
 Joint stiffness 2  
 Lacrimation increased 1 2  
 Loss of proprioception 1  
 Lymphadenitis 2  
 Lymphadenopathy 21  
 Lymph node pain 6  
 Malaise 3  
 Mental impairment 1  
 Migraine 1  
 Muscle spasms 2  
 Muscular weakness 3  
 Musculoskeletal discomfort 2  
 Musculoskeletal stiffness 2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	42		3
	2		
	1		
	1		
	23		1
	2		1
			3
	1		
	1		
		1	1
			1
	2		
	1		
	3		
1	3		1
	5		2
	1		
			3
	1		6
			2
	1		1
			1
1	1		
	1		
	2		1
	1		
	1		1
	1		2
	1		
	2		2
	74		12
	62		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash		3		2		1
Rash macular		1		1		
Rash pruritic		3		3		
Respiratory distress		1				1
Restless legs syndrome		1		1		
Rhabdomyolysis		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Skin burning sensation		1				1
Skin tightness		1				1
Sleep disorder		1		1		
Sleep disorder due to general medical condition, insomnia type		1		1		
Somatic dysfunction		1				1
Somnolence		8		6		2
Stomatitis		1				1
Syncope		2				2
Tachycardia		6		1		5
Thirst		2		1		1
Throat irritation		4		4		
Tongue spasm		1				1
Toothache		1		1		
Upper respiratory tract congestion		1		1		
Vaccination failure	1	1			1	1
Vaccination site discolouration		1		1		
Vaccination site erythema		12		10		2
Vaccination site haematoma		1				1
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation	1	1	1	1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		2				2
Vaccination site oedema		8		6		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	65	1	62		3
Vaccination site pruritus		4		3		1
Vaccination site rash		2				2
Vaccination site reaction		2		2		
Vaccination site swelling		1		1		
Vaccination site warmth		5		4		1
Vertigo		3		3		
Vision blurred		1				1
Vomiting		7		6		1
	14	871	9	694	5	177

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1		1		
Angina pectoris		1				1
Anosmia	1	1			1	1
Arthralgia		11		11		
Asthenia		5		3		2
Back pain		1		1		
Blepharitis		1		1		
Blood pressure decreased		1		1		
Body temperature increased		9		9		
Bundle branch block left		1				1
Chills		8		8		
COVID-19	2	3			2	3
Disturbance in attention		3				3
Dizziness	1	2		1	1	1
Drug ineffective		1				1
Eye pain		3		3		
Fatigue	1	14		9	1	5
Headache		9		8		1
Head discomfort		1		1		
Hyperhidrosis		2		2		
Hypertension		1		1		
Increased appetite		1		1		
Lymphadenopathy		1		1		
Migraine		1		1		
Muscular weakness		2				2
Myalgia		13		12		1
Nausea		1		1		
Oropharyngeal pain		3		2		1
Pain in extremity		1		1		
Pyrexia		7		4		3
Rash	1	1	1	1		
Rhinorrhoea	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder		1		1		
Somnolence		1		1		
Tachycardia		1				1
Transient ischaemic attack	1	1			1	1
Tunnel vision		1				1
Urticaria	1	1	1	1		
Vaccination failure	2	2			2	2
Vaccination site pain		8		7		1
Vasculitic rash	1	1	1	1		
Vertebrobasilar stroke	1	1			1	1
Vertigo	1	1	1	1		
	14	130	4	96	10	34

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LEBANON**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Back pain		1		1		
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chills	1	3	1	3		
COVID-19		1		1		
Decreased appetite		1		1		
Dermatitis allergic		1		1		
Dizziness		1		1		
Dysphonia		1				1
Dyspnoea		1		1		
Erythema	1	1			1	1
Extrasystoles		1				1
Fatigue	1	1	1	1		
Headache	1	4	1	4		
Hyperhidrosis	1	1	1	1		
Hypersensitivity		1				1
Hypertension	1	2		1	1	1
Hypoaesthesia	1	1	1	1		
Incorrect route of product administration		1		1		
Influenza		1		1		
Insomnia	1	1	1	1		
Irritable bowel syndrome		1		1		
Limb discomfort		1		1		
Loss of consciousness	1	1			1	1
Malaise		1		1		
Mood altered	1	1	1	1		
Muscle twitching		1		1		
Myalgia		2		2		
Oropharyngeal pain		2		2		
Pain		1		1		
Pain in extremity		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		2		2		
Pruritus	1	1			1	1
Pyrexia	1	3	1	3		
Rash		2				2
Respiratory tract oedema		1				1
Throat tightness	1	1			1	1
Urticaria		1		1		
Vaccination site pain		1		1		
Vision blurred	1	1	1	1		
	14	54	9	42	5	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Arthralgia	1	1	1	1		
Back pain		1		1		
Chills		1				1
Dyspnoea	1	1	1	1		
Facial paresis		1				1
Fatigue		1		1		
Flushing	1	1	1	1		
Hypertension		1				1
Panic attack	1	1	1	1		
Paraesthesia		1		1		
Pyrexia		1				1
Sciatica		1		1		
Speech disorder		1		1		
Tachycardia	1	1	1	1		
	5	15	5	10		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient	1	1	1	1		
Chills	2	2	2	2		
COVID-19	7	13	1	3	6	10
Death	10	11			10	11
Dehydration	1	1	1	1		
Diarrhoea	1	1	1	1		
Drug ineffective	2	4			2	4
Facial paralysis	1	1			1	1
Feeling cold	1	1	1	1		
Hypertension	2	2	2	2		
Hypotension	1	1	1	1		
Incorrect route of product administration		1		1		
Lung disorder	1	1			1	1
Paraesthesia		1		1		
Pyelonephritis	1	1			1	1
Pyrexia	1	2	1	2		
Rhinorrhoea	2	2	2	2		
Tachycardia	1	1	1	1		
Throat irritation	2	2	2	2		
Vaccination failure	4	4			4	4
	41	53	16	21	25	32

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**LIECHTENSTEIN**

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**LITHUANIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		3		2		1
Accidental overdose		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Angina pectoris	2	3			2	3
Anxiety	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	3	10	3	9		1
Asthenia	8	23	7	17	1	6
Axillary pain	3	5	3	4		1
Balance disorder		1		1		
Blood pressure abnormal	1	1	1	1		
Blood pressure ambulatory increased	1	1	1	1		
Blood pressure decreased		2				2
Blood pressure fluctuation		2		1		1
Blood pressure increased		7		1		6
Body temperature increased	2	4	2	3		1
Bone pain	3	5	3	5		
Cardiogenic shock		1				1
Chest discomfort		1				1
Chest pain		1		1		
Chills	4	16	4	14		2
Chronic sinusitis	1	1	1	1		
Cognitive disorder		1				1
Cold sweat		1		1		
Condition aggravated		2				2
Confusional state		1		1		
Convulsions local		1				1
Coordination abnormal		1				1
Cough	2	2	2	2		
COVID-19 pneumonia		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	2		
		1	1
		1	1
	4		2
			2
1	8	1	4
	1		
	1		
			1
	1		3
	1		
			1
2	2		1
	1		
1	1		
			1
2	3		
			1
1	1		
1	5	1	5
1	5		1
	1		
	1		
	1		1
5	16	1	7
1	1		
1	5		3
			1
	1		

Death		1
Decreased appetite	1	2
Deep vein thrombosis	1	1
Depressed level of consciousness	1	1
Diarrhoea		6
Disorientation		2
Dizziness	2	12
Dysgeusia		1
Dyspepsia		1
Dysphagia		1
Dyspnoea		4
Ear pain		1
Epilepsy		1
Erythema	2	3
Exposure during pregnancy		1
Eye disorder	1	1
Eyelid function disorder		1
Eye pain	2	3
Facial asymmetry		1
Facial nerve disorder	1	1
Facial paralysis	1	5
Fatigue	1	6
Feeling abnormal		1
Feeling drunk		1
Feeling hot		2
Flatulence		1
Gait disturbance	1	1
Headache	6	23
Head discomfort	1	1
Heart rate increased	1	8
Heart rate irregular		1
Herpes simplex		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	1	1	1	1		
Hyperhidrosis	1	2	1	2		
Hypersensitivity		1				1
Hypertension		2		1		1
Hypertensive crisis		1				1
Hypoacusis		1		1		
Hypoaesthesia	1	9	1	8		1
Hypoaesthesia oral		1				1
Hypotension		1				1
Injected limb mobility decreased	1	1	1	1		
Insomnia	1	1	1	1		
Irritability		1				1
Lacrimation increased		1				1
Lip swelling		1		1		
Local reaction		1				1
Loss of consciousness		4				4
Lymphadenopathy	1	6	1	5		1
Lymph node abscess	9	9			9	9
Lymph node pain		1				1
Lymph node palpable		1				1
Malaise	1	3	1	1		2
Memory impairment		1		1		
Mobility decreased	1	1	1	1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Muscular weakness		2		2		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	2	13	2	11		2
Myositis		1		1		
Nasopharyngitis	3	3	3	3		
Nausea	5	13	4	9	1	4
Neck pain	1	3	1	3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia		1				1
Non-cardiac chest pain	1	1	1	1		
Pain		2		1		1
Pain in extremity	6	14	5	13	1	1
Pain of skin	1	1	1	1		
Pallor	1	1			1	1
Paraesthesia	1	3	1	2		1
Paresis		1				1
Peripheral coldness		1		1		
Peripheral swelling		4		3		1
Peritonitis		1				1
Pneumonia	1	1			1	1
Polymyositis		1				1
Product preparation issue		1				1
Pruritus		2		2		
Pyrexia	6	20	6	19		1
Rash papular		1				1
Rhinorrhoea	1	1	1	1		
Seizure		5				5
Sensation of foreign body		1				1
Skin mass		1				1
Somnolence	1	3	1	3		
Stress		1		1		
Swelling face		1		1		
Syncope		6				6
Tachycardia		2		1		1
Taste disorder		1				1
Tendon pain		1		1		
Thrombosis	1	1			1	1
Tinnitus		2		1		1
Tremor		4		2		2
Underdose		1		1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary incontinence		1		1		
Vaccination failure		1				1
Vaccination site erythema	3	10	3	9		1
Vaccination site induration	1	1	1	1		
Vaccination site inflammation		1		1		
Vaccination site pain	4	17	4	16		1
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling	4	9	4	8		1
Vaccination site warmth		3		2		1
Visual impairment	1	1	1	1		
Vomiting		6		2		4
	117	428	92	278	25	150

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Angina pectoris		1				1	
Apathy		1		1			
Arthralgia	1	4	1	4			
Asthenia	1	1	1	1			
Back pain		1		1			
Chills		1		1			
Cough	1	2	1	2			
COVID-19	1	1	1	1			
Death		2					2
Dizziness		1		1			
Dry eye	1	1	1	1			
Dyspnoea		1		1			
Ear pain	1	1	1	1			
Eye irritation		1		1			
Eye pain	1	2	1	2			
Feeling of body temperature change	1	1	1	1			
Headache	1	3	1	3			
Lacrimation increased	1	2	1	2			
Mucosal disorder	1	1	1	1			
Myalgia	2	6	2	6			
Off label use		1		1			
Overdose		1		1			
Pain in extremity	1	2	1	2			
Peritonsillar abscess	1	1			1		1
Product use issue		1		1			
Pulmonary oedema		1					1
Pyrexia	2	6	2	6			
Rash	1	1	1	1			
Rash maculo-papular	1	1	1	1			
Sensitive skin		1		1			
Slow response to stimuli	1	1	1	1			
Sneezing		1		1			

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence		1		1		
Tonsillar hypertrophy	1	1	1	1		
Tremor		1		1		
Vaccination complication		1		1		
Vaccination site pain	1	2	1	2		
	22	58	21	53	1	5

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Chronic gastritis		1		1		
Diverticulum		1		1		
Haemolytic anaemia		1				1
		4		3		1

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**LUXEMBOURG**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper		1				1
Acute coronary syndrome	1	1			1	1
Allergic oedema	1	1	1	1		
Anxiety	1	2	1	1		1
Arrhythmia	1	1			1	1
Arthralgia	3	12	3	3		9
Asthenia		2				2
Asthmatic crisis		1				1
Blood pressure increased		1				1
Bradypnea		1				1
Chest discomfort	1	3			1	3
Chest pain		1				1
Chillblains	1	1	1	1		
Chills	3	16	3	3		13
Cough		1				1
Decreased appetite		1				1
Dermatitis allergic		1				1
Dermatitis bullous		1				1
Diarrhoea	1	7	1	1		6
Diplopia		1				1
Dizziness	2	5			2	5
Dry mouth		1				1
Dry skin		1				1
Dysaesthesia		1				1
Dysgeusia		1				1
Dysphonia	1	1			1	1
Dyspnoea		4				4
Dyspnoea exertional		1				1
Epilepsy	2	3			2	3
Epistaxis		1				1
Erythema nodosum		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid oedema	2	2	1	1	1	1
Eye movement disorder		1				1
Face oedema	1	2			1	2
Fall		1				1
Fatigue	4	22	2	3	2	19
Feeding disorder		1				1
Feeling abnormal		1				1
Feeling hot		1				1
General physical health deterioration		1				1
Haematoma	1	1	1	1		
Headache	5	28	3	3	2	25
Hemiparaesthesia		1				1
Herpes zoster		1		1		
Hyperhidrosis		1				1
Hypersensitivity		3				3
Hypertension	2	6	1	1	1	5
Hyperthermia	1	1	1	1		
Hypoaesthesia	1	1			1	1
Hypotension	1	4		1	1	3
Influenza	1	4			1	4
Laryngeal discomfort		1				1
Loss of consciousness		1				1
Lymphadenopathy	3	3	3	3		
Malaise	2	11	1	3	1	8
Migraine		1				1
Musculoskeletal stiffness	1	2			1	2
Myalgia	3	19	3	3		16
Nausea	2	9	1	1	1	8
Neck pain		1		1		
Oral herpes		1		1		
Oropharyngeal discomfort		1				1
Oxygen saturation decreased		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain		1				1
Pain in extremity	3	4	2	2	1	2
Palpitations		1				1
Paraesthesia		2				2
Paraesthesia oral	1	1	1	1		
Paresis	1	1			1	1
Peripheral coldness	1	1			1	1
Peripheral swelling	2	3	1	2	1	1
Pneumonia	1	1			1	1
Productive cough		1				1
Pruritus	1	5	1	1		4
Pulmonary embolism	1	1			1	1
Pulmonary pain		1				1
Pyrexia	3	15	1	1	2	14
Rash		2				2
Respiratory failure		1				1
SARS-CoV-2 ant body test negative		1				1
Skin haemorrhage		1				1
Somnolence		1				1
Swelling		1				1
Swelling face		2		1		1
Tachycardia	1	4			1	4
Tetany	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Throat tightness	1	1			1	1
Tinnitus	1	1			1	1
Tongue ulceration		1				1
Tremor	1	2	1	1		1
Urinary incontinence		1				1
Urinary tract infection	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination complication		3				3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain		2				2
Vaccination site reaction	12	17	12	12		5
Vertigo	1	1	1	1		
Vitamin B12 deficiency		1				1
Vlith nerve paralysis	1	1			1	1
Vomiting		4				4
Wheezing		2				2
	84	303	51	60	33	243

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1			1	1
Acute kidney injury		1				1
Altered state of consciousness		1				1
Arrhythmia		1				1
Arthralgia	2	4	1	1	1	3
Asthenia		1		1		
Back pain		1		1		
Cerebral haemorrhage	1	1			1	1
Chest pain		1		1		
Conjunctivitis		1				1
COVID-19	1	1			1	1
Deep vein thrombosis	1	1			1	1
Dizziness		1				1
Dry mouth		1				1
Dysphonia		1				1
Dyspnoea		1				1
Eye pain	1	1			1	1
Fall	1	1			1	1
Fatigue		6				6
Formication		1				1
Haemoglobin decreased		1				1
Headache	4	8	3	3	1	5
Heart rate increased		1				1
Hot flush	1	1			1	1
Hyperhidrosis		1				1
Hypernatraemia		1				1
Hypersomnia		1		1		
Hypertension	1	1			1	1
Hyperthermia		1				1
Hypotension		1				1
Hypoxia		1				1
Influenza		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Injected limb mobility decreased		1					1
Injection site reaction	1	1	1	1			
Insomnia		1					1
Loss of consciousness		1					1
Lung disorder		1					1
Lymphadenopathy		1					1
Malaise	1	1			1		1
Muscular weakness		1					1
Myalgia	2	6	1	2	1		4
Nasopharyngitis		1		1			
Nausea	1	2			1		2
Neck pain	1	1			1		1
Pain in extremity		2					2
Pallor		1					1
Palpitations		2					2
Paraesthesia		1					1
Presyncope		1					1
Pruritus		1					1
Pulmonary embolism	2	2			2		2
Pulse abnormal		1					1
Pyrexia	1	3	1	1			2
Rash		1					1
Rectal haemorrhage		1					1
Sepsis		1					1
Tremor	1	1			1		1
Vaccination complication		1					1
Vaccination site pain		1					1
Vaccination site reaction	4	6	4	4			2
	28	91	11	18	17		73

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Drug ineffective		1				1
Influenza		1		1		
Lymphadenopathy		1		1		
Myalgia		1		1		
		5		3		2

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Country Where Event Occurred

**MACAO**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
		1		1

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Country Where Event Occurred  
**MACEDONIA, THE FORMER YUGOSLAV**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia		1		1		
Body temperature increased		2		2		
Eye oedema		1		1		
Headache	2	3	2	3		
Hypersensitivity		1		1		
Incorrect route of product administration		1		1		
Lip oedema		1		1		
Loss of consciousness	1	1			1	1
Malaise		2		2		
Myalgia	1	2	1	2		
Nasopharyngitis		1		1		
Pyrexia		1		1		
Rhinorrhoea		1		1		
Vaccination site pain	1	1	1	1		
	6	20	5	19	1	1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Administration site pain		1		1
Body temperature increased		1		1
Headache		1		1
Malaise		2		2
Myalgia		1		1
Pyrexia		3		3
Rash maculo-papular		1		1
		10		10

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Country Where Event Occurred

**MALAYSIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Death		1				1
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Malaise		1		1		
Maternal exposure during pregnancy	1	1	1	1		
Pyrexia	1	1	1	1		
Rash erythematous	1	1	1	1		
Rash papular	1	1	1	1		
Skin necrosis	1	1			1	1
Vaccination site pain	1	1	1	1		
	10	12	9	10	1	2

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness		1		1		
Seizure		1				1
Vaccination site pain		1		1		
		3		2		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Constipation	1	1	1	1		
COVID-19		1		1		
Hair texture abnormal	1	1	1	1		
Headache	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Neuropathy peripheral		2				2
No adverse event		1		1		
Urticaria		1		1		
	4	9	4	7		2

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 \* AE=Adverse Event  
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Country Where Event Occurred

**MALTA**

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		2		
Activated partial thromboplastin time prolonged		1		1		
Activated partial thromboplastin time ratio increased		1		1		
Alanine aminotransferase increased		1		1		
Altered state of consciousness		1				1
Anaphylactic reaction	3	7			3	7
Arthralgia	1	2	1	2		
Arthritis infective	1	1			1	1
Asthenia		1		1		
Asthma		2				2
Blood alkaline phosphatase increased		1		1		
Blood osmolarity increased		1		1		
Blood urea increased		1		1		
Bone pain		1		1		
Bronchospasm		1				1
Burning sensation	2	2	1	1	1	1
Cerebellar atrophy		1				1
Cerebral atrophy		1				1
Chest discomfort	2	2			2	2
Chest pain	2	2	1	1	1	1
Chills	1	7	1	7		
Cough		2		1		1
COVID-19		2		1		1
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Decreased appetite		1		1		
Defaecation urgency		1		1		
Dehydration		1		1		
Diarrhoea		3		2		1
Dizziness		4		4		

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
			1
		2	3
		1	4
1	3	1	3
		1	1
			3
3	12		
	1		
		1	1
	1		
	1		
			1
	1		
	1		
1	3		
1	1		
	1		
	3		
	1	3	4
1	1		1
	3		
			1
			1
	1		
	1		
1	5		
	1		1
		1	1
	1		
	1		
	1		

Dysgeusia 2  
 Dysphagia 1  
 Dysphonia 2 3  
 Dyspnoea 1 4  
 Erythema 2 6  
 Eye swelling 1 1  
 Facial paralysis 3  
 Fatigue 3 12  
 Feeling abnormal 1 1  
 Feeling of body temperature change 1 1  
 Gait disturbance 1 1  
 Gait inability 1 1  
 Generalised tonic-clonic seizure 1 1  
 Goitre 1 1  
 Haematocrit decreased 1 1  
 Haemoglobin decreased 1 1  
 Headache 1 3  
 Heart rate increased 1 1  
 Hot flush 1 1  
 Hyperhidrosis 3 3  
 Hypersensitivity 3 5  
 Hypertension 1 2  
 Hypoaesthesia 3 3  
 Hypothermia 1 1  
 Hypoxia 1 1  
 Injection 1 1  
 Insomnia 1 1  
 Lethargy 1 5  
 Limb discomfort 2 2  
 Lip swelling 1 1  
 Lymphadenopathy 1 1  
 Lymphocyte count decreased 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise		4		4		
Mean cell haemoglobin concentration increased		1		1		
Migraine		1		1		
Mobility decreased		1		1		
Monocyte count decreased		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	1	6	1	6		
Nausea		3		2		1
Neck pain	1	2	1	2		
Neutrophil count increased		1		1		
Night sweats		1		1		
Normochromic normocytic anaemia		1		1		
Off label use	1	2	1	2		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain		7		7		
Pain in extremity	1	7	1	6		1
Palpitations	3	5		1	3	4
Panic reaction		1		1		
Paraesthesia		5		5		
Peripheral coldness		1		1		
Peripheral swelling	1	1	1	1		
Platelet count decreased		1		1		
Poor peripheral circulation		1		1		
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Pruritus	3	7	1	3	2	4
Pyrexia	2	13	2	13		
Rash		4		2		2
Rash erythematous		3		1		2
Rash pruritic	1	2			1	2
Red blood cell count decreased		1		1		

\* I=Interval, C=Cumulative  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory depression		1				1
Respiratory distress		1				1
Restlessness		1		1		
Reticulocyte count increased		1		1		
Septic shock		1				1
Sinus tachycardia		1				1
Somnolence		3		3		
Swelling face	2	4		1	2	3
Swollen tongue	1	1			1	1
Syncope	1	2			1	2
Tachycardia		2				2
Tachypnoea		2				2
Throat tightness		1				1
Thrombocytopenia		1				1
Tremor	1	1			1	1
Urticaria		1				1
Vaccination failure		1				1
Vaccination site discomfort		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site induration		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain		4		4		
Vaccination site pruritus	2	2	2	2		
Vaccination site rash	1	1	1	1		
Vaccination site urticaria		2		1		1
Vision blurred	2	2			2	2
Vomiting		3		2		1
Wheezing		2				2
	55	262	24	172	31	90

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		1				1
Arthralgia	1	2	1	2		
Atrial fibrillation		1				1
Basophil count increased		1		1		
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood magnesium decreased		1		1		
Blood phosphorus decreased		1		1		
Blood urea increased		1		1		
Bone pain	1	1	1	1		
Cerebral atrophy		1				1
Cerebrovascular accident	1	1			1	1
Chills	1	3	1	3		
Cough		1		1		
COVID-19	1	3			1	3
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Deep vein thrombosis		1				1
Discomfort		1		1		
Drug ineffective		2				2
Ear swelling		1		1		
Eosinophil count decreased		1		1		
Erythema	1	2	1	2		
Facial paralysis	2	2			2	2
Fatigue	1	4	1	2		2
Flushing	1	1	1	1		
Haematocrit decreased		1		1		
Haemoglobin decreased		1		1		
Headache	3	3	2	2	1	1
Hot flush	1	1	1	1		
Hypersensitivity	1	2	1	2		
Hypertension		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia		1				1
Hypoxia		1				1
Immature granulocyte count increased		1		1		
Influenza like illness		1		1		
Injection site pain		1		1		
Lethargy	3	6	3	6		
Lymphadenopathy	1	1	1	1		
Lymph node pain		1		1		
Lymphocyte count decreased		1		1		
Malaise		2		2		
Monocyte count increased		1		1		
Muscle spasms	1	1	1	1		
Muscle twitching		1		1		
Myalgia	2	3	2	3		
Nausea		1		1		
Neck pain	1	1			1	1
Neutrophil count increased		1		1		
Nucleated red cells		1		1		
Ocular hyperaemia		1		1		
Oropharyngeal pain		1		1		
Pain	2	2	2	2		
Pain in extremity	1	2	1	1		1
Parosmia		1		1		
Periorbital swelling		1		1		
Platelet count increased		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia	3	10	3	8		2
Rash	1	1	1	1		
Red blood cell count decreased		1		1		
Red cell distribution width increased		1		1		
Retinal vein occlusion	1	1			1	1
Sepsis		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling		1				1
Swelling face	1	1	1	1		
Taste disorder	1	1	1	1		
Toothache	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination failure	1	1			1	1
Vaccination site pain	2	8	2	8		
White blood cell count increased		1		1		
	39	112	30	84	9	28

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		4				4
Drug ineffective		4				4
Fear of injection		1		1		
Hot flush		1		1		
Lip swelling		1		1		
Pruritus		1		1		
Syncope		1				1
Urticaria		1		1		
		14		5		9

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Country Where Event Occurred

**MEXICO**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	3	1	2	1	1
Abdominal distension		1		1		
Abdominal pain	31	135	22	117	9	18
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	6	1	5		1
Abdominal symptom	1	1	1	1		
Abnormal faeces	2	4	1	2	1	2
Abscess	3	4	2	3	1	1
Acne	2	2	2	2		
Ageusia		4		3		1
Aggression	2	2	2	2		
Agitation		1		1		
Akathisia		1		1		
Allergy to vaccine		4		3		1
Allodynia		2		2		
Amnesia	1	1			1	1
Anaphylactic reaction	10	24			10	24
Anaphylactic shock	14	40			14	40
Angina pectoris		1				1
Angioedema	2	10			2	10
Anosmia	6	19	5	16	1	3
Antibody test abnormal	1	1	1	1		
Antibody test negative	1	1	1	1		
Anxiety	12	32	6	23	6	9
Aphasia		1		1		
Aphonia	2	2	2	2		
Aphthous ulcer	2	2	2	2		
Arrhythmia	4	6			4	6
Arthralgia	110	431	86	376	24	55
Arthritis	1	1	1	1		
Asterixis	1	1			1	1
Asthenia	198	605	159	527	39	78

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	1	2	1	2		
Asthmatic crisis		1				1
Asymptomatic COVID-19		1				1
Ataxia		1		1		
Atrial fibrillation		1				1
Atrophy	1	1	1	1		
Auricular swelling		1		1		
Axillary pain	1	4	1	4		
Axonal neuropathy		1				1
Back pain	9	27	7	24	2	3
Balance disorder	2	4	1	2	1	2
Blepharitis	1	1	1	1		
Blepharospasm		1		1		
Blindness		1				1
Blindness transient		1				1
Blister	1	2	1	2		
Blood glucose increased	2	3	2	3		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic increased		1		1		
Blood pressure increased	18	41	11	26	7	15
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased	45	127	38	114	7	13
Bone pain		2		1		1
Bradycardia	1	13			1	13
Brain oedema		1				1
Brain stem ischaemia	1	2			1	2
Breast pain		1		1		
Bronchial disorder		2		2		
Bronchospasm	24	63	11	30	13	33
Burning sensation	3	6	2	2	1	4
Cardio-respiratory arrest	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular disorder	1	1	1	1		
Cellulitis	17	35			17	35
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	2	2			2	2
Chest discomfort	4	18	1	13	3	5
Chest pain	18	76	12	60	6	16
Chills	102	412	77	351	25	61
Choking sensation		1				1
Choluria	1	1			1	1
Clonic convulsion		1				1
Colitis		1		1		
Condition aggravated	2	4	1	2	1	2
Confusional state		2		1		1
Conjunctival haemorrhage	3	4			3	4
Conjunctival hyperaemia	1	4		3	1	1
Conjunctivitis	4	12	4	12		
Contusion	2	3	2	3		
Conversion disorder	1	2	1	2		
Cough	63	243	44	201	19	42
Counterfeit product administered	1	1	1	1		
COVID-19	10	31	7	17	3	14
COVID-19 pneumonia	1	3			1	3
C-reactive protein increased		1		1		
Crying	11	26	10	23	1	3
Cyanosis	1	3	1	3		
Cystitis	1	1	1	1		
Deafness		1				1
Deafness unilateral		2				2
Death		2				2
Decreased activity		1		1		
Decreased appetite	20	71	19	64	1	7

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration	1	2	1	2		
Delirium	1	1			1	1
Demyelination		3				3
Depressed level of consciousness	2	4			2	4
Dermatitis allergic	2	2	2	2		
Dermatosis		2		2		
Diabetic ketoacidosis		1				1
Diarrhoea	43	152	28	127	15	25
Diarrhoea haemorrhagic		1				1
Diffuse large B-cell lymphoma	1	1			1	1
Diplegia		1				1
Discharge		1		1		
Discomfort	9	27	8	24	1	3
Disease recurrence	1	4		2	1	2
Disorientation		5		4		1
Disseminated Bacillus Calmette-Guerin infection	4	7			4	7
Disturbance in attention	1	1	1	1		
Diverticulum intestinal	1	1			1	1
Dizziness	157	562	109	452	48	110
Dizziness postural		1		1		
Drug hypersensitivity	1	2			1	2
Drug ineffective	2	12			2	12
Dry mouth	4	16	2	10	2	6
Dry throat	1	2	1	1		1
Dysaesthesia		3		2		1
Dysarthria	1	3	1	3		
Dysgeusia	9	23	8	19	1	4
Dyslalia	1	1			1	1
Dysmenorrhoea		1		1		
Dyspepsia	1	2	1	2		
Dysphagia	1	17	1	13		4
Dysphonia	4	8	2	6	2	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dyspnoea	86	495
Dyspnoea at rest		1
Dyspnoea exertional		5
Dystonia	1	1
Ear discomfort		2
Ear disorder		1
Ear infection		2
Ear pain	1	4
Eating disorder	1	1
Ecchymosis	2	2
Embolism	2	2
Encephalitis post immunisation		1
Epigastric discomfort		1
Epiglottic oedema		1
Epilepsy	1	1
Epistaxis		5
Erythema	51	163
Expired product administered	1	2
Exposure during pregnancy	1	3
External ear inflammation		1
Eye discharge	1	1
Eye disorder	1	3
Eye inflammation		1
Eye injury	3	13
Eye irritation	4	12
Eyelid oedema	3	8
Eyelid pain		1
Eyelid ptosis	2	4
Eyelid rash		1
Eyelid sensory disorder		1
Eyelids pruritus		1
Eye pain	3	13

Spontaneous			
Nonserious		Serious	
I	C	I	C
59	374	27	121
			1
	5		
		1	1
	2		
	1		
	2		
1	3		1
1	1		
1	1	1	1
		2	2
			1
	1		
			1
		1	1
	4		1
39	139	12	24
1	2		
1	3		
	1		
1	1		
1	3		
	1		
1	9	2	4
4	12		
1	6	2	2
	1		
2	4		
	1		
	1		
2	12	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pruritus	1	4	1	4		
Eye swelling	1	3	1	2		1
Face oedema	2	7	2	7		
Facial nerve disorder		2		2		
Facial paralysis	6	20			6	20
Facial paresis	1	3	1	3		
Facial spasm	1	1	1	1		
Faeces discoloured		1		1		
Fall	2	3	1	2	1	1
Fasting	1	1	1	1		
Fatigue	140	474	112	416	28	58
Febrile convulsion	9	20	6	13	3	7
Feeling abnormal	1	6	1	4		2
Feeling cold	2	6	1	5	1	1
Feeling drunk	1	1	1	1		
Feeling hot	3	16	3	11		5
Feeling of body temperature change		1		1		
Feeling of despair		2		2		
Fibrosis	1	1	1	1		
Flushing	1	9		7	1	2
Foreign body sensation in eyes		1		1		
Frequent bowel movements		1		1		
Gait disturbance	1	4	1	4		
Gastritis	1	3	1	3		
Gastroenteritis		1		1		
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal hypermotility	1	1	1	1		
Gastrointestinal hypomotility	1	1	1	1		
Gastrointestinal motility disorder	1	2	1	2		
Generalised tonic-clonic seizure	1	3			1	3
General physical condition abnormal		1				1
General physical health deterioration	1	8	1	8		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Genital paraesthesia	1	1	1	1		
Genital tract inflammation		1		1		
Gingival bleeding	1	1	1	1		
Gingival pain	1	1	1	1		
Gingival swelling	1	1	1	1		
Glabellar reflex abnormal		1		1		
Glossodynia	1	1	1	1		
Groin pain	1	1	1	1		
Guillain-Barre syndrome	2	4			2	4
Haematochezia	5	11			5	11
Haematoma	2	2	2	2		
Haemolytic anaemia	1	1			1	1
Haemoptysis		1		1		
Haemorrhage	12	16			12	16
Haemorrhagic disorder	6	6			6	6
Hallucination, visual	1	2			1	2
Headache	270	890	208	758	62	132
Head discomfort		2		2		
Heart rate abnormal		2		2		
Heart rate decreased		1		1		
Heart rate increased	4	11	4	10		1
Hemiparaesthesia	3	6			3	6
Hemiparesis	3	10			3	10
Hemiplegia		2				2
Hepatic pain		1		1		
Herpes zoster	1	2	1	2		
Hot flush		1		1		
Hunger		2		2		
Hyperaemia	2	6	2	5		1
Hyperaesthesia	1	6	1	6		
Hyperglycaemia	1	2			1	2
Hyperhidrosis	7	32	2	20	5	12

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperpyrexia		1				1	
Hyperreflexia	1	1	1	1			
Hypersensitivity	6	32	5	26	1	6	
Hypersomnia	1	2	1	2			
Hypertension	21	80	10	49	11	31	
Hypertensive crisis	9	50			9	50	
Hypertensive emergency	1	2			1	2	
Hyperthermia	2	10	1	9	1	1	
Hypoacusis		1		1			
Hypoaesthesia	7	29	5	19	2	10	
Hypoaesthesia oral	4	14	3	11	1	3	
Hypoglycaemia		1				1	
Hypokinesia	1	8	1	7		1	
Hyposmia	1	1	1	1			
Hypotension	4	14	2	7	2	7	
Hypothermia	3	13			3	13	
Hypotonia	2	3	2	3			
Hypoventilation	1	2			1	2	
Hypovolaemic shock	12	19			12	19	
Hypoxia	1	1			1	1	
Immunology test abnormal	1	1	1	1			
Inappropriate schedule of product administration	2	6	2	6			
Incorrect route of product administration	1	1	1	1			
Induration	44	124	38	114	6	10	
Inflammation	34	126	29	114	5	12	
Influenza	1	4	1	4			
Influenza like illness	1	1	1	1			
Injection site haemorrhage		1		1			
Injection site pain	1	1	1	1			
Insomnia	1	3	1	3			
Intracranial aneurysm	1	1			1	1	
Intussusception	7	10			7	10	

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Irritability	29	89	20	73	9	16
Irritability postvaccinal		2		2		
Ischaemic stroke	1	1			1	1
Jaundice	1	1			1	1
Joint injury		1		1		
Joint range of motion decreased	1	1	1	1		
Joint stiffness		1		1		
Joint swelling		1		1		
Lacrimation increased	3	10	3	10		
Laryngeal inflammation		1				1
Laryngeal oedema	3	6			3	6
Laryngospasm	1	3	1	1		2
Larynx irritation		1				1
Laziness	1	1	1	1		
Lethargy	1	3		1	1	2
Leukopenia		2				2
Limb discomfort	2	3	2	2		1
Lip discolouration		1		1		
Lip disorder		1		1		
Lip oedema	3	7	3	7		
Lip pain	1	1	1	1		
Livedo reticularis	2	3	2	3		
Localised oedema	2	3	2	3		
Local reaction	10	36	10	35		1
Loss of consciousness	2	15			2	15
Loss of personal independence in daily activities		2		1		1
Lung disorder	1	1	1	1		
Lymphadenitis	1	2	1	2		
Lymphadenopathy	27	73	24	65	3	8
Lymphangitis		1				1
Lymph node pain		1		1		
Lymphopenia		1		1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	24	74	18	64	6	10
Mass		1		1		
Maternal exposure during pregnancy	5	14	5	14		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Mean cell haemoglobin decreased	1	1	1	1		
Mean cell volume decreased	1	1	1	1		
Mean platelet volume decreased	1	1	1	1		
Mechanical urticaria		1		1		
Meningitis		2				2
Menstrual disorder		1		1		
Metamorphopsia		1		1		
Metrorrhagia		1		1		
Migraine	1	1	1	1		
Mobility decreased	1	7	1	7		
Monocyte count increased	1	1	1	1		
Mononeuropathy		2				2
Monoparesis	2	3	1	1	1	2
Monoplegia		1				1
Motor dysfunction		1		1		
Mouth haemorrhage		1				1
Movement disorder	2	6	1	4	1	2
Mucosal dryness	1	1	1	1		
Mucous stools		1		1		
Muscle atrophy		1		1		
Muscle contractions involuntary	1	5		3	1	2
Muscle contracture		2		2		
Muscle fatigue	2	2	2	2		
Muscle rigidity		1		1		
Muscle spasms	3	9	3	8		1
Muscle spasticity		1				1
Muscle strength abnormal	1	1	1	1		
Muscle tightness		1		1		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	10	5	8
1	1		
1	2		
101	444	25	58
			1
			1
		1	2
		1	1
	1		
1	1		
	1		
		1	1
2	14		
1	2		
1	2		
1	4		
101	366	38	67
			1
5	19		
			1
	3		
			1
1	1		
2	5		2
			2
	1		
42	125	6	14
1	1		
	1		
			1
1	1		
3	6	1	1

Muscular weakness	7	18
Musculoskeletal chest pain	1	1
Musculoskeletal stiffness	1	2
Myalgia	126	502
Myelitis		1
Myelitis transverse		1
Myocardial infarction	1	2
Myoclonic epilepsy	1	1
Myoclonus		1
Myopathy	1	1
Nail discolouration		1
Narcolepsy	1	1
Nasal congestion	2	14
Nasal obstruction	1	2
Nasal pruritus	1	2
Nasopharyngitis	1	4
Nausea	139	433
Near death experience		1
Neck pain	5	19
Nerve degeneration		1
Nervousness		3
Nervous system disorder		1
Neuralgia	1	1
Neuritis	2	5
Neuropathy peripheral		2
Night sweats		1
Nodule	48	139
Noninfective gingivitis	1	1
Nystagmus		1
Obstructive airways disorder		1
Ocular discomfort	1	1
Ocular hyperaemia	4	7

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Odynophagia	17	47	12	38	5	9
Oedema	46	181	35	151	11	30
Oedema peripheral	7	14	6	13	1	1
Off label use	2	9	2	9		
Oral candidiasis	1	1	1	1		
Oral discomfort	1	1			1	1
Oral disorder	2	2	1	1	1	1
Oral dysaesthesia		1		1		
Oral herpes	1	1	1	1		
Oropharyngeal discomfort		7		4		3
Oropharyngeal pain	63	277	50	247	13	30
Otitis externa		1		1		
Otitis media	1	1	1	1		
Otitis media acute		1		1		
Overdose	1	1	1	1		
Oxygen saturation abnormal	2	9	1	5	1	4
Oxygen saturation decreased	7	34	5	20	2	14
Pain	168	556	139	488	29	68
Pain in extremity	29	64	29	61		3
Pain in jaw		1		1		
Pain of skin		1		1		
Pallor	1	8	1	6		2
Palpitations	5	19	4	15	1	4
Panic attack	1	1	1	1		
Papule	1	2	1	2		
Paraesthesia	34	104	21	74	13	30
Paraesthesia mucosal	1	1			1	1
Paraesthesia oral	12	29	8	21	4	8
Paralysis	2	13			2	13
Paraparesis	1	1			1	1
Paresis	2	2	2	2		
Pelvic discomfort	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pelvic pain		1		1			
Pericardial disease	1	1	1	1			
Periorbital oedema		1		1			
Peripheral coldness	3	8	2	7	1	1	
Peripheral motor neuropathy		1					1
Peripheral swelling	2	3	1	1	1	2	
Peripheral vascular disorder	1	1			1	1	
Peroneal nerve injury		1					1
Persistent depressive disorder		1		1			
Petechiae	1	3			1	3	
Petit mal epilepsy		1					1
Pharyngeal disorder	1	3	1	3			
Pharyngeal erythema	1	1	1	1			
Pharyngeal hypoaesthesia		1					1
Pharyngeal inflammation		2					2
Pharyngeal oedema		5					5
Pharyngeal paraesthesia	2	5	1	2	1	3	
Photophobia		3		3			
Photopsia	2	5	1	3	1	2	
Photosensitivity reaction		1		1			
Pigmentation disorder		1		1			
Platelet count decreased	1	1			1	1	
Platelet count increased	1	1	1	1			
Pneumonia	3	15			3	15	
Poor quality product administered	2	2	2	2			
Presyncope	1	4	1	2		2	
Product colour issue	1	1	1	1			
Product complaint	1	1	1	1			
Productive cough	2	3	1	2	1	1	
Product use issue	1	6	1	6			
Prurigo		1		1			
Pruritus	59	158	43	125	16	33	

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pulmonary oedema		1				1	
Pulmonary pain	1	1	1	1			
Purpura		3		2		1	
Pyelonephritis		1				1	
Pyrexia	108	373	91	329	17	44	
Radiculitis brachial	1	1	1	1			
Radiculopathy		2				2	
Rales		1		1			
Rash	41	135	32	103	9	32	
Rash erythematous		1		1			
Rash macular	1	2	1	1		1	
Rash maculo-papular	2	4	1	3	1	1	
Raynaud's phenomenon	1	2	1	2			
Reflexes abnormal	1	1	1	1			
Respiratory arrest	1	1			1	1	
Respiratory disorder	1	2	1	2			
Respiratory distress	81	492			81	492	
Respiratory failure	1	1			1	1	
Respiratory tract infection viral		1		1			
Restlessness		1		1			
Rhinalgia		1		1			
Rhinitis	1	3	1	3			
Rhinorrhoea	45	208	43	193	2	15	
Ruptured cerebral aneurysm		1				1	
Sacroiliitis		1				1	
Salivary hypersecretion	1	1	1	1			
SARS-CoV-2 ant body test negative		1		1			
Sciatica		1				1	
Sciatic nerve neuropathy		1				1	
Screaming	1	1	1	1			
Secretion discharge		1		1			
Seizure	15	51			15	51	

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	6	8	12
	1		
126	387	25	53
	1		
1	1		1
		1	1
		1	3
	1	1	2
1	1		
1	2		
	1		
	1		
	1		
1	1		
	2		
1	1		
		1	1
	2		
	1		
1		1	1
			1
	2		
1	1		
1	2		
3	13	1	2
1	2		
1	1		
	1		
			1
2	3	2	3
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stress	1	1	1	1		
Stridor	1	2			1	2
Subarachnoid haemorrhage	1	2			1	2
Suffocation feeling		2		2		
Suspected counterfeit product	1	1	1	1		
Suspected COVID-19	1	4		3	1	1
Sweating fever		1				1
Swelling	4	7	4	5		2
Swelling face	2	3	1	2	1	1
Swollen tongue	1	1	1	1		
Syncope	7	55			7	55
Synovial cyst	2	2	2	2		
Systemic lupus erythematosus		1				1
Tachyarrhythmia		1		1		
Tachycardia	90	366	58	282	32	84
Tachypnoea	5	9	1	3	4	6
Taste disorder	1	1	1	1		
Temperature intolerance		2		2		
Temperature regulation disorder	1	1	1	1		
Tenderness		3		3		
Tension headache		1		1		
Thermal burns of eye	1	2			1	2
Thirst		3		2		1
Throat irritation	1	14	1	12		2
Throat tightness	2	3	1	2	1	1
Thrombocytopenia	1	1			1	1
Thrombocytopenic purpura	2	3	1	2	1	1
Thrombosis	1	1			1	1
Tinnitus	3	10	1	7	2	3
Tongue oedema		3		2		1
Tongue paralysis	1	1			1	1
Toothache		2		2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Transaminases increased		1					1
Tremor	6	17	5	16	1		1
Tympanic membrane disorder		1		1			
Type I hypersensitivity		1					1
Upper-airway cough syndrome		1		1			
Upper airway obstruction		1					1
Urinary incontinence		1		1			
Urinary tract infection		1		1			
Urticaria	7	12	5	10	2		2
Vaccination complication	2	2	1	1	1		1
Vaccination site abscess	1	2	1	2			
Vaccination site cellulitis	6	19	5	11	1		8
Vaccination site discolouration	1	1	1	1			
Vaccination site discomfort	3	4	3	4			
Vaccination site erythema	10	21	9	19	1		2
Vaccination site haematoma	1	1	1	1			
Vaccination site haemorrhage	1	2	1	1			1
Vaccination site hyperaesthesia	2	4	2	4			
Vaccination site hypersensitivity	10	34	10	34			
Vaccination site hypoaesthesia	1	3	1	3			
Vaccination site induration	9	29	8	24	1		5
Vaccination site inflammation	5	17	4	15	1		2
Vaccination site joint movement impairment	1	1	1	1			
Vaccination site joint pain		1		1			
Vaccination site movement impairment		3		3			
Vaccination site nodule	4	12	3	10	1		2
Vaccination site oedema	5	17	4	14	1		3
Vaccination site pain	79	234	75	223	4		11
Vaccination site paraesthesia	1	4	1	4			
Vaccination site pruritus	3	5	3	5			
Vaccination site rash	1	1	1	1			
Vaccination site reaction	4	16	4	15			1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site recall reaction	1	1	1	1		
Vaccination site swelling	2	3	2	3		
Vaccination site warmth	1	14	1	14		
Vaginal haemorrhage		1		1		
Vasodilatation		1		1		
Vertigo	9	27	8	22	1	5
Vestibular neuronitis		1				1
Vision blurred	7	27	6	23	1	4
Visual impairment		1		1		
Vomiting	61	175	39	137	22	38
Wheezing	2	2			2	2
Wrong technique in product usage process	5	5	5	5		
Xerophthalmia	1	1			1	1
	3,725	12,727	2668	9793	1057	2934

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1		1		
Abdominal pain	15	38	13	33	2	5
Abdominal pain upper	1	3	1	3		
Abscess	4	4	4	4		
Acute myocardial infarction	1	2			1	2
Affect lability		1		1		
Ageusia		3		3		
Alanine aminotransferase increased	1	1	1	1		
Anaphylactic reaction		3				3
Anaphylactic shock		5				5
Anosmia	3	8	3	8		
Antibody test abnormal		1		1		
Antibody test negative	1	2	1	2		
Anxiety	4	11	3	7	1	4
Aphasia		1		1		
Application site pain		1		1		
Arrhythmia		2				2
Arthralgia	53	160	49	146	4	14
Aspartate aminotransferase increased	1	1			1	1
Asthenia	76	208	63	184	13	24
Asthmatic crisis		1				1
Atrial fibrillation		1				1
Atypical pneumonia		1				1
Aura		1				1
Axillary mass		1		1		
Axillary pain	2	3	2	3		
Back pain	3	6	3	6		
Balance disorder	1	1	1	1		
Blister	1	2			1	2
Blood glucose decreased		1				1
Blood pressure abnormal	1	3	1	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Blood pressure increased	4	8	2	5	2	3
Body temperature increased	11	31	10	26	1	5
Bowel movement irregularity		1		1		
Bradycardia	1	6			1	6
Bronchospasm	4	10	3	8	1	2
Burning sensation	1	1	1	1		
Burn oral cavity	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Catarrh	1	1	1	1		
Cellulitis	2	9			2	9
Cerebral haematoma		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort		2		2		
Chest pain	4	17	3	15	1	2
Chills	43	133	36	117	7	16
Choking	1	1			1	1
Choluria		1				1
Coagulation time prolonged		1				1
Cold sweat		1		1		
Colitis	1	1	1	1		
Condition aggravated		1				1
Confusional state		2		2		
Conjunctival haemorrhage		1				1
Cough	18	64	17	57	1	7
Counterfeit product administered	3	3	3	3		
COVID-19	9	28	7	15	2	13
COVID-19 pneumonia		2				2
Crying	2	6	2	6		
Cyanosis	1	2		1	1	1
Death	1	1			1	1
Decreased appetite	8	19	8	16		3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deficiency of bile secretion		1				1
Dehydration		3		1		2
Demyelinating polyneuropathy	1	1			1	1
Depressed level of consciousness		3				3
Diabetes mellitus	1	1			1	1
Diarrhoea	25	75	19	62	6	13
Diplopia	1	2	1	2		
Discomfort	5	16	3	14	2	2
Disease recurrence		1		1		
Disorientation	1	3		2	1	1
Disseminated Bacillus Calmette-Guerin infection	3	5			3	5
Disturbance in attention		1		1		
Dizziness	41	136	34	117	7	19
Drug hypersensitivity	1	1			1	1
Drug ineffective	3	14			3	14
Dry mouth	3	6	3	5		1
Dysaesthesia		2		2		
Dysgeusia	3	4	3	4		
Dyskinesia	1	1	1	1		
Dyslipidaemia	1	1	1	1		
Dyspnoea	26	115	19	89	7	26
Dyspnoea exertional	1	1	1	1		
Dysstasia		2		1		1
Dystonia	1	1			1	1
Ear discomfort		3		3		
Ear infection	1	1	1	1		
Ear pain	2	4	2	4		
Ecchymosis		1		1		
Electrolyte imbalance		1				1
End stage renal disease	1	1			1	1
Epiglottic oedema		1				1
Epistaxis	3	4	1	2	2	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Erythema	9	26
Exposure to SARS-CoV-2		1
Eye injury		6
Eye irritation		2
Eyelid ptosis	1	1
Eye movement disorder		1
Eye pain	3	7
Facial paralysis	2	9
Fall	2	3
Fatigue	52	166
Febrile convulsion	2	11
Feeling abnormal	1	1
Feeling cold		1
Feeling of despair	1	1
Flank pain		1
Flushing		1
Foreign body in throat		1
Gait disturbance	1	2
Gastritis	1	1
Gastroenteritis	1	1
Gastrointestinal disorder		1
Gastrointestinal motility disorder	1	1
Gastroesophageal reflux disease	1	1
Generalised oedema	1	1
Generalised tonic-clonic seizure	2	5
General physical health deterioration	1	4
General symptom	1	1
Guillain-Barre syndrome	5	5
Haematochezia	4	8
Haemorrhage	10	10
Haemorrhagic disorder	3	4
Hallucination, visual		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
7	23	2	3
	1		
	5		1
	2		
1	1		
			1
3	7		
		2	9
1	1	1	2
45	149	7	17
2	9		2
1	1		
	1		
1	1		
	1		
	1		
			1
1	2		
1	1		
		1	1
			1
1	1		
		2	5
1	4		
		1	1
		5	5
		4	8
		10	10
		3	4
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	85	264	74	238	11	26
Heart rate increased		3		3		
Heart rate irregular		1				1
Hemiparaesthesia	1	2			1	2
Hemiparesis		1				1
Hepatic function abnormal	1	1	1	1		
Hip fracture		1				1
Hot flush	1	2	1	2		
Hyperaemia	1	1	1	1		
Hyperaesthesia	1	1	1	1		
Hyperbilirubinaemia		1				1
Hyperglycaemia	2	2	2	2		
Hyperhidrosis	6	14	3	11	3	3
Hypernatraemia		1				1
Hypersensitivity	1	7		4	1	3
Hypertension	6	22	2	10	4	12
Hypertensive crisis	2	17			2	17
Hyperthermia	4	6	4	6		
Hypoacusis		2		2		
Hypoaesthesia	2	10	2	9		1
Hypoaesthesia oral		1		1		
Hypokinesia	1	1	1	1		
Hyposmia		1		1		
Hypotension	5	11	2	6	3	5
Hypothermia	1	4			1	4
Hypovolaemic shock	8	12			8	12
Inappropriate schedule of product administration	2	4	2	4		
Induration	17	41	16	38	1	3
Inflammation	8	21	7	18	1	3
Influenza	1	1	1	1		
Influenza like illness		2		2		
Insomnia	1	2		1	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intussusception	2	3			2	3
Irritability	10	23	6	18	4	5
Irritability postvaccinal		1		1		
Jaundice		1				1
Lacrimation increased		3		3		
Laryngeal obstruction		1				1
Laryngeal oedema		1				1
Lateropulsion		1				1
Leukopenia		1				1
Limb discomfort	1	1	1	1		
Lip disorder		1		1		
Local reaction	4	17	4	15		2
Loss of consciousness	2	4			2	4
Lymphadenopathy	9	15	9	14		1
Lymphopenia		1				1
Malaise	11	32	10	29	1	3
Masticatory pain		1		1		
Measles	1	1			1	1
Melaena	1	1			1	1
Mobility decreased	1	7	1	7		
Mouth swelling	1	1			1	1
Movement disorder	1	1			1	1
Mucosal dryness	1	1	1	1		
Muscle fatigue		1		1		
Muscle spasms		2		2		
Muscle tightness	1	1	1	1		
Muscular weakness	3	8	1	5	2	3
Myalgia	62	196	53	174	9	22
Myalgia intercostal	1	1	1	1		
Nasal abscess	1	1			1	1
Nasal congestion	1	3	1	3		
Nasopharyngitis	1	3		1	1	2

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
36	104	8	21
4	4		
1	1		1
		1	1
2	2		
		1	1
17	41	1	3
	1		
	3		
3	14		1
6	27	3	7
1	3		
2	3		
	1		
	1		
	1	1	2
11	54	2	6
	5		1
43	145	13	22
	2		
8	15	2	2
			1
1	2		
	1		
	1		
2	4		
7	23	1	2
		1	1
		3	13
		1	1
	1		

Nausea	44	125
Neck pain	4	4
Nervousness	1	2
Nervous system disorder	1	1
Neutrophil count increased	2	2
Night sweats	1	1
Nodule	18	44
Ocular discomfort		1
Ocular hyperaemia		3
Odynophagia	3	15
Oedema	9	34
Oedema peripheral	1	3
Off label use	2	3
Oral administration complication		1
Oral candidiasis		1
Oropharyngeal discomfort	1	3
Oropharyngeal pain	13	60
Oxygen saturation decreased		6
Pain	56	167
Painful respiration		2
Pain in extremity	10	17
Pain in jaw		1
Pain of skin	1	2
Palate injury		1
Pallor		1
Palmar erythema		1
Palpitations	2	4
Paraesthesia	8	25
Paraesthesia oral	1	1
Paralysis	3	13
Paraparesis	1	1
Parosmia		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
	1		
1	1		
1	2		
1	1		
			1
1	2		
	1		
2	2		
	1		
2	5		
	1		
	1		
1	2		
	1		
8	26	1	4
38	149	5	16
8	28	3	9
	1		1
1	1		
1	1	1	1
1	1	1	1
24	113	24	113
1	2	1	2
	1		
19	62	2	5
	1		1
	1		
1	3		2
	1		1
2	13	2	13

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sensitisation		1		1			
Sensitive skin	54	134	42	117	12	17	
Septic shock	1	1			1	1	
Shock		1				1	
Sinus tachycardia	1	1	1	1			
Skin discolouration	1	1	1	1			
Skin lesion	1	1	1	1			
Somnolence	2	8	2	8			
Stasis dermatitis	1	1	1	1			
Stevens-Johnson syndrome	1	2			1	2	
Sudden infant death syndrome	1	1			1	1	
Suffocation feeling		1				1	
Suspected counterfeit product	3	3	3	3			
Suspected COVID-19	1	1			1	1	
Swelling	1	2	1	2			
Swollen tongue	1	1	1	1			
Syncope	8	23			8	23	
Tachycardia	21	78	15	62	6	16	
Tachypnoea	1	4		2	1	2	
Tenderness		1		1			
Thermal burn	1	1			1	1	
Thirst		1		1			
Thrombocytopenia		1				1	
Thrombosis	2	2			2	2	
Tinnitus	1	4	1	4			
Toxic epidermal necrolysis	1	1			1	1	
Toxicity to various agents	1	1			1	1	
Transaminases increased		1				1	
Traumatic lung injury		2		2			
Tremor	4	7	3	6	1	1	
Urinary incontinence		1		1			
Urinary tract infection	1	1	1	1			

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	2	2	2	2		
Vaccination site cellulitis	2	5	2	3		2
Vaccination site discomfort	2	3	2	3		
Vaccination site erythema		2		2		
Vaccination site haematoma	1	1	1	1		
Vaccination site hypersensitivity	1	3	1	3		
Vaccination site induration	1	4	1	4		
Vaccination site inflammation		2		2		
Vaccination site movement impairment	3	4	3	4		
Vaccination site nodule		2		2		
Vaccination site pain	32	80	30	75	2	5
Vaccination site pruritus		2		1		1
Vaccination site rash		1				1
Vaccination site reaction	2	5	2	5		
Vaccination site swelling	3	3	3	3		
Vaccination site warmth		1		1		
Vascular test abnormal		1		1		
Vertigo	2	7	2	6		1
Vision blurred	1	4	1	3		1
Vomiting	23	56	17	42	6	14
Wheezing	1	4		2	1	2
White blood cell count increased		1				1
Wrong product administered	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	1,272	3,786	962	2955	310	831

\* I=Interval, C=Cumulative  
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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abnormal faeces		1		1		
Allergy to vaccine		3		3		
Anaphylactoid reaction		1				1
Arthralgia		25		25		
Asthenia		22		21		1
Back pain		1		1		
Blood pressure increased		1				1
Body temperature increased		5		5		
Chest discomfort		1		1		
Chest pain		1				1
Chills		10		10		
Cough		9		9		
COVID-19	1	4	1	1		3
COVID-19 pneumonia		1				1
Decreased appetite		3		3		
Diarrhoea		4		4		
Discomfort		4		4		
Dizziness		14		13		1
Drug ineffective		4				4
Dysgeusia		2		2		
Dyspnoea		7		3		4
Ear pain		1		1		
Epilepsy		1				1
Erythema		3		3		
Erythema multiforme		1				1
Exposure via breast milk		1		1		
Eye pain		1		1		
Fatigue		1		1		
Feeling hot		1		1		
Headache		39		38		1
Hot flush		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	1		1
			2
	1		
	2		
	1		
	2		
	3		
	2		
	22		
	10		
	1		
	1		
	1		
	8		
	3		
	1		1
	13		1
	2		
	1		
	4		1
	2		1
	1		
	1		
	3		3
	3		
	20		
	10		1
	1		
	6		
	5		5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensitive skin		1		1		
Sensory loss		1		1		
Suspected COVID-19		1				1
Swelling		1		1		
Syncope		2				2
Tachycardia		12		10		2
Urticaria		1		1		
Vaccination site erythema		2		2		
Vaccination site hyperaesthesia		1		1		
Vaccination site induration		2		2		
Vaccination site inflammation		1		1		
Vaccination site nodule		3		3		
Vaccination site oedema		1		1		
Vaccination site pain		31		30		1
Vaccination site rash		1		1		
Vomiting		3		3		
Wrong product administered	1	1	1	1		
	2	378	2	336		42

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Country Where Event Occurred

**MONACO**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
Drug ineffective		1		1
Speech disorder		1		1
		3		3

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Country Where Event Occurred

**NETHERLANDS**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	3	11			3	10		1
Abdominal pain	9	10			7	8	2	2
Abdominal pain lower	1	1			1	1		
Abdominal pain upper	1	9			1	9		
Abnormal behaviour	1	1					1	1
Abnormal dreams		1				1		
Abnormal faeces		1						1
Abnormal loss of weight	1	1			1	1		
Abortion missed	2	2					2	2
Abortion spontaneous	8	10					8	10
Acne	1	1			1	1		
Acute coronary syndrome		1						1
Acute kidney injury	1	1					1	1
Acute myocardial infarction	3	3					3	3
Adrenal disorder		1						1
Affect lability	1	1			1	1		
Ageusia	2	5			2	5		
Agitation	1	1			1	1		
Allergy to vaccine		1		1				1
Allodynia		1				1		
Altered state of consciousness		1						1
Amaurosis fugax	1	1			1	1		
Amnesia	2	2					2	2
Amylase increased	1	1			1	1		
Anal sphincter hypertonia		1				1		
Anamnestic reaction	1	1					1	1
Anaphylactic reaction	1	13					1	13
Anaphylactic shock	1	4					1	4
Anembryonic gestation	1	1					1	1
Aneurysm		1						1
Angina pectoris	3	5					3	5
Angina unstable		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angioedema	7	12
Anosmia	1	4
Anxiety	5	6
Aortic dissection	1	1
Aortic valve stenosis	1	2
Apallic syndrome	1	2
Apathy		1
Aphasia	4	12
Aphonia		3
Aphthous ulcer		1
Arrhythmia	8	12
Arthralgia	143	339
Arthritis	1	2
Asthenia	4	11
Asthma		3
Ataxia	1	2
Atrial fibrillation	4	16
Auricular swelling		1
Autonomic nervous system imbalance		2
Axillary pain	3	15
Azotaemia		2
Back pain	3	7
Bacterial infection	1	1
Bacterial test positive	1	1
Balance disorder	2	7
Basilar artery thrombosis		1
Bedridden		2
Blindness	3	6
Blindness unilateral	2	3
Blister	1	2
Blood alkaline phosphatase increased	1	1
Blood bilirubin increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	12
		1	4		
		5	5		1
				1	1
				1	2
				1	2
			1		
		1	3	3	9
			1		2
			1		
				8	12
		139	331	4	8
		1	1		1
		4	8		3
					3
				1	2
1	1			4	16
			1		
					2
		3	15		
					2
		3	7		
				1	1
				1	1
		1	5	1	2
					1
			1		1
1	1			3	6
				2	3
			1	1	1
		1	1		
		1	2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood cholesterol increased		1
Blood creatinine increased		1
Blood glucose decreased	1	1
Blood glucose fluctuation		1
Blood glucose increased	1	4
Blood potassium decreased	1	1
Blood pressure decreased		5
Blood pressure increased	6	10
Blood pressure systolic increased	1	2
Blood sodium decreased	1	1
Blood urea increased	1	2
Blood uric acid increased		1
Body temperature decreased		1
Body temperature increased	8	51
Bradycardia		4
Bradykinesia	1	1
Bradyphrenia	1	2
Brain death	1	1
Breast disorder female		1
Bronchitis		1
Bronchospasm		1
Bundle branch block right		1
Burning sensation	2	4
Cachexia		2
Candida infection		1
Cardiac arrest	3	10
Cardiac asthma	2	3
Cardiac death	1	1
Cardiac disorder	2	3
Cardiac failure	5	18
Cardiac failure congestive		1
Carotid arteriosclerosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	1		
			1		
		1	3		1
		1	1		
			1		4
		4	7	2	3
			1	1	1
		1	1		
		1	2		
			1		
					1
		8	48		3
					4
		1	1		
		1	1		1
				1	1
			1		
					1
			1		
		2	4		
					2
					1
				3	10
				2	3
				1	1
		1	1	1	2
				5	18
					1
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Catatonia		2
Cerebellar haematoma	1	1
Cerebellar infarction	1	1
Cerebellar ischaemia	1	1
Cerebral amyloid angiopathy	1	1
Cerebral haemorrhage	3	3
Cerebral infarction	9	15
Cerebral ischaemia	1	2
Cerebral thrombosis	3	3
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	1	17
Cervical radiculopathy	1	1
Chest discomfort	7	14
Chest injury	1	1
Chest pain	13	29
Chillblains	3	3
Chills	192	474
Choking		1
Choking sensation		2
Cholecystitis		1
Chorea		1
Chronic obstructive pulmonary disease		2
Circulatory collapse		2
Coagulopathy	1	1
Cognitive disorder		1
Cold sweat	3	7
Coma hepatic		1
Concussion		1
Condition aggravated	1	5
Confusional state	12	16
Conjunctival haemorrhage		2
Consciousness fluctuating		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	1
				1	1
				1	1
				3	3
				9	15
				1	2
				3	3
				1	1
				1	17
		1	1		
		5	10	2	4
				1	1
		10	23	3	6
		3	3		
		189	463	3	11
					1
					2
					1
					1
					2
					2
		1	1		
					1
		3	5		2
					1
					1
			2	1	3
		4	7	8	9
					2
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Constipation		2
Contusion	5	5
Conversion disorder		1
Coombs negative haemolytic anaemia	1	1
Coordination abnormal	3	5
Cough	2	13
COVID-19	4	15
C-reactive protein increased	3	6
Cyanosis		1
Cystitis	2	6
Cystitis noninfective	1	1
Dacryocystitis	1	1
Dandruff		1
Dark circles under eyes		1
Deafness	1	1
Deafness transitory	1	1
Deafness unilateral	1	3
Death	2	12
Decreased appetite	5	17
Deep vein thrombosis	15	17
Dehydration	1	4
Delirium	4	11
Delirium febrile		1
Dementia		1
Depressed level of consciousness	2	8
Depressed mood	1	3
Depression	1	3
Derealisation		1
Dermatitis	1	1
Dermatitis allergic	1	1
Dermatitis bullous	1	2
Diabetes mellitus inadequate control	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		3	3	2	2
					1
				1	1
		2	3	1	2
		2	11		2
		1	6	3	9
		3	4		2
					1
		2	4		2
				1	1
				1	1
			1		
			1		
				1	1
				1	1
			1	1	2
				2	12
		3	12	2	5
				15	17
			1	1	3
				4	11
					1
					1
				2	8
		1	3		
			1	1	2
			1		
		1	1		
		1	1		
				1	2
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diaphragmalgia		1
Diarrhoea	16	35
Dilatation atrial		1
Diplopia	5	7
Discomfort	3	5
Disease recurrence	3	3
Disorganised speech		1
Disorientation	2	2
Disturbance in attention		3
Dizziness	30	104
Drug hypersensitivity		1
Drug ineffective	2	5
Dry eye	1	2
Dry mouth		2
Dysarthria		3
Dysgeusia	2	9
Dysgraphia	2	2
Dyspepsia	1	1
Dysphagia	2	12
Dysphonia	1	3
Dyspnoea	27	81
Dyspnoea at rest	2	2
Dyspnoea exertional	2	4
Ear discomfort	1	1
Ear pain	1	4
Ecchymosis	1	1
Eczema	1	1
Electrocardiogram ST segment abnormal		1
Embolism	1	1
Emotional distress	1	1
Emotional poverty	1	1
Encephalitis autoimmune	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		14	33	2	2
					1
		5	6		1
		2	4	1	1
				3	3
			1		
		1	1	1	1
			3		
		22	91	8	13
					1
				2	5
		1	2		
			2		
			2		1
		2	9		
		1	1	1	1
		1	1		
		1	3	1	9
				1	3
	1	13	41	14	40
				2	2
		1	2	1	2
		1	1		
		1	4		
				1	1
		1	1		
				1	1
		1	1		
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Endocrine ophthalmopathy	1	1
Enterocolitis		1
Eosinophil count decreased		1
Epilepsy	9	16
Epistaxis	6	8
Eructation		1
Erysipelas		3
Erythema	7	31
Erythema nodosum	1	1
Escherichia urinary tract infection	1	1
Exposure during pregnancy		2
Exposure to SARS-CoV-2		1
Extensive swelling of vaccinated limb	105	270
Extrasystoles	1	2
Eye disorder	1	2
Eye haemorrhage	1	1
Eye pain	2	3
Eye pruritus	1	3
Eye swelling	2	4
Eye symptom	1	1
Face oedema	1	1
Facial neuralgia	1	1
Facial pain	1	2
Facial paralysis	4	8
Facial paresis	2	3
Faeces discoloured	1	2
Fall	7	16
Fatigue	320	698
Fear	1	2
Febrile convulsion	1	1
Feeding disorder	1	2
Feeling abnormal	6	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1		
				9	16
		3	4	3	4
			1		
					3
		6	25	1	6
				1	1
				1	1
			2		
			1		
		105	270		
		1	2		
		1	2		
				1	1
		1	2	1	1
		1	3		
		2	3		1
		1	1		
				1	1
		1	1		
				1	1
			1	1	1
				4	8
		1	2	1	1
		1	2		
1	1	4	9	3	7
		305	662	15	36
			1	1	1
		1	1		
		1	2		
		4	10	2	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling cold	1	8
Feeling drunk		2
Feeling hot	3	13
Feeling jittery	1	3
Feeling of body temperature change	1	1
Fibrin D dimer increased	1	1
Flank pain	1	1
Fluid intake reduced		1
Fluid retention		2
Flushing		4
Food allergy		1
Gait disturbance	4	9
Gait inability	3	3
Gamma-glutamyltransferase increased	1	2
Gastroenteritis		1
Gastrointestinal haemorrhage	1	3
Gastrointestinal obstruction		1
Gastrointestinal pain		1
Gaze palsy		1
Generalised tonic-clonic seizure	1	3
General physical health deterioration	6	13
Genital paraesthesia		1
Giant cell arteritis	1	2
Gingival discomfort	1	1
Glomerular filtration rate decreased	1	3
Glomerulonephritis minimal lesion		1
Glossodynia		1
Glucose tolerance impaired		1
Guillain-Barre syndrome	1	1
Haematochezia	1	1
Haematocrit decreased	1	1
Haematocrit increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	7		1
			2		
		3	11		2
		1	3		
		1	1		
				1	1
		1	1		
					1
			1		1
			4		
			1		
		2	6	2	3
		2	2	1	1
		1	2		
					1
				1	3
					1
			1		
					1
				1	3
		1	4	5	9
			1		
				1	2
		1	1		
		1	3		
					1
			1		
			1		
				1	1
				1	1
		1	1		
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematoma	2	2
Haemodynamic instability	1	1
Haemoglobin decreased	4	4
Haemoptysis	2	2
Haemorrhage	1	1
Haemorrhoids		1
Hallucination	2	3
Hallucination, visual	1	1
Hand deformity		1
Hand fracture		1
Headache	339	764
Head discomfort		3
Head injury	1	1
Heart rate abnormal	1	1
Heart rate decreased	1	3
Heart rate increased	4	11
Hemianaesthesia		1
Hemiparesis	2	6
Hemiplegia	1	3
Hepatic failure		1
Hepatitis	1	1
Hepatitis C		1
Hepatitis cholestatic		1
Herpes ophthalmic	1	2
Herpes virus infection		1
Herpes zoster	2	6
Herpes zoster reactivation		1
Hiatus hernia		1
Hip fracture		1
Hot flush	2	5
Hyperacusis		1
Hyperaesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				1	1
		2	2	2	2
		1	1	1	1
				1	1
			1		
				2	3
				1	1
					1
					1
		331	746	8	18
					1
					2
				1	1
		1	1		
		1	2		1
		3	6	1	5
					1
				2	6
				1	3
					1
				1	1
					1
				1	2
					1
			1		
			3	2	3
					1
					1
		1	4	1	1
					1
			1		
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperaesthesia teeth		1
Hyperglycaemia		1
Hyperhidrosis	4	21
Hyperkalaemia	1	1
Hypernatraemia		2
Hyperpyrexia	28	62
Hypersensitivity	5	19
Hypersensitivity vasculitis	1	1
Hypersomnia		2
Hypertension	11	26
Hypertensive crisis		1
Hypertensive urgency	1	1
Hyperventilation	2	4
Hypoacusis		1
Hypoaesthesia	1	7
Hypoaesthesia oral		3
Hypoglycaemia		1
Hypokalaemia		1
Hypokinesia	1	1
Hyponatraemia		1
Hypophagia		4
Hypotension	5	12
Hypothermia	2	4
Hypotony of eye	1	1
Hypoxia	3	6
Ill-defined disorder	1	1
Illness		1
Imperception	1	1
Inappropriate schedule of product administration	6	7
Incontinence	1	1
Incorrect route of product administration		1
Increased tendency to bruise		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		3	19	1	2
				1	1
					2
				28	62
		3	9	2	10
				1	1
			2		
		7	15	4	11
					1
				1	1
		1	1	1	3
			1		
		1	6		1
			2		1
			1		
					1
		1	1		
			1		
			1		
1	1	2	5	3	7
				2	4
				1	1
				3	6
				1	1
					1
				1	1
		6	7		
				1	1
			1		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased upper airway secretion		1
Infarction	1	1
Infection		2
Inflammation	2	3
Influenza like illness	1	6
Ingrowing nail		1
Injected limb mobility decreased	2	3
Injection site discomfort		1
Injection site erythema	1	6
Injection site haematoma		1
Injection site induration		1
Injection site inflammation	5	10
Injection site pain	8	20
Injection site pruritus	2	5
Injection site swelling	3	8
Injection site warmth	4	9
Insomnia	1	1
International normalised ratio fluctuation	1	1
International normalised ratio increased	1	1
Intestinal ischaemia	1	2
Intestinal obstruction	1	1
Intracranial pressure increased	1	1
Ischaemic cerebral infarction	6	12
Ischaemic stroke		1
Jaundice	1	3
Joint abscess	1	1
Joint stiffness	1	1
Lacrimation increased	1	2
Lacunar infarction	1	1
Laryngitis		1
Left ventricular hypertrophy	1	1
Leukopenia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					2
		1	2	1	1
		1	5		1
			1		
		2	3		
			1		
		1	6		
			1		
			1		
		5	10		
		8	20		
		2	5		
		3	8		
		4	9		
		1	1		
				1	1
				1	1
				1	2
				1	1
				1	1
				6	12
					1
				1	3
				1	1
		1	1		
		1	2		
				1	1
			1		
				1	1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Limb discomfort	3	6
Limb injury	1	2
Lip blister		1
Lip swelling	1	2
Listless	3	4
Livedo reticularis		1
Localised infection	1	1
Loss of consciousness	10	28
Loss of control of legs	1	1
Loss of personal independence in daily activities		3
Lung disorder	1	2
Lymphadenopathy	30	72
Lymphangitis		2
Lymph node pain	5	6
Macular degeneration		1
Malaise	315	728
Maternal exposure during pregnancy	2	2
Mean cell volume increased	1	1
Melaena		1
Memory impairment		3
Meniere's disease		2
Mental impairment	3	4
Mesenteric artery thrombosis		1
Migraine	3	4
Monoparesis	1	1
Mood altered	1	2
Mouth swelling	2	2
Mucosal dryness	1	1
Multiple organ dysfunction syndrome	1	2
Multiple sclerosis	1	2
Muscle contractions involuntary	1	1
Muscle disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5	1	1
			1	1	1
			1		
		1	2		
		3	4		
					1
				1	1
			1	10	27
				1	1
			2		1
		1	1		1
		30	72		
					2
		5	6		
					1
		285	654	30	74
		1	1	1	1
		1	1		
					1
			3		
					2
				3	4
					1
		3	4		
				1	1
		1	2		
		1	1	1	1
		1	1		
				1	2
				1	2
		1	1		
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle rigidity	1	1
Muscle spasms	3	9
Muscle strain	2	4
Muscle tightness		1
Muscle twitching	1	3
Muscular weakness	4	7
Musculoskeletal discomfort		1
Musculoskeletal disorder		1
Musculoskeletal pain	11	12
Musculoskeletal stiffness	4	7
Mutism		1
Myalgia	324	729
Myocardial infarction	6	14
Myoclonus	1	1
Nasal congestion	1	2
Nasopharyngitis	4	10
Nausea	166	397
Neck pain	4	6
Nephrolithiasis	2	3
Nephrotic syndrome		2
Neuralgia	2	3
Neuritis		1
Neurologic neglect syndrome	1	1
Neuropathy peripheral	4	4
Nightmare		1
Nystagmus		1
Occupational exposure to product		1
Ocular discomfort		1
Ocular hyperaemia		2
Odynophagia	1	1
Oedema	1	4
Oedema peripheral	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	8	1	1
		2	4		
			1		
		1	2		1
		2	4	2	3
			1		
			1		
		11	12		
		4	7		
					1
		318	717	6	12
				6	14
		1	1		
		1	2		
		4	9		1
		154	366	12	31
		3	5	1	1
				2	3
					2
		2	3		
					1
				1	1
				4	4
			1		
			1		
			1		
			1		1
		1	1		
		1	3		1
			1	2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Off label use	6	7
Oliguria		1
Oophoritis	1	1
Ophthalmic herpes zoster	1	1
Optic nerve infarction	1	1
Optic neuritis		1
Oral bacterial infection		1
Oral discomfort	1	1
Oral herpes	2	2
Oral mucosal blistering	1	3
Oral mucosal erythema	1	1
Oral pain	1	1
Oral pruritus		1
Oropharyngeal blistering	1	1
Oropharyngeal discomfort		2
Oropharyngeal pain	6	19
Oscillopsia	1	1
Oxygen saturation abnormal	2	3
Oxygen saturation decreased	2	6
Pain	27	39
Painful respiration	1	2
Pain in extremity	22	56
Pain in jaw	3	4
Pain of skin	2	5
Pallor	2	12
Palpitations	12	34
Panic attack	1	1
Panniculitis	1	1
Paraesthesia	9	29
Paraesthesia ear		1
Paraesthesia oral	4	16
Paralysis	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	7		
			1		
				1	1
				1	1
				1	1
					1
					1
		1	1		
		2	2		
			2	1	1
				1	1
		1	1		
					1
				1	1
			2		
		6	18		1
		1	1		
		1	1	1	2
		1	1	1	5
		26	35	1	4
		1	2		
		20	52	2	4
		2	3	1	1
		2	5		
		1	5	1	7
		10	26	2	8
		1	1		
				1	1
		8	27	1	2
			1		
		3	14	1	2
				2	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Parkinson's disease	1	1
Pelvic fracture	1	1
Pelvic pain	2	2
Pericarditis		2
Periorbital oedema	1	1
Periorbital swelling		1
Peripheral coldness		6
Peripheral swelling	2	7
Peroneal nerve palsy		2
Petechiae	1	1
Pharyngeal erythema	1	1
Pharyngeal oedema		1
Pharyngeal paraesthesia	1	2
Pharyngeal swelling	4	11
Photophobia	1	1
Piloerection	1	1
Platelet count decreased	1	2
Pleural effusion		1
Pneumonia	8	11
Pneumonia aspiration	1	6
Pollakiuria	1	1
Polyuria		1
Post concussion syndrome		1
Posterior revers ble encephalopathy syndrome	1	1
Postmenopausal haemorrhage	1	2
Presyncope	5	14
Productive cough		1
Prolapse		1
Pruritus	3	19
Psychotic symptom		2
Pulmonary embolism	17	18
Pulmonary infarction	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		2	2		
					2
		1	1		
			1		
			4		2
		1	5	1	2
			1		1
		1	1		
				1	1
					1
				1	2
		3	4	1	7
		1	1		
		1	1		
			1	1	1
					1
				8	11
				1	6
		1	1		
			1		
			1		
				1	1
				1	2
		4	11	1	3
			1		
			1		
	1	3	17		2
					2
				17	18
				2	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulmonary mass	1	1
Pulmonary oedema	1	2
Pulmonary pain	1	3
Puncture site pain		1
Pupillary disorder		1
Pyrexia	172	373
Rash	3	12
Rash erythematous	2	7
Rash macular		1
Rash maculo-papular		1
Rash papular		3
Rash pruritic	1	2
Rash vesicular		1
Raynaud's phenomenon		1
Rectal haemorrhage	1	2
Rectal prolapse		1
Red blood cell count decreased	1	1
Reduced facial expression	1	1
Renal disorder		1
Renal failure		2
Renal impairment	1	2
Renal infarct	1	1
Respiration abnormal		1
Respiratory disorder		2
Respiratory failure	2	3
Respiratory rate decreased		2
Respiratory rate increased		3
Respiratory tract infection		2
Respiratory tract infection viral	1	1
Respiratory tract irritation	2	2
Respiratory tract oedema		1
Resting tremor		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
		1	3		
			1		
			1		
		159	331	13	42
	1	3	8		4
		2	7		
			1		
			1		
			3		
			1	1	1
			1		
			1		
				1	2
					1
		1	1		
				1	1
			1		
					2
	1			1	2
	1			1	1
					1
			2		
	2			2	3
			2		
			1		2
					2
	1			1	1
	2	2	2		
					1
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restless legs syndrome		1
Restlessness		4
Retching		3
Retinal artery occlusion	1	1
Retinal detachment	1	1
Retinal vein occlusion	2	2
Rheumatoid arthritis	1	2
Rhinitis		1
Rhinorrhoea	2	3
Right ventricular failure	1	2
Salivary gland pain		1
Salivary hypersecretion		1
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test positive		1
Secondary adrenocortical insufficiency	1	1
Seizure	3	7
Sensation of foreign body	1	2
Sensitive skin	1	2
Sensory disturbance	1	1
Sepsis	1	2
Shock		2
Sialoadenitis		2
Sinus bradycardia	1	1
Sinus tachycardia	1	3
Skin burning sensation	1	3
Skin discolouration	4	5
Skin induration	1	1
Skin swelling	1	1
Skin warm		1
Sleep disorder	1	1
Slow speech	1	1
Sneezing		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			4		
			1		2
				1	1
				1	1
				2	2
				1	2
			1		
		2	3		
				1	2
			1		
					1
			1		
					1
				1	1
				3	7
				1	2
		1	2		
		1	1		
				1	2
					2
					2
				1	1
		1	3		
		1	3		
		2	3	2	2
		1	1		
		1	1		
			1		
		1	1		
		1	1		
			2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Snoring		1
Soft tissue swelling	1	1
Somnambulism		2
Somnolence	2	9
Speech disorder	4	6
Splenic infarction	1	1
Sputum increased		1
Status epilepticus	1	2
Stiff person syndrome	1	1
Stiff tongue	1	1
Stomatitis	1	1
Stridor		1
Subdural haematoma	1	1
Sudden cardiac death	1	3
Sudden death	3	10
Sudden hearing loss	2	6
Suicidal ideation		1
Supraventricular tachycardia		1
Suspiciousness		1
Swelling	6	12
Swelling face	2	12
Swelling of eyelid	1	4
Swollen tongue		8
Syncope	42	76
Tachycardia	1	9
Tachypnoea	2	3
Taste disorder	1	2
Thinking abnormal		1
Thirst	1	1
Thirst decreased		1
Throat tightness	2	5
Thrombocytopenia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			2		
			5	2	4
		1	2	3	4
				1	1
			1		
				1	2
				1	1
		1	1		
		1	1		
					1
				1	1
				1	3
				3	10
				2	6
					1
					1
			1		
		6	12		
			7	2	5
		1	3		1
			3		5
				42	76
		1	7		2
		2	3		
		1	2		
			1		
		1	1		
					1
		1	2	1	3
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombophlebitis	3	5
Thrombophlebitis superficial	1	1
Thrombosis	10	14
Thrombotic cerebral infarction	1	1
Thunderclap headache		1
Tinea versicolour		1
Tinnitus	4	9
Tongue disorder		4
Tongue oedema		1
Tonsillitis		1
Torticollis		1
Toxic skin eruption	1	1
Transient aphasia	1	1
Transient ischaemic attack	19	27
Traumatic haematoma	1	1
Tremor	4	11
Trichodynia		1
Troponin increased	1	1
Type 1 diabetes mellitus	1	1
Underweight		1
Unresponsive to stimuli	1	4
Upper limb fracture		1
Urinary incontinence	2	3
Urinary retention		3
Urinary tract infection	1	4
Urine output decreased		1
Urosepsis		2
Urticaria	2	14
Vaccination failure	1	2
Vaccination site bruising	16	32
Vaccination site discomfort	4	9
Vaccination site erythema	107	286

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	2
				1	1
				10	14
				1	1
			1		
1	1	3	8	1	1
			2		2
					1
			1		
			1		
				1	1
				1	1
				19	27
				1	1
		3	10	1	1
			1		
				1	1
				1	1
			1		
				1	4
					1
		1	2	1	1
					3
			2	1	2
			1		
					2
		1	9	1	5
				1	2
		16	32		
		4	9		
		107	286		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site haematoma	21	56			21	56		
Vaccination site haemorrhage		1				1		
Vaccination site induration	9	20			9	20		
Vaccination site inflammation	72	190			72	190		
Vaccination site movement impairment	2	2			2	2		
Vaccination site pain	258	605			258	603		2
Vaccination site pallor	1	1					1	1
Vaccination site papule		1				1		
Vaccination site pruritus	51	121			51	121		
Vaccination site rash		3				3		
Vaccination site reaction	2	5			2	5		
Vaccination site swelling	142	349			140	347	2	2
Vaccination site urticaria		1				1		
Vaccination site warmth	126	322			126	322		
Vasculitis	2	2			2	2		
Vertigo	2	13			1	12	1	1
Viral infection	1	2					1	2
Vision blurred	4	7			4	7		
Visual impairment	6	11			3	4	3	7
Vomiting	13	44			10	29	3	15
Vulvovaginal pain	1	1			1	1		
Weight decreased		4				3		1
Weight increased		1				1		
Wheezing		1				1		
White blood cell count increased	1	1			1	1		
Wound haemorrhage	1	1			1	1		
Wound infection		1						1
Wrist fracture		1						1
	4,009	9,505	5	9	3348	8014	661	1491

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1						1
Abdominal pain	3	4			3	4		
Abdominal pain upper	1	2			1	2		
Abscess	1	1					1	1
Accommodation disorder		1				1		
Activated partial thromboplastin time shortened		1				1		
Acute abdomen		1						1
Acute cardiac event	1	1					1	1
Acute myocardial infarction	2	4					2	4
Acute respiratory failure		1						1
Ageusia		1				1		
Alanine aminotransferase decreased		1				1		
Alanine aminotransferase increased	1	1			1	1		
Allergy to vaccine	1	1			1	1		
Anaemia	1	1			1	1		
Anaphylactic reaction	2	2					2	2
Angina pectoris	2	3					2	3
Angioedema		1						1
Anosmia		1				1		
Anxiety	1	3			1	3		
Aortic valve stenosis		1						1
Apathy		1						1
Aphasia	2	2					2	2
Appendicitis	1	1					1	1
Apraxia	1	1					1	1
Arrhythmia	2	5					2	5
Arterial thrombosis		1						1
Arthralgia	18	36			16	31	2	5
Arthritis	1	1					1	1
Aspartate aminotransferase increased	2	2			2	2		
Aspiration		1						1
Asthenia	1	3					1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Atrial f brillation	2	8
Atrial flutter	1	2
Atrioventricular block complete	1	1
Back pain	1	2
Balance disorder		2
Basilar artery thrombosis	1	1
Basophil count decreased	1	1
Blindness	1	1
Blood alcohol decreased	1	1
Blood alkaline phosphatase increased	1	1
Blood bicarbonate decreased	1	2
Blood bilirubin increased	1	2
Blood calcium decreased	1	1
Blood cholesterol abnormal	1	1
Blood cholesterol increased	1	1
Blood creatine phosphokinase increased	1	1
Blood creatinine increased	1	1
Blood glucose decreased		2
Blood glucose increased	1	2
Blood lactate dehydrogenase increased	1	1
Blood lactic acid increased		1
Blood potassium decreased	1	1
Blood pressure abnormal	1	1
Blood pressure decreased	1	1
Blood pressure increased		1
Blood sodium decreased	1	1
Blood urea abnormal	1	1
Blood urea increased	1	1
Body temperature decreased		2
Body temperature increased	3	8
Bradypnea	1	1
Cachexia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	8
			1	1	1
				1	1
			1	1	1
			1		1
				1	1
		1	1		
				1	1
		1	1		
		1	1		
		1	2		
		1	2		
		1	1		
		1	1		
		1	1		
		1	1		
			2		
		1	2		
		1	1		
			1		
		1	1		
				1	1
					1
		1	1		
		1	1		
		1	1		
			1		1
		1	6	2	2
		1	1		
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiac arrest	3	6
Cardiac asthma	3	3
Cardiac death		2
Cardiac disorder	1	2
Cardiac failure	3	11
Cardiac failure acute	2	4
Cardiac ventricular thrombosis		1
Cardiogenic shock	1	3
Cardiopulmonary failure		1
Carotid artery thrombosis	1	1
Cerebral haemorrhage	4	8
Cerebral infarction	6	8
Cerebral thrombosis	1	1
Cerebrovascular accident	7	11
Cerebrovascular disorder		1
Chest discomfort	1	1
Chest injury	1	1
Chest pain	5	8
Chills	24	52
Chronic obstructive pulmonary disease	1	2
Circulatory collapse	1	3
Cold sweat	1	1
Condition aggravated	4	7
Confusional state	2	6
Conjunctival oedema		1
Constipation		1
Coronary artery disease	1	1
Cough		5
COVID-19	5	13
COVID-19 pneumonia	1	2
C-reactive protein increased	4	5
Cyanosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	6
				3	3
					2
				1	2
				3	11
				2	4
					1
				1	3
					1
				1	1
				4	8
				6	8
				1	1
1	1			7	11
					1
		1	1		
				1	1
		1	2	4	6
		21	41	3	11
		1	1		1
				1	3
				1	1
		1	1	3	6
			2	2	4
					1
			1		
				1	1
			4		1
		1	2	4	11
				1	2
		3	4	1	1
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cystitis	2	2
Deafness neurosensory		1
Deafness unilateral	1	1
Death	5	21
Decreased appetite		4
Decreased immune responsiveness		1
Deep vein thrombosis	6	10
Dehydration	1	1
Delirium	8	12
Delusion		1
Dementia Alzheimer's type		1
Depressed level of consciousness	3	7
Depressed mood	1	1
Depression		3
Diabetes mellitus inadequate control		1
Diarrhoea	2	7
Diplopia	3	3
Disease recurrence	2	4
Dissociation		1
Disturbance in attention		1
Dizziness	6	14
Drug ineffective	4	6
Dysarthria	4	7
Dysphagia	2	7
Dysphonia	1	1
Dyspnoea	10	31
Dyspnoea exertional	1	1
Dysstasia	1	2
Ear pain		1
Ecchymosis		1
Electrolyte imbalance		1
Emotional disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
				1	1
				5	21
			3		1
					1
				6	10
				1	1
				8	12
			1		
					1
				3	7
		1	1		
			3		
					1
		2	6		1
		2	2	1	1
				2	4
			1		
			1		
		6	13		1
				4	6
			1	4	6
			2	2	5
				1	1
		1	10	9	21
				1	1
			1	1	1
			1		
					1
					1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Encephalitis enteroviral		1
Endocarditis		1
Eosinophil count decreased	1	1
Epilepsy	8	18
Epistaxis	3	3
Erectile dysfunction		1
Erysipelas		1
Erythema	3	3
Extensive swelling of vaccinated limb	5	16
Eye haematoma	1	1
Eye haemorrhage	2	2
Eyelid ptosis	1	1
Eye movement disorder	1	1
Eye swelling	1	1
Facial bones fracture	1	1
Facial paralysis	6	6
Facial paresis	1	1
Fall	5	10
Fatigue	40	93
Febrile convulsion	1	1
Feeding disorder	1	1
Feeling abnormal	1	2
Feeling cold		1
Feeling hot	1	2
Fibrin D dimer increased	1	1
Fluid intake reduced	1	2
Fluid retention	1	1
Fracture		1
Gait disturbance	1	2
Gait inability	1	1
Gamma-glutamyltransferase increased	1	1
Gastric haemorrhage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	1		
				8	18
				3	3
					1
					1
		2	2	1	1
		4	15	1	1
				1	1
				2	2
		1	1		
		1	1		
		1	1		
				1	1
				6	6
				1	1
			1	5	9
		33	74	7	19
		1	1		
				1	1
		1	2		
			1		
			1	1	1
		1	1		
			1	1	1
				1	1
		1	2		
				1	1
		1	1		
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gastrointestinal disorder		1
Gastrointestinal haemorrhage		3
Generalised tonic-clonic seizure		3
General physical health deterioration	1	2
Glomerular filtration rate decreased		1
Haemarthrosis	1	1
Haematemesis		1
Haematocrit decreased	3	3
Haemoglobin abnormal	1	1
Haemoglobin decreased	4	5
Haemophagocytic lymphohistiocytosis	1	1
Haemophilia		1
Haemorrhage		1
Hallucination		1
Headache	50	86
Head injury	1	1
Heart rate decreased	1	1
Heart rate increased	1	3
Heart rate irregular		1
Hemiparesis	2	4
Hemiplegia	1	1
Hepatic failure	1	1
Hepatitis acute	1	1
Hernia pain		1
Herpes ophthalmic		1
Herpes zoster		2
Hip fracture	1	1
Hyperaesthesia	1	2
Hyperhidrosis	1	4
Hyperpyrexia	5	9
Hypersensitivity	1	1
Hypersensitivity vasculitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					3
					3
				1	2
			1		
				1	1
					1
		3	3		
		1	1		
		3	4	1	1
				1	1
					1
					1
		47	79	3	7
				1	1
		1	1		
		1	1		2
			1		
				2	4
				1	1
				1	1
			1		
			2		
				1	1
			1	1	1
		1	2		2
				5	9
		1	1		
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersomnia		1
Hypertension	4	5
Hypertriglyceridaemia	1	1
Hyperventilation	1	2
Hypoaesthesia	1	1
Hypoglycaemia		2
Hypophagia		2
Hypotension	3	7
Hypovolaemic shock		1
Hypoxia	3	8
Immune system disorder		1
Immune thrombocytopenia		1
Inappropriate schedule of product administration		2
Incontinence		2
Infection	1	2
Infection susceptibility increased		1
Inflammation	2	2
Inflammatory marker increased		1
Injected limb mobility decreased		1
Injection site pruritus	1	1
Injection site swelling	1	1
Insomnia	1	1
Intentional product use issue	1	1
Intention tremor	1	1
International normalised ratio increased	1	1
Interstitial lung disease		1
Intestinal haemorrhage	1	2
Iridocyclitis	1	1
Ischaemic cerebral infarction	8	11
Ischaemic stroke	1	1
IVth nerve paralysis	1	1
Jaundice	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				4	5
				1	1
		1	2		
		1	1		
					2
					2
		1	2	2	5
					1
				3	8
					1
					1
			2		
					2
				1	2
					1
		1	1	1	1
					1
			1		
		1	1		
		1	1		
		1	1		
				1	1
				1	1
					1
				1	2
				1	1
				8	11
				1	1
				1	1
		1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Kidney infection	1	1					1	1
Left ventricular dysfunction		1						1
Left ventricular failure	1	1					1	1
Lethargy		1				1		
Limb discomfort	1	1					1	1
Lip swelling	1	2					1	2
Loss of consciousness	2	2					2	2
Lung disorder		4				1		3
Lymphadenopathy	5	7			4	6	1	1
Lymphocyte count decreased	2	2			1	1	1	1
Malaise	51	107			40	78	11	29
Meniere's disease	1	3					1	3
Metabolic acidosis		1				1		
Migraine		1						1
Mobility decreased	1	3			1	2		1
Monoparesis	1	1					1	1
Monoplegia	1	1					1	1
Mouth swelling		1						1
Movement disorder	4	4			2	2	2	2
Muscle strain	1	2				1	1	1
Muscular weakness	2	5			1	3	1	2
Musculoskeletal chest pain	1	1					1	1
Musculoskeletal disorder	1	1					1	1
Musculoskeletal pain	5	5			5	5		
Musculoskeletal stiffness	1	1			1	1		
Mutism	1	1					1	1
Myalgia	51	87			47	77	4	10
Myelodysplastic syndrome		1						1
Myelopathy	1	1					1	1
Myocardial infarction	4	6					4	6
Nasal congestion	1	1					1	1
Nasopharyngitis	1	4			1	4		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nausea	17	40
Neck pain	1	1
Neuropathy peripheral	1	1
Neutrophil count decreased	1	1
Neutrophil count increased	2	2
Night blindness		1
Night sweats	1	1
Ocular myasthenia	1	1
Oedema	1	1
Oedema peripheral	2	2
Off label use		1
Oropharyngeal pain		5
Oxygen saturation decreased	2	14
Pain	3	5
Pain in extremity	4	7
Pain in jaw	1	1
Pallor		2
Pancytopenia	1	1
Paraesthesia	2	5
Paraesthesia oral	1	1
Paralysis	1	2
Parkinson's disease	1	1
Parosmia		1
Pemphigoid		1
Pericarditis	1	1
Peripheral coldness		2
Peripheral swelling		2
Personality disorder		1
Petechiae	3	3
Pharyngeal swelling	2	2
Pituitary apoplexy		1
Platelet count decreased	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		16	32	1	8
				1	1
				1	1
				1	1
		2	2		
			1		
		1	1		
				1	1
				1	1
		1	1	1	1
			1		
			5		
				2	14
		2	4	1	1
		4	6		1
		1	1		
			2		
				1	1
		2	5		
		1	1		
				1	2
				1	1
			1		
			2		
			1		1
			1		
		3	3		
				2	2
					1
		3	3		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Platelet count increased	1	1
Pleural effusion	2	2
Pneumonia	7	17
Pneumonia aspiration	1	4
Pneumonia bacterial	1	1
Poor quality product administered	1	1
Poor quality sleep		1
Postictal state		1
Productive cough	1	1
Product storage error	1	1
Prothrombin time ratio increased	1	1
Pruritus	2	3
Pulmonary arterial pressure increased	1	1
Pulmonary embolism	13	17
Pulmonary haemorrhage		1
Pulmonary hypertension	1	1
Pulmonary infarction	1	1
Pyelonephritis	1	1
Pyrexia	33	61
Quadriplegia	1	1
Rash	3	5
Rash erythematous		2
Rash papular		1
Rectal haemorrhage	1	1
Red blood cell count decreased	2	2
Renal disorder	1	1
Renal failure	1	1
Renal impairment		1
Respiratory disorder		1
Respiratory failure	2	6
Respiratory rate increased	1	2
Restlessness	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	2
				7	17
				1	4
				1	1
		1	1		
			1		
			1		
				1	1
		1	1		
		1	1		
		1	2	1	1
				1	1
				13	17
					1
				1	1
				1	1
				1	1
		22	33	11	28
				1	1
		2	4	1	1
			2		
			1		
				1	1
		2	2		
		1	1		
				1	1
					1
				2	6
			1	1	1
			1	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rhinitis		1				1		
Rhinorrhoea	1	1			1	1		
SARS-CoV-2 test positive	1	2					1	2
Sciatica		1						1
Scrotal injury		1				1		
Seizure	3	3					3	3
Serum ferritin abnormal	1	1					1	1
Skin discolouration		1				1		
Small intestinal obstruction		1						1
Sneezing	1	1			1	1		
Soft tissue infection		1						1
Somnolence		4						4
Speech disorder	2	2					2	2
Spinal cord compression	1	1					1	1
Spinal epidural haemorrhage	1	1					1	1
Spinal meningeal cyst	1	1					1	1
Spinal osteoarthritis	1	1			1	1		
Status epilepticus		1						1
Stridor	2	2					2	2
Subdural haematoma	1	1					1	1
Sudden cardiac death		1						1
Sudden death	2	4					2	4
Sudden hearing loss	1	1					1	1
Supraventricular tachycardia		1				1		
Suspected COVID-19		2				1		1
Swelling face	1	2			1	1		1
Swelling of eyelid	1	1			1	1		
Swollen tongue	1	2			1	1		1
Symptom recurrence	1	1					1	1
Syncope	6	10	1	1			6	10
Tachycardia		2						2
Tachypnoea		1						1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Taste disorder		1
Thrombocytopenia	3	3
Thrombophlebitis	1	1
Thrombosis	6	7
Thrombosis mesenteric vessel		1
Tinnitus		1
Tonsillitis		1
Toothache		1
Transient ischaemic attack	19	21
Tremor	1	2
Troponin increased		1
Unresponsive to stimuli	1	4
Urinary retention	1	2
Urinary tract infection	2	3
Urosepsis	1	2
Urticaria	3	6
Uvulitis		1
Vaccination site bruising	1	3
Vaccination site erythema	9	19
Vaccination site haematoma	2	3
Vaccination site induration		1
Vaccination site inflammation	10	17
Vaccination site pain	34	63
Vaccination site pruritus	3	4
Vaccination site reaction	1	1
Vaccination site swelling	7	19
Vaccination site warmth	5	16
Vascular stent thrombosis	1	1
Vasculitis	1	1
Ventricular fibrillation	2	3
Vertigo		1
Vestibular neuronitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				3	3
		1	1		
				6	7
					1
			1		
			1		
			1		
1	1			19	21
			1	1	1
			1		
				1	4
				1	2
		1	1	1	2
				1	2
		3	6		
			1		
		1	3		
		8	18	1	1
		2	3		
			1		
		10	17		
		33	62	1	1
		3	4		
		1	1		
		7	19		
		5	16		
				1	1
		1	1		
				2	3
					1
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vision blurred		2				2			
Visual impairment	2	2			1	1	1	1	
Vomiting	4	9			2	4	2	5	
Weight decreased		2				1			1
White blood cell count decreased	1	1			1	1			
White blood cell count increased	1	1			1	1			
Wound		1				1			
	851	1,663	3	3	459	901	392	762	

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	1	1			1	1
Anembryonic gestation	1	1			1	1
Angioedema		1				1
Circumstance or information capable of leading to medication error		1		1		
Crohn's disease	1	1			1	1
Death		1				1
Exposure via breast milk		1		1		
Incorrect dose administered		1		1		
Maternal exposure during pregnancy	1	1			1	1
Product label confusion		1		1		
Product packaging quantity issue		1		1		
Product preparation error	1	2	1	2		
	5	13	1	7	4	6

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**NEW ZEALAND**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia	1	3	1	3
Nausea	1	1	1	1
	2	4	2	4

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asymptomatic COVID-19		1		1
Drug ineffective		1		1
Exposure to SARS-CoV-2		1		1
Hypersensitivity	5	5	5	5
Influenza like illness	1	1	1	1
Reactogenicity event	1	1	1	1
	7	10	7	10

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Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Chest discomfort		1		1
Chills		1		1
Disorientation		1		1
Dizziness		1		1
Fatigue		1		1
Headache		1		1
Inappropriate schedule of product administration		2		2
Pain in extremity		1		1
Poor quality sleep		1		1
		11		11

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**NORWAY**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain	2	11		6	2	5
Abdominal pain upper	4	9		2	4	7
Abnormal dreams		1		1		
Abortion spontaneous		1				1
Acute coronary syndrome		1				1
Acute kidney injury		1				1
Acute myocardial infarction		5				5
Agitation		1				1
Allergy to vaccine		2				2
Altered state of consciousness		5				5
Amnesia		2		1		1
Anaphylactic reaction	4	10			4	10
Angina pectoris		1				1
Angioedema		3				3
Antinuclear antibody increased	1	1	1	1		
Anti-thyroid antibody	1	1	1	1		
Anxiety		3		1		2
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Apathy		2				2
Aphasia	1	2			1	2
Apnoea		2				2
Apnoeic attack		1				1
Appendicitis	2	2			2	2
Arrhythmia	1	2			1	2
Arterial haemorrhage		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	8	16	8	15		1
Arthritis		1		1		
Arthritis bacterial		1				1
Asthenia	3	12	1	4	2	8

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Asthma		1					1
Atelectasis		1					1
Atrial fibrillation		1					1
Atrioventricular block first degree		1					1
Auditory disorder	1	1	1	1			
Axillary mass		1					1
Axillary pain		2		1			1
Back pain	3	10	2	5	1		5
Balance disorder		2		1			1
Basedow's disease		1					1
Bedridden	1	6	1	2			4
Blepharospasm		1		1			
Blindness	1	1			1		1
Blood glucose decreased		1		1			
Blood glucose fluctuation		3		3			
Blood glucose increased		1		1			
Blood pressure decreased		7		1			6
Blood pressure diastolic decreased		1		1			
Blood pressure increased		2		1			1
Blood pressure systolic increased	2	2			2		2
Body temperature decreased		1		1			
Body temperature fluctuation	1	1			1		1
Body temperature increased		1		1			
Bone pain		1					1
Bradycardia		3					3
Breast enlargement		1		1			
Breast pain		1		1			
Breath sounds abnormal		1					1
Bronchitis		1		1			
Burning sensation		1					1
Cardiac arrest	1	2			1		2
Cardiac failure		1					1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
			1
	1		
		4	8
			3
		1	2
		1	14
			1
	1		1
2	4		6
3	17		10
			1
			3
		2	4
	1		1
	2		8
			1
	1		
			2
1	1	2	4
	6		10
		1	1
		1	2
			1
1	8	1	4
		2	2
	3	1	11
			1
	1		
			18

Cardiac fibrillation	1	1
Cardio-respiratory arrest		1
Cardiovascular disorder		1
Carotid arteriosclerosis		1
Cerebral haemorrhage	4	8
Cerebral infarction		3
Cerebral thrombosis	1	2
Cerebrovascular accident	1	14
Cerebrovascular disorder		1
Chest discomfort		2
Chest pain	2	10
Chills	3	27
Chronic kidney disease		1
Chronic obstructive pulmonary disease		3
Circulatory collapse	2	4
Cognitive disorder		2
Cold sweat		10
Coma		1
Communication disorder		1
Concomitant disease aggravated		2
Concussion	1	2
Condition aggravated	3	5
Confusional state		16
Contusion	1	1
Coordination abnormal	1	2
Coronary artery occlusion		1
Cough	2	12
COVID-19	2	2
C-reactive protein increased	1	14
Cyanosis		1
Cystic lung disease		1
Death		18

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Decreased activity		1		1			
Decreased appetite	1	11	1	5			6
Decubitus ulcer		1		1			
Deep vein thrombosis	3	4			3		4
Dehydration	1	2		1	1		1
Delirium		1					1
Dementia		1					1
Dementia Alzheimer's type		1					1
Depressed level of consciousness		3					3
Depressed mood		1		1			
Dermatitis allergic		1					1
Diabetes mellitus inadequate control	1	1			1		1
Diarrhoea	2	20		12	2		8
Discomfort	2	6	1	4	1		2
Disease recurrence		5		1			4
Disorientation	1	1			1		1
Disturbance in attention		1		1			
Dizziness	14	41	6	21	8		20
Drooling		1		1			
Drug ineffective	1	1			1		1
Drug interaction	1	2	1	1			1
Drug reaction with eosinophilia and systemic symptoms	1	1			1		1
Dry mouth		3		2			1
Dry skin		1		1			
Dysarthria	2	5	1	1	1		4
Dysgeusia	1	3	1	3			
Dyskinesia		1					1
Dysphagia		3					3
Dysphonia		2		2			
Dyspnoea	11	47	5	16	6		31
Ear discomfort	1	3	1	3			

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
	1		
	1		1
1	1	1	1
	1		1
1	1	1	1
	1		1
2	3	2	3
1	7	1	4
1	1	1	1
	2		
1	1	1	1
	2		2
	1		
	1		1
	2		2
3	8	2	5
	1		1
3	18	3	16
17	85	3	21
1	5		1
	1		
	1		
	5		2
	1		
	2		2
	1		1
	1		
	1		
1	2	1	1
	1		
	1		1

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Fracture		1					1
Frostbite		1					1
Gastric haemorrhage	1	1			1		1
Gastroenteritis		1					1
Gastrointestinal haemorrhage		1					1
Gastrointestinal necrosis		1					1
Generalised tonic-clonic seizure		1					1
General physical health deterioration	7	42	3	9	4		33
Giant cell arteritis	1	1			1		1
Glomerulonephritis chronic		1					1
Grip strength decreased	1	2			1		2
Haematemesis	1	2			1		2
Haematoma		1					1
Haemoglobin decreased	1	2			1		2
Haemorrhage		1					1
Haemorrhage subcutaneous	1	2			1		2
Haemothorax		1					1
Hallucination		3					3
Hallucination, auditory		1					1
Hallucinations, mixed	1	1			1		1
Headache	23	83	12	62	11		21
Head injury		1					1
Heart rate increased	2	8		2	2		6
Heart rate irregular		2		1			1
Hemiparesis	2	4			2		4
Hemiplegia		1					1
Herpes simplex reactivation	1	1	1	1			
Hot flush		1		1			
Hyperaesthesia		1					1
Hyperglycaemia	1	2	1	1			1
Hyperhidrosis		3		3			
Hypernatraemia		1					1

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	2	1	5
	1		
	3	1	1
			1
	2		3
1	5		2
1	3	1	2
	1		
	1		
		2	2
			1
1	1		
1		1	11
			1
			1
1		1	1
	1		
1		1	1
	2		
	1		1
1		1	1
			5
	2		
1		2	3
	1		
1	1		
			1
			1
			1
	1		
	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iridocyclitis	1	1			1	1
Ischaemic stroke	2	3			2	3
Joint swelling		1		1		
Kidney fibrosis		1				1
Left ventricular failure		1				1
Lethargy	1	2		1	1	1
Limb discomfort	1	3		2	1	1
Lip pruritus		1				1
Local reaction		1				1
Loss of consciousness	1	8			1	8
Loss of personal independence in daily activities	1	1			1	1
Lower respiratory tract infection		1				1
Lung opacity		1				1
Lymphadenitis	2	2	1	1	1	1
Lymphadenopathy		3		2		1
Lymphangitis	1	1			1	1
Malaise	4	31	3	22	1	9
Malignant hypertension		1				1
Marasmus		1				1
Maternal exposure during pregnancy		1		1		
Mediastinal haemorrhage		1				1
Melaena		1				1
Memory impairment	1	1	1	1		
Mental impairment	1	1			1	1
Mesenteric artery embolism		1				1
Metastases to peritoneum		1				1
Middle insomnia		1		1		
Migraine	1	3	1	2		1
Mobility decreased		1		1		
Monoparesis		1				1
Motor dysfunction		1		1		
Mouth haemorrhage	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Mouth swelling		1					1
Multiple fractures		1					1
Muscle contractions involuntary	1	1	1	1			
Muscle spasms	1	5		1	1		4
Muscle twitching		1		1			
Muscular weakness	1	3			1		3
Musculoskeletal stiffness	1	7		5	1		2
Myalgia	7	34	6	28	1		6
Myopia	1	1			1		1
Nasal congestion		1		1			
Nasal pruritus		1					1
Nasopharyngitis		1		1			
Nausea	12	58	8	41	4		17
Neck pain		4		3			1
Nephrolithiasis	1	1			1		1
Neuroborreliosis		1					1
Neuropathy peripheral		2					2
Night sweats		1		1			
Obstructive airways disorder		1					1
Ocular hyperaemia		2		1			1
Oedema peripheral		3		1			2
Ophthalmic herpes zoster	1	1			1		1
Oral pruritus		2					2
Orbital oedema		1					1
Oropharyngeal pain	1	9		6	1		3
Oropharyngeal swelling	1	1			1		1
Orthostatic hypotension		1		1			
Oxygen saturation decreased	1	12	1	1			11
Pain	3	12	3	10			2
Pain in extremity	5	11	4	8	1		3
Pain of skin		1					1
Pallor		8		2			6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	2	5	1	2	1	3
Pancytopenia	1	1			1	1
Panic attack	1	1	1	1		
Paraesthesia	1	7	1	3		4
Paraesthesia oral	1	2		1	1	1
Paranasal sinus discomfort		1		1		
Parosmia	1	1	1	1		
Pericardial haemorrhage		1				1
Pericarditis		1				1
Peripheral coldness		1		1		
Peripheral swelling	2	5	2	3		2
Petechiae	3	5	1	1	2	4
Pharyngeal paraesthesia	1	1			1	1
Pharyngeal swelling	1	3		1	1	2
Photophobia		3		2		1
Pneumonia	2	9			2	9
Pneumonia aspiration		2				2
Pneumonitis		1				1
Presyncope	3	8	1	2	2	6
Product administered at inappropriate site		1		1		
Productive cough		3				3
Pruritus	2	13		3	2	10
Psychomotor hyperactivity		2		1		1
Pulmonary embolism	3	4			3	4
Pulmonary necrosis		1				1
Pulmonary oedema		1				1
Pupil fixed		2				2
Pyrexia	16	77	11	45	5	32
Rales		2		1		1
Rash	1	8		5	1	3
Rash erythematous	1	3		2	1	1
Rash pruritic	1	3		1	1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure	2	2			2	2
Respiratory alkalosis		1				1
Respiratory arrest		3				3
Respiratory failure		3				3
Respiratory rate decreased		1		1		
Respiratory rate increased	1	7	1	2		5
Respiratory tract congestion		1				1
Respiratory tract infection		1				1
Restlessness		9		2		7
Retching		6		3		3
Rhinorrhoea		3		3		
Salmonella test positive	1	1			1	1
Secretion discharge		2				2
Seizure		1				1
Sepsis		3				3
Skin haemorrhage	1	2	1	2		
Skin laceration		1				1
Sleep disorder		1		1		
Sneezing		1		1		
Snoring	1	1			1	1
Somnolence		11		7		4
Speech disorder		5		2		3
Staphylococcal sepsis	1	1			1	1
Status epilepticus		1				1
Status migrainosus		1				1
Stridor	1	2			1	2
Subdural haematoma	1	1			1	1
Subdural haemorrhage	1	1			1	1
Sudden death		6				6
Supraventricular extrasystoles		1				1
Swelling	1	1			1	1
Swelling face	2	5	1	2	1	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling of eyelid	1	2	1	1		1
Syncope	7	25			7	25
Tachycardia	2	5	2	4		1
Tachypnoea		3		1		2
Tenderness		1		1		
Tendon pain		1		1		
Terminal state		1				1
Therapeutic product effect decreased	1	1	1	1		
Thirst		2		1		1
Throat clearing		1		1		
Throat irritation		2				2
Throat tightness	1	3			1	3
Thrombocytopenia	3	4			3	4
Thrombophlebitis	2	2	2	2		
Thrombophlebitis superficial	1	1			1	1
Thrombosis		1				1
Time perception altered	1	1	1	1		
Tooth avulsion		1				1
Transfusion reaction	1	1	1	1		
Transient ischaemic attack		2				2
Tremor	1	5	1	2		3
Urinary incontinence		1				1
Urinary tract infection		4		3		1
Urosepsis	1	1			1	1
Urticaria	2	8		1	2	7
Vaccination failure	1	1			1	1
Vaccination site erythema		8		7		1
Vaccination site hypoaesthesia		1		1		
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	2	28	1	21	1	7
Vaccination site paraesthesia		2		2		
Vaccination site pruritus		4		3		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1		1		
Vaccination site reaction		3		2		1
Vaccination site swelling		4		2		2
Vaccination site warmth		2		2		
Vaccine breakthrough infection	1	1			1	1
Ventricular tachycardia		1				1
Vertigo		1		1		
Vertigo positional		1				1
Vision blurred	1	1			1	1
Visual impairment	1	2	1	1		1
Vomiting	3	28	1	9	2	19
Weight decreased		1		1		
Wheezing	1	2			1	2
White blood cell count increased		1				1
	340	1,630	140	715	200	915

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		2		1
Abdominal pain upper		5		2		3
Abdominal wall haemorrhage		1				1
Abnormal behaviour		1				1
Acute kidney injury	1	1			1	1
Aggression	1	1	1	1		
Altered state of consciousness		2				2
Anal incontinence		1				1
Anaphylactic reaction	1	3			1	3
Angina pectoris		1				1
Apallic syndrome		1				1
Aphasia	2	3			2	3
Apnoea		1				1
Arteriovenous fistula thrombosis	2	2			2	2
Arthralgia	3	8	1	5	2	3
Arthritis		1				1
Arthritis reactive		1				1
Aspiration		1				1
Asthenia	2	3	1	2	1	1
Atrial f brillation	1	3			1	3
Atrial flutter		1				1
Autonomic nervous system imbalance		1				1
Back pain		4		3		1
Bacterial sepsis		1				1
Bacterial test positive		1		1		
Balance disorder	1	5		1	1	4
Bedridden		1				1
Blood glucose increased	1	1	1	1		
Blood pressure decreased	2	5		1	2	4
Blood pressure systolic decreased	1	1			1	1
Body temperature increased	1	1			1	1
Bone pain	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia		2				2
Brain stem stroke		1				1
Cardiac arrest		1				1
Cardiac failure		3				3
Carotid artery occlusion	1	1			1	1
Cerebellar infarction	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	5	6			5	6
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	3	8			3	8
Chest discomfort	1	1	1	1		
Chest pain	6	10	2	2	4	8
Chills	3	6		3	3	3
Cholecystitis		1				1
Chronic obstructive pulmonary disease	1	3			1	3
Cognitive disorder		1				1
Cold sweat		3		2		1
Condition aggravated		2		1		1
Confusional state	5	15	1	4	4	11
Conjunctivitis		1		1		
Constipation		2		1		1
Coordination abnormal	1	1	1	1		
Cough	2	8		3	2	5
COVID-19	2	2	1	1	1	1
C-reactive protein increased	9	16	3	5	6	11
Cyanosis		1				1
Death	2	10			2	10
Decreased appetite		4		2		2
Deep vein thrombosis	2	2			2	2
Defaecation disorder		1				1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
			1
			1
			3
		1	1
		1	1
		1	1
		1	2
		5	6
		1	1
		3	8
1	1		
2	2	4	8
	3	3	3
			1
		1	3
			1
	2		1
	1		1
1	4	4	11
	1		
	1		1
	3	2	5
1	1	1	1
3	5	6	11
			1
		2	10
	2		2
		2	2
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration		1				1
Delirium	2	4			2	4
Dementia		1				1
Demyelinating polyneuropathy	1	1			1	1
Depressed level of consciousness	2	4			2	4
Diarrhoea	2	10	1	5	1	5
Diplopia	1	3		1	1	2
Disease recurrence	1	1			1	1
Disturbance in attention		1		1		
Diverticulitis		1				1
Dizziness	5	14		6	5	8
Drug ineffective	1	1			1	1
Drug interaction	2	2	2	2		
Dry mouth		1		1		
Duodenitis		1				1
Dysarthria	1	2	1	1		1
Dysgeusia		1				1
Dysphagia	1	4	1	2		2
Dysphonia		2		2		
Dyspnoea	7	20	1	2	6	18
Dyspnoea at rest		1				1
Epilepsy		4				4
Epistaxis		1		1		
Erythema	1	4	1	4		
Facial paralysis		2				2
Facial paresis		1				1
Faeces discoloured		1		1		
Fall	2	5	1	3	1	2
Fatigue	5	25	1	16	4	9
Fear of death	1	1	1	1		
Feeling cold		2		2		
Feeling hot	2	4	1	3	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	2	1	2		
Gait disturbance	1	2	1	1		1
Gastric disorder		1				1
Gastritis		1		1		
Gastrointestinal haemorrhage		1				1
General physical health deterioration	8	26	2	8	6	18
General symptom		1				1
Glomerulonephritis minimal lesion		1				1
Guillain-Barre syndrome	1	1			1	1
Haematoma		1				1
Haemoglobin decreased		1				1
Haemorrhage		2				2
Hallucination		3				3
Hallucination, auditory		1				1
Hallucination, visual		1				1
Headache	1	8		5	1	3
Head injury		1				1
Heart rate decreased		1				1
Heart rate increased	1	6		2	1	4
Hemianopia	1	1			1	1
Hemiparesis		1				1
Hemiplegia	2	3			2	3
Hepatic cyst	1	1			1	1
Hyperaesthesia	1	1			1	1
Hypercapnia	1	1			1	1
Hyperhidrosis	1	3	1	3		
Hyperkalaemia		1				1
Hypertension		2		1		1
Hyperventilation		2		2		
Hypoaesthesia		2		2		
Hypokinesia		1				1
Hypophagia	1	3			1	3

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	6	1	1		5
Hypoxia		3				3
Illness	1	1	1	1		
Immobile		1				1
Immune-mediated adverse reaction	1	1			1	1
Inappropriate schedule of product administration	2	2	2	2		
Incorrect route of product administration		2		2		
Increased bronchial secretion	1	1			1	1
Increased viscosity of upper respiratory secretion	1	1	1	1		
Infection		3		1		2
Infective exacerbation of chronic obstructive airways disease		1				1
Inferior vena caval occlusion	1	1			1	1
Inflammation		1				1
Inflammatory marker increased	1	1			1	1
Influenza like illness	1	5	1	4		1
Injection site muscle weakness		1		1		
International normalised ratio increased		1				1
Interstitial lung disease		1				1
Iridocyclitis	1	1			1	1
Irritability postvaccinal		1				1
Lethargy	1	5		2	1	3
Leukocytosis		2		1		1
Listless		1		1		
Livedo reticularis		1		1		
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities	1	1			1	1
Lung consolidation	1	1			1	1
Lung opacity	1	2			1	2
Lymphadenopathy		1		1		
Malaise	1	9	1	7		2

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
1	2		
		1	1
		1	1
			1
1	1	1	1
1	1	2	2
			1
	5	3	5
		1	2
	3		
			1
1	10	3	10
	2		1
			1
1	1		
		1	2
		1	1
			1
	1		1
			1
2	2		
			1
1	1		1
		1	1
	1	2	6
1	3	2	4
	4		
1	1		
	1		2
1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis		1				1
Paresis	1	1	1	1		
Pericardial effusion		2				2
Pericarditis	4	5			4	5
Peripheral coldness		2		1		1
Peripheral swelling	1	1			1	1
Personality change		1				1
Pleural effusion		2				2
Pleurisy		1				1
Pneumonia	3	16			3	16
Pneumonia aspiration	1	1			1	1
Pneumonia bacterial	1	1			1	1
Pneumonitis	1	1			1	1
Postictal state		1		1		
Presyncope		1				1
Productive cough		2				2
Pruritus	1	2		1	1	1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	3	9			3	9
Pulmonary thrombosis	1	1			1	1
Pyelonephritis		1				1
Pyrexia	6	29	1	15	5	14
Rales		2		1		1
Rash		3		2		1
Rash pruritic	1	2		1	1	1
Rectal haemorrhage	1	2			1	2
Red blood cell sedimentation rate increased	1	1	1	1		
Renal impairment		1				1
Respiration abnormal		1				1
Respiratory acidosis	1	1			1	1
Respiratory arrest		1				1
Respiratory disorder		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure	4	7			4	7
Respiratory rate increased		4		3		1
Restlessness	1	4		3	1	1
Retching	1	1			1	1
Rhinorrhoea		3		3		
Sepsis		1				1
Shock		1				1
Sleep disorder	1	1			1	1
Somnolence	1	6		2	1	4
Sputum increased		1		1		
Sudden cardiac death		1				1
Sudden death		2				2
Syncope	2	8			2	8
Tachycardia		4		1		3
Tenderness		1		1		
Thrombocytopenia	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial	2	2	1	1	1	1
Thrombotic stroke		1				1
Transient ischaemic attack	3	3			3	3
Tremor	1	3		1	1	2
Troponin increased		1				1
Tubulointerstitial nephritis		1				1
Unresponsive to stimuli	1	4			1	4
Urinary incontinence		1		1		
Urinary retention		2				2
Urinary tract infection		2		2		
Urticaria		1				1
Vaccination site erythema		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling		2		1		1
Vaccination site warmth		1				1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	2	2			2	2
Vision blurred	1	2			1	2
Visual impairment	1	2		1	1	1
Vlth nerve paralysis	1	1			1	1
Vomiting		15		7		8
Wheezing	1	1			1	1
White blood cell count increased	2	2	2	2		
	229	745	54	255	175	490

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event		1		1		
Adverse reaction		1		1		
COVID-19	1	1			1	1
Death		1				1
Diarrhoea		1		1		
Dry mouth		2		2		
Fatigue		2		2		
Incorrect dose administered		5		5		
Intentional product use issue	1	1	1	1		
Intercepted product preparation error		1		1		
Nausea		1		1		
Poor quality product administered		6		6		
Product preparation error		2		2		
Product preparation issue		8		8		
Product temperature excursion issue	1	7	1	7		
Pyrexia		1		1		
Vaccination failure	1	1			1	1
Wrong technique in product usage process		1		1		
	4	43	2	40	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**OMAN**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
Product supply issue		1		1
		2		2

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Fatigue		1		1
Gastritis		1		1
Headache		1		1
Pain		1		1
Pyrexia		1		1
Therapeutic response unexpected		1		1
		7		7

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**PANAMA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2	2	2		
Anaphylactic reaction		1				1
Arthralgia	1	1	1	1		
Asthenia		4		4		
Chills		1		1		
Dry throat	1	1	1	1		
Dysphagia	1	1	1	1		
Dyspnoea	1	1			1	1
Erythema		1		1		
Gait disturbance	1	1			1	1
Headache	1	1	1	1		
Hemiparesis	1	1			1	1
Hypersensitivity	1	2	1	2		
Hypoaesthesia oral	1	1			1	1
Hypotonia		1		1		
Hypotonic-hyporesponsive episode		2		1		1
Incorrect route of product administration		1		1		
Irritability		1		1		
Lip dry	1	1	1	1		
Local reaction	1	2	1	2		
Lymphadenopathy	1	1	1	1		
Overdose		1		1		
Pallor		1		1		
Palpitations		1		1		
Paraesthesia	1	1			1	1
Pulmonary pain	1	1			1	1
Pyrexia	1	1			1	1
Rash erythematous		1				1
Rash pruritic		1				1
Syncope		3				3
Vaccination site pain	2	2	1	1	1	1
Vaccination site reaction		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	19	42	11	27	8	15

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state	1	1	1	1
Fatigue	1	1	1	1
Flatulence		1		1
Vaccination site pain	1	2	1	2
	3	5	3	5

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Rash pruritic		6		6
		6		6

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**PERU**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Arthralgia	1	1	1	1		
Cough	1	1	1	1		
COVID-19	2	2	1	1	1	1
Diarrhoea	1	1	1	1		
Discomfort	1	1	1	1		
Drug ineffective	1	1			1	1
Off label use	2	2	2	2		
Pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Product use issue	2	2	2	2		
Pyrexia	3	3	3	3		
	17	17	15	15	2	2

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	1	1	1	1		
Chest pain	1	1	1	1		
Discomfort	1	1	1	1		
Epistaxis	1	1			1	1
Exposure via breast milk	1	1	1	1		
Fatigue	1	1	1	1		
Headache	4	5	4	5		
Heart rate increased	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Nasal dryness	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Pyrexia	4	4	4	4		
Vaccination site pain	1	2	1	2		
	20	22	19	21	1	1

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**POLAND**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	3	11		5	3	6
Abdominal pain lower		1		1		
Abdominal pain upper		4		2		2
Acute myocardial infarction		1				1
Adnexa uteri pain		1		1		
Ageusia		7		6		1
Agitation		1				1
Alanine aminotransferase increased		1				1
Allergic reaction to excipient		1		1		
Allergic respiratory symptom		1				1
Allergy to vaccine		1				1
Anal incontinence	2	4		1	2	3
Anaphylactic reaction		9				9
Anaphylactic shock	1	9			1	9
Angioedema	1	8			1	8
Anosmia	1	9	1	8		1
Anuria		4				4
Anxiety		4		3		1
Aphasia	1	3		1	1	2
Aphthous ulcer		1		1		
Arrhythmia	1	5			1	5
Arthralgia	7	46	4	29	3	17
Arthritis		1		1		
Arthropathy		1		1		
Asphyxia		1				1
Asthenia	15	92	7	58	8	34
Asthma		6				6
Asymptomatic COVID-19	4	5			4	5
Atrial fibrillation		2				2
Atrial flutter		1				1
Axillary mass		1		1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain		4		4		
Back pain	2	8	2	7		1
Balance disorder		1		1		
Basophil count decreased		1		1		
Bladder disorder		1		1		
Bleeding varicose vein	1	1			1	1
Blood creatine phosphokinase increased		2		1		1
Blood glucose increased		1				1
Blood pressure abnormal		2		1		1
Blood pressure decreased	1	16	1	4		12
Blood pressure diastolic increased		1				1
Blood pressure increased	5	17	2	3	3	14
Blood smear test abnormal		1		1		
Blood urine present		1		1		
Body temperature decreased		1		1		
Body temperature increased	1	6		4	1	2
Bone pain	2	10		7	2	3
Brachial plexus injury		1				1
Bradycardia		1				1
Brain stem stroke	1	1			1	1
Brain stem syndrome		1				1
Breast enlargement		1		1		
Breast pain		2		1		1
Breath sounds abnormal		1				1
Bronchial oedema		1				1
Burning sensation		2		2		
Cardiac arrest	2	4			2	4
Cardiogenic shock		1				1
Cardiovascular disorder	1	2	1	1		1
Cerebral haematoma		1				1
Cerebrovascular accident	1	2			1	2
Chest discomfort		5		5		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Chest pain		3		1			2
Chills	10	57	6	38	4	19	
Choking		1				1	
Choking sensation		1				1	
Chorea		1		1			
Coagulopathy		2		1		1	
Cognitive disorder		1		1			
Cold sweat		1				1	
Confusional state	1	6		3	1	3	
Conjunctival hyperaemia		2		1		1	
Contusion	1	6	1	1		5	
Coronary artery thrombosis		1				1	
Cough	4	10	1	4	3	6	
COVID-19	16	47	1	7	15	40	
C-reactive protein increased	1	1	1	1			
Cyanosis		2				2	
Cystitis		1		1			
Death	1	4			1	4	
Decreased activity		1		1			
Decreased appetite	1	8		6	1	2	
Decreased nasolabial fold		1		1			
Defaecation urgency		1		1			
Delirium		1				1	
Diarrhoea	6	18	4	11	2	7	
Discomfort		2		2			
Disease recurrence		1				1	
Disorientation	1	1			1	1	
Distractibility		1		1			
Disturbance in attention	1	4	1	4			
Dizziness	2	27	2	18		9	
Drug hypersensitivity	1	1			1	1	
Drug ineffective	9	28			9	28	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth	1	2	1	2		
Dysgeusia		3		1		2
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	6	25	3	10	3	15
Dyspnoea exertional	1	1			1	1
Dysstasia		1		1		
Ear swelling		1				1
Eating disorder		1		1		
Ecchymosis		1				1
Electrolyte imbalance		1		1		
Encephalopathy		1				1
Eosinophil count decreased		1		1		
Epigastric discomfort	1	1			1	1
Epistaxis		2		2		
Erysipelas	1	1			1	1
Erythema	2	8		2	2	6
Erythema multiforme		1				1
Essential hypertension	1	1			1	1
Exercise tolerance decreased	1	2	1	2		
Exposure during pregnancy	1	4	1	4		
Extensive swelling of vaccinated limb		1		1		
Eye disorder		1		1		
Eye pain	1	6		2	1	4
Face oedema		1				1
Facial paralysis	3	8			3	8
Faeces soft	1	1			1	1
Fall	1	2			1	2
Fatigue	7	25	6	22	1	3
Feeling abnormal		10		10		
Feeling cold	2	12	1	7	1	5
Feeling hot	1	9	1	8		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Fibrin D dimer increased		1					1
Flatulence	1	1			1		1
Flushing		3		2			1
Gait disturbance		2		2			
Gastrointestinal disorder	1	1	1	1			
Generalised tonic-clonic seizure		1					1
Gingival swelling	1	1	1	1			
Guillain-Barre syndrome		1					1
Haematoma		1		1			
Haematuria		2		1			1
Haemorrhage subcutaneous		1					1
Haemorrhagic diathesis	1	1			1		1
Haemorrhagic stroke		1					1
Hallucination, olfactory	1	1			1		1
Headache	12	94	8	69	4		25
Head discomfort		2		2			
Head injury	1	1			1		1
Heart rate increased	1	7		4	1		3
Helplessness		1					1
Herpes virus infection		2		2			
Hot flush		2		1			1
Hydronephrosis		1					1
Hyperacusis		1		1			
Hyperaesthesia	2	5	2	3			2
Hyperaesthesia teeth		1		1			
Hyperhidrosis	2	18		13	2		5
Hyperpyrexia	2	2			2		2
Hypersensitivity		10		1			9
Hypertension	1	3		1	1		2
Hypoaesthesia	3	21	2	11	1		10
Hypoaesthesia oral	1	6	1	2			4
Hypopnoea	1	1			1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension		1				1
Hypotonia		1				1
Hypotonic-hyporesponsive episode	1	15		1	1	14
Hypoxia		1				1
Illiteracy		1				1
Illness		1		1		
Inappropriate schedule of product administration	1	6	1	6		
Incorrect dose administered		1		1		
Incorrect route of product administration	1	3	1	3		
Infection		1		1		
Inflammation		3		3		
Influenza like illness	1	9	1	8		1
Initial insomnia		1		1		
Injection site erythema		1		1		
Injection site pain	1	6	1	6		
Injection site swelling		2		2		
Insomnia		4		4		
International normalised ratio increased	1	1	1	1		
Iritis		1		1		
Joint range of motion decreased		1		1		
Joint swelling		3		1		2
Lacrimation increased		3				3
Lagophthalmos	1	1	1	1		
Laryngeal oedema		1				1
Laryngospasm		3				3
Lethargy		1		1		
Limb discomfort		1		1		
Lip blister		1				1
Lip swelling		1				1
Lividity		3				3
Localised oedema		1				1
Loss of consciousness	1	17			1	17

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung disorder		1		1		
Lymphadenopathy	4	25	1	11	3	14
Lymph node pain	1	13		3	1	10
Lymphocyte count decreased		1		1		
Macule	1	1			1	1
Malaise	3	33		27	3	6
Maternal exposure during pregnancy		2		2		
Memory impairment	2	3	1	2	1	1
Mental disorder		1		1		
Migraine		2		2		
Monocyte count decreased		1		1		
Monoparesis		1				1
Mood altered		1		1		
Movement disorder	1	3	1	2		1
Muscle injury		1				1
Muscle spasms		1		1		
Muscle tightness		1		1		
Muscular weakness		3		1		2
Musculoskeletal chest pain		1		1		
Musculoskeletal pain	1	2		1	1	1
Musculoskeletal stiffness		3		3		
Mutism		1		1		
Myalgia	14	72	10	47	4	25
Myocardial hypoxia		1				1
Nasal congestion		2		1		1
Nasopharyngitis		1		1		
Nausea	4	40	1	27	3	13
Neck pain		8		6		2
Nervousness	1	2		1	1	1
Neuropathy peripheral	1	1			1	1
Neutrophil count increased		1		1		
Nightmare		1		1		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
			2
2	13		1
	1		
			1
	1		
1	2		
1	3		1
	1		4
	6		1
	1		
9	52	1	9
	1		
	2	1	1
	1	1	6
	1	1	4
			1
3	7		1
			1
			1
	1		
	2		1
1	2	1	1
	1		3
			2
	1		1
1	1		
	2		1
			2
	1		
	2		

Oedema  
Oedema peripheral  
Off label use  
Oliguria  
Optic neuritis  
Oral candidiasis  
Oral herpes  
Oropharyngeal pain  
Oxygen saturation decreased  
Pain  
Painful respiration  
Pain in extremity  
Pain in jaw  
Pain of skin  
Pallor  
Palpitations  
Pancreatitis acute  
Paraesthesia  
Paraesthesia oral  
Paralysis  
Paresis  
Parosmia  
Peripheral coldness  
Peripheral swelling  
Petechiae  
Pharyngeal hypoaesthesia  
Pharyngeal swelling  
Phlebitis  
Photophobia  
Pneumonia  
Poor quality product administered  
Presyncope

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product temperature excursion issue		1		1		
Product use issue	1	11	1	10		1
Protein urine present		2		2		
Pruritus	2	5		3	2	2
Psoriatic arthropathy	1	1			1	1
Pulmonary congestion	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	1			1	1
Pulpitis dental		1		1		
Pyrexia	22	119	15	78	7	41
Radicular pain		1		1		
Radiculitis brachial		1		1		
Rash	2	3	1	2	1	1
Rash erythematous	1	2		1	1	1
Rash papular		1				1
Rash vesicular	2	2			2	2
Renal failure		1				1
Renal pain		1		1		
Respiratory failure		1				1
Respiratory tract infection		1				1
Respiratory tract oedema		1				1
Restlessness		1				1
Retching		1		1		
Rhinitis		1				1
Rhinorrhoea		6		6		
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 ant body test positive	1	1	1	1		
SARS-CoV-2 test positive		2		1		1
Sciatica	1	2		1	1	1
Seizure	2	17			2	17
Sensation of foreign body		1				1
Sensory disturbance		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock symptom		1				1
Sinus headache		1				1
Sinusitis		1		1		
Skin hypertrophy		1		1		
Skin lesion		1				1
Skin mass		1		1		
Sluggishness	1	1			1	1
Somnolence		6		5		1
Speech disorder	2	7		1	2	6
Spinal pain		3		2		1
Stress		1				1
Stupor	1	1			1	1
Subclavian vein thrombosis		1				1
Sudden death	1	1			1	1
Suppressed lactation		2		1		1
Supraventricular extrasystoles	1	1			1	1
Suspected COVID-19		2		1		1
Swelling		2		1		1
Swelling face	1	2			1	2
Swollen tongue		2				2
Syncope	2	14			2	14
Systemic lupus erythematosus		1				1
Tachycardia	4	15	1	3	3	12
Tachypnoea		3				3
Taste disorder		3		3		
Temperature intolerance		1		1		
Therapeutic response unexpected		2		2		
Thirst		2		2		
Throat tightness		1		1		
Thrombophlebitis	1	1	1	1		
Thrombosis	2	7			2	7
Tinnitus	1	5		4	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Toothache		2		1			1
Tracheal oedema		1					1
Transaminases increased		1					1
Tremor		4		3			1
Trigeminal neuralgia		1		1			
Trigeminal neuritis		1					1
Type 2 diabetes mellitus	1	1			1		1
Urinary incontinence	1	3			1		3
Urticaria	2	6	1	2	1		4
Vaccination complication		2		2			
Vaccination failure	5	10			5		10
Vaccination site abscess sterile		1					1
Vaccination site erythema	3	14	3	11			3
Vaccination site extravasation		2		2			
Vaccination site induration		1		1			
Vaccination site macule		1		1			
Vaccination site movement impairment		3		3			
Vaccination site oedema	2	5	1	2	1		3
Vaccination site pain	7	75	5	67	2		8
Vaccination site pruritus	2	10	2	10			
Vaccination site reaction	1	22		9	1		13
Vaccination site swelling	1	15	1	12			3
Vaccination site warmth		4		4			
Vein disorder		1		1			
Venous thrombosis	1	1			1		1
Ventricular extrasystoles		1					1
Vertigo		4		1			3
Viral infection		1		1			
Vision blurred		1		1			
Visual acuity reduced		1					1
Visual field defect		1		1			
Visual impairment		3		1			2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	3	22	2	12	1	10
Walking disability		1		1		
	318	1,905	137	1062	181	843

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3	1	3		
Abdominal pain lower		1				1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Ageusia		1		1		
Alanine aminotransferase increased		1				1
Altered state of consciousness	1	2			1	2
Anaphylactic reaction		1				1
Angioedema		2				2
Angiopathy		1				1
Anosmia		1		1		
Anuria		1				1
Apnoea	1	1			1	1
Arrhythmia	2	2			2	2
Arteriosclerosis	1	2	1	1		1
Arthralgia		9		6		3
Aspartate aminotransferase increased		2				2
Asthenia	7	25	5	20	2	5
Asthmatic crisis		1				1
Asymptomatic COVID-19	1	2		1	1	1
Atrial f brillation	1	1			1	1
Atrial flutter	1	1			1	1
Axillary pain	1	1	1	1		
Back pain		3		3		
Balance disorder	1	2		1	1	1
Blister		1				1
Blood creatine phosphokinase increased		1				1
Blood glucose increased	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure decreased	2	2	1	1	1	1
Blood pressure increased	3	4		1	3	3
Bone density decreased	1	1	1	1		

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		1
			1
			1
		3	6
			1
	1	1	1
			2
			1
			1
	1	12	4
	1		1
			1
	1	1	1
1	1		
			1
1	2	1	1
	9	9	19
			1
			1
			1
	3	3	6
	1	1	1
	1	1	1
			1
	3	5	
			1
			1
		1	1
	3	4	5
	8	8	18
	1	1	2
			1
		2	

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	2	5			2	5
Emphysema	1	1	1	1		
Erythema		1		1		
Erythema multiforme		1				1
Eyelid oedema		1				1
Facial paralysis		1				1
Fall	2	2			2	2
Fatigue	2	8	1	6	1	2
Febrile convulsion		2				2
Feeling abnormal	1	1			1	1
Feeling cold	1	3		2	1	1
Feeling hot	1	2	1	2		
Feeling of relaxation		1				1
Flatulence		1		1		
Gait disturbance		2		1		1
Gait inability	1	1			1	1
Gastrointestinal disorder		1				1
Gastrointestinal haemorrhage		1				1
General physical health deterioration		1				1
Grip strength decreased		1		1		
Haematemesis		2				2
Haemoptysis	1	1	1	1		
Headache	1	16	1	15		1
Heart rate abnormal	1	1	1	1		
Heart rate increased	1	2	1	1		1
Herpes virus infection		1		1		
Herpes zoster		1		1		
Hot flush		1		1		
Hyperhidrosis	1	3	1	1		2
Hypersensitivity		3		2		1
Hypertension	2	3	1	1	1	2
Hypoaesthesia		2		1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral		1				1
Hypotension		1		1		
Hypotonia		2				2
Hypotonic-hyporesponsive episode	1	1			1	1
Incorrect route of product administration	1	2	1	2		
Increased upper airway secretion		1		1		
Infection		1				1
Influenza		1		1		
Influenza like illness		1		1		
Insomnia		5		5		
Intervertebral disc protrusion		1				1
Ischaemic stroke	1	1			1	1
Labyrinthitis	1	2			1	2
Laryngospasm		1				1
Lethargy	1	1			1	1
Lip swelling		1		1		
Loss of consciousness	3	4			3	4
Lung disorder	1	1	1	1		
Lung opacity	1	1	1	1		
Lymphadenopathy	1	9	1	5		4
Lymph node pain		5		1		4
Malaise	2	10	1	6	1	4
Melaena		1				1
Memory impairment		1		1		
Metabolic acidosis		1				1
Middle insomnia		1		1		
Multiple sclerosis relapse		1				1
Muscle spasms		1		1		
Muscle tightness		1		1		
Muscular weakness		2		1		1
Myalgia	1	17	1	16		1
Nasopharyngitis	1	2	1	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	2	7	1	5	1	2
Neuritis cranial		1				1
Night sweats		1		1		
Oedema	1	1			1	1
Oedema peripheral	1	1	1	1		
Oxygen saturation decreased	3	5	1	1	2	4
Pain		2		2		
Pain in extremity		4		4		
Pallor		1				1
Palpitations		1		1		
Pancreatitis acute	1	1			1	1
Paraesthesia		1		1		
Paralysis		1				1
Paraparesis		3				3
PCO2 abnormal	1	1			1	1
Peripheral swelling	1	2			1	2
Pleural effusion		1		1		
Pneumonia	2	3			2	3
Pneumonia viral	2	2			2	2
Presyncope	1	1			1	1
Product administered at inappropriate site		1		1		
Prostatic specific antigen increased		1				1
Prostatitis		1				1
Pruritus		1		1		
Pulmonary calcification	1	1	1	1		
Pulmonary mass	1	1	1	1		
Pyrexia	8	36	3	19	5	17
Rash		3		1		2
Rash macular		1		1		
Rash morbilliform		1				1
Rash papular		2		1		1
Rash pruritic		1		1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Renal failure	1	1
Respiration abnormal		1
Respiratory disorder	1	1
Respiratory failure	2	4
Rhabdomyolysis		1
Rhinorrhoea		2
Seizure	1	4
Sepsis		1
Shock	1	1
Somnolence	1	2
Speech disorder		2
Spinal cord compression		1
Sudden cardiac death	1	1
Sudden death		1
Swelling	1	2
Swollen tongue		2
Syncope	2	5
Tachycardia		1
Throat tightness		1
Thrombocytopenia	1	1
Thrombosis	1	1
Tinnitus	1	1
Tongue oedema		1
Transient ischaemic attack		1
Tremor	1	1
Trigeminal nerve disorder		1
Ulnar nerve palsy		1
Urinary tract inflammation		1
Urticaria		1
Vaccination failure	1	1
Vaccination site erythema		2
Vaccination site hypersensitivity		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
		1	1
		2	4
			1
	2		
		1	4
			1
		1	1
	1	1	1
	2		
			1
		1	1
			1
1	1		1
	1		1
		2	5
			1
			1
		1	1
		1	1
1	1		
			1
			1
1	1		
			1
	1		
		1	1
	2		
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration		1		1		
Vaccination site infection		1		1		
Vaccination site pain	1	28	1	26		2
Vaccination site paraesthesia		1		1		
Vaccination site rash		1				1
Vaccination site reaction		3		1		2
Vaccination site scab		1		1		
Vaccination site swelling		1		1		
Vaccination site vesicles		1		1		
Vestibular neuronitis	1	1	1	1		
Visual field defect		1		1		
Visual impairment	1	1	1	1		
Vomiting		2		1		1
	142	525	45	255	97	270

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		4		1		3
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Adverse reaction	1	1	1	1		
Ageusia		1				1
Allergic reaction to excipient		1		1		
Allergic respiratory symptom		1				1
Allergy to vaccine		1				1
Altered state of consciousness		1				1
Anaemia		1				1
Anaphylactic reaction		3				3
Anaphylactic shock		3				3
Angioedema		2				2
Anosmia		1				1
Antibody test abnormal		10		10		
Anxiety		2		1		1
Aortic aneurysm rupture		1				1
Apnoea		1				1
Arrhythmia		2				2
Arthralgia		26		14		12
Arthropathy		1		1		
Asthenia	2	35	1	7	1	28
Asthma		2				2
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Back pain		4		3		1
Bladder cancer		1				1
Blood pressure decreased	1	5			1	5
Blood pressure fluctuation		2				2
Blood pressure increased		5				5
Blood thyroid stimulating hormone decreased		1				1
Body temperature fluctuation		1		1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Body temperature increased		4		1			3
Bone pain		3					3
Bradyarrhythmia		1					1
Burning sensation		1		1			
Bursitis		1		1			
Cardiac arrest		1					1
Cardiac death		1					1
Cardiogenic shock		1					1
Cardiovascular disorder		1					1
Cerebrovascular accident		1					1
Chest pain		6					6
Chills		26		13			13
Chromaturia	1	1			1		1
Circumstance or information capable of leading to medication error		1		1			
Condition aggravated	1	1			1		1
Confusional state		1					1
Conjunctival hyperaemia		1					1
Conjunctival pallor		1					1
Cough		5		1			4
COVID-19	2	10			2		10
C-reactive protein increased		3		1			2
Crying		1		1			
Cyanosis		1					1
Deafness		2					2
Death		7					7
Decreased appetite		4					4
Depressed level of consciousness		1					1
Dermatitis allergic		1					1
Diarrhoea	2	12	1	4	1		8
Disorientation		1					1
Disturbance in attention		1					1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		10
			1
1		1	8
			1
	1		3
			1
2		2	12
			1
	1		
			1
			3
			1
1	8		
			1
			1
			5
			1
			1
			1
			3
			1
	2		
			6
			3
			2
			1
			1
1	7	1	23
1		1	3
			1
	1		
			2
			2

Dizziness

11

Drug hypersensitivity

1

Drug ineffective

1

8

Dry mouth

1

Dysgeusia

4

Dysphagia

1

Dyspnoea

2

12

Dyspnoea at rest

1

Ear pain

1

Encephalopathy

1

Erythema

3

Erythema multiforme

1

Exposure via breast milk

1

8

Extrasystoles

1

Eyelids pruritus

1

Eye pain

5

Eye pruritus

1

Face oedema

1

Facial paralysis

3

Fall

1

Fatigue

2

Febrile convulsion

6

Feeling cold

4

Feeling hot

2

Formication

1

Goitre

1

Headache

1

30

Heart rate increased

1

3

Hemiparesis

1

Hot flush

1

Hyperaesthesia

2

Hyperhidrosis

2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			12
			1
	2		8
			2
	1		1
			1
			3
			1
	3		6
	1		
	1		
			1
	1		
			1
	1		
			1
	1		
			1
	1		
			1
	1		
			1
	4		4
	4		4
	1		1
	1		1
	1		1
	7		7
4	9	3	18
4	6	3	16
	14		5
1		1	1
			1
			1
	1		

Hypersensitivity 12  
Hypertension 1  
Hypoaesthesia 10  
Hypoaesthesia eye 2  
Hypoaesthesia oral 2  
Hypopnoea 1  
Hypotension 3  
Hypothermia 1  
Hypotonic-hyporesponsive episode 9  
Incorrect route of product administration 1  
Infection 1  
Inflammation 1  
Insomnia 1  
Irregular breathing 1  
Joint effusion 1  
Joint injury 1  
Joint range of motion decreased 1  
Joint stiffness 1  
Joint swelling 1  
Lacrimation increased 4  
Laryngospasm 4  
Lip pruritus 1  
Lip swelling 1  
Lividity 1  
Loss of consciousness 7  
Lymphadenopathy 4 27  
Lymph node pain 4 22  
Malaise 19  
Mobility decreased 1 1  
Muscular weakness 1  
Musculoskeletal pain 1  
Musculoskeletal stiffness 1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	3	38	1	15	2	23
Myocardial hypoxia		1				1
Myocardial infarction		2				2
Myocarditis		1				1
Myoglobinuria	1	1			1	1
Nausea		14		5		9
Neck pain		2				2
Needle issue		1		1		
Ocular hyperaemia		1				1
Oedema		2				2
Oedema peripheral		1				1
Off label use		1		1		
Oropharyngeal pain		2		1		1
Oxygen saturation decreased		4		1		3
Pain		3		1		2
Pain in extremity	1	13		4	1	9
Pallor		2				2
Palpitations		2				2
Paraesthesia	1	6			1	6
Paresis		1		1		
Parosmia	1	3	1	1		2
Parotitis		1		1		
Pneumonia		3				3
Poor quality product administered		3		3		
Poor quality sleep		1		1		
Presyncope		3				3
Product contamination physical		1		1		
Product label confusion		2		2		
Product preparation error		1		1		
Pruritus		3				3
Pulmonary oedema		2				2
Pyrexia	5	75	1	21	4	54

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	1	9		1	1	8
Rash erythematous		1				1
Rash rubelliform		2				2
Reaction to excipient		1		1		
Respiratory arrest		2				2
Respiratory disorder		1				1
Rhinitis		2				2
Rhinorrhoea		2				2
Seizure		3				3
Sensory disturbance		2				2
Skin exfoliation		1				1
Sleep disorder	1	1			1	1
Somnolence		4		2		2
Spinal pain		1				1
Swelling		2		2		
Swelling face		1				1
Syncope		9				9
Synovial disorder		1		1		
Tachyarrhythmia		1				1
Tachycardia		13		1		12
Taste disorder		2		1		1
Tension headache		1		1		
Therapeutic response unexpected	1	1	1	1		
Throat irritation		1		1		
Thyroiditis		1				1
Thyroid pain		1				1
Tonsillar hypertrophy		1		1		
Tremor		2				2
Trigeminal neuralgia		1				1
Urticaria		5				5
Vaccination failure	1	2			1	2
Vaccination site abscess sterile		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site discomfort		1					1
Vaccination site erythema		5		2			3
Vaccination site extravasation		1					1
Vaccination site hypersensitivity		1		1			
Vaccination site induration		1		1			
Vaccination site inflammation		1		1			
Vaccination site oedema		1		1			
Vaccination site pain	1	13	1	10			3
Vaccination site pruritus		1		1			
Vaccination site reaction	1	34		3	1		31
Vaccination site swelling		3		3			
Vaccination site warmth		2		1			1
Vertigo		2					2
Visual impairment		1					1
Vomiting	2	12	1	2	1		10
Walking disability		1					1
White blood cell count increased		1					1
Yellow skin		1					1
		1		1			
	45	844	12	230	33		614

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Country Where Event Occurred

**PORTUGAL**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		6				6
Abdominal distension		1				1
Abdominal pain	7	26	2	3	5	23
Abdominal pain lower		1				1
Abdominal pain upper	3	12	1	3	2	9
Abnormal faeces		1				1
Aborted pregnancy		1				1
Abortion spontaneous	1	2			1	2
Acidosis	1	1			1	1
Acne		1				1
Adenopathy syphilitic	1	2			1	2
Administration site bruise		1		1		
Ageusia		3		1		2
Agitation	1	2			1	2
Allergy to vaccine		3				3
Altered state of consciousness	1	2			1	2
Amenorrhoea	1	1	1	1		
Amnesia		1		1		
Amylase increased		1				1
Anaemia		1		1		
Anaphylactic reaction	4	16			4	16
Anaphylactic shock		2				2
Anaphylactoid reaction		2				2
Angina pectoris		1				1
Angioedema		10				10
Anosmia		5		3		2
Anxiety	4	12	4	7		5
Apathy	1	1			1	1
Aphonia	1	1			1	1
Aphthous ulcer		3				3
Apnoea	1	1			1	1
Arrhythmia		5				5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	36	154	5	12	31	142
Asthenia	12	105	3	12	9	93
Asthenopia		1				1
Asymptomatic COVID-19	8	23		2	8	21
Atelectasis		1		1		
Atrioventricular block complete		1				1
Autonomic nervous system imbalance		1				1
Autophony		1				1
Axillary lymphadenectomy	1	1			1	1
Axillary mass		1				1
Axillary pain	4	28	2	8	2	20
Back pain		15		1		14
Balance disorder		4				4
Bedridden		1				1
Bladder disorder	1	1			1	1
Blindness	1	1			1	1
Blood glucose increased		1				1
Blood pressure decreased	1	2			1	2
Blood pressure diastolic increased	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased		7		1		6
Body temperature decreased		1				1
Body temperature increased		6		1		5
Bone pain		2		1		1
Bradycardia	1	6			1	6
Bradyphrenia		2				2
Bradypnoea	1	1			1	1
Breast pain		5		2		3
Breast swelling	1	2		1	1	1
Bronchospasm	1	6			1	6
Burning sensation	3	7	1	1	2	6
Cardiac failure		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory arrest	2	4			2	4
Cerebral venous sinus thrombosis	1	2			1	2
Cerebrovascular accident	3	5			3	5
Chest discomfort		13		4		9
Chest pain	4	23			4	23
Chills	35	167	10	25	25	142
Choking sensation		1				1
Cholinergic syndrome		1				1
Choroiditis		1				1
Circumoral oedema		1				1
Cold sweat		4				4
Computerised tomogram thorax abnormal		1		1		
Condition aggravated	1	6	1	3		3
Confusional state		1				1
Conjunctival irritation		1				1
Contraindicated product administered	1	1	1	1		
Corneal degeneration		1				1
Corneal opacity		1				1
Cough	8	41	1	8	7	33
COVID-19	20	96	4	18	16	78
COVID-19 pneumonia		1				1
Crohn's disease		1				1
Crying		2		1		1
Cyanosis		1				1
Deafness		1				1
Deafness transitory		1				1
Deafness unilateral		1				1
Death	3	4			3	4
Decreased appetite	4	24		1	4	23
Deep vein thrombosis	3	3			3	3
Depressed level of consciousness		1				1
Depressed mood		1				1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	4
		1	2
		3	5
	4		9
		4	23
10	25	25	142
			1
			1
			1
			1
			4
	1		
1	3		3
			1
			1
1	1		
			1
			1
1	8	7	33
4	18	16	78
			1
			1
	1		1
			1
			1
		3	4
	1	4	23
		3	3
			1
			1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic		1				1
Dermatitis exfoliative	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Diarrhoea	22	72	7	13	15	59
Diastolic hypertension		1				1
Diplopia	1	1	1	1		
Discomfort	1	3			1	3
Disease recurrence		1				1
Disorientation	1	1			1	1
Disturbance in attention	1	1			1	1
Dizziness	22	107	11	20	11	87
Dizziness postural		1				1
Drooling		1		1		
Drug hypersensitivity		1				1
Drug ineffective	13	46			13	46
Drug interaction		1				1
Dry eye		1		1		
Dry mouth	1	6	1	2		4
Dry skin	1	1			1	1
Dry throat		1				1
Dysarthria		5		1		4
Dysgeusia	6	18	5	8	1	10
Dyskinesia		1				1
Dyslexia		1				1
Dyspepsia	1	3			1	3
Dysphagia	2	9	1	1	1	8
Dysphonia	3	10		3	3	7
Dyspnoea	11	40		7	11	33
Dyspnoea at rest	1	3			1	3
Dyspnoea exertional	2	2			2	2
Dysstasia		1				1
Dysuria	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Ear pain		3					3
Eczema		1					1
Epistaxis	1	3	1	2			1
Eructation		1		1			
Erythema	1	24		4	1		20
Exophthalmos		1					1
Exposure during pregnancy	2	7	1	6	1		1
Exposure to SARS-CoV-2		1					1
Exposure via breast milk		1		1			
Extrapyramidal disorder		1					1
Extrasystoles		2		1			1
Eye disorder		2		1			1
Eye irritation	1	5	1	4			1
Eyelid myokymia		1					1
Eyelid oedema		3					3
Eyelid sensory disorder		1		1			
Eye movement disorder		1					1
Eye pain		2		2			
Eye paraesthesia		1					1
Eye pruritus		1					1
Eye swelling		1					1
Face oedema	4	17	2	2	2		15
Facial asymmetry		1					1
Facial nerve disorder		1					1
Facial paralysis	2	7			2		7
Facial paresis		2					2
Facial spasm		2		1			1
Faeces soft		1					1
Fall		1		1			
Fatigue	49	189	9	28	40		161
Febrile convulsion		1					1
Feeling abnormal		2		1			1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold	4	14	2	3	2	11
Feeling hot	6	27	5	8	1	19
Feeling of body temperature change		1				1
Fibrin D dimer increased	2	2	2	2		
Flatulence		3		1		2
Flushing	2	10	1	2	1	8
Food refusal	1	1			1	1
Functional gastrointestinal disorder		2				2
Gait disturbance		2		1		1
Gait inability	1	3		1	1	2
Gastric disorder		1				1
Gastrointestinal pain		1				1
Generalised tonic-clonic seizure		2				2
Glossodynia	1	1	1	1		
Gonorrhoea		1				1
Granulomatous lymphadenitis		1				1
Haematoma		3		1		2
Haemoglobinuria	1	1			1	1
Haemoptysis		1				1
Hallucination		1				1
Headache	91	467	33	90	58	377
Head discomfort	1	3	1	1		2
Heart rate increased		5		1		4
Hemiparaesthesia	1	1			1	1
Hot flush		4				4
Hydrocephalus	1	1			1	1
Hyperaesthesia		2				2
Hyperglycaemia		4		1		3
Hyperhidrosis	4	20	1	2	3	18
Hyperlactacidaemia	1	1			1	1
Hypersensitivity		5				5
Hypertension	8	33	4	4	4	29

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive crisis		5				5
Hyperthermia	1	12		2	1	10
Hyperventilation		1				1
Hypoacusis		2				2
Hypoaesthesia	5	14	3	5	2	9
Hypoaesthesia oral	2	12	2	4		8
Hypoglycaemia		3				3
Hypokalaemia		3				3
Hypoperfusion		1				1
Hypopnoea	1	1			1	1
Hyposmia		1				1
Hypotension	3	19		1	3	18
Hypothermia		2				2
Hypothyroidism		1				1
Hypotonic-hyporesponsive episode		1				1
Illness		1		1		
Impaired work ability		2		1		1
Impetigo	1	1			1	1
Inappropriate schedule of product administration		5		4		1
Incorrect route of product administration	1	19	1	19		
Inflammation		3				3
Influenza	2	4			2	4
Influenza like illness		1				1
Injected limb mobility decreased		2		1		1
Injection site erythema		1		1		
Injection site pain	1	3	1	3		
Injection site warmth		1		1		
Insomnia	4	17	2	4	2	13
Inspiratory capacity decreased		2				2
Jaundice	1	1			1	1
Joint range of motion decreased	1	2			1	2
Joint swelling	1	2			1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lacrimation increased		1					1
Lacunar stroke	1	1			1		1
Laryngeal oedema		6					6
Lethargy		1					1
Leukocytosis	1	1			1		1
Leukocyturia		1		1			
Limb discomfort	1	3	1	1			2
Lipase increased		1					1
Lip oedema	1	9	1	1			8
Lip pruritus		1					1
Lip swelling		2					2
Localised oedema		6		1			5
Loss of consciousness		1					1
Loss of personal independence in daily activities	1	3		1	1		2
Lung infiltration	1	1			1		1
Lymphadenitis	3	10	3	4			6
Lymphadenopathy	48	198	9	30	39		168
Lymph node pain		3					3
Lymph node palpable		2		1			1
Lymphoedema		1					1
Lymphoproliferative disorder	1	1			1		1
Macule		1					1
Magnetic resonance imaging brain abnormal		1		1			
Malaise	14	93	9	21	5		72
Mastitis	1	2			1		2
Maternal exposure during pregnancy		5		5			
Meningitis viral	1	1			1		1
Menstrual disorder	1	1	1	1			
Mental fatigue	1	1			1		1
Metrorrhagia		1					1
Migraine	2	7	1	2	1		5
Mobility decreased	2	4	1	1	1		3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Motor dysfunction	1	2
Movement disorder	3	4
Muscle contractions involuntary		1
Muscle fatigue	2	4
Muscle rigidity		1
Muscle spasms		2
Muscle tightness		1
Muscular weakness	1	10
Musculoskeletal discomfort		1
Musculoskeletal disorder	2	2
Musculoskeletal stiffness		5
Myalgia	97	531
Myalgia intercostal		1
Myelitis		1
Myelosuppression		1
Myoclonus		2
Nasal congestion		4
Nasal discomfort		1
Nasal dryness		1
Nasal obstruction		2
Nasopharyngitis		1
Nausea	58	212
Neck mass		1
Neck pain	4	8
Nervousness		1
Neuralgia		1
Neuropathy peripheral		1
Neutrophilia	1	1
Night sweats		3
Nodule	1	1
Non-cardiac chest pain	1	1
Nystagmus		4

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
2	2	1	2
			1
1	2	1	2
			1
	1		1
			1
		1	10
			1
		2	2
	1		4
28	94	69	437
			1
			1
			1
			2
	1		3
	1		
	1		
	1		1
			1
24	42	34	170
	1		
1	1	3	7
			1
			1
			1
		1	1
			3
1	1		
1	1		
			4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Ocular discomfort		1		1			
Ocular hyperaemia		2					2
Odynophagia	2	14	1	4	1		10
Oedema	1	7		1	1		6
Oedema mouth		2					2
Oedema peripheral	5	12	1	4	4		8
Oesophageal disorder		1					1
Oesophageal pain		1					1
Off label use	2	11	2	11			
Oliguria	2	2	1	1	1		1
Oral candidiasis	1	2			1		2
Oral discomfort	1	1	1	1			
Oral herpes		2					2
Oral pain		1					1
Oropharyngeal discomfort	3	12	2	4	1		8
Oropharyngeal oedema		1					1
Oropharyngeal pain	5	11	2	3	3		8
Overdose	5	16	5	15			1
Oxygen saturation decreased	4	8			4		8
Pain	16	56	6	12	10		44
Painful respiration		1					1
Pain in extremity	17	55	3	8	14		47
Palatal disorder	1	1			1		1
Pallor		7					7
Palmar-plantar erythrodysesthesia syndrome		1					1
Palpitations	6	18	1	4	5		14
Pancreatitis		1					1
Pancytopenia		1					1
Paraesthesia	17	69	8	19	9		50
Paraesthesia oral	3	16	2	3	1		13
Paralysis		2					2
Pericarditis		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Perineal pain		1					1
Peripheral coldness	1	5			1		5
Peripheral swelling	2	5			2		5
Petechiae		1					1
Pharyngeal erythema		1					1
Pharyngeal hypoaesthesia	2	2	1	1	1		1
Pharyngeal inflammation		1		1			
Pharyngeal oedema		1					1
Pharyngeal paraesthesia	1	5			1		5
Pharyngeal swelling	1	1			1		1
Pharyngitis		1					1
Phlebitis		1					1
Phonophobia		1					1
Photophobia		6		2			4
Piloerection		3					3
Pityriasis rosea		1					1
Platelet count increased	1	1	1	1			
Pleuritic pain		1					1
Pneumonia		1					1
Pneumonia aspiration	1	2			1		2
PO2 decreased	1	1			1		1
Polydipsia	1	5			1		5
Poor quality sleep		2					2
Postural orthostatic tachycardia syndrome		1					1
Presyncope	8	32	5	7	3		25
Product administered at inappropriate site		1		1			
Productive cough		2		1			1
Product use issue	2	11	2	11			
Proteinuria		1		1			
Pruritus	3	35	1	6	2		29
Pulmonary embolism	4	4			4		4
Puncture site haematoma		1					1

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			3
			1
10	52	47	324
3	8	7	36
1	3		2
		5	8
	1	1	5
	1		2
2	3	2	5
		1	1
			1
			1
			2
		1	1
		1	1
			1
	1		1
2	7		10
	1		7
	1		
			1
		1	6
	1		1
			1
	2		4
		1	1
	2		
			1
		1	1
			2
		1	1

Purpura		3
Pyelonephritis		1
Pyrexia	57	376
Rash	10	44
Rash erythematous	1	5
Rash macular	5	8
Rash maculo-papular	1	6
Rash papular		3
Rash pruritic	4	8
Rash vesicular	1	1
Renal tubular necrosis		1
Respiratory disorder		1
Respiratory distress		2
Respiratory failure	1	1
Respiratory tract infection	1	1
Retinal haemorrhage		1
Rhinitis		2
Rhinorrhoea	2	17
SARS-CoV-2 test positive		8
Scar		1
Sciatica		1
Seizure	1	6
Sensitive skin		2
Sensory disturbance		1
Sensory loss		6
Shock	1	1
Sinusitis		2
Sinus tachycardia		1
Skin burning sensation		1
Skin exfoliation	1	1
Skin lesion		2
Skin reaction	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin warm	2	4		1	2	3
Sleep disorder		2				2
Sneezing	1	2	1	1		1
Somnolence	19	50	10	21	9	29
Speech disorder	2	3		1	2	2
Spinal pain	1	1			1	1
Status epilepticus	1	1			1	1
Stiff tongue		1				1
Stomatitis		2		1		1
Stroke in evolution		1				1
Sudden hearing loss		2				2
Suppressed lactation		1		1		
Swelling	2	11	1	1	1	10
Swelling face		1				1
Syncope	3	17			3	17
Synovial cyst	2	9			2	9
Tachyarrhythmia		3				3
Tachycardia	7	46	2	5	5	41
Tachypnoea	1	3			1	3
Takayasu's arteritis		1				1
Taste disorder		6		1		5
Tenosynovitis		1		1		
Tension headache		1				1
Terminal ileitis		1				1
Throat irritation	1	9	1	3		6
Throat tightness	2	7			2	7
Thrombocytopenia		1				1
Thrombophlebitis	2	3			2	3
Thrombosis	2	2			2	2
Thrombotic microangiopathy		1				1
Thyroid function test abnormal		1		1		
Thyroid mass	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	4			1	4
Tongue disorder	1	1			1	1
Tongue dry		1				1
Tongue eruption		2				2
Tongue oedema	4	13	2	2	2	11
Tongue pruritus		1				1
Tongue rough	1	1	1	1		
Tonic clonic movements		1				1
Tonsillar inflammation	1	1	1	1		
Tonsillitis		1				1
Transaminases increased		1				1
Tremor	3	31	2	5	1	26
Trichoglossia		1		1		
Trigeminal palsy		1				1
Trismus		1				1
Urinary tract infection	1	6			1	6
Urticaria	2	12	1	2	1	10
Urticaria papular		1				1
Vaccination complication		4		1		3
Vaccination failure	11	39			11	39
Vaccination site abscess		1		1		
Vaccination site discolouration		1				1
Vaccination site eczema		2		1		1
Vaccination site erythema	14	53	6	15	8	38
Vaccination site haematoma	5	6	3	3	2	3
Vaccination site induration		10		2		8
Vaccination site inflammation	1	12		1	1	11
Vaccination site injury		1				1
Vaccination site joint inflammation	1	1			1	1
Vaccination site joint movement impairment	3	3			3	3
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment	3	4	1	1	2	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	21	62	7	17	14	45
Vaccination site pain	106	369	40	120	66	249
Vaccination site paraesthesia	1	3	1	2		1
Vaccination site pruritus	6	25	4	7	2	18
Vaccination site rash	4	6	2	2	2	4
Vaccination site reaction	2	7	2	3		4
Vaccination site swelling	4	26	1	4	3	22
Vaccination site urticaria		1				1
Vaccination site warmth	2	18	1	5	1	13
Vaginal haemorrhage	1	2			1	2
Vasculitis	1	2			1	2
Ventricular extrasystoles		1				1
Vertigo	3	13	1	2	2	11
Vertigo positional		1				1
Vision blurred	2	7	1	3	1	4
Visual acuity reduced		1		1		
Visual impairment	1	2			1	2
Vitreous floaters	1	1			1	1
Vomiting	18	63	3	6	15	57
Vulvovaginal burning sensation	1	2	1	1		1
Vulvovaginal swelling		1				1
Weight decreased		1		1		
Wheezing	2	4		1	2	3
Wound		1		1		
	1,220	5,531	378	1084	842	4447

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal pain	1	1	1	1		
Abdominal pain upper		1		1		
Acute kidney injury	2	2			2	2
Acute myocardial infarction	1	3			1	3
Acute pulmonary oedema	1	1			1	1
Anaphylactic reaction	1	4			1	4
Angioedema	1	1			1	1
Aphasia	1	1			1	1
Aphthous ulcer	1	1	1	1		
Arrhythmia		1				1
Arteriosclerosis	1	1	1	1		
Arthralgia	3	19	1	3	2	16
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	3	29	3	7		22
Asymptomatic COVID-19	3	6			3	6
Atrial fibrillation	1	1			1	1
Atrioventricular block complete		1				1
Aura	1	1	1	1		
Axillary pain	1	4			1	4
Back pain	1	5	1	1		4
Bacterial infection		1				1
Balance disorder		1				1
Blindness	1	1			1	1
Blindness unilateral		1				1
Blood glucose fluctuation		1		1		
Blood pressure diastolic decreased		1		1		
Blood pressure systolic increased		1		1		
Blood thyroid stimulating hormone increased		1				1
Bradycardia		2				2
Breast discomfort	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorder		1				1
Cerebrovascular accident	3	3			3	3
Cheilitis	1	1	1	1		
Chest pain	2	3	1	1	1	2
Chillblains		1		1		
Chills	9	32	4	8	5	24
Cholangitis	1	1			1	1
Cholestasis	1	1			1	1
Chronic kidney disease	1	1			1	1
Condition aggravated	1	3			1	3
Confusional state		1				1
Conus medullaris syndrome	1	1			1	1
Cough	1	7			1	7
COVID-19	4	33	1	7	3	26
COVID-19 pneumonia	1	3			1	3
Cutaneous vasculitis		1				1
Deafness neurosensory	1	1			1	1
Deafness unilateral	1	1			1	1
Death		4				4
Decreased appetite	2	8	1	2	1	6
Diarrhoea	1	8	1	1		7
Discomfort	1	2			1	2
Disorientation	2	2	1	1	1	1
Dizziness	6	17	3	4	3	13
Drug-induced liver injury	1	1			1	1
Drug ineffective	2	13			2	13
Drug interaction	1	1			1	1
Dry mouth		2		1		1
Dysgeusia	1	1	1	1		
Dyspepsia	1	1	1	1		
Dysphagia		2				2
Dyspnoea	1	3			1	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain	1	1	1	1		
Ecchymosis	1	1			1	1
Eczema		1				1
Embolic stroke	1	1			1	1
Embolism		1				1
Embolism venous	2	2			2	2
Epistaxis	2	4	1	2	1	2
Erythema	1	5	1	3		2
Escherichia bacteraemia	1	1			1	1
Exposure via breast milk		1		1		
Eyelid oedema		1				1
Eye pain		1		1		
Face oedema		2		1		1
Facial paralysis		3				3
Fall	1	3		1	1	2
Fatigue	6	19	5	9	1	10
Feeling cold		2				2
Feeling hot	1	3	1	1		2
Flushing	2	3	2	2		1
Functional gastrointestinal disorder		1				1
Gait inability		1		1		
Generalised tonic-clonic seizure		1				1
General symptom		1				1
Glossodynia		1		1		
Gynaecomastia	1	1			1	1
Haematoma	1	1			1	1
Haemorrhagic transformation stroke	1	1			1	1
Headache	20	79	14	28	6	51
Head injury		1				1
Heart rate decreased		1				1
Hemianaesthesia		1				1
Hemidysaesthesia		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparesis	1	1			1	1
Hemiplegia	1	1			1	1
Hepatitis	1	1			1	1
Hyperhidrosis	1	7	1	2		5
Hypersensitivity		1				1
Hypertension		3				3
Hypoacusis		1				1
Hypoaesthesia	1	3	1	2		1
Hypoaesthesia oral		2		1		1
Hypotension		6				6
Hypothermia	1	1			1	1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration		1		1		
Influenza		2				2
Influenza like illness		1		1		
Injection site pain		1		1		
Insomnia	1	9	1	4		5
Intercostal neuralgia		2				2
International normalised ratio decreased	1	1	1	1		
International normalised ratio increased	1	1			1	1
Ischaemic stroke	2	3			2	3
Joint range of motion decreased	1	3	1	1		2
Lacunar stroke	1	1			1	1
Lethargy		1				1
Leukaemoid reaction		1				1
L bido decreased		1		1		
Limb discomfort	1	1	1	1		
Limb mass		1		1		
Lip oedema		1				1
Loss of consciousness	1	2			1	2
Loss of personal independence in daily activities	1	2			1	2
Lymphadenitis	1	1			1	1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
7	10	4	18
1	3	2	10
2	2	1	1
1	1		
			1
			2
1	1		1
			1
			1
	1	1	3
			1
8	26	10	72
			1
			2
			1
1	1		
2	3	2	15
1	3		1
			1
1	1		
	1		
	1		
	1		2
1	1		
	3		
			1
2	3	1	2
			2
1	2		
			3

Lymphadenopathy

11

28

Malaise

3

13

Mobility decreased

3

3

Monocyte count increased

1

1

Mood altered

1

Motor dysfunction

2

Muscle contractions involuntary

1

2

Muscle fatigue

1

Muscle spasms

1

Muscle twitching

1

Muscular weakness

1

4

Musculoskeletal stiffness

1

Myalgia

18

98

Myocardial infarction

1

Myocarditis

2

Nasal congestion

1

Nasal oedema

1

1

Nausea

4

18

Neck pain

1

4

Nervousness

1

Nipple disorder

1

1

Occupational exposure to SARS-CoV-2

1

Ocular discomfort

1

Odynophagia

3

Oedema

1

1

Oedema peripheral

1

Off label use

3

Ophthalmic herpes simplex

1

Oropharyngeal discomfort

3

5

Oropharyngeal pain

2

Overdose

1

2

Oxygen saturation decreased

3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	2	7	2	4		3
Pain in extremity	4	10	4	7		3
Pallor		4		1		3
Palpitations	1	3	1	1		2
Paraesthesia	5	9	5	6		3
Paraesthesia oral	1	2	1	1		1
Patella fracture	1	1			1	1
Pericardial effusion	1	1			1	1
Peripheral artery occlusion	1	1			1	1
Peripheral artery stenosis	1	1			1	1
Peripheral swelling	1	1	1	1		
Pharyngeal cyst	2	2			2	2
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation		1				1
Piloerection		1				1
Pityriasis rosea		1				1
Pleuritic pain		1				1
Pneumonia	1	1			1	1
Presyncope	3	6	2	2	1	4
Procedural haemorrhage		1				1
Product administered at inappropriate site	1	1	1	1		
Productive cough		1				1
Product use issue		1		1		
Pruritus	1	8	1	2		6
Purpura	1	1			1	1
Pyrexia	14	71	5	17	9	54
Rash	2	10	1	2	1	8
Rash macular		3		1		2
Rash papular		1		1		
Renal colic		1				1
Respiratory tract congestion		1				1
Restlessness	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rhabdomyolysis		1
Rhinalgia	1	1
Rhinorrhoea		3
Salivary hypersecretion		1
SARS-CoV-2 test positive		1
Seizure	1	2
Sensation of foreign body	1	1
Sepsis	1	1
Sinus tachycardia		1
Skin burning sensation		1
Skin exfoliation		1
Skin reaction		1
Skin warm		3
Sleep disorder		1
Soft tissue haemorrhage		1
Somnolence	2	10
Sudden cardiac death	1	1
Swelling	1	1
Syncope	2	5
Systemic inflammatory response syndrome	1	1
Tachycardia	2	8
Taste disorder		2
Throat irritation		3
Throat tightness		2
Tinnitus	1	2
Tongue coated		1
Tongue discomfort		1
Tongue dry		1
Tonsillar hypertrophy		1
Transient ischaemic attack	1	1
Tremor		8
Upper-airway cough syndrome		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
	1		2
	1		
		1	1
1	1		
		1	1
			1
			1
			1
			3
			1
	1		
1	5	1	5
		1	1
1	1		
		2	5
		1	1
1	3	1	5
			2
	2		1
	1		1
	1	1	1
			1
			1
			1
		1	1
	1		7
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper gastrointestinal haemorrhage	1	1			1	1
Urinary tract infection bacterial		1				1
Urticaria		4		1		3
Urticaria cholinergic		1		1		
Vaccination failure	5	16			5	16
Vaccination site discomfort	2	4	2	2		2
Vaccination site erythema	6	10	5	8	1	2
Vaccination site induration	3	4	3	3		1
Vaccination site inflammation	1	1	1	1		
Vaccination site nodule		1		1		
Vaccination site oedema	3	6	3	6		
Vaccination site pain	35	85	29	56	6	29
Vaccination site pruritus	1	5	1	2		3
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	4	1	2		2
Vaccination site warmth	1	4	1	4		
Vertigo		3		1		2
Vision blurred	1	1	1	1		
Visual impairment		1				1
Vomiting	3	7	2	2	1	5
Wheezing	1	1			1	1
	306	1,062	165	345	141	717

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	1			1	1
Abdominal pain upper		2		1		1
Acute myocardial infarction	1	1			1	1
Allodynia	1	1			1	1
Anaphylactic reaction		2				2
Anosmia		1				1
Arthralgia	10	21	1	3	9	18
Asthenia	3	15		3	3	12
Atrial fibrillation	1	1			1	1
Axillary pain	1	3	1	2		1
Back pain	1	1			1	1
Bedridden		1				1
Blood pressure increased	2	2			2	2
Body temperature abnormal		1				1
Bradycardia		1				1
Bronchospasm		1				1
Chest discomfort		1				1
Chest pain	3	5	1	2	2	3
Chills	8	21		6	8	15
Conjunctival haemorrhage		1				1
Constipation	1	1			1	1
Contusion	1	1			1	1
Cough	4	5	1	1	3	4
COVID-19	1	20	1	7		13
Cyanosis		1				1
Decreased appetite	1	2		1	1	1
Diarrhoea	5	10		3	5	7
Dizziness	4	16	2	6	2	10
Dizziness postural		1				1
Drug ineffective		13				13
Dry mouth		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	5		
		1	1
		3	4
			1
			1
	1		1
	2		2
		1	1
3	8		
	1	1	4
	6	14	19
	1	2	4
			1
3	19	17	50
			1
			1
			1
1	1		1
	4		3
		2	3
	2		
	1		1
			1
			1
2	2		
	1		
			1
			7
			1
			3

Dysgeusia 4 5  
 Dyspepsia 1 1  
 Dyspnoea 3 4  
 Ear pain 1 1  
 Episcleritis 1 1  
 Epistaxis 1 1  
 Eructation 1 1  
 Erythema 4 4  
 Erythema nodosum 1 1  
 Exposure via breast milk 3 8  
 Face oedema 1 5  
 Fatigue 14 25  
 Flushing 2 5  
 Groin pain 1 1  
 Headache 20 69  
 Hemiparaesthesia 1 1  
 Herpes zoster 1 1  
 Hyperaemia 1 1  
 Hyperglycaemia 1 1  
 Hyperhidrosis 1 2  
 Hypersensitivity 7 7  
 Hypertension 2 3  
 Hyperthermia 2 2  
 Hypoaesthesia 2 2  
 Hypoaesthesia oral 1 1  
 Hypotension 1 1  
 Incorrect dose administered 2 2  
 Infant irritability 1 1  
 Inflammation 1 1  
 Laryngeal oedema 7 7  
 Lethargy 1 1  
 Lip oedema 3 3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip swelling		1				1
Localised oedema	1	1			1	1
Lymphadenopathy	4	14		2	4	12
Malaise	2	6		4	2	2
Migraine		2		1		1
Mobility decreased	1	1			1	1
Muscular weakness	1	1	1	1		
Myalgia	22	80	2	20	20	60
Myoclonus		1				1
Nasal congestion	1	1			1	1
Nausea	12	29	2	9	10	20
Neuropathy peripheral	1	1			1	1
Odynophagia		2				2
Oedema	1	1			1	1
Oedema mouth		1				1
Oedema mucosal		1				1
Oedema peripheral	2	3			2	3
Oral disorder		1				1
Oropharyngeal discomfort		1				1
Oropharyngeal oedema		1		1		
Oropharyngeal pain	1	3		2	1	1
Orthopnoea	1	1			1	1
Osteitis		1				1
Overdose	2	5	2	5		
Oxygen saturation decreased		1				1
Pain	6	7	2	2	4	5
Pain in extremity		1		1		
Pain in jaw		1				1
Pallor		2		1		1
Paraesthesia	5	12	2	3	3	9
Paraesthesia oral		4		1		3
Petechiae		1				1

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope		2		1		1
Procedural nausea		1				1
Productive cough		1				1
Pruritus	1	4	1	1		3
Pyrexia	12	55	3	18	9	37
Rash	3	19	1	7	2	12
Rash macular		2				2
Rash maculo-papular		1		1		
Rash pruritic		2		2		
Respiratory distress	1	1			1	1
Rhinorrhoea		3				3
Salivary hypersecretion	1	1	1	1		
SARS-CoV-2 test positive		2				2
Sensation of foreign body		1				1
Sensory loss		1				1
Sleep disorder	1	2			1	2
Sneezing	1	1			1	1
Somnolence	2	7		2	2	5
Stomatitis		1		1		
Syncope	2	6			2	6
Tachycardia	2	10	1	5	1	5
Taste disorder		2		2		
Throat irritation		3		2		1
Tongue discomfort		1				1
Tongue disorder		1		1		
Tongue dry	1	1	1	1		
Tongue oedema	1	4	1	1		3
Tonsillitis bacterial		1				1
Tooth abscess	1	1	1	1		
Tremor		7		3		4
Urticaria		2				2
Urticaria cholinergic		1		1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination failure		2					2
Vaccination site erythema	6	9	1	2	5	7	
Vaccination site haemorrhage		1		1			
Vaccination site hypoaesthesia	1	1	1	1			
Vaccination site inflammation	1	2			1	2	
Vaccination site joint pain	1	1			1	1	
Vaccination site lymphadenopathy		1					1
Vaccination site movement impairment	1	2			1	2	
Vaccination site oedema	9	13		2	9	11	
Vaccination site pain	26	58	12	37	14	21	
Vaccination site pruritus	1	1			1	1	
Vaccination site swelling		2		1		1	
Vaccination site warmth	1	1	1	1			
Varicella		1					1
Vertigo		3					3
Vomiting		6		1			5
	242	763	56	240	186	523	

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**PUERTO RICO**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		3		
Abdominal pain		2		2		
Antinuclear antibody positive		1		1		
Arthralgia		6		6		
Asthenia		1		1		
Axillary pain		1		1		
Back pain		1		1		
Balance disorder		1		1		
Blood pressure increased		1		1		
Bone disorder		1		1		
Bone pain		1		1		
Burning sensation		3		3		
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain		1		1		
Chills		5		5		
Decreased appetite		1		1		
Diarrhoea		3		3		
Discomfort		1		1		
Dizziness		2		2		
Dry mouth		1		1		
Dysgeusia		1		1		
Dyskinesia		1				1
Dyspepsia		1		1		
Dysphonia		1		1		
Erythema		1		1		
Facial pain		1		1		
Facial paralysis	1	3			1	3
Fatigue		9		9		
Flushing		2		2		
Gingival bleeding		1		1		
Haematoma		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache		17		17		
Heart rate decreased		1				1
Heart rate increased		1		1		
Hypertension	1	2		1	1	1
Hypoaesthesia	1	6	1	6		
Inappropriate schedule of product administration		1		1		
Inflammation		1		1		
Injection site discomfort		1		1		
Injection site pruritus		1		1		
Injection site swelling		1		1		
Injection site warmth		1		1		
Joint range of motion decreased		1		1		
Joint swelling		1		1		
Loss of personal independence in daily activities		1		1		
Lymphadenopathy	1	6	1	6		
Malaise		1		1		
Maternal exposure during pregnancy		1		1		
Migraine		1				1
Movement disorder		1		1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Myalgia		9		9		
Nausea		5		5		
Neck pain		2		2		
Night sweats		1				1
Nodule		1		1		
Off label use		1		1		
Oral discomfort		1		1		
Pain		4		4		
Pain in extremity		5		5		
Palpitations		1		1		
Paraesthesia		2		2		

Spontaneous			
Nonserious		Serious	
I	C	I	C
	17		
			1
	1		
	1	1	1
1	6		
	1		
	1		
	1		
	1		
	1		
	1		
	1		
	1		
	1		
1	6		
	1		
	1		
			1
	1		
	1		
	1		
	9		
	5		
	2		
			1
	1		
	1		
	1		
	4		
	5		
	1		
	2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral swelling		1		1		
Photophobia		1		1		
Product administered at inappropriate site		1		1		
Productive cough		1		1		
Pruritus	1	2	1	2		
Pyrexia		11		11		
Rash	2	3	2	3		
Red blood cell sedimentation rate increased		1		1		
Rhinorrhoea		1		1		
Sinus arrhythmia		1				1
Somnolence		1		1		
Speech disorder		1		1		
Stress		1		1		
Swelling		1		1		
Swelling face		1		1		
Tachycardia		2		2		
Taste disorder		2		2		
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling	1	5	1	5		
	9	188	7	178	2	10

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Antibody test abnormal		1		1		
Arthralgia		2		2		
Asymptomatic COVID-19		1		1		
Blood test abnormal		1		1		
Chills		1		1		
Death	1	1			1	1
Deep vein thrombosis	1	1			1	1
Dehydration		1		1		
Depression		1		1		
Dizziness		1		1		
Dyspnoea		2		1		1
Fatigue	1	5	1	5		
Feeling cold	1	1			1	1
Flatulence		1		1		
Gait disturbance		1		1		
Headache	1	4	1	4		
Head discomfort		1		1		
Hyperhidrosis	1	1			1	1
Hypertension		1		1		
Illness		1				1
Inappropriate schedule of product administration	1	2	1	2		
Insomnia	1	1	1	1		
Limb discomfort		1		1		
Lymphadenitis		1		1		
Muscle spasms		1		1		
Musculoskeletal stiffness		1		1		
Nausea		1		1		
Neuralgia		1		1		
Off label use	1	1	1	1		
Pain		2		2		
Pain in extremity	1	2	1	2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		1		1		
Pneumonia		1				1
Pyrexia	1	4	1	4		
Rash		1		1		
Tachycardia		1		1		
Thirst		1		1		
Thrombosis	1	1			1	1
Urinary tract infection		1				1
	12	55	7	46	5	9

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Fatigue		1		1
Headache		1		1
Myalgia		1		1
Poor quality product administered		10		10
Pyrexia		1		1
		15		15

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Country Where Event Occurred

**QATAR**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
COVID-19	1	1			1	1
Dizziness		1				1
Dysgeusia		1		1		
Dyspepsia		2		2		
Erythema		1				1
Exposure during pregnancy	1	1	1	1		
Feeling cold		1		1		
Headache		1		1		
Mood altered		1		1		
Nausea		1				1
Peripheral coldness		1		1		
Product use issue	1	1	1	1		
Vaccination failure	1	1			1	1
	4	15	2	9	2	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	2		1	1	1
Back pain	1	1			1	1
Blood pressure decreased		1		1		
Confusional state	1	1	1	1		
COVID-19	1	1			1	1
Depressed mood	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness		1				1
Drug ineffective	1	1			1	1
Dyspnoea		1				1
Erythema	1	1	1	1		
Facial paralysis		1				1
Feeling hot		1				1
Gait disturbance	1	1	1	1		
Headache	1	1	1	1		
Heart rate decreased	1	1	1	1		
Heart rate increased		1		1		
Herpes zoster		1		1		
Hyperhidrosis		1				1
Hypertension	1	1	1	1		
Hypotension	1	1	1	1		
Middle insomnia	1	1	1	1		
Muscle spasticity	1	1			1	1
Myalgia		1		1		
Neck pain	1	1			1	1
Overdose		1		1		
Pain in extremity	1	1			1	1
Presyncope		1				1
Product preparation error		1		1		
Pyrexia	1	1	1	1		
Sleep disorder	1	1	1	1		
Starvation	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		1				1
Tachycardia	1	1	1	1		
Vertigo	1	1			1	1
	22	36	13	20	9	16

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1				1
COVID-19		1		1		
C-reactive protein increased		1				1
Herpes zoster		1		1		
Inflammatory marker increased		1				1
Neuralgia		1		1		
Neutrophil count increased		1				1
Ocular hyperaemia		1				1
Platelet count increased		1				1
Pyrexia		1				1
Rash		1				1
Red blood cell sedimentation rate increased		1				1
Rhinovirus infection		1				1
Tachycardia		1				1
White blood cell count increased		1				1
		15		3		12

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ROMANIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	4	8	1	2	3	6
Abdominal pain upper		2		1		1
Abortion spontaneous		1				1
Acoustic neuroma	1	1			1	1
Acute coronary syndrome		1				1
Administration site pain	2	3	2	2		1
Administration site reaction	4	4	4	4		
Administration site swelling	1	1	1	1		
Adnexa uteri pain		1				1
Adverse reaction		1		1		
Ageusia		3		2		1
Amenorrhoea	1	1	1	1		
Anaphylactic reaction	1	6			1	6
Anaphylactic shock	2	5			2	5
Anaphylactoid reaction	1	2			1	2
Angina pectoris		2				2
Angioedema	1	5			1	5
Angle closure glaucoma		1				1
Anosmia		2		2		
Anxiety		9		1		8
Apnoea	1	1			1	1
Arrhythmia		1				1
Arthralgia	11	39	8	23	3	16
Asphyxia	1	2			1	2
Asthenia	9	30	6	20	3	10
Asthmatic crisis		1				1
Asymptomatic COVID-19		1				1
Atrial fibrillation		1				1
Atrioventricular block		1				1
Autoimmune disorder	1	1			1	1
Axillary pain	2	5		3	2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Back disorder		1		1			
Back pain	4	5		1	4	4	
Balance disorder	2	3	1	1	1	2	
Blister		1				1	
Blood fibrinogen increased	1	1	1	1			
Blood glucose decreased	1	1			1	1	
Blood glucose increased	1	1			1	1	
Blood pressure abnormal	1	2	1	1		1	
Blood pressure decreased		1				1	
Blood pressure diastolic increased		1				1	
Blood pressure fluctuation	1	3			1	3	
Blood pressure increased	1	6		1	1	5	
Blood pressure systolic increased		1				1	
Blood uric acid increased	1	1	1	1			
Body temperature abnormal		1		1			
Bone pain	3	9		3	3	6	
Breast inflammation	2	2			2	2	
Breast pain	1	4		1	1	3	
Bronchospasm	1	4		1	1	3	
Burning sensation	1	3		1	1	2	
Burn of internal organs		1				1	
Cardiac fibrillation		1				1	
Cerebral small vessel ischaemic disease		1				1	
Cerebrovascular accident	2	3			2	3	
Chest discomfort	3	6	1	3	2	3	
Chest pain	3	11		1	3	10	
Chills	27	85	9	39	18	46	
Circumoral oedema		1				1	
Cold sweat		2				2	
Condition aggravated	1	2		1	1	1	
Confusional state		1		1			
Cough	2	9	1	3	1	6	

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	14	41	1	5	13	36
Crying		1		1		
Cyanosis		3		1		2
Death		1				1
Decreased appetite	3	6	1	2	2	4
Deep vein thrombosis	1	2			1	2
Dementia	1	1			1	1
Depressed level of consciousness		1				1
Dermatitis allergic	2	5	1	1	1	4
Diabetes mellitus	1	1			1	1
Diarrhoea	4	11	2	3	2	8
Diplopia	3	4	1	1	2	3
Discomfort	1	2	1	2		
Disease recurrence	1	1			1	1
Disorientation	1	1			1	1
Disturbance in attention	1	2			1	2
Dizziness	21	47	6	19	15	28
Drug eruption		2				2
Drug ineffective	7	29			7	29
Dry mouth	1	3			1	3
Dysgeusia	1	2			1	2
Dysphagia	1	4		1	1	3
Dysphonia		1		1		
Dyspnoea	7	17		2	7	15
Dysstasia	1	1			1	1
Ear discomfort		1		1		
Ear pain		1				1
Emotional distress		1		1		
Epiglottic oedema		1				1
Epistaxis		1		1		
Eructation		1				1
Erythema		15		7		8

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema nodosum		2		1		1
Exposure during pregnancy	1	2	1	2		
Extensive swelling of vaccinated limb		1				1
Eye haemorrhage	2	2			2	2
Eyelid oedema		1				1
Eyelid ptosis		1				1
Eye pain	1	2			1	2
Eye pruritus		1		1		
Face oedema		2				2
Facial neuralgia		1				1
Facial pain	1	1			1	1
Facial paralysis	1	7			1	7
Facial paresis		2				2
Faeces soft		1				1
Fatigue	23	66	12	44	11	22
Fear		1		1		
Feeling abnormal		2				2
Feeling cold		2		1		1
Feeling hot	1	2			1	2
Flatulence	1	1			1	1
Flushing		1		1		
Foaming at mouth		1				1
Gait disturbance	1	1			1	1
Gastric pH decreased		1		1		
General physical condition abnormal		2		2		
General physical health deterioration		1		1		
Goitre		1				1
Headache	45	127	19	63	26	64
Head discomfort	2	2			2	2
Heart rate abnormal		1		1		
Heart rate decreased	1	2			1	2
Heart rate increased	4	14			4	14

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemianaesthesia	1	1			1	1
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	1			1	1
Hepatitis		1				1
Hepatocellular injury		1				1
Herpes virus test	1	1	1	1		
Herpes zoster		1				1
High density lipoprotein decreased	1	1	1	1		
Hot flush		1		1		
Hyperaemia		1				1
Hyperaesthesia		1		1		
Hyperhidrosis	3	13		4	3	9
Hyperpyrexia		1				1
Hypersensitivity	18	22	16	18	2	4
Hypertension	16	37	2	4	14	33
Hypertensive crisis	1	2			1	2
Hypoacusis	2	2			2	2
Hypoaesthesia	11	19	1	5	10	14
Hypoaesthesia eye	1	1			1	1
Hypoaesthesia oral	2	3			2	3
Hypocalcaemia		1				1
Hypokinesia		1		1		
Hypotension		5		1		4
Hypothyroidism		1				1
Hypotonia		1				1
Illness		1				1
Immobile	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incomplete course of vaccination	1	1	1	1		
Incorrect route of product administration	1	5	1	3		2
Inflammation		2		2		
Influenza		1		1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
			1
			1
1	1		
			1
1	1		
	1		
	4	3	9
			1
16	18	2	4
2	4	14	33
		1	2
		2	2
1	5	10	14
		1	1
		2	3
			1
	1		
	1		4
			1
			1
			1
		1	1
1	1		
1	1		
1	3		2
	2		
	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness		2		2		
Injected limb mobility decreased		3		3		
Insomnia		4		1		3
Intracranial pressure increased		1				1
Jaw disorder		1				1
Joint ankylosis		1				1
Joint stiffness		1				1
Laboratory test abnormal	1	2	1	2		
Laryngeal oedema		2				2
Laryngospasm		1				1
Limb injury		1				1
Lipase increased		1		1		
Lip dry	1	1			1	1
Lip oedema		6		2		4
Lip swelling		1				1
Listeria test positive	1	1	1	1		
Loss of consciousness	3	5			3	5
Loss of personal independence in daily activities		1		1		
Lung disorder		1		1		
Lymphadenitis	3	7	2	4	1	3
Lymphadenopathy	9	26	3	11	6	15
Lymph node pain		1		1		
Lymph node palpable	1	1	1	1		
Lymphopenia		1				1
Malaise	7	22	1	8	6	14
Maternal exposure during pregnancy	1	3	1	3		
Mean cell haemoglobin increased		1		1		
Memory impairment		1				1
Menstrual disorder		1				1
Menstruation irregular	1	1			1	1
Mental status changes	1	1			1	1
Metamorphopsia		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine		3		1		2
Mobility decreased	1	2		1	1	1
Monoplegia		1				1
Mouth swelling	1	1			1	1
Mucosal dryness		1				1
Muscle contractions involuntary		1		1		
Muscle rigidity	1	1			1	1
Muscular weakness		2		1		1
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness	1	1			1	1
Myalgia	28	96	10	46	18	50
Myocardial infarction	1	1			1	1
Myocardial ischaemia		1				1
Myoclonus		2				2
Nasal congestion	1	1			1	1
Nasal discomfort		2		2		
Nasal dryness	1	3		1	1	2
Nasal oedema		1				1
Nausea	22	62	8	26	14	36
Neck pain		1		1		
Nephropathy		1				1
Nervous system disorder		2		2		
Neurological symptom		3				3
Neuropathy peripheral	1	1			1	1
Night sweats	2	2	1	1	1	1
Nitrite urine present	1	1	1	1		
No adverse event		1		1		
Nystagmus		1		1		
Obstructive airways disorder		1				1
Ocular discomfort	3	3	2	2	1	1
Ocular hyperaemia		1		1		
Odynophagia		1		1		

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
		1	3
			1
1	2		
		1	1
			2
		3	3
	1		
		2	4
1	11	2	3
4	24	8	10
		2	2
		1	2
1	1	5	10
1	6	6	18
	1		
			1
			1
			1
1	1	1	1
2	3	2	2
1	1	1	1
			1
		1	1
			1
			1
1	1	1	1
			1
			1
1	1	1	1
			1
			1
1	1	1	1
			1
			1
		1	1
			1

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	3
	3	1	2
			1
	1		
1	1		
1	5		5
1	2		2
	2		
9	45	20	49
			1
1	7	1	4
			3
	2		2
			1
			1
1	1		
			3
			1
	1		1
			3
			1
			1
1	1		
			1
	1		1
			2
	1		
			2
	1		
			1
		1	1
			2

Polyuria 2 3  
 Presyncope 1 5  
 Productive cough 1 1  
 Product use issue 1 1  
 Protein urine present 1 10  
 Pruritus 1 4  
 Pulse abnormal 1 2  
 Pulse volume decreased 29 94  
 Pyrexia 2 11  
 Rales 3 3  
 Rash 2 4  
 Rash erythematous 1 1  
 Rash pruritic 1 1  
 Rash vesicular 1 1  
 Raynaud's phenomenon 1 1  
 Red blood cells urine positive 1 3  
 Renal pain 1 1  
 Respiration abnormal 2 2  
 Respiratory disorder 3 3  
 Respiratory distress 1 1  
 Rhinalgia 1 1  
 Rhinorrhoea 1 1  
 SARS-CoV-2 ant body test negative 1 3  
 SARS-CoV-2 ant body test positive 2 3  
 SARS-CoV-2 test positive 3 3  
 Scar pain 1 1  
 Seizure 2 2  
 Sensory loss 1 1  
 Shock 1 1  
 Sialoadenitis 1 1  
 Sinus tachycardia 2 2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation	1	1			1	1
Skin discolouration	1	1	1	1		
Skin hypertrophy	1	1			1	1
Skin plaque		1				1
Sleep disorder	1	1			1	1
Somnolence	9	26	4	14	5	12
Speech disorder		1				1
Spinal pain	1	2		1	1	1
Stomatitis	2	2			2	2
Stress		1		1		
Stridor		1		1		
Suffocation feeling	2	4	1	1	1	3
Suppressed lactation		1		1		
Supraventricular tachycardia		1				1
Suspected COVID-19		2				2
Swelling		1		1		
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	11	22			11	22
Systemic inflammatory response syndrome		1				1
Systolic hypertension		1				1
Tachyarrhythmia	1	1			1	1
Tachycardia	4	26		7	4	19
Tachypnoea		1				1
Taste disorder	2	3	1	2	1	1
Teething	1	1			1	1
Tendon pain	1	1			1	1
Thirst	2	3			2	3
Throat tightness		1		1		
Thyroiditis subacute		1		1		
Tinnitus	2	3		1	2	2
Tongue oedema		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tongue spasm		1					1
Toxocariasis	1	1			1		1
Toxoplasma serology positive	1	1	1	1			
Tremor	3	7		1	3		6
Type 2 diabetes mellitus	1	1			1		1
Urinary incontinence	1	1			1		1
Urine ketone body present	1	1	1	1			
Urticaria	2	13		3	2		10
Urticaria papular		1		1			
Use of accessory respiratory muscles		1		1			
Vaccination failure	5	10			5		10
Vaccination site discolouration		1		1			
Vaccination site erythema	3	12	3	9			3
Vaccination site granuloma	1	1	1	1			
Vaccination site induration	2	5	2	4			1
Vaccination site inflammation		2		1			1
Vaccination site joint movement impairment		2					2
Vaccination site lymphadenopathy		2		2			
Vaccination site macule	1	1	1	1			
Vaccination site movement impairment	3	6	1	4	2		2
Vaccination site nodule		1		1			
Vaccination site oedema		3		3			
Vaccination site pain	30	95	21	67	9		28
Vaccination site papule	1	1	1	1			
Vaccination site paraesthesia		2		1			1
Vaccination site pruritus	2	4	2	4			
Vaccination site reaction	10	16	10	16			
Vaccination site swelling	3	6	3	6			
Vaccination site urticaria		1		1			
Ventricular extrasystoles		1		1			
Vertigo	7	21		3	7		18
Vestibular disorder		1		1			

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	1	2			1	2
Visual field defect		1				1
Visual impairment	2	3	1	1	1	2
Vomiting	5	23	2	8	3	15
Weight decreased		1				1
Wheezing		2		1		1
White blood cells urine positive	1	1	1	1		
Wrong technique in product usage process		1		1		
	635	1,885	223	781	412	1104

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acute pulmonary oedema		2				2
Adverse event		1		1		
Ageusia	1	3	1	2		1
Agitation		1				1
Allergy to vaccine		1		1		
Anaphylactic reaction	1	1			1	1
Angina pectoris		1				1
Anosmia	1	2			1	2
Anxiety		4		3		1
Aphonia		1		1		
Arrhythmia		2				2
Arthralgia	3	12	1	5	2	7
Asthenia		5		3		2
Asthma		1				1
Back pain	2	5		2	2	3
Balance disorder		1				1
Blepharitis		1				1
Blood pressure increased	2	4	1	3	1	1
Blood pressure systolic increased		2		1		1
Body temperature abnormal		1		1		
Body temperature increased	1	2		1	1	1
Bone pain	1	2		1	1	1
Bronchitis	1	1			1	1
Bronchospasm	1	2	1	1		1
Cardiac arrest		1				1
Cardio-respiratory arrest		1				1
Cataract	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest discomfort	1	1	1	1		
Chest pain	1	3		2	1	1
Chills	11	27	6	15	5	12

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		2		2		
Coma		2				2
Condition aggravated		2				2
Contusion		1		1		
Coronavirus infection		1				1
Cough		2		2		
COVID-19	12	34	3	5	9	29
Death		2				2
Decreased appetite	2	3	1	1	1	2
Deep vein thrombosis	1	1			1	1
Dehydration		1				1
Diarrhoea	1	5	1	3		2
Disease recurrence		1				1
Disturbance in attention		2		1		1
Dizziness	2	12	1	7	1	5
Drug ineffective	7	28			7	28
Dysphonia		1		1		
Dyspnoea	3	5	1	1	2	4
Dyspnoea exertional	1	1			1	1
Ear pain		1		1		
Erythema		4		3		1
Exposure to SARS-CoV-2	1	1	1	1		
Eyelid oedema		1		1		
Eyelid ptosis		1		1		
Facial pain		1		1		
Facial paralysis	1	2			1	2
Facial paresis	1	1			1	1
Fatigue	5	14	3	11	2	3
Feeling abnormal	2	3	2	3		
Feeling cold	2	2			2	2
Feeling hot	1	2		1	1	1
Gait disturbance		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General physical health deterioration		2		2		
Guillain-Barre syndrome	1	1			1	1
Headache	9	30	5	22	4	8
Heart rate increased	4	4	1	1	3	3
Herpes zoster		1		1		
Horner's syndrome		1				1
Hyperglycaemia		3		1		2
Hyperhidrosis	1	5		2	1	3
Hyperkalaemia		2				2
Hypersensitivity		1		1		
Hypertension	4	8		2	4	6
Hyperthermia		1		1		
Hypoacusis	2	2			2	2
Hypoaesthesia	2	4	1	3	1	1
Hypoaesthesia oral		1				1
Hypotension	1	2			1	2
Hypoxic-ischaemic encephalopathy		1				1
Impaired work ability		1				1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		2		1		1
Infarction		1				1
Influenza like illness		1		1		
Insomnia	2	3		1	2	2
Lethargy		1		1		
Lividity	1	1			1	1
Localised oedema		1				1
Loss of consciousness	2	3			2	3
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenitis	1	1			1	1
Lymphadenopathy	2	8	2	7		1
Malaise	2	6		3	2	3
Medication error		1		1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Metabolic acidosis		1
Monoplegia	1	1
Movement disorder		1
Muscle contractions involuntary		1
Muscle contracture	1	1
Muscle swelling		1
Muscular weakness		2
Myalgia	7	26
Nasal vestibulitis		1
Nausea	1	7
Nervous system disorder		1
Neuronal neuropathy	1	1
No adverse event		1
Oedema		1
Off label use		1
Oral pigmentation	1	1
Oropharyngeal pain	1	1
Oxygen saturation abnormal	1	1
Oxygen saturation decreased		1
Pain		1
Pain in extremity	3	8
Pallor	1	2
Palpitations	1	1
Panic attack	1	3
Paraesthesia	2	8
Paraesthesia ear		1
Peripheral arterial occlusive disease		1
Peripheral swelling		1
Presyncope		1
Product preparation issue		1
Product use issue		1
Pruritus		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
			1
			1
		1	1
	1		
	2		
3	13	4	13
			1
1	4		3
	1		
		1	1
	1		
	1		
1	1		
		1	1
		1	1
	1		
	1		
2	7	1	1
	1	1	1
		1	1
1	3		
	5	2	3
	1		
			1
	1		
	1		
	1		
	1		
	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	11	37	7	21	4	16
Rash		4		3		1
Rash erythematous		1				1
Rectal haemorrhage		1				1
Respiratory failure		1				1
Rhinorrhoea	3	4	2	3	1	1
SARS-CoV-2 ant body test negative		2		2		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive		2				2
Seizure		1				1
Sitting disability		1				1
Skin discolouration		1		1		
Skin irritation		2				2
Somnolence	4	7	2	4	2	3
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19	1	3		1	1	2
Sweating fever	1	1			1	1
Swelling		1		1		
Syncope	5	12			5	12
Syringe issue		1		1		
Tachycardia		1		1		
Thirst	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus	1	1			1	1
Tongue disorder		1		1		
Transaminases increased		1		1		
Tremor		1		1		
Urticaria	1	3	1	3		
Vaccination failure	2	4			2	4
Vaccination site erythema		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site movement impairment		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	7	33	5	27	2	6
Vaccination site reaction	9	9	9	9		
Vertigo	2	5	2	3		2
Viral infection	1	1			1	1
Vision blurred	1	1			1	1
Visual acuity reduced		1				1
Visual impairment	1	2			1	2
Vomiting		1				1
Walking disability		1		1		
Weight increased		1				1
Wrong product administered		2		2		
Wrong technique in product usage process		2		2		
	181	579	70	286	111	293

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	2			2	2
Arrhythmia	2	2			2	2
Arthralgia		6		6		
Asthenia	7	7	7	7		
Asymptomatic COVID-19		1				1
Blood pressure abnormal		1		1		
Body temperature abnormal		1		1		
Burning sensation		1				1
Chills	6	7	5	6	1	1
Circumstance or information capable of leading to medication error		3		3		
Cough		1		1		
COVID-19	94	107			94	107
Death	6	6			6	6
Decreased appetite	1	1	1	1		
Dizziness	1	1			1	1
Drug ineffective	18	33			18	33
Erythema		3		3		
Exposure via breast milk		1		1		
Facial paralysis		1				1
Facial paresis	2	2	2	2		
Fatigue	6	8	6	8		
Feeling cold		1		1		
Feeling hot		1		1		
Headache	11	15	9	13	2	2
Heart rate increased		1		1		
Hyperhidrosis	1	2		1	1	1
Hypersensitivity	1	1	1	1		
Hypertension	3	3	2	2	1	1
Incorrect route of product administration		1		1		
Influenza like illness	5	5	5	5		
Injected limb mobility decreased		1		1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intercepted medication error		1		1		
Lethargy		1		1		
Local reaction	1	1	1	1		
Lymphadenopathy		2		2		
Malaise	2	4	1	3	1	1
Medication error		2		2		
Muscle contracture		1		1		
Muscle spasms		1				1
Muscular weakness	2	2	2	2		
Myalgia	12	15	12	15		
Nausea		1		1		
Neuralgia		1				1
Neuropathy peripheral		1				1
Off label use		1		1		
Pain		1		1		
Pain in extremity		6		6		
Paraesthesia		2		1		1
Product preparation error	1	13	1	13		
Product preparation issue	3	8	3	8		
Product quality issue		1		1		
Pyrexia	8	17	7	16	1	1
SARS-CoV-2 ant body test negative		4		4		
SARS-CoV-2 ant body test positive		4		4		
SARS-CoV-2 test positive		4		2		2
Somnolence	1	1			1	1
Syncope		2				2
Tachycardia	1	1	1	1		
Underdose	2	3	2	3		
Vaccination failure		1				1
Vaccination site discomfort		3		3		
Vaccination site erythema	1	13	1	13		
Vaccination site inflammation		1		1		

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site nodule		1		1		
Vaccination site pain	2	18	2	18		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
Wrong technique in product usage process	3	14	3	14		
	206	380	75	209	131	171

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Country Where Event Occurred

**SAUDI ARABIA**

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Arthralgia		1		1		
Chills		2		2		
Dizziness		1		1		
Dysstasia		1				1
Fatigue		3		2		1
Gait disturbance		2		1		1
Headache	1	5	1	5		
Hyperhidrosis		2		2		
Lymphadenopathy		1		1		
Lymphoma	1	1			1	1
Malaise	1	1	1	1		
Mastication disorder		1		1		
Menstruation irregular	1	1	1	1		
Mobility decreased		2		1		1
Mouth ulceration		1		1		
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	4	1	3		1
Nausea		1		1		
Oropharyngeal pain		1		1		
Pain	1	3	1	2		1
Pain in extremity		1				1
Pain in jaw		1		1		
Pain of skin		1		1		
Pyrexia	1	3	1	3		
Sciatica		1		1		
Somnolence		1		1		
Tremor	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain	1	2	1	2		
Vaccination site pruritus		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		1		1		
Vaginal infection		1		1		
Vomiting		1				1
	9	53	8	43	1	10

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acquired haemophilia		1				1
Anaphylactic shock		1				1
Arthralgia		1		1		
Asthenia		1		1		
Cardiac arrest		1				1
Carotid artery stenosis		1				1
COVID-19	1	3	1	3		
Dizziness		1				1
Fatigue		3		3		
Feeling hot	1	1	1	1		
Gait inability		1				1
Headache		1		1		
Heart rate decreased		1				1
Herpes zoster		1		1		
Hot flush	1	1	1	1		
Hyperhidrosis		2		1		1
Hypotension		1				1
Lymphadenopathy		2		2		
Malaise		1		1		
Mobility decreased		2		2		
Myalgia		2		2		
Nasopharyngitis		1		1		
Night sweats	1	1	1	1		
Pain		3		3		
Pain in extremity		1				1
Peripheral coldness		1		1		
Pollakiuria		1		1		
Pyrexia		4		3		1
Rhinorrhoea		1		1		
Sciatica		1		1		
Seizure	1	2			1	2

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\* AE=Adverse Event

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sitting disability		1				1	
Sleep disorder	1	1	1	1			
Syncope		3					3
Temperature intolerance	1	1	1	1			
Vaccination site pain		4		4			
Vomiting		2					2
	7	58	6	39	1		19

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Accidental overdose		1		1			
Arthralgia		1		1			
Asthenia		1		1			
Axillary pain	1	1	1	1			
C-reactive protein increased		1		1			
Fatigue		1		1			
Inappropriate schedule of product administration		1		1			
Lymphadenopathy		1		1			
Myalgia		1		1			
Pain in extremity		2		2			
Peripheral coldness		1		1			
Product preparation issue		1		1			
Pulmonary embolism	1	1			1	1	
Red blood cell sedimentation rate increased		1		1			
	2	15	1	14	1		1

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Country Where Event Occurred

**SERBIA**

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		2		1		1
Anaphylactoid reaction		1				1
Anosmia		1		1		
Anxiety		1		1		
Arthralgia		10		10		
Asphyxia		2				2
Asthenia		6		6		
Axillary pain		1		1		
Back pain		1		1		
Blepharospasm		1				1
Blood pressure increased		2		1		1
Body temperature increased	2	9	2	9		
Bone pain		1		1		
Bronchospasm		1				1
Burning sensation	1	1	1	1		
Chest pain		2		1		1
Chills		7		7		
Conjunctivitis		1		1		
Cough		1				1
COVID-19	1	5	1	4		1
Deafness		1				1
Deafness unilateral		1				1
Decreased appetite		1		1		
Diarrhoea		1		1		
Disease recurrence	1	1	1	1		
Dizziness	2	5	2	4		1
Drug ineffective		1				1
Dry mouth		1		1		
Erythema		8		7		1
Exposure during pregnancy		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	1	1	1	1		
Face oedema		1				1
Facial paralysis		1				1
Facial paresis		1				1
Fall		1		1		
Fatigue	1	5	1	4		1
Fear of death		1		1		
Feeling abnormal		1		1		
Feeling cold		2		2		
Feeling hot	1	2	1	2		
Haematoma		1		1		
Headache	3	15	3	14		1
Herpes zoster		1		1		
Huntington's disease		1				1
Hyperhidrosis	1	2	1	2		
Hypersensitivity		2		1		1
Hypertension		6		2		4
Hypoaesthesia		1		1		
Hypoaesthesia oral		2		1		1
Hypopnoea		1				1
Inflammatory marker increased		1		1		
Influenza like illness		2		2		
Insomnia	1	1	1	1		
Joint stiffness		2		1		1
Localised oedema		1		1		
Lymphadenopathy		1		1		
Malaise	1	9	1	8		1
Maternal exposure during pregnancy		1		1		
Movement disorder		1		1		
Muscular weakness		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	10	1	10		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myositis		1				1
Nasal congestion		1		1		
Nasopharyngitis		1		1		
Nausea	1	9	1	8		1
No adverse event		2		2		
Oedema mucosal		1				1
Oedema peripheral	1	2	1	2		
Oropharyngeal pain		1		1		
Pain		2		2		
Pain in extremity	2	9	2	9		
Pallor		2		2		
Palpitations		1		1		
Paraesthesia		2		2		
Pruritus	1	1	1	1		
Pulmonary pain		1		1		
Pyrexia	1	21	1	21		
Rash	1	2	1	1		1
Rash macular		2				2
Skin burning sensation		1				1
Sleep disorder		1		1		
Somnolence	1	2	1	2		
Superficial vein prominence	1	1	1	1		
Swelling		1		1		
Swelling of eyelid		1		1		
Swollen tongue		1		1		
Syncope		2				2
Tachycardia		1				1
Tinnitus		1		1		
Tongue oedema		1				1
Tremor		1		1		
Urticaria		2		2		
Vaccination complication		4		4		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema		2		2		
Vaccination site induration		1		1		
Vaccination site oedema		2		2		
Vaccination site pain		9		9		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vision blurred		2		1		1
Vomiting		1		1		
Wrong product administered		1		1		
	26	260	26	217		43

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Abscess		1				1
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Anxiety		1		1		
Arthralgia		2		1		1
Asthenia	2	3	1	2	1	1
Axillary pain		1				1
Back pain	1	1			1	1
Balance disorder		1				1
Blood lactate dehydrogenase increased		1				1
Body temperature increased	1	5	1	4		1
Bone pain		1		1		
Bronchospasm		1		1		
Chest discomfort		1		1		
Chest pain		1				1
Chills	1	4	1	2		2
Confusional state		1		1		
Cough	1	2	1	1		1
COVID-19	3	5	3	4		1
COVID-19 pneumonia		1				1
C-reactive protein increased	1	2	1	1		1
Diarrhoea		1		1		
Dizziness		1		1		
Drug ineffective	1	2			1	2
Dysgeusia		1				1
Dyspnoea		3				3
Fall		1				1
Fatigue	2	5	2	5		
Fear	1	1			1	1
Fibrin D dimer increased	1	1	1	1		
Headache	2	9	1	7	1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	1	1	1		
Hyperaesthesia	1	1	1	1		
Hyperhidrosis		2		1		1
Hypersensitivity		1		1		
Hypertension	1	2			1	2
Inappropriate schedule of product administration	1	2	1	2		
Insomnia		1				1
Intraocular pressure increased		1				1
Ischaemic stroke		1				1
Lacrimation increased		1		1		
Lip disorder	1	1	1	1		
Lip pruritus		1		1		
Lip swelling		1		1		
Loss of consciousness		1				1
Lymphadenitis		1				1
Lymphadenopathy		2		1		1
Malaise	3	11	3	9		2
Monocyte count increased		1		1		
Muscular weakness		1		1		
Myalgia	1	5	1	4		1
Myocardial infarction	1	1			1	1
Nasal congestion		1				1
Nausea	2	9	2	8		1
Neck pain		1				1
Nervousness		1				1
No adverse event		1		1		
Oedema mouth		1		1		
Off label use	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Overdose	1	1			1	1
Oxygen saturation decreased		1				1
Pain		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	3	1	3		
Pain in jaw		1		1		
Pancreatitis acute		1				1
Paraesthesia oral		1		1		
Peripheral swelling		1				1
Phlebitis		1				1
Pneumonia		1		1		
Product supply issue		1		1		
Pruritus		1		1		
Pulmonary pain		1				1
Pyrexia	2	15	1	11	1	4
Rash		1		1		
Red blood cell count increased	1	1	1	1		
Red blood cell sedimentation rate increased		1				1
Rhinorrhoea		1				1
SARS-CoV-2 test positive		3		1		2
Skin burning sensation	1	1	1	1		
Skin reaction		1				1
Sneezing		1				1
Somnolence		1				1
Swelling		1				1
Syncope	2	2			2	2
Tachycardia		1				1
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
Tremor	1	1	1	1		
Urticaria		2		2		
Vaccination complication		1		1		
Vaccination failure		1				1
Vaccination site erythema		1		1		
Vaccination site haematoma		1				1
Vaccination site pain		6		6		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		1		1		
Vomiting		2		2		
Wheezing		1				1
	45	182	32	113	13	69

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematemesis		1				1
Nausea		1				1
Pyrexia		2		1		1
SARS-CoV-2 ant body test negative		1		1		
Vaccination site erythema		1		1		
Vaccination site pain		1		1		
Vomiting		1				1
		8		4		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SINGAPORE**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	4	4			4	4
Abdominal tenderness	1	1			1	1
Acute kidney injury	1	1			1	1
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	12	14			12	14
Anaphylactic shock		3				3
Angioedema	3	4			3	4
Arthralgia	2	2			2	2
Arthritis	1	1			1	1
Asthenia	2	2	1	1	1	1
Asthma	1	1			1	1
Bicytopenia	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood pressure increased	2	2			2	2
Blood pressure systolic increased	2	2			2	2
Breath sounds abnormal	1	1			1	1
Chest discomfort	10	11	2	2	8	9
Chest pain	2	2			2	2
Chills	4	5		1	4	4
Cough	1	3			1	3
Deafness neurosensory	1	1			1	1
Decreased appetite	1	1			1	1
Dehydration	1	1			1	1
Diarrhoea	2	3		1	2	2
Diplopia	1	1			1	1
Disease progression	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness	16	17	5	5	11	12
Dry eye	1	1			1	1
Dry mouth	1	1	1	1		
Dysacusis		1		1		
Dyskinesia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	2	2			2	2
Dysphonia	7	8	1	1	6	7
Dyspnoea	19	21	1	1	18	20
Dyspnoea exertional	1	1	1	1		
Dysstasia	1	1			1	1
Enlarged uvula	2	3			2	3
Erythema	2	2			2	2
Extrasystoles	1	1			1	1
Eye disorder	1	1			1	1
Eye movement disorder	1	1			1	1
Eye pruritus	2	2	1	1	1	1
Eye swelling	1	1			1	1
Facial asymmetry	1	1			1	1
Facial paralysis	2	2			2	2
Fall	1	1			1	1
Fatigue	4	4	3	3	1	1
Femoral neck fracture	1	1			1	1
Flushing	2	2			2	2
Gait disturbance	1	1			1	1
Gastrooesophageal reflux disease	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Haematocrit increased	1	1			1	1
Haematuria	1	1			1	1
Haemoglobin increased	1	1			1	1
Headache	5	6	4	5	1	1
Head discomfort		1		1		
Heart rate increased	1	2			1	2
Hepatitis	1	1			1	1
Hunger	1	1	1	1		
Hyperhidrosis	2	2	1	1	1	1
Hypersensitivity	2	3		1	2	2
Hypertension	4	5			4	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1	4	4
		5	5
		1	1
		1	1
		1	2
1	1		
			1
	1		
1	1	1	1
2	2	2	2
1	1	1	1
2	2	1	1
9	9	4	5
1	1	1	1
1	1	1	1
1	1		
1	1	1	1
2	2		
2	2	2	2
2	2		
2	2	1	1
3	3	2	1
1	1		
1	1	1	1
7	8	1	6
3	3		3
1	1	1	
1	1		1
1	1	1	
2	2		2
1	1	1	1
1	1	1	1
1	1		
1	1	1	1
1	1		
1	1	1	1
1	1		
1	1	1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		4	5
		1	1
3	3	6	6
		1	1
1	2	7	7
1	1		
		1	2
		1	1
		1	1
		1	1
		1	1
		1	1
		1	1
		1	1
		1	1
		1	1
		1	1
1	1		
		2	2
		5	5
		1	1
		2	2
		1	1
		1	1
		4	4
		3	3
		1	1
2	2	2	2
1	1	6	6
		1	1
		1	1
		1	1
		1	1
		2	2

Pruritus 4 5  
Pupillary light reflex tests abnormal 1 1  
Pyrexia 9 9  
Radiculopathy 1 1  
Rash 8 9  
Rash erythematous 1 1  
Rash macular 1 2  
Rash maculo-papular 1 1  
Rash papular 1 1  
Renal impairment 1 1  
Respiratory rate decreased 1 1  
Respiratory rate increased 1 1  
Respiratory tract infection 1 1  
Rheumatoid arthritis 1 1  
Rhinorrhoea 1 1  
Secretion discharge 1 1  
Seizure 2 2  
Sensation of foreign body 5 5  
Sensory disturbance 1 1  
Somnolence 2 2  
Status epilepticus 1 1  
Swelling of eyelid 1 1  
Syncope 4 4  
Tachycardia 3 3  
Tenosynovitis 1 1  
Throat irritation 4 4  
Throat tightness 7 7  
Tic 1 1  
Tonic convulsion 1 1  
Transaminases increased 1 1  
Troponin increased 1 1  
Unresponsive to stimuli 2 2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper respiratory tract congestion	1	1	1	1		
Urticaria	7	9			7	9
Vaccination site erythema		1		1		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site mass		1		1		
Vaccination site pain	2	4		2	2	2
Vaccination site paraesthesia	1	1			1	1
Vaccination site rash	1	1			1	1
Vaccination site urticaria	1	1			1	1
Vertigo	1	1	1	1		
Vestibular neuronitis	1	1			1	1
Vision blurred	1	1			1	1
Vlth nerve paralysis	1	1			1	1
Vomiting	5	6	1	1	4	5
Wheezing	3	3	1	1	2	2
	311	347	50	62	261	285

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acute psychosis	1	1			1	1
Alanine aminotransferase increased	1	1			1	1
Anaphylactic reaction	3	3			3	3
Anaphylactic shock		1				1
Angioedema	1	3			1	3
Aspartate aminotransferase increased	1	1			1	1
Asthma	1	1			1	1
Blepharospasm	1	1	1	1		
Blood alkaline phosphatase increased	1	1			1	1
Blood bilirubin increased	1	1			1	1
Blood pressure increased	1	1			1	1
Blood pressure systolic increased	1	1			1	1
Body temperature increased	1	1			1	1
Cellulitis	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	1	1			1	1
Cold sweat	1	1			1	1
Complement factor C3 increased	1	1			1	1
Confusional state	2	2			2	2
Cough	1	1			1	1
Deep vein thrombosis	1	1			1	1
Dermatitis bullous	1	1			1	1
Diarrhoea	1	2			1	2
Dizziness	3	3			3	3
Drooling	1	1			1	1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dyskinesia	3	3			3	3
Dysphonia		1				1
Dyspnoea	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional	1	1			1	1
Enlarged uvula		1				1
Eosinophilia	1	1			1	1
Erythema multiforme	1	1			1	1
Eye movement disorder	2	2			2	2
Facial paralysis	1	1			1	1
Fall	1	1			1	1
Fatigue	1	1	1	1		
Feeding disorder	1	1			1	1
Flushing	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Hand dermatitis	1	1	1	1		
Headache	1	1			1	1
Heart rate increased	1	1			1	1
Hypoaesthesia	1	1			1	1
Hypotension	1	1			1	1
Influenza like illness	1	1	1	1		
Lip swelling		1				1
Malaise	1	1			1	1
Mental status changes	1	1			1	1
Myalgia	1	1	1	1		
Myocardial infarction	1	1			1	1
Nausea	1	2	1	1		1
Neck pain	1	1			1	1
Pain in extremity	1	1	1	1		
Palatal oedema	1	1			1	1
Pallor	1	1			1	1
Palpitations	1	2			1	2
Parosmia	2	2	2	2		
Periorbital swelling	2	3	1	1	1	2
Petit mal epilepsy	1	1			1	1
Poor quality product administered		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	1	1			1	1
Rash	5	7	2	4	3	3
Rash macular	1	2			1	2
Rash maculo-papular		1		1		
Rash pruritic	1	1			1	1
Seizure	2	2			2	2
Sinus tachycardia	1	1			1	1
Skin abrasion	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachycardia	1	1			1	1
Throat tightness	1	2			1	2
Tongue biting	1	1			1	1
Tonic clonic movements	1	1			1	1
Toxic neuropathy	1	1			1	1
Transaminases increased	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Urticaria	3	3	1	1	2	2
Vaccination complication	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vision blurred	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	3	3	1	1	2	2
Wheezing	1	1			1	1
	101	119	16	21	85	98

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Acute generalised exanthematous pustulosis	1	1			1	1
Anaphylactic shock		1				1
Chills		1		1		
Eye swelling		1		1		
Fibroma		1		1		
Gianotti-Crosti syndrome		1		1		
Injection site pruritus	1	1	1	1		
Injection site swelling		1		1		
Lip swelling	1	1	1	1		
Poor quality product administered	1	1	1	1		
Pyrexia		1		1		
Skin lesion		1		1		
Taste disorder		1		1		
Urticaria		1		1		
Vaccination site reaction		1		1		
	4	16	3	14	1	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SLOVAKIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Abnormal dreams		1		1		
Anaphylactic reaction		2				2
Angioedema		2				2
Arthralgia	7	25	7	24		1
Asthenia	11	29	9	25	2	4
Asymptomatic COVID-19		1				1
Axillary pain		3		3		
Axillary vein thrombosis		1				1
Back pain	1	3	1	3		
Balance disorder	1	1	1	1		
Blood glucose increased	2	2	2	2		
Blood pressure decreased	3	4		1	3	3
Blood pressure increased	7	16	2	5	5	11
Body temperature increased	11	20	10	19	1	1
Bone pain	2	2	2	2		
Brachial plexus injury	1	1			1	1
Brain contusion		1				1
Burning sensation		3		3		
Cardiac failure		1				1
Cervicobrachial syndrome	1	1			1	1
Chest discomfort		3		3		
Chest pain	2	2	2	2		
Chills	18	57	18	53		4
Condition aggravated	1	1	1	1		
Conjunctivitis		2		1		1
Cough	1	6	1	6		
COVID-19	5	11		3	5	8
Cyanosis	1	1			1	1
Deafness	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
1	1	1	1
	1		
2	4		
	1		
4	12		1
		4	6
	1		1
	1		
	1		
1	1		
1	5		1
		1	1
			1
1	3		
	1		
2	3		
	1		2
	1		
1	2		1
1	1		1
14	37		
3	8		
	1		
	1		
	1		
16	53		
1	3		
	1		
1	2		
2	5		1
1	5		2

Decreased appetite 2 3  
 Dehydration 2 2  
 Dermatitis allergic 1 1  
 Diarrhoea 2 4  
 Diplopia 1 1  
 Dizziness 4 13  
 Drug ineffective 4 6  
 Dry mouth 2 2  
 Dry throat 1 1  
 Dysaesthesia 1 1  
 Dyskinesia 1 1  
 Dyspnoea 1 6  
 Epilepsy 1 1  
 Erysipelas 1 1  
 Erythema 1 3  
 Eye allergy 1 1  
 Eye irritation 2 3  
 Eye oedema 3 3  
 Eye pruritus 1 1  
 Face oedema 1 3  
 Fall 1 2  
 Fatigue 14 37  
 Feeling hot 3 8  
 Feeling of body temperature change 1 1  
 Flatulence 1 1  
 Gait disturbance 1 1  
 Headache 16 53  
 Head discomfort 1 3  
 Heart rate decreased 1 1  
 Heart rate increased 1 2  
 Hot flush 2 6  
 Hyperhidrosis 1 7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypersensitivity		2		1			1
Hypertension		4		3			1
Hypertensive crisis		1					1
Hypoaesthesia		1		1			
Influenza like illness		2		2			
Insomnia		2		2			
Insulin resistance		1					1
Lacrimation increased	1	1	1	1			
Limb discomfort		1		1			
Lip oedema		1		1			
Loss of consciousness	1	3			1		3
Lymphadenopathy	3	7	3	7			
Lymph node pain	1	1	1	1			
Malaise	5	13	5	13			
Maternal exposure during pregnancy		2		2			
Migraine		1		1			
Movement disorder	1	2	1	2			
Muscular weakness	1	1			1		1
Musculoskeletal chest pain	1	1	1	1			
Musculoskeletal discomfort		1		1			
Myalgia	8	31	8	31			
Myocardial ischaemia		1					1
Nausea	8	23	8	20			3
Neck pain	2	2	2	2			
Ocular discomfort		1		1			
Ocular hyperaemia		1		1			
Oedema		1		1			
Oedema peripheral		1		1			
Oral discomfort		1		1			
Oropharyngeal pain		1		1			
Pain	1	5	1	5			
Pain in extremity	16	43	16	43			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	5		
		1	1
5	11		3
	2		1
	2		
2	2		
	2		
1	2		2
	1		
		1	1
	2		
13	39		2
	2		
	1		
			2
1	1		
1	1		
	2		
			1
			1
			2
2	4	1	1
1		1	1
			1
2		2	2
3		3	8
	1		
1	4		3
			1
1	1		
1	2		
1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation		2		2		
Throat tightness		1		1		
Thrombosis	1	1			1	1
Tinnitus	3	4	3	4		
Tissue infiltration		1		1		
Tongue discolouration	1	1	1	1		
Tongue dry	1	1			1	1
Tremor		1				1
Tryptase decreased		1		1		
Urticaria		1				1
Vaccination failure	1	2			1	2
Vaccination site bruising	1	1	1	1		
Vaccination site dermatitis		1		1		
Vaccination site erythema	4	8	4	8		
Vaccination site hypersensitivity		1		1		
Vaccination site induration	2	3	2	3		
Vaccination site joint movement impairment		1		1		
Vaccination site movement impairment		1		1		
Vaccination site oedema	6	10	6	10		
Vaccination site pain	16	51	16	51		
Vaccination site pruritus	2	3	2	3		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Venous thrombosis limb	1	2			1	2
Vertigo	4	11	3	10	1	1
Viral infection	1	1			1	1
Vision blurred	1	1	1	1		
Visual impairment	1	1			1	1
Vomiting	2	5	2	4		1
	275	784	231	663	44	121

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		1				1
Abdominal pain upper		1		1		
Acute myocardial infarction		1				1
Altered state of consciousness	1	2			1	2
Amnesia	1	1			1	1
Aphasia	1	1			1	1
Arthralgia	4	4	4	4		
Asphyxia	1	1			1	1
Asthenia	5	10	5	8		2
Atrial fibrillation		1				1
Axillary pain	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure decreased		3				3
Blood pressure increased	1	4	1	2		2
Body temperature increased	6	9	5	7	1	2
Bradycardia		1				1
Cardiac discomfort	1	1	1	1		
Cardiac fibrillation		1				1
Cerebral ischaemia	1	1			1	1
Chest discomfort	1	1			1	1
Chills	7	18	7	17		1
Cold sweat		1		1		
Cough	1	2	1	2		
COVID-19		1				1
Cutaneous vasculitis		1		1		
Decreased appetite	1	2	1	2		
Diarrhoea	1	4		2	1	2
Disorientation	1	1	1	1		
Dizziness	4	7	3	4	1	3
Dry mouth	1	1	1	1		
Dysphagia	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	2
1	1		
	2		
	1		
1	2		
1	1		
			1
1	3		
6	10		
1	2		
			1
1	1		1
	1		
	1		
1	1		
1	1		
2	4		
1	1	1	1
	2		1
	1		
	1		1
1	1		
5	11		
	1		
3	6		
	1		
1	1		
1	2		
3	4		
	1		
1	2		1
1	1		

Dyspnoea

2

3

Enlarged uvula

1

1

Erythema

2

Eyelid rash

1

Eye pain

1

2

Eye pruritus

1

1

Facial paresis

1

Fatigue

1

3

Headache

6

10

Heart rate increased

1

2

Hot flush

1

Hyperhidrosis

1

2

Incorrect dose administered

1

Inflammation

1

Insomnia

1

1

Lymphadenitis

1

1

Lymphadenopathy

2

4

Lymphangitis

1

1

Malaise

2

Medication error

1

Micturition urgency

1

Musculoskeletal stiffness

1

1

Myalgia

5

11

Mydriasis

1

Nausea

3

6

No adverse event

1

Oropharyngeal pain

1

1

Pain

1

2

Pain in extremity

3

4

Pain of skin

1

Pallor

1

3

Palpitations

1

1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	1	3	1	2		1
Peripheral coldness		1		1		
Petechiae		1		1		
Presyncope	1	2	1	1		1
Product administered at inappropriate site		1		1		
Pruritus	1	1	1	1		
Pyrexia	8	16	8	15		1
Rash	1	2	1	2		
Rash papular		1		1		
Rash pruritic		1		1		
Rash pustular		1		1		
Retching	1	1	1	1		
SARS-CoV-2 test positive		1		1		
Speech disorder	1	1			1	1
Syncope		3				3
Tachycardia	3	3	3	3		
Thirst	1	1	1	1		
Thrombosis		1				1
Tinnitus	1	1	1	1		
Tonic convulsion		1				1
Vaccination site oedema	1	1	1	1		
Vaccination site pain	6	13	6	13		
Vaccination site urticaria		1		1		
Vertigo	1	3	1	3		
Vision blurred	2	2	2	2		
Vomiting	1	3		1	1	2
Wheezing	1	1			1	1
	108	227	94	177	14	50

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1	1	1		
Arthralgia	4	4	4	4		
Blood pressure decreased		1		1		
Body temperature fluctuation	1	1	1	1		
Body temperature increased	3	4	3	3		1
Chills	2	4	2	3		1
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Dysarthria	1	1	1	1		
Erythema		1				1
Fatigue	3	6	3	6		
Feeling abnormal		1		1		
Flushing	1	1	1	1		
Headache	1	4	1	3		1
Lymphadenopathy		2		2		
Malaise	1	1	1	1		
Muscular weakness		1		1		
Myalgia	3	4	3	4		
Nausea	1	2	1	2		
Pain		1		1		
Pain in extremity	1	2	1	2		
Palpitations		1		1		
Paraesthesia	1	2	1	1		1
Presyncope		1		1		
Pruritus		1				1
Pyrexia	3	5	3	5		
Rash	1	1	1	1		
Rash vesicular	1	1	1	1		
Vaccination site inflammation	1	1	1	1		
Vaccination site oedema		1		1		
Vaccination site pain	2	5	2	4		1
Vaccination site swelling		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	34	64	32	54	2	10

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**SLOVENIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Abdominal pain upper	1	1	1	1		
Acute myocardial infarction	1	2			1	2
Anaphylactic reaction		1				1
Angioedema		1				1
Aphasia	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia		6		6		
Asthenia		2		2		
Asymptomatic bacteriuria		1				1
Aura		1		1		
Autoimmune thyroiditis		1				1
Axillary pain		1				1
Bedridden		1				1
Blindness unilateral		1				1
Blood pressure increased		1		1		
Body temperature increased	1	9		8	1	1
Bone pain		1		1		
Bradycardia	3	3			3	3
Cardiac arrest		1				1
Cardiac failure	1	1			1	1
Cardiopulmonary failure	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort	2	3		1	2	2
Chest pain	2	5	1	3	1	2
Chills		6		6		
Circulatory collapse	2	3			2	3
Confusional state	1	1	1	1		
Coordination abnormal		1				1
COVID-19		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
1	6	1	1
			1
	3	1	2
		1	1
	2		
	1		1
			1
	1		1
			1
1	1		
		1	1
	1		
	1		
			1
1	1	1	2
2	16	2	5
1	1		
	1	1	1
			1
		1	1
			1
			2
2	17	1	3
1	1		
		1	1
	1		
		1	5
			1
	1		1
	2		
	2		

Death 1  
Diabetes mellitus 1  
Diarrhoea 2  
Disease recurrence 1  
Dizziness 1  
Dysarthria 1  
Dysgeusia 2  
Dyspnoea 2  
Ear pain 1  
Erythema 2  
Exposure during pregnancy 1  
Extrasystoles 1  
Eyelid disorder 1  
Eyelid oedema 1  
Eye pruritus 1  
Facial paralysis 1  
Fall 2  
Fatigue 2  
Feeling cold 1  
Feeling hot 1  
Gait disturbance 1  
Gait inability 1  
General physical health deterioration 1  
Guillain-Barre syndrome 2  
Headache 2  
Head injury 1  
Hot flush 1  
Hypersensitivity 1  
Hypertension 1  
Hyperventilation 1  
Hypoaesthesia 2  
Hyposmia 2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration		1		1		
Infection		1				1
Insomnia		2		2		
Irritability	1	1			1	1
Ischaemic stroke	1	1			1	1
Lip oedema	1	1			1	1
Lip swelling		1		1		
Loss of consciousness	3	10			3	10
Lymphadenitis		1		1		
Lymphadenopathy		4		4		
Malaise		13		8		5
Migraine		2		1		1
Migraine with aura		1				1
Monoparesis	1	1			1	1
Mood altered	1	1			1	1
Muscular weakness	1	1	1	1		
Myalgia		9		8		1
Myocardial infarction		1				1
Nasopharyngitis		2		2		
Nausea		7		4		3
Neck pain		1		1		
Neurological symptom		1		1		
Oedema peripheral	1	1			1	1
Off label use		1		1		
Oral herpes		1				1
Oxygen saturation decreased		1				1
Pain		1		1		
Pain in extremity		1		1		
Paraesthesia		7		4		3
Paraesthesia oral	1	3		1	1	2
Paresis		1				1
Peripheral coldness		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pityriasis rosea		1		1			
Pneumonia		1					1
Pneumothorax spontaneous	1	1			1		1
Presyncope	1	1	1	1			
Pyrexia		9		8			1
Rash	1	2	1	2			
Rash pruritic		2		2			
Restlessness		1		1			
Sensation of foreign body	1	1			1		1
Sensory disturbance		1		1			
Sinusitis		1		1			
Sinus tachycardia		1					1
Skin burning sensation		1		1			
Soliloquy	1	1	1	1			
Somnolence	1	8		5	1		3
Speech disorder		1		1			
Suffocation feeling		1					1
Swollen tongue		2		2			
Syncope		2					2
Tachycardia		2		2			
Thinking abnormal		1		1			
Throat tightness		1		1			
Thrombophlebitis superficial	1	1			1		1
Tongue pruritus		2		2			
Total lung capacity decreased	1	1			1		1
Unresponsive to stimuli		1					1
Urticaria		1					1
Uterine spasm		1					1
Vaccination failure		1					1
Vaccination site erythema		10		10			
Vaccination site oedema		4		4			
Vaccination site pain	7	45	5	41	2		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		3		3		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	1	1			1	1
Ventricular extrasystoles	1	2		1	1	1
Vertigo	2	9		3	2	6
Vomiting		4		2		2
Walking disability	1	1			1	1
Wheezing		1				1
White blood cell count increased		1		1		
	68	372	19	238	49	134

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Aphasia		1				1
Asthenia	1	2	1	1		1
Atrial fibrillation	1	3			1	3
Atrial tachycardia		1				1
Basilar artery thrombosis		1				1
B-cell lymphoma		1				1
B-cell type acute leukaemia		1				1
Body temperature increased		3		2		1
Bronchial disorder		1				1
Cardiac failure congestive	1	1			1	1
Cardiac tamponade		1				1
Cardiopulmonary failure		1				1
Cerebral haemorrhage	1	1			1	1
Cerebral thrombosis		1				1
Chest discomfort		1				1
Chest pain	1	2			1	2
Confusional state		1				1
Cough		1				1
COVID-19		3				3
COVID-19 pneumonia		1				1
Deep vein thrombosis	1	2			1	2
Dementia		1				1
Dizziness		1				1
Drug ineffective	1	2			1	2
Dyspnoea	2	5			2	5
Epilepsy	1	3			1	3
Fatigue	1	3	1	3		
Feeling abnormal	1	1	1	1		
Feeling hot		1				1
Gastrointestinal haemorrhage	1	1			1	1
Headache		4		3		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypokalaemia		1				1
Hypotension		1				1
Inappropriate schedule of product administration	1	2	1	2		
Insomnia		1		1		
Ischaemic cerebral infarction		1				1
Loss of consciousness		1				1
Lower respiratory tract infection	1	1			1	1
Malaise		4		2		2
Miosis		1				1
Myalgia		2		1		1
Myocardial infarction		1				1
Myocardial rupture		1				1
Nausea	1	1	1	1		
Neutropenia		1				1
Night sweats		1				1
Oedema peripheral		1				1
Off label use	1	2	1	2		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		2				2
Pain in extremity		1				1
Pharyngeal erythema		1		1		
Pneumonia		1				1
Protein total increased		1		1		
Pulmonary embolism	1	3			1	3
Pulmonary oedema	1	1			1	1
Pyrexia		1				1
Quadriplegia		1				1
Seizure		1				1
Sensory disturbance		1				1
Skin disorder		1				1
Speech disorder		1				1
Sudden cardiac death	2	2			2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death		2				2
Superficial vein prominence	1	1			1	1
Suspected COVID-19	1	1			1	1
Syncope		3				3
Tachycardia	1	1			1	1
Thrombocytopenia		2				2
Tongue biting		1				1
Tongue movement disturbance		1		1		
Transient ischaemic attack		1				1
Unresponsive to stimuli	1	2			1	2
Vaccination failure		1				1
Vaccination site pain		6		5		1
Vertebral artery thrombosis		1				1
Vertigo	2	2	2	2		
	27	120	8	30	19	90

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Fatigue		1		1
Lymphadenopathy		1		1
Malaise		2		2
Myalgia		1		1
Nightmare		1		1
Pain		1		1
Pyrexia		1		1
		9		9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**SPAIN**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal discomfort		2				1			1
Abdominal distension	1	3			1	3			
Abdominal mass	1	1			1	1			
Abdominal pain	11	25			10	15	1		10
Abdominal pain lower	1	3			1	2			1
Abdominal pain upper	1	11				6	1		5
Abdominal symptom		1				1			
Abnormal faeces		1				1			
Abortion induced		1							1
Abortion missed	1	2					1		2
Abortion spontaneous		3							3
Acoustic neuritis		1							1
Activated partial thromboplastin time prolonged	1	1					1		1
Acute hepatic failure	1	1					1		1
Acute kidney injury	1	5					1		5
Acute leukaemia		1							1
Acute myocardial infarction	1	4					1		4
Acute respiratory failure	2	8					2		8
Adnexa uteri pain	1	1			1	1			
Adrenal mass		1				1			
Ageusia	5	10			3	3	2		7
Agitation	2	3					2		3
Allergic cough		1				1			
Allergic oedema		2							2
Allergy to vaccine	1	8				1	1		7
Allodynia		1				1			
Alopecia	1	1					1		1
Amaurosis fugax	2	2					2		2
Amenorrhoea	1	1					1		1
Amnesia	1	7				3	1		4
Anaemia	2	2					2		2
Anal incontinence	1	2			1	1			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anal sphincter atony		3
Anaphylactic reaction	4	43
Anaphylactic shock		4
Androgenetic alopecia	1	1
Angina pectoris		2
Angioedema	5	29
Angular cheilitis		1
Anisometropia	1	1
Anosmia	4	8
Anxiety	2	7
Aortic dissection		1
Aortic valve calcification	1	1
Aphasia	2	8
Aphonia	1	7
Aphthous ulcer	1	6
Appendicitis	1	3
Arrhythmia	2	3
Arthralgia	35	111
Arthritis	1	1
Arthritis allergic		1
Arthritis reactive		1
Asphyxia		2
Asthenia	35	109
Asthenopia	1	3
Asthma		3
Asthmatic crisis		1
Asymptomatic COVID-19	6	17
Ataxia	1	1
Atelectasis	1	2
Atrial fibrillation	4	10
Atrioventricular block first degree		1
Atrophic glossitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				4	43
					4
				1	1
					2
				5	29
			1		
		1	1		
		3	3	1	5
		1	6	1	1
					1
				1	1
			1	2	7
		1	2		5
		1	4		2
				1	3
				2	3
		27	67	8	44
				1	1
					1
					2
		25	53	10	56
				1	3
			1		2
					1
		2	3	4	14
				1	1
		1	1		1
				4	10
			1		
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atypical haemolytic uraemic syndrome	1	1
Autoantibody negative		1
Autoimmune demyelinating disease		1
Autoimmune hepatitis	1	2
Autoimmune hypothyroidism	1	1
Axillary pain	3	15
Axonal neuropathy	1	1
Bacille Calmette-Guerin scar reactivation		1
Back pain	4	19
Bacterial test	1	1
Balance disorder	5	15
Base excess decreased	1	1
Bedridden	1	2
Biliary colic		2
Biliary cyst	1	1
Bladder spasm		2
Bladder sphincter atony		2
Blepharospasm	1	2
Blindness transient		1
Blindness unilateral	1	1
Blister	1	3
Blood bicarbonate decreased	1	1
Blood bicarbonate increased	1	1
Blood calcium decreased	1	1
Blood creatinine increased	1	1
Blood fibrinogen decreased	1	1
Blood fibrinogen increased		1
Blood glucose decreased		1
Blood glucose increased		2
Blood iron decreased		1
Blood lactate dehydrogenase increased	2	2
Blood pressure abnormal	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
				1	2
				1	1
		3	10		5
		1	1		
			1		
		4	12		7
				1	1
		2	6	3	9
		1	1		
				1	2
					2
		1	1		
					2
					2
			1	1	1
					1
				1	1
		1	1		2
				1	1
		1	1		
		1	1		
		1	1		
			1		
					1
			1		1
			1		
		1	1	1	1
		1	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood pressure decreased		1
Blood pressure diastolic decreased		1
Blood pressure diastolic increased	1	1
Blood pressure increased	1	11
Blood pressure systolic increased	1	2
Blood thyroid stimulating hormone increased		1
Blood urea increased	1	1
Body temperature decreased	1	2
Body temperature increased		2
Brachial plexus injury		1
Bradycardia		8
Bradykinesia		2
Bradyphrenia	2	7
Breast haematoma	1	1
Breast mass		1
Breast oedema		1
Breath sounds abnormal		1
Bronchial hyperreactivity		2
Bronchiectasis		1
Bronchitis		1
Bronchitis bacterial		1
Bronchospasm	1	13
Bundle branch block right	1	1
Burning sensation		3
Burning sensation mucosal		1
Butterfly rash		1
Cachexia		1
Cardiac disorder	1	2
Cardiac failure	4	10
Cardiac failure acute	1	3
Cardiac failure congestive	2	2
Cardiac tamponade		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				1	1
			8	1	3
		1	2		
			1		
				1	1
			1	1	1
			2		
					1
					8
			1		1
		1	3	1	4
				1	1
			1		
					1
					2
					1
					1
					1
				1	13
				1	1
					3
			1		
			1		
					1
		1	1		1
				4	10
				1	3
				2	2
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiomegaly	2	2
Cardio-respiratory arrest	1	6
Cardio-respiratory distress		1
Cardiothoracic ratio increased	1	1
Carotid bruit		2
Catarrh	1	1
Cellulitis	2	7
Cellulitis staphylococcal		1
Cephalhaematoma	1	1
Cerebellar syndrome		1
Cerebral haematoma	1	1
Cerebral haemorrhage	4	4
Cerebral infarction	1	1
Cerebral ischaemia	1	1
Cerebral venous sinus thrombosis	1	1
Cerebral venous thrombosis	1	2
Cerebrovascular accident	1	5
Cerebrovascular disorder	1	1
Cervicobrachial syndrome	1	1
Cheilitis		4
Chest discomfort	2	18
Chest injury		1
Chest pain	7	31
Chills	24	103
Choking		2
Choking sensation	1	7
Chromaturia		1
Chronic kidney disease	1	1
Chronic lymphocytic leukaemia	1	1
Chronic respiratory failure		1
Circumoral swelling		1
Citrobacter infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				1	6
					1
				1	1
					2
		1	1		
				2	7
					1
				1	1
					1
				1	1
				4	4
				1	1
				1	2
				1	5
				1	1
		1	1		
					4
		1	4	1	14
					1
		3	8	4	23
		20	62	4	41
					2
			1	1	6
			1		
				1	1
				1	1
					1
			1		
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Clostridium difficile colitis		1
Cognitive disorder	1	2
Cold sweat	1	3
Colitis	1	1
Colitis ulcerative		1
Concomitant disease aggravated	1	4
Condition aggravated	3	16
Confusional state	4	11
Conjunctival haemorrhage	3	8
Conjunctival hyperaemia	2	2
Conjunctival laceration		1
Constipation	4	7
Contusion	2	4
Corneal reflex decreased		1
Costochondritis		1
Cough	8	39
COVID-19	17	59
COVID-19 pneumonia	2	9
Craniocerebral injury	2	5
C-reactive protein increased	1	3
Cyanosis	1	4
Cytomegalovirus test positive	1	1
Deafness		1
Deafness unilateral		1
Death	1	4
Decreased appetite	4	12
Deep vein thrombosis	5	7
Dehydration		2
Delirium	2	2
Delirium febrile		1
Demyelination	1	2
Dental caries		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
		1	2		1
		1	1		
					1
				1	4
		1	3	2	13
		1	3	3	8
				3	8
				2	2
			1		
		3	5	1	2
			1	2	3
					1
					1
		7	17	1	22
		10	17	7	42
				2	9
				2	5
		1	3		
		1	1		3
				1	1
					1
					1
				1	4
		2	4	2	8
				5	7
			1		1
				2	2
					1
				1	2
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Depressed level of consciousness	3	13
Depressed mood	1	2
Dermatitis allergic	2	6
Dermatitis atopic	1	1
Dermatitis bullous		2
Diabetes mellitus		2
Diabetes mellitus inadequate control	1	2
Diabetic ketoacidosis		1
Diabetic metabolic decompensation		1
Diaphragmalgia	1	1
Diarrhoea	34	100
Diarrhoea haemorrhagic		2
Dilatation atrial	1	1
Dilatation ventricular	1	1
Diplopia	3	5
Discomfort	5	15
Disease recurrence	3	6
Disorganised speech		1
Disorientation	3	7
Disturbance in attention		3
Dizziness	42	158
Dizziness postural	2	3
Drowning		1
Drug eruption	1	1
Drug hypersensitivity		2
Drug ineffective	4	36
Drug interaction		1
Dry eye	1	2
Dry mouth	1	6
Dry skin	1	1
Dry throat		2
Duodenal ulcer haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	13
		1	2		
				2	6
				1	1
					2
					2
				1	2
					1
					1
				1	1
		29	59	5	41
					2
				1	1
				1	1
		1	1	2	4
		3	9	2	6
		1	1	2	5
					1
		1	3	2	4
			1		2
		30	73	12	85
		1	2	1	1
					1
		1	1		
					2
				4	36
			1		
			1	1	1
			1	1	5
				1	1
			1		1
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysaesthesia		7
Dysarthria	2	5
Dyschromatopsia	1	1
Dysgeusia	1	11
Dyskinesia		1
Dyslexia	1	1
Dysmenorrhoea		1
Dyspepsia	2	3
Dysphagia	5	16
Dysphonia	4	9
Dyspnoea	20	87
Dyspnoea at rest		1
Dyspnoea exertional	2	9
Dysstasia		1
Dystonia		1
Dysuria		3
Ear discomfort		1
Ear infection		1
Ear pain	1	6
Eating disorder		1
Ecchymosis		1
Eczema		1
Eczema herpeticum		1
Electrocardiogram normal	1	1
Electrocardiogram QRS complex shortened		2
Electrocardiogram ST segment elevation	1	1
Electrocardiogram T wave inversion		1
Electrolyte imbalance		1
Embolic stroke	1	1
Embolism		1
Encephalitis		4
Encephalopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		6
			2	2	3
				1	1
			5	1	6
				1	1
			1		
		1	1	1	2
		2	4	3	12
		2	2	2	7
		7	12	13	75
					1
		1	2	1	7
			1		
					1
			1		2
					1
					1
					1
				1	1
					2
				1	1
					1
				1	1
					1
				1	1
					1
					4
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Enterococcal infection	1	1
Epidermal necrosis		1
Epigastric discomfort		1
Epiglottitis		1
Epilepsy	1	2
Episcleritis		1
Epistaxis	1	3
Epstein-Barr virus antibody positive	1	1
Erythema	10	53
Erythema multiforme		1
Escherichia infection	1	2
Essential hypertension		1
Essential tremor	1	2
Euphoric mood		3
Exposure during pregnancy		2
Extensive swelling of vaccinated limb	2	3
Extensor plantar response		1
Extrasystoles	1	2
Eye discharge	1	1
Eye haemorrhage	1	1
Eyelid oedema	1	6
Eye pain	2	7
Eye pruritus	1	5
Eye swelling		1
Face injury		1
Face oedema	2	11
Facial bones fracture	1	1
Facial neuralgia	1	1
Facial pain		2
Facial paralysis	7	35
Facial paresis	1	2
Faeces discoloured		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					1
				1	2
					1
				1	3
				1	1
		8	21	2	32
					1
				1	2
					1
		1	1		1
			1		2
			1		1
		2	3		
			1		
				1	2
				1	1
				1	1
			1	1	5
			2	2	5
			2	1	3
					1
					1
				2	11
				1	1
		1	1		
			1		1
				7	35
			1	1	1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Faeces soft	1	2
Fall	3	12
Fatigue	32	113
Febrile convulsion		3
Feeling abnormal	2	6
Feeling cold		6
Feeling drunk		1
Feeling hot	4	16
Fibrin D dimer increased	3	6
Fibrinolysis	1	1
Fibromyalgia	1	1
Flatulence	2	4
Floppy eyelid syndrome		1
Fluid overload	1	1
Flushing		4
Folate deficiency		1
Food allergy		1
Foreign body in throat		1
Foreign body sensation in eyes	1	3
Formication	1	4
Fracture		1
Fumbling		1
Fungal skin infection		1
Gait disturbance	1	8
Gait inability	1	5
Galactorrhoea		1
Gal bladder enlargement		1
Gamma-glutamyltransferase increased		1
Gastric disorder		1
Gastritis	1	1
Gastroenteritis	2	3
Gastrointestinal disorder	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			4	3	8
		24	63	8	50
					3
		2	3		3
			1		5
			1		
		4	10		6
		1	1	2	5
				1	1
				1	1
		2	3		1
					1
				1	1
			1		3
			1		
					1
		1	3		1
			1	1	3
					1
					1
			3	1	5
			1	1	4
					1
			1		1
		2	2		1
		2	2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gastrointestinal haemorrhage	1	2
Gastrointestinal somatic symptom disorder	1	1
Gastrooesophageal reflux disease		1
Generalised oedema		2
Generalised tonic-clonic seizure	2	3
General physical health deterioration	3	9
Genital herpes		1
Genital ulceration		1
Gingival bleeding	2	3
Gingival discolouration		1
Gingivitis		1
Glomerular filtration rate decreased	1	1
Glossitis		4
Glossodynia		1
Goitre		1
Granulomatous liver disease		1
Groin pain		1
Guillain-Barre syndrome	2	3
Haematochezia		1
Haematocrit decreased		1
Haematoma	3	7
Haematoma muscle	2	3
Haemoglobin decreased	1	3
Haemoglobin increased	1	1
Haemoptysis	1	2
Haemorrhage		2
Haemorrhage intracranial	1	1
Haemorrhagic diathesis		1
Hallucination	2	3
Hallucinations, mixed	1	1
Hallucination, visual	1	1
Headache	123	374

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	1		
			1		
					2
				2	3
		2	4	1	5
			1		
		1	1	1	2
			1		
			1		
		1	1		
					4
					1
			1		
					1
					1
				2	3
					1
			1		
		2	4	1	3
				2	3
		1	2		1
		1	1		
				1	2
					2
				1	1
					1
				2	3
				1	1
				1	1
		96	204	27	170

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Head discomfort	1	1
Head injury	2	3
Heart rate decreased	1	1
Heart rate increased	1	4
Heart rate irregular	1	1
Hemianaesthesia		1
Hemidysaesthesia		1
Hemihyperaesthesia	1	1
Hemiparaesthesia	1	7
Hemiparesis	1	4
Hemiplegia	2	4
Hepatic cyst	1	2
Hepatic enzyme abnormal	1	1
Hepatitis	1	2
Hepatitis acute	2	4
Hepatitis B virus test positive	1	1
Hepatomegaly		1
Herpes ophthalmic		1
Herpes simplex		1
Herpes virus infection	1	2
Herpes zoster	15	37
Herpes zoster cutaneous disseminated		1
Herpes zoster oticus		1
Herpes zoster reactivation		2
Hiatus hernia	2	3
Hot flush		3
Hyperaemia		1
Hyperaesthesia	2	3
Hyperdynamic left ventricle		1
Hyperfibrinogenaemia		1
Hyperglycaemia	2	6
Hyperhidrosis	3	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	3
				1	1
			2	1	2
				1	1
					1
					1
				1	1
				1	7
				1	4
				2	4
		1	2		
				1	1
				1	2
				2	4
		1	1		
					1
					1
		1	1		1
1	1	2	7	13	30
					1
					1
					2
			1	2	2
			1		2
			1		
		2	2		1
					1
					1
			1	2	5
		2	4	1	11

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperkalaemia	1	1
Hypernatraemia		2
Hypersensitivity	4	27
Hypersensitivity vasculitis	1	1
Hypersexuality		1
Hypertension	13	49
Hypertensive crisis	4	25
Hypertensive emergency	1	1
Hypertensive encephalopathy	1	1
Hypertensive urgency	1	3
Hyperthermia		1
Hyperthyroidism		1
Hypertransaminasaemia		4
Hyperventilation		1
Hypoacusis		6
Hypoaesthesia	7	31
Hypoaesthesia eye	1	1
Hypoaesthesia oral	3	9
Hypocalcaemia	1	2
Hypoglycaemia	1	6
Hypokalaemia		1
Hypokinesia	1	1
Hyponatraemia	1	2
Hypophosphataemia		1
Hyporeflexia		2
Hypotension	6	27
Hypothermia	4	7
Hypothyroidism		1
Hypovolaemic shock		1
Hypoxia		6
Idiopathic angioedema		1
Ileus paralytic	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		1
		2	4	2	23
				1	1
					1
		5	13	8	36
				4	25
				1	1
				1	1
				1	3
					1
					1
			1		3
					1
					6
		3	9	4	22
				1	1
		1	3	2	6
			1	1	1
			1	1	5
					1
		1	1		
				1	2
			1		
			1		1
		1	6	5	21
				4	7
					1
					1
					6
					1
				1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ill-defined disorder	1	1
Immobilisation syndrome	1	1
Immune system disorder		1
Immune thrombocytopenia	4	6
Immunisation reaction		1
Inappropriate schedule of product administration	1	5
Incoherent	1	2
Incorrect dose administered	2	2
Incorrect route of product administration	2	4
Induration		2
Infection	1	1
Inflammation	3	10
Inflammatory bowel disease	1	2
Influenza		4
Influenza like illness		4
Injection site erythema		2
Injection site haematoma		1
Injection site inflammation		1
Injection site paraesthesia		1
Injury	2	2
Insomnia	3	8
Insulin resistance		1
Interstitial lung disease		2
Intestinal ischaemia		1
Intestinal obstruction	1	2
Intraventricular haemorrhage	1	1
Iridocyclitis	1	1
Iron deficiency		1
Ischaemia	1	1
Ischaemic stroke	9	14
Jaw disorder		1
Joint contracture		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
					1
				4	6
			1		
		1	5		
				1	2
		2	2		
		2	4		
			1		1
		1	1		
		2	5	1	5
				1	2
			1		3
			3		1
			2		
			1		
			1		
		1	1	1	1
		2	4	1	4
			1		
					2
					1
				1	2
				1	1
			1		
				1	1
				9	14
			1		
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Joint injury	1	2
Joint range of motion decreased		2
Joint swelling		1
Joint warmth		1
Kaposi's sarcoma AIDS related		1
Keratitis	2	2
Lacrimation increased		5
Lacunar stroke		1
Laryngeal disorder		1
Laryngeal oedema	2	12
Laryngeal pain		1
Laryngitis		1
Laryngospasm		1
Larynx irritation		1
Lethargy	1	1
Leukocytosis	1	2
Leukopenia		1
Lichen planus		1
Limb discomfort	1	3
Limb immobilisation		1
Lipase decreased	1	1
Lip blister		1
Lip erythema		1
Lip oedema	1	11
Lipoma	1	1
Lip pruritus		5
Lip swelling	2	7
Lividity		1
Localised infection		1
Localised oedema	1	2
Local reaction	2	5
Loss of consciousness	4	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					2
					1
					1
					1
				2	2
			1		4
					1
					1
				2	12
					1
					1
					1
					1
				1	1
		1	1		1
					1
		1	2		1
					1
		1	1		
			1		
					1
					1
			2	1	9
		1	1		
			3		2
		1	1	1	6
					1
					1
				1	2
			1	2	4
				4	21

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Loss of personal independence in daily activities		1
Lower respiratory tract infection		1
Lung infiltration		1
Lymphadenitis	7	15
Lymphadenopathy	25	129
Lymphangitis		2
Lymph node pain		1
Lymphocyte count decreased	1	1
Lymphocyte count increased	1	1
Lymphocytosis	1	1
Lymphopenia		2
Macroglossia	1	1
Macular oedema		1
Malaise	51	168
Malnutrition		1
Mass		2
Maternal exposure during pregnancy	1	4
Maternal exposure timing unspecified	1	1
Mean cell haemoglobin concentration decreased	1	1
Mechanical urticaria		1
Medication error		1
Melaena	1	3
Memory impairment		1
Meniere's disease	1	1
Meningism		1
Meningitis herpes	1	1
Menometrorrhagia		1
Menorrhagia		1
Menstruation delayed		2
Mental impairment		4
Metrorrhagia	1	8
Micturition urgency	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
		4	6	3	9
		9	48	16	81
					2
					1
		1	1		
		1	1		
		1	1		
			2		
				1	1
					1
		45	102	6	66
			1		
					2
		1	4		
		1	1		
		1	1		
					1
			1		
				1	3
					1
				1	1
					1
				1	1
					1
					2
					4
				1	8
				1	2

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle insomnia		1
Migraine	1	9
Migraine with aura	1	2
Misophonia		1
Mobility decreased	3	13
Monoparesis	1	1
Monoplegia		2
Mood altered		1
Morganella infection	1	1
Mouth swelling		1
Mouth ulceration		1
Movement disorder		2
Mucosal dryness		1
Multiple organ dysfunction syndrome		4
Muscle contractions involuntary	1	4
Muscle contracture		3
Muscle fatigue		1
Muscle rigidity	1	2
Muscle spasms	1	6
Muscle tightness	1	4
Muscular weakness	1	11
Musculoskeletal chest pain		2
Musculoskeletal discomfort		3
Musculoskeletal disorder	1	1
Musculoskeletal pain	5	31
Musculoskeletal stiffness		6
Myalgia	73	218
Myelitis		1
Myocardial infarction	1	1
Myocardial ischaemia	1	2
Myocardial rupture	1	1
Myoclonic dystonia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	7
		1	1		1
					1
		1	4	2	9
				1	1
					2
					1
				1	1
					1
			1		1
					1
					4
		1	2		2
			2		1
			1		
				1	2
		1	4		2
			1	1	3
		1	5		6
			2		
					3
				1	1
		2	9	3	22
			2		4
		60	130	13	88
					1
				1	1
				1	2
				1	1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Myositis	1	4
Nasal congestion	5	12
Nasal herpes		1
Nasal pruritus		1
Nasopharyngitis	1	1
Nausea	49	162
Neck mass		1
Neck pain	2	13
Necrosis		1
Neoplasm	1	2
Nervousness	2	6
Nervous system disorder		1
Neuralgia	1	3
Neuralgic amyotrophy	2	2
Neuropathy peripheral	1	4
Neurosensory hypoacusis		1
Neutropenia		1
Neutrophil count increased	2	3
Neutrophilia	1	1
Neutrophilic dermatosis	1	1
Night sweats		3
No adverse event	1	1
Nodule		1
Noninfective gingivitis		1
Normochromic normocytic anaemia		1
Nuchal rigidity		4
Ocular hyperaemia		2
Odynophagia	2	16
Oedema		5
Oedema mouth	1	2
Oedema peripheral	5	15
Off label use	2	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
		5	9		3
					1
					1
		1	1		
		46	101	3	61
			1		
		1	4	1	9
					1
		1	2		
			2	2	4
					1
		1	1		2
				2	2
				1	4
					1
					1
		2	3		
				1	1
				1	1
			1		2
		1	1		
			1		
			1		1
					4
					2
		2	3		13
			4		1
			1	1	1
		2	3	3	12
		2	11		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmic herpes zoster		1
Oral candidiasis	1	3
Oral discomfort		1
Oral herpes	3	10
Oral pain		2
Oral pruritus	1	3
Oropharyngeal discomfort	1	5
Oropharyngeal oedema		3
Oropharyngeal pain	4	13
Orthopnoea	1	1
Orthostatic hypotension		1
Osteoarthritis	1	1
Ovarian cyst		1
Overdose	4	5
Oxygen saturation decreased	4	11
Pain	9	30
Pain in extremity	15	57
Palatal oedema	1	9
Palatal swelling	1	2
Pallor		7
Palpitations	6	22
Pancreatitis chronic	1	1
Pancytopenia	1	2
Panic reaction		1
Papule		2
Paraesthesia	17	88
Paraesthesia mucosal		1
Paraesthesia oral		17
Paraparesis		1
Paresis		1
Parosmia	1	1
Parotid gland enlargement	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		1
			1		
		1	4	2	6
			2		
		1	1		2
				1	5
					3
		1	6	3	7
				1	1
					1
		1	1		
					1
		4	5		
		1	2	3	9
		7	17	2	13
		11	35	4	22
				1	9
		1	1		1
			2		5
		2	5	4	17
				1	1
				1	2
					1
			1		1
		4	21	13	67
					1
			2		15
					1
			1		
				1	1
		1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Parotitis		2
Partial seizures		2
Patella fracture	1	1
Pelvic pain		1
Periarthritis		2
Pericardial haemorrhage	1	1
Pericarditis	1	5
Periorbital haematoma		1
Periorbital oedema		1
Periorbital pain		1
Periorbital swelling		1
Peripheral coldness	3	5
Peripheral embolism	1	1
Peripheral ischaemia		2
Peripheral paralysis		1
Peripheral swelling	2	7
Persistent depressive disorder		1
Persistent generalised lymphadenopathy	1	1
Pertussis		2
Petechiae	2	6
Petit mal epilepsy		5
Pharyngeal erythema		3
Pharyngeal hypoaesthesia		1
Pharyngeal inflammation	1	2
Pharyngeal oedema	1	4
Pharyngeal swelling	2	4
Pharyngitis		1
Phlebitis	1	2
Phonophobia		1
Photophobia	1	7
Photopsia		1
Pigmentation disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					2
				1	1
			1		
					2
				1	1
				1	5
					1
			1		
					1
			1		
					2
		3	3		
				1	1
					2
					1
		2	4		3
					1
				1	1
					2
			1	2	5
					5
					3
					1
				1	2
		1	1		3
				2	4
					1
			1	1	1
					1
		1	2		5
			1		
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pityriasis rosea	1	4
Platelet count decreased	1	1
Platelet count increased		1
Pleural effusion	1	5
Pleuritic pain	1	1
Pleuropericarditis		1
Pneumonia	2	7
Pneumonitis	1	2
Pneumothorax	1	1
PO2 decreased	2	2
Polymenorrhoea	1	1
Polyuria	1	1
Poor peripheral circulation	2	2
Poor quality product administered	3	3
Poor quality sleep		1
Portal vein thrombosis	1	1
Positron emission tomogram	1	1
Post viral fatigue syndrome		1
Prerenal failure	1	1
Presyncope	7	22
Proctalgia		1
Proctitis		1
Productive cough	2	3
Product preparation error	3	3
Product use issue		7
Prothrombin level decreased	1	1
Prothrombin time prolonged	1	2
Pruritus	19	79
Psoriasis		1
Psoriatic arthropathy		1
Psychomotor hyperactivity		4
Pulmonary embolism	18	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
				1	1
			1		
			1	1	4
		1	1		
					1
				2	7
				1	2
				1	1
		2	2		
		1	1		
				1	1
		2	2		
		3	3		
					1
				1	1
				1	1
					1
				1	1
		3	6	4	16
			1		
					1
		1	1	1	2
		3	3		
			7		
				1	1
			1	1	1
		13	26	6	53
					1
					1
			1		3
				18	24

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulmonary haemorrhage	1	1
Pulmonary hypertension	1	1
Pulmonary infarction	1	2
Pulmonary thrombosis	2	3
Pulse abnormal		2
Purpura		1
Pustule		1
Pyelonephritis	1	1
Pyrexia	156	455
Rales	1	1
Rash	14	59
Rash erythematous	1	8
Rash macular		1
Rash maculo-papular	1	4
Rash papular	3	5
Rash pruritic	2	9
Raynaud's phenomenon		4
Reaction to excipient		1
Rectal discharge		1
Rectal haemorrhage	2	5
Rectal tenesmus		1
Red blood cell sedimentation rate increased		2
Renal cyst	1	2
Renal failure		1
Renal impairment	1	2
Respiration abnormal		1
Respiratory acidosis	1	2
Respiratory arrest		1
Respiratory disorder	1	3
Respiratory distress	6	20
Respiratory failure	1	4
Respiratory rate decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	2
				2	3
					2
					1
					1
				1	1
		135	267	21	188
				1	1
		10	18	4	41
				1	8
			1		
			1	1	3
				3	5
			1	2	8
					4
					1
				2	5
					1
			2		
		1	2		
					1
				1	2
					1
				1	2
					1
				1	3
				6	20
				1	4
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract infection	2	3
Restless legs syndrome		1
Restlessness	2	4
Retinal artery occlusion	1	1
Retinal vein occlusion		1
Rhinitis	2	4
Rhinorrhoea	4	11
Rib fracture	1	1
Salivary hypersecretion	1	1
SARS-CoV-2 ant body test negative		1
SARS-CoV-2 ant body test positive		3
SARS-CoV-2 test positive	1	4
Scab	1	1
Scleritis		1
Scoliosis	1	1
Seizure	2	7
Sensation of foreign body	1	4
Sense of oppression		2
Sensory disturbance		1
Sensory loss	1	7
Sepsis		1
Septic shock	1	1
Serum ferritin abnormal		1
Severe acute respiratory syndrome		1
Sialoadenitis	1	1
Silent thyroiditis	1	1
Sinus bradycardia		1
Sinusitis	1	2
Sinus tachycardia	5	8
Skeletal injury		1
Skin exfoliation		2
Skin lesion		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					1
			1	2	3
				1	1
					1
		2	3		1
		4	8		3
				1	1
				1	1
			1		
			3		
		1	3		1
		1	1		
					1
				1	1
				2	7
				1	4
					2
					1
			3	1	4
					1
				1	1
			1		1
				1	1
				1	1
			1		
		1	2		
			1	5	7
					1
					2
			2		3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin necrosis		2
Skin odour abnormal		1
Skin reaction	1	3
Skin tightness		1
Skin ulcer	2	4
Slow speech		1
Sneezing	2	2
Somnolence	3	20
Spasmodic dysphonia		1
Speech disorder	1	3
Spinal cord injury		1
Spinal osteoarthritis	1	1
Spinal pain		2
Spontaneous haematoma		1
Staphylococcal infection	1	1
Status epilepticus		1
Stomatitis		5
Stridor		1
Subarachnoid haemorrhage	1	1
Subcutaneous abscess		1
Subcutaneous haematoma	1	1
Sudden cardiac death	1	1
Sudden death	1	10
Sudden visual loss	1	1
Suffocation feeling		2
Superinfection bacterial		1
Supraventricular extrasystoles	1	1
Supraventricular tachycardia	1	2
Swelling	1	4
Swelling face	2	5
Swollen tongue	2	8
Syncope	14	64

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
		1	2		1
			1		
		2	3		1
					1
		2	2		
		3	12		8
			1		
			1	1	2
					1
				1	1
					2
					1
				1	1
					1
			4		1
					1
				1	1
					1
				1	1
				1	10
				1	1
					2
					1
				1	1
				1	2
		1	3		1
		2	2		3
				2	8
				14	64

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Systemic lupus erythematosus		1
Systemic lupus erythematosus rash	1	1
Tachyarrhythmia		1
Tachycardia	13	67
Tachycardia paroxysmal		1
Tachypnoea		6
Temperature regulation disorder	3	24
Tenderness		1
Tendon disorder		1
Tendonitis	1	1
Tension headache	1	5
Thirst	1	1
Throat irritation	2	17
Throat tightness		4
Thrombocytopenia	4	5
Thrombophlebitis	4	4
Thrombophlebitis superficial	4	4
Thrombosis	2	2
Thrombotic microangiopathy		1
Thrombotic thrombocytopenic purpura		1
Thunderclap headache		1
Thyroxine decreased		1
Tic		2
Tinnitus	2	12
Tongue coated		1
Tongue discomfort		1
Tongue eruption		2
Tongue erythema		1
Tongue injury		1
Tongue oedema		11
Tongue pruritus	1	6
Tongue ulceration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
					1
		6	16	7	51
			1		1
			1		5
		2	12	1	12
					1
					1
		1	1		
		1	2		3
		1	1		
		1	5	1	12
					4
				4	5
		1	1	3	3
		1	1	3	3
				2	2
					1
					1
					1
			1		
		1	5	1	7
					1
			1		
			2		
					1
			1		
			1		10
		1	2		4
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tonic clonic movements		1
Tonsillitis		2
Tooth avulsion		1
Toxic skin eruption	1	2
Transferrin abnormal		1
Transient global amnesia		1
Transient ischaemic attack	2	5
Tremor		8
Tricuspid valve incompetence	1	1
Trigeminal neuralgia		1
Troponin T increased	1	2
Tunnel vision		1
Upper limb fracture	1	2
Upper respiratory tract infection		1
Urinary incontinence	1	1
Urinary retention		1
Urinary sediment abnormal		1
Urinary tract infection	2	12
Urinary tract infection bacterial		1
Urine output decreased		1
Urosepsis	1	1
Urticaria	23	55
Uterine haemorrhage		2
Uvulitis	1	1
Vaccination complication		2
Vaccination failure	8	18
Vaccination site abscess		1
Vaccination site cellulitis		2
Vaccination site discomfort	1	4
Vaccination site erosion		1
Vaccination site erythema	5	15
Vaccination site haematoma	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
					1
				1	2
			1		
					1
				2	5
			2		6
				1	1
					1
				1	2
					1
			1	1	1
					1
		1	1		
			1		1
			3	2	9
					1
			1		
				1	1
		18	23	5	32
					2
				1	1
			1		1
				8	18
					1
					2
		1	3		1
			1		
		5	8		7
		1	1	1	4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site haemorrhage		1
Vaccination site hyperaesthesia	1	2
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia	2	4
Vaccination site induration	2	6
Vaccination site inflammation	18	37
Vaccination site joint erythema	4	12
Vaccination site joint inflammation		2
Vaccination site joint movement impairment		1
Vaccination site joint swelling		1
Vaccination site lymphadenopathy	4	18
Vaccination site movement impairment	3	5
Vaccination site oedema	2	5
Vaccination site pain	58	164
Vaccination site paraesthesia	1	4
Vaccination site pruritus	4	13
Vaccination site rash	3	4
Vaccination site reaction	1	3
Vaccination site swelling	2	9
Vaccination site warmth	3	9
Vaginal discharge		1
Vaginal haemorrhage		2
Vasculitis	2	3
Vasoplegia syndrome	1	1
Venous thrombosis limb	4	5
Ventricular enlargement	1	1
Vertigo	2	16
Vertigo positional	1	1
Vestibular migraine	1	1
Viral rash		1
Vision blurred	2	14
Visual acuity reduced		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		1
		1	1		
			1	2	3
		2	5		1
		17	28	1	9
		3	6	1	6
					2
					1
			1		
		2	8	2	10
		3	4		1
		2	2		3
		51	114	7	50
			1	1	3
		4	7		6
		2	2	1	2
		1	2		1
		1	5	1	4
		3	4		5
			1		
			1		1
				2	3
				1	1
				4	5
				1	1
			5	2	11
				1	1
				1	1
			3	2	11
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment		1						1
Vitamin B12 decreased		1				1		
Vitamin D decreased		1				1		
Vitamin D deficiency		1				1		
Vitreous detachment		1						1
Vitreous floaters		1						1
Vomiting	32	104			26	52	6	52
Vulval ulceration		1						1
Vulvovaginal candidiasis	1	1					1	1
Wheezing	2	8			2	2		6
White blood cell count decreased		1						1
White blood cell count increased		1				1		
White matter lesion	1	1					1	1
Wound	1	1					1	1
Wrong technique in product usage process		1				1		
X-ray abnormal	1	1					1	1
Yawning		1				1		
	1,812	6,221	1	1	1029	2452	783	3769

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	5		4	1	1
Abdominal pain	1	5	1	1		4
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Activated partial thromboplastin time shortened	1	1	1	1		
Acute coronary syndrome	1	1			1	1
Acute generalised exanthematous pustulosis		1				1
Acute kidney injury		1				1
Acute myocardial infarction	3	3			3	3
Acute psychosis	1	1			1	1
Acute pulmonary oedema	1	1			1	1
Acute respiratory distress syndrome		1				1
Acute respiratory failure	3	4			3	4
Ageusia		1				1
Agitation	3	3	1	1	2	2
Alcohol poisoning		1				1
Allergic reaction to excipient		1				1
Allergy to vaccine		1				1
Amnesia		1		1		
Anaphylactic reaction	1	6			1	6
Anaphylactic shock		2				2
Angioedema		6				6
Anosmia		1				1
Antibody test abnormal		1		1		
Antipsychotic drug level increased		1				1
Anuria	1	1			1	1
Anxiety		1		1		
Apathy	1	1			1	1
Aphthous ulcer		1				1
Apnoea		1				1
Arrhythmia		1				1
Arthralgia	12	18	11	11	1	7

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Arthritis		1					1
Arthritis reactive	1	1			1		1
Asphyxia		1					1
Aspiration		1					1
Asthenia	10	25	4	8	6		17
Asthma		1					1
Asthmatic crisis		1					1
Asymptomatic COVID-19	1	6		2	1		4
Atelectasis		1					1
Autoimmune haemolytic anaemia	1	1			1		1
Axillary pain		1					1
Back pain		4		1			3
Bacteraemia	1	1			1		1
Bacterial disease carrier		1					1
Balance disorder		1					1
Basal ganglia stroke	1	1			1		1
Basilar artery thrombosis	1	1			1		1
Blepharitis	1	2	1	2			
Blood chloride decreased		1		1			
Blood fibrinogen increased	1	1	1	1			
Blood gases abnormal	1	1			1		1
Blood pressure abnormal		1					1
Blood pressure decreased		1					1
Blood pressure increased	1	3	1	1			2
Blood sodium decreased		1		1			
Bradycardia		1					1
Bradyphrenia	1	1	1	1			
Brain oedema		1					1
Bronchospasm	2	5			2		5
Bruxism		1		1			
Bundle branch block left	1	1			1		1
Bursitis		2					2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	1	3			1	3
Cardiac failure	4	6			4	6
Cardiac failure acute	1	4			1	4
Cardio-respiratory arrest	2	7			2	7
Catarrh		1				1
Cell death	1	1			1	1
Cellulitis		2				2
Cerebellar infarction	1	1			1	1
Cerebral disorder		1				1
Cerebral haematoma	1	2			1	2
Cerebral haemorrhage	2	2			2	2
Cerebral infarction	1	1			1	1
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	3	4			3	4
Cervicobrachial syndrome		1				1
Chest discomfort		4				4
Chest pain	1	8			1	8
Chills	3	19	3	9		10
Cholestasis	1	1			1	1
Chronic kidney disease	1	1			1	1
Chronic obstructive pulmonary disease	1	1			1	1
Chronic respiratory failure		1				1
Circadian rhythm sleep disorder	1	1			1	1
Circulatory collapse	1	1			1	1
Cognitive disorder	2	2			2	2
Cold sweat		1				1
Condition aggravated	2	6	1	1	1	5
Confusional state		4		1		3
Constipation	1	1			1	1
Contusion		1		1		
Coombs positive haemolytic anaemia	1	1			1	1
Coordination abnormal	1	2		1	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	8	1	3		5
COVID-19	10	36	5	8	5	28
COVID-19 pneumonia		3				3
Craniocerebral injury		1				1
C-reactive protein increased		1		1		
Cyanosis		1		1		
Deafness unilateral		1				1
Death		3				3
Decreased appetite		2				2
Decreased nasolabial fold		1				1
Deep vein thrombosis	6	9			6	9
Dehydration		1		1		
Delirium	1	1			1	1
Delusion	1	1			1	1
Depressed level of consciousness		9				9
Depressed mood		1		1		
Dermatitis allergic	1	1			1	1
Dermatitis bullous		1				1
Dermatitis contact		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	9	32	7	14	2	18
Diplopia	1	3	1	1		2
Discomfort	1	3		1	1	2
Disease recurrence	1	2			1	2
Disorientation	2	6		2	2	4
Disturbance in attention		4				4
Dizziness	2	14	1	5	1	9
Drowning		1				1
Drug ineffective	3	15			3	15
Drug interaction		1				1
Dry mouth	1	2			1	2
Dysaesthesia		1				1

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
		1	1
1	2	3	28
	1		1
2	2	1	1
1	1		1
	1		
			1
			1
			1
1	1	1	1
1	1	1	1
1	1	1	1
3	5	3	5
2	2		
			1
2	3		1
			1
			2
			1
			1
1	4	1	4
			1
4	13	4	13
1	2	1	2
1	6	1	3
9	27	3	12
1	2	1	2
	2		1
	2		1
1	3		2
1	1	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibrin D dimer increased	1	1			1	1
Flushing		1		1		
Formication		1		1		
Gait disturbance	1	6			1	6
Gait inability	2	3		1	2	2
Gastric disorder	1	1	1	1		
Gastritis	1	1	1	1		
Gastroenteritis	2	3	1	2	1	1
Gastrointestinal haemorrhage	1	1			1	1
Gastrooesophageal reflux disease		1				1
Gaze palsy		1				1
Generalised tonic-clonic seizure		4				4
General physical health deterioration		1				1
Genital blister		1		1		
Giant cell arteritis	1	1			1	1
Giant papillary conjunctivitis		1				1
Gingival swelling	1	1			1	1
Gingivitis		1		1		
Guillain-Barre syndrome	2	3			2	3
Haematoma	2	2	1	1	1	1
Haematuria	2	3		1	2	2
Haemoglobin decreased		1		1		
Haemophagocytic lymphohistiocytosis		1				1
Haemorrhage		1				1
Haemorrhagic stroke	1	2			1	2
Hallucination	1	1			1	1
Hallucination, auditory	1	1			1	1
Hallucination, visual		1				1
Headache	17	56	17	29		27
Head injury		1		1		
Heart rate increased		1				1
Hepatic failure		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic steatosis	1	1			1	1
Hepatitis acute		1				1
Hepatitis cholestatic	1	1			1	1
Herpes ophthalmic	1	2			1	2
Herpes simplex	1	2	1	1		1
Herpes zoster	4	19	1	2	3	17
Herpes zoster cutaneous disseminated	1	1			1	1
Herpes zoster reactivation		1				1
Hyperaesthesia		1				1
Hypercholesterolaemia	1	1	1	1		
Hyperglycaemia	2	3			2	3
Hyperhidrosis		2		1		1
Hypernatraemia		1				1
Hyperpyrexia		1				1
Hypersensitivity	1	2			1	2
Hypersensitivity vasculitis	1	1			1	1
Hypersomnia		1				1
Hypertension	1	4			1	4
Hypertensive crisis		2				2
Hypoacusis		1				1
Hypoaesthesia		3		1		2
Hypokinesia	1	1			1	1
Hyponatraemia	1	1			1	1
Hyporesponsive to stimuli		1				1
Hypotension	2	6		2	2	4
Hypothermia		1				1
Hypotonia		1		1		
Hypoxia	1	7			1	7
Inappropriate schedule of product administration		3		3		
Incorrect dose administered		2		2		
Incorrect route of product administration	1	3	1	3		
Increased bronchial secretion		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infant irritability		1				1
Infection		1				1
Infectious mononucleosis		1				1
Infective exacerbation of bronchiectasis	1	1			1	1
Inflammation	1	1	1	1		
Influenza	1	2	1	1		1
Influenza like illness		1		1		
Injection site pain		1		1		
Insomnia	1	1	1	1		
Intestinal ischaemia		1				1
Intestinal obstruction		1				1
Ischaemic cerebral infarction		1				1
Ischaemic stroke	1	5			1	5
Jaw fracture		1				1
Joint contracture		1		1		
Labyrinthitis		1				1
Large intestine infection	1	1			1	1
Laryngeal erythema		1				1
Laryngeal oedema		2				2
Laryngospasm		1		1		
Leukoencephalopathy		1				1
Ligament sprain		1		1		
Limb discomfort	1	1			1	1
Lip oedema		1				1
Lip swelling	1	1			1	1
Liver function test abnormal	1	1			1	1
Loss of consciousness		5				5
Loss of personal independence in daily activities	1	1			1	1
Lung disorder		2				2
Lung infiltration		2		2		
Lymphadenopathy	1	11		2	1	9
Lymphangitis		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphocyte percentage decreased		1		1		
Lymphopenia		1		1		
Malaise	12	38	9	21	3	17
Meningoradiculitis	1	1			1	1
Mental disorder		1				1
Mental impairment	1	2			1	2
Migraine with aura		1				1
Migraine without aura	1	1			1	1
Miosis		1				1
Mononeuropathy		1				1
Monoparesis	1	1			1	1
Monoplegia	1	1			1	1
Mouth swelling		1				1
Movement disorder		1				1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis		1				1
Muscle contractions involuntary		1		1		
Muscle contracture		2		2		
Muscle spasms		2		1		1
Muscular weakness		4		2		2
Musculoskeletal discomfort		1				1
Musculoskeletal pain	1	5		1	1	4
Myalgia	14	36	13	20	1	16
Myocardial infarction		1				1
Myocarditis		3				3
Myoclonic dystonia		1				1
Myoclonus		1				1
Nasal congestion		2				2
Nasal disorder	1	1	1	1		
Nasopharyngitis		2		2		
Nausea	2	14	2	5		9
Neck pain		2		1		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
9	21	3	17
		1	1
			1
		1	2
			1
		1	1
			1
		1	1
		1	1
			1
			1
	1		
	2		
	1		1
	2		2
			1
	1	1	4
13	20	1	16
			1
			3
			1
			1
			2
1	1		
	2		
2	5		9
	1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nervousness		1		1			
Nervous system disorder	1	1			1	1	
Neuralgia		2		1		1	
Neuralgic amyotrophy	1	1			1	1	
Neurogenic shock		1				1	
Neuropathy peripheral	1	1			1	1	
Neutrophil count increased		1		1			
Neutrophilia		1		1			
Neutrophil percentage increased		1		1			
Night sweats	2	2	1	1	1	1	
N-terminal prohormone brain natriuretic peptide increased	1	1			1	1	
Ocular dysmetria	1	1	1	1			
Oculofacial paralysis	1	1			1	1	
Odynophagia		2		1		1	
Oedema		2		1		1	
Oedema mouth		1				1	
Oedema peripheral		1				1	
Off label use		2		2			
Ophthalmic herpes zoster		1				1	
Optic neuritis		1				1	
Oral candidiasis		1		1			
Oral discomfort	1	1	1	1			
Oral disorder		1				1	
Oral dysaesthesia		1				1	
Oral mucosal blistering		1		1			
Oral pruritus		1				1	
Oropharyngeal discomfort		1		1			
Oropharyngeal pain	1	1	1	1			
Oxygen saturation decreased	1	6			1	6	
Pain	4	6	3	5	1	1	
Pain in extremity	3	7	1	3	2	4	

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pain in jaw		1		1			
Palatal oedema		4					4
Palatal swelling		1					1
Palpitations		2					2
Panniculitis		1					1
Paraesthesia	5	18	1	4	4		14
Paraesthesia oral	1	3	1	1			2
Paraparesis		1					1
Parotid gland enlargement	1	1	1	1			
PCO2 decreased	1	1	1	1			
Penile discomfort		1		1			
Pericarditis	2	4			2		4
Periorbital abscess		1					1
Peripheral artery thrombosis		1					1
Peripheral coldness		1					1
Peripheral sensory neuropathy	1	1			1		1
Peripheral swelling		1					1
Peripheral venous disease	1	1			1		1
Pernio-like erythema		2		1			1
Petechiae	1	1	1	1			
Petit mal epilepsy		1					1
Pharyngeal inflammation	1	1	1	1			
Pharyngotonsillitis	1	2			1		2
Phlebitis superficial	1	2	1	1			1
Photopsia	1	1	1	1			
Pleuritic pain		2					2
Pneumonia	2	7			2		7
Pneumonia aspiration	2	4			2		4
PO2 decreased	1	1	1	1			
Pollakiuria	1	1			1		1
Polyarthrits		1					1
Poor quality product administered	2	2	2	2			

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Post thrombotic syndrome	1	1
Presyncope		3
Productive cough		1
Product preparation error	2	2
Product use issue		1
Prothrombin time prolonged	1	1
Pruritus	2	6
Psychotic disorder	1	1
Pulmonary embolism	11	15
Pulmonary infarction	1	1
Pulmonary sepsis	1	1
Pyrexia	42	115
Rash	1	5
Rash macular	1	1
Rash pruritic	1	1
Rash vesicular	1	1
Raynaud's phenomenon		1
Rectal haemorrhage		1
Renal failure	3	4
Renal impairment		1
Respiratory arrest		1
Respiratory disorder	1	1
Respiratory distress		3
Respiratory failure	3	7
Respiratory tract infection	1	3
Restlessness		1
Retinal artery occlusion	1	1
Retinal vein thrombosis	1	1
Rhinalgia		1
Rhinitis	2	2
Rotator cuff syndrome	2	2
SARS-CoV-2 ant body test negative		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			3
	1		
2	2		
	1		
1	1		
		2	6
1	1		
		11	15
		1	1
		1	1
32	60	10	55
	1	1	4
		1	1
		1	1
1	1		
			1
			1
		3	4
			1
			1
1	1		
			3
		3	7
		1	3
	1		
		1	1
		1	1
	1		
2	2		
		2	2
	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 ant body test positive		1				1
SARS-CoV-2 test positive	1	3	1	3		
Seizure	2	5			2	5
Sensation of foreign body		1				1
Sensory disturbance		1				1
Sensory loss	2	2	1	1	1	1
Sepsis		1				1
Septic arthritis staphylococcal	1	1			1	1
Septic shock	1	1			1	1
Serology negative		1		1		
Shock		1				1
Shoulder injury related to vaccine administration		1		1		
Sinus arrest		1				1
Skin lesion		1				1
Skin reaction		1				1
SLE arthritis		1				1
Slow speech	1	2	1	1		1
Somnolence		3		1		2
Speech disorder		1				1
Stupor		1				1
Sudden death	3	6			3	6
Suicide attempt		1				1
Suspected COVID-19	1	1			1	1
Swelling face		1				1
Syncope	1	9			1	9
Systemic inflammatory response syndrome		1				1
Tachycardia	2	7			2	7
Tachypnoea		1		1		
Temperature intolerance	1	1	1	1		
Temperature regulation disorder	1	4	1	2		2
Tendonitis		1				1
Tenosynovitis		1				1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	3		
		2	5
			1
			1
1	1	1	1
			1
		1	1
	1		
			1
	1		
			1
			1
1	1		1
	1		2
			1
			1
		3	6
			1
		1	1
		1	9
			1
	2	2	7
			1
1	1		
1	2		2
			1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tension headache	1	2	1	2		
Testicular pain	1	1	1	1		
Thalamic infarction	1	1			1	1
Throat irritation		2		1		1
Throat tightness	1	1	1	1		
Thrombocytopenia	3	3			3	3
Thrombophlebitis superficial	2	3			2	3
Tic		1				1
Tinnitus	1	3			1	3
Tongue disorder	1	1	1	1		
Tongue oedema		1				1
Toxicity to various agents		1				1
Transaminases increased		1				1
Transient ischaemic attack	2	3			2	3
Tremor		6		1		5
Trigeminal neuralgia		1				1
Troponin I increased	1	1			1	1
Tuberculosis		1				1
Type IV hypersensitivity reaction		1				1
Underdose		5		5		
Upper gastrointestinal haemorrhage	1	1			1	1
Urinary retention		1				1
Urinary sediment present		1		1		
Urinary tract infection	1	2			1	2
Urinary tract infection pseudomonal	1	1			1	1
Urticaria	2	8	1	2	1	6
Uvulitis		1				1
Vaccination complication		2				2
Vaccination failure	3	6			3	6
Vaccination site discomfort	1	1			1	1
Vaccination site erythema		2		2		
Vaccination site haematoma		2				2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	1		
		1	1
	1		1
1	1		
		3	3
		2	3
			1
		1	3
1	1		
			1
			1
			1
		2	3
	1		5
			1
		1	1
			1
			1
	5		
		1	1
			1
1	2	1	2
1	1	1	1
1	2	1	6
			1
			2
		3	6
		1	1
	2		
			2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration	1	2	1	1		1
Vaccination site inflammation	3	4	2	3	1	1
Vaccination site joint erythema		1		1		
Vaccination site joint inflammation	1	1	1	1		
Vaccination site lymphadenopathy		4				4
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	14	30	13	20	1	10
Vaccination site paraesthesia	1	3	1	1		2
Vaccination site rash	1	1	1	1		
Vaccination site reaction		2		1		1
Vaccination site swelling	1	1			1	1
Ventricular dysfunction	1	1			1	1
Ventricular extrasystoles		1				1
Ventricular fibrillation	1	1			1	1
Vertigo		4				4
Vestibular neuronitis	1	1			1	1
Viral keratouveitis	1	1			1	1
Vision blurred		2				2
Visual impairment	1	2			1	2
Vitreous detachment		1				1
Volvulus		1				1
Vomiting	9	21	6	8	3	13
Wheezing	1	1	1	1		
White blood cell count increased		1		1		
White matter lesion	1	1	1	1		
	473	1,434	207	443	266	991

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
Chorioretinopathy		1				1
COVID-19		4		2		2
Diarrhoea	1	4		2	1	2
Dizziness	1	2	1	2		
Drug ineffective		2				2
Exposure via breast milk	1	5	1	5		
Fatigue	1	2	1	1		1
Feeling hot	1	1	1	1		
Foetal heart rate abnormal		1				1
Headache	3	4	3	3		1
Hypertension		1				1
Inappropriate schedule of product administration	2	2	2	2		
Lymphadenopathy	1	1			1	1
Malaise	2	2	1	1	1	1
Maternal exposure during pregnancy		1				1
Myalgia	4	4	4	4		
Odynophagia	1	1	1	1		
Overdose		4		4		
Pain		2		1		1
Paraesthesia	1	1	1	1		
Petechiae		1		1		
Product preparation issue		4		4		
Pyrexia	3	5	3	3		2
Sinus tachycardia	1	1			1	1
Somnolence		1		1		
Syncope		2				2
Tenderness		1		1		
Vaccination site joint erythema	1	2	1	2		
Vaccination site joint swelling	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vomiting	2	3	2	3		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong technique in product usage process	1	1	1	1		
	31	70	27	50	4	20

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**SWAZILAND**

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
Angioedema		1				1
Death		1				1
Dermatitis allergic		1		1		
Dyspnoea		1		1		
Headache		1		1		
Influenza like illness		1		1		
Nasopharyngitis		1		1		
Pyrexia		1		1		
Skin swelling		1		1		
		10		7		3

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**SWEDEN**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		4		1		3
Abdominal distension		1				1
Abdominal infection	1	1			1	1
Abdominal pain	4	19	1	8	3	11
Abdominal pain lower		2				2
Abdominal pain upper		8		3		5
Abdominal symptom		1				1
Abdominal wall haemorrhage	1	1			1	1
Abnormal sensation in eye		1				1
Abortion spontaneous		1				1
Acne		1		1		
Acute kidney injury	1	3			1	3
Acute left ventricular failure		1				1
Acute myocardial infarction	2	5			2	5
Adrenocortical insufficiency acute		1				1
Ageusia		6		3		3
Aggression		1				1
Allergy to vaccine		2		1		1
Allodynia		1		1		
Altered state of consciousness	1	1			1	1
Amenorrhoea		1		1		
Amnesia		3				3
Anaemia	1	1			1	1
Anaphylactic reaction	4	23			4	23
Anaphylactic shock		2				2
Angina pectoris		1				1
Angioedema	1	4			1	4
Anosmia		7		3		4
Anxiety		7		5		2
Aortic aneurysm rupture		1				1
Aortic arteriosclerosis	1	2		1	1	1
Apathy		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	3			1	3
Apnoea		1				1
Areflexia		1				1
Arrhythmia	1	5			1	5
Arterial thrombosis	1	1			1	1
Arteriosclerosis		2				2
Arthralgia	5	45	1	22	4	23
Arthritis	1	4		2	1	2
Aspiration	1	1			1	1
Asthenia	5	34	1	13	4	21
Asthenopia		3				3
Asthma		1				1
Atelectasis		1				1
Atrial f brillation	2	4			2	4
Atrial flutter	1	2			1	2
Atrial septal defect		1				1
Atrial thrombosis		1				1
Atrioventricular block complete		1				1
Atypical pneumonia	1	1			1	1
Autonomic nervous system imbalance		1				1
Axillary pain	1	10		7	1	3
Back pain	4	21	1	11	3	10
Balance disorder	5	7	1	1	4	6
Basedow's disease		1				1
Basilar artery thrombosis	1	1			1	1
Bedridden	1	3		2	1	1
Biliary colic	1	1			1	1
Biliary dilatation	1	1			1	1
Biliary tract disorder		1				1
Blindness	1	3			1	3
Blindness transient		1				1
Blister		2		1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood alkaline phosphatase increased		1					1
Blood bilirubin increased		1					1
Blood creatinine increased	2	2			2		2
Blood glucose decreased		1					1
Blood glucose increased		3		1			2
Blood phosphorus decreased		1		1			
Blood potassium increased	1	1			1		1
Blood pressure abnormal		1					1
Blood pressure decreased	1	9		2	1		7
Blood pressure fluctuation		1					1
Blood pressure increased	2	6		1	2		5
Blood pressure systolic increased		2		1			1
Body temperature decreased		2					2
Body temperature increased	2	3	1	2	1		1
Bone disorder		1		1			
Brain injury		1					1
Brain scan abnormal		1					1
Breast pain	1	1			1		1
Breath sounds abnormal		1					1
Bronchospasm		1					1
Bundle branch block left	1	1	1	1			
Burning sensation		1					1
Cachexia		1					1
Cardiac arrest	3	9			3		9
Cardiac discomfort	1	1			1		1
Cardiac disorder	1	4			1		4
Cardiac failure	3	9			3		9
Cardiac failure acute		1					1
Cardiac failure chronic		1					1
Cardiac flutter		1					1
Cardiac murmur	1	1			1		1
Cardiogenic shock		1					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cardiopulmonary failure		1					1
Cardiovascular disorder	1	1			1		1
Central pain syndrome		1					1
Cerebral artery embolism	1	1			1		1
Cerebral atrophy		1					1
Cerebral haemorrhage	2	3			2		3
Cerebral infarction	2	4			2		4
Cerebral microangiopathy	1	1			1		1
Cerebrovascular accident	5	12			5		12
Cerebrovascular disorder		1					1
Chest discomfort	2	15	1	7	1		8
Chest pain	7	26	1	9	6		17
Chills	9	89	2	46	7		43
Cholecystitis		1					1
Chronic gastritis		1					1
Chronic obstructive pulmonary disease		4					4
Chronic respiratory failure		1					1
Circulatory collapse		2					2
Clostridium difficile colitis	1	1			1		1
Coeliac artery stenosis		1					1
Cognitive disorder		1					1
Cold sweat	1	9		3	1		6
Concomitant disease aggravated		1					1
Concussion	1	1	1	1			
Condition aggravated	7	18	1	3	6		15
Confusional state	2	12	1	1	1		11
Contusion	2	2			2		2
Coordination abnormal	1	2			1		2
Coronary artery stenosis		1					1
Cor pulmonale acute		1					1
Cough	6	27	1	12	5		15
COVID-19	7	21	2	4	5		17

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
COVID-19 pneumonia		1					1
Cranial nerve disorder		1					1
C-reactive protein abnormal		1		1			
C-reactive protein increased	5	9	2	4	3		5
Crepitations		2		1			1
Crying		1		1			
Cyanosis	1	4	1	2			2
Deafness unilateral		2					2
Death	2	29			2		29
Decreased appetite	2	14	1	6	1		8
Deep vein thrombosis	14	20			14		20
Dehydration	1	3	1	2			1
Dementia		1					1
Dementia Alzheimer's type		1					1
Depressed level of consciousness	1	7			1		7
Depressed mood		3		1			2
Depression		1		1			
Derealisation		1					1
Diarrhoea	4	38	1	20	3		18
Discomfort	3	8		3	3		5
Disease recurrence	5	10	1	2	4		8
Dissociation		1					1
Disturbance in attention	2	7		2	2		5
Diverticulitis		1					1
Diverticulum		1		1			
Dizziness	17	91	1	28	16		63
Drug eruption		2		1			1
Drug ineffective	1	8			1		8
Dry mouth	1	3			1		3
Dry skin		1		1			
Dysaesthesia	1	1	1	1			
Dysarthria	1	7		1	1		6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia		7		2		5
Dyspepsia		1		1		
Dysphagia	4	9	1	1	3	8
Dysphonia	1	9		5	1	4
Dyspnoea	16	82	2	17	14	65
Dyspnoea exertional	2	4			2	4
Dysstasia		2				2
Ear discomfort		2				2
Ear pain	1	3			1	3
Ear swelling	1	1			1	1
Eczema		1		1		
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram T wave inversion		1				1
Embolism	1	3			1	3
Embolism arterial	1	1			1	1
Encephalitis	1	2			1	2
Encephalopathy		1				1
Epilepsy	2	4			2	4
Epistaxis	1	3		2	1	1
Erysipelas	2	4			2	4
Erythema	7	33	4	17	3	16
Escherichia urinary tract infection		1				1
Extrasystoles		2				2
Eye disorder		2				2
Eye inflammation		1				1
Eye irritation		2				2
Eye pain		7				7
Eye pruritus		2				2
Eye swelling		2				2
Facial discomfort	1	1	1	1		
Facial neuralgia		1				1
Facial pain		2				2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis	2	10			2	10
Facial paresis	2	11			2	11
Fall	5	8	1	2	4	6
Fatigue	24	171	7	89	17	82
Feeding disorder	2	2	1	1	1	1
Feeling abnormal	2	14	1	6	1	8
Feeling cold	6	20	2	13	4	7
Feeling drunk		1		1		
Feeling hot	3	24	2	11	1	13
Feeling of body temperature change		3				3
Feeling of despair		1				1
Femoral neck fracture		1				1
Fibromyalgia		1				1
Flank pain		1		1		
Flatulence		1		1		
Fluid retention		1				1
Flushing		3				3
Food refusal		1				1
Formication		4		1		3
Furuncle		1				1
Gait disturbance	1	3		1	1	2
Gait inability		1				1
Gal bladder disorder		1				1
Gal bladder oedema		1				1
Gamma-glutamyltransferase increased		1				1
Gastric disorder	1	2		1	1	1
Gastritis		1		1		
Gastroenteritis	1	1			1	1
Generalised oedema		2				2
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration	4	35		7	4	28
Glomerular filtration rate decreased	2	2	1	1	1	1

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	1
			1
			1
1		1	5
			2
1		1	1
1		1	2
1		1	1
1		1	1
			2
			1
1		1	3
23		15	87
1		1	6
			1
			1
			1
2		2	15
			1
			1
3		3	8
1		1	1
			1
1		1	1
4		4	9
			2
			1
			1
			1
			1
			7
			1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperparathyroidism primary		1		1			
Hypersensitivity	2	34		4	2		30
Hypersomnia		2		1			1
Hypersomnia-bulimia syndrome		1					1
Hypertension	2	14		3	2		11
Hyperventilation		3					3
Hypoacusis		6					6
Hypoaesthesia	7	59	2	17	5		42
Hypoaesthesia oral		12		4			8
Hypoalbuminaemia		1		1			
Hypoglycaemia		3					3
Hypokalaemia	1	2			1		2
Hypokinesia		1					1
Hypophagia		1					1
Hypopnoea		1					1
Hypotension	5	17	1	4	4		13
Hypothermia		2					2
Hypoxia		1					1
Illness	2	5		1	2		4
Immune thrombocytopenia		1					1
Immunisation reaction		1					1
Inappropriate schedule of product administration	1	1	1	1			
Incorrect route of product administration	1	5	1	5			
Increased upper airway secretion		2		2			
Infection	2	7		1	2		6
Inflammation	1	3			1		3
Influenza like illness	2	10	1	5	1		5
Infrequent bowel movements		1		1			
Initial insomnia		1					1
Injected limb mobility decreased		1		1			
Insomnia	1	6		2	1		4
Intention tremor		1					1

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\* AE=Adverse Event

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Intestinal haemorrhage	1	2
Intestinal ischaemia	1	2
Irregular breathing		1
Ischaemic stroke	5	7
Jaundice		1
Jaw disorder		1
Joint lock		1
Joint range of motion decreased	1	2
Joint stiffness	1	3
Joint swelling		2
Laryngeal oedema		1
Laziness		1
Left ventricular hypertrophy		1
Lethargy	1	2
Leukocytosis		1
Leukopenia	2	2
Limb discomfort		2
Limb injury	1	1
Lip pruritus	1	2
Lip swelling		8
Lip ulceration	1	1
Livedo reticularis		1
Liver disorder		2
Local reaction		1
Loss of consciousness	5	13
Loss of personal independence in daily activities	1	2
Lung infiltration	1	1
Lymphadenitis		1
Lymphadenopathy	3	24
Lymphadenopathy mediastinal		1
Lymph node pain		9
Lymphoedema		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
		1	2
	1		
		5	7
			1
			1
			1
	1	1	1
	2	1	1
	1		1
			1
	1		
			1
		1	2
			1
		2	2
	1		1
		1	1
		1	2
	2		6
1	1		
	1		
			2
	1		
		5	13
	1	1	1
		1	1
			1
1	14	2	10
	1		
	7		2
			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	7	48	3	28	4	20
Mass		1				1
Memory impairment	1	7		2	1	5
Meningism	1	1			1	1
Meningitis		1				1
Meningitis herpes		1				1
Mental fatigue		7		1		6
Mesenteric artery embolism		1				1
Metabolic acidosis	1	1			1	1
Metabolic disorder	1	2	1	1		1
Metrorrhagia		1				1
Migraine	3	12		5	3	7
Mobility decreased		2		1		1
Monoparesis	1	1			1	1
Monoplegia		1				1
Mouth swelling		1				1
Mouth ulceration	1	1	1	1		
Multiple sclerosis	1	3			1	3
Muscle contractions involuntary		1				1
Muscle fatigue		1				1
Muscle spasms	4	12	2	4	2	8
Muscle tightness		1				1
Muscle tone disorder		1				1
Muscle twitching		4				4
Muscular weakness	7	25		4	7	21
Musculoskeletal chest pain		2				2
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness		16		7		9
Myalgia	12	81	3	40	9	41
Myelitis		1				1
Myelosuppression		1				1
Myocardial fibrosis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	2	9			2	9
Myocardial ischaemia		3				3
Myocardial rupture		1				1
Myocarditis	1	2			1	2
Myopia		1				1
Nail discolouration		1				1
Nasal congestion		10		4		6
Nasopharyngitis	6	12	2	5	4	7
Nausea	13	94	3	46	10	48
Neck pain	1	14		8	1	6
Nervousness		2		1		1
Neuralgia	1	3	1	2		1
Neurological symptom		1				1
Neuropathy peripheral		2				2
Nightmare		3				3
Night sweats		1		1		
Nodule		1		1		
Obstructive airways disorder	1	2			1	2
Ocular discomfort		1				1
Oedema peripheral	1	2	1	1		1
Oesophageal ulcer haemorrhage	1	1			1	1
Off label use	1	2	1	2		
Ophthalmic herpes zoster		1				1
Oral discomfort		3				3
Oral herpes		3		2		1
Oral mucosal blistering		1				1
Oral pain		1		1		
Oral pruritus	1	7	1	4		3
Oral viral infection		1				1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	3	17		11	3	6
Oropharyngeal spasm		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
	1		
	2	3	13
5	33	9	39
	1		
7	70	9	41
	2		2
	2	1	2
	1		1
1	4		3
	6	3	22
		2	2
			2
			2
1	12	2	28
			1
	5	1	7
			1
		1	1
			2
		1	1
			3
			1
			1
			3
	1		1
			1
			1
			3
			1
			1
		1	1
			1
1	4	6	11

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	2	3	1	1	1	2
Petit mal epilepsy		1				1
Pharyngeal disorder		1				1
Pharyngeal erythema		2		1		1
Pharyngeal hypoaesthesia		3				3
Pharyngeal oedema	1	1			1	1
Pharyngeal paraesthesia		2				2
Pharyngeal swelling	3	15		4	3	11
Pharyngitis		1		1		
Phlebitis	1	1			1	1
Photophobia		4				4
Physical deconditioning		2		1		1
Pleural effusion	1	5		1	1	4
Pleurisy		1				1
Pneumonia	1	6			1	6
Pneumonia aspiration	1	1			1	1
Polyarthrits	1	1			1	1
Polymyalgia rheumatica		1				1
Polyneuropathy	1	1			1	1
Poor quality product administered		5		5		
Poor quality sleep		1				1
Postoperative wound complication		1				1
Post stroke epilepsy	1	1			1	1
Post viral fatigue syndrome		1		1		
Presyncope	1	5		1	1	4
Procalcitonin increased	2	2			2	2
Product administered at inappropriate site	1	2	1	2		
Product colour issue		5		5		
Productive cough	2	3			2	3
Product preparation issue		3		3		
Product use issue		1		1		
Pruritus	6	28	2	11	4	17

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Psychotic disorder	1	2			1	2
Pulmonary artery thrombosis		1				1
Pulmonary embolism	20	31			20	31
Pulmonary infarction	1	1			1	1
Pulmonary oedema		5				5
Pulmonary pain		3		1		2
Pulse abnormal		3		2		1
Pulse pressure decreased		1		1		
Purpura		1				1
Pyrexia	30	230	9	115	21	115
Rash	3	17	1	7	2	10
Rash erythematous		5		1		4
Rash macular	1	2	1	2		
Rash maculo-papular		1				1
Rash pruritic		3		2		1
Reading disorder		1				1
Red blood cell sedimentation rate increased		1				1
Reduced facial expression		1				1
Renal failure		1				1
Renal impairment		1				1
Renal infarct		1				1
Renal pain		3		2		1
Renal tubular necrosis	1	1			1	1
Respiratory arrest	1	3			1	3
Respiratory disorder	1	1			1	1
Respiratory distress	2	11			2	11
Respiratory failure	2	3			2	3
Respiratory rate increased		5				5
Restless legs syndrome		2				2
Retinal haemorrhage	1	1			1	1
Retroperitoneal haemorrhage	1	1			1	1
Rhinalgia		2		1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinitis		1		1		
Rhinorrhoea	5	15	1	11	4	4
Rib fracture	1	1			1	1
Scapula fracture	1	1			1	1
Sciatica		2		1		1
Seizure	1	6			1	6
Seizure like phenomena		2				2
Sensation of foreign body		1				1
Sensory disturbance		2		1		1
Sepsis		2				2
Septic shock	1	2			1	2
Sinus congestion		1		1		
Sinus disorder		1		1		
Skin burning sensation		1				1
Skin discolouration	1	5		2	1	3
Skin reaction		1		1		
Skin turgor decreased		1				1
Skin ulcer	1	4			1	4
Skin warm		1		1		
Sleep disorder	2	5			2	5
Sleep paralysis		1				1
Sleep talking		1				1
Sluggishness	1	1			1	1
Sneezing		1		1		
Somnolence		7		3		4
Speech disorder	2	2	1	1	1	1
Spinal pain		1		1		
Spontaneous haematoma	1	1			1	1
Stevens-Johnson syndrome		1				1
Stomatitis		1				1
Subarachnoid haemorrhage	1	3			1	3
Subdural haematoma	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death	1	5			1	5
Sudden hearing loss		1				1
Sudden visual loss	1	1			1	1
Supraventricular extrasystoles		1				1
Suspected COVID-19		1		1		
Swelling		7		3		4
Swelling face	2	11	1	4	1	7
Swollen tongue	2	10			2	10
Syncope	4	20			4	20
Systemic lupus erythematosus	1	1			1	1
Tachycardia	1	15		5	1	10
Tachypnoea		2		1		1
Taste disorder		3				3
Temperature regulation disorder		1		1		
Tenderness	2	3		1	2	2
Throat irritation	2	12		4	2	8
Throat tightness		5		1		4
Thrombocytopenia	7	7			7	7
Thrombophlebitis	3	4	1	1	2	3
Thrombophlebitis superficial	1	1			1	1
Thrombosis	6	9			6	9
Tinnitus	2	12			2	12
Tongue discomfort		1				1
Tongue movement disturbance		1				1
Tongue pruritus	1	4			1	4
Toxic epidermal necrolysis		1				1
Transaminases increased		1				1
Transient ischaemic attack	5	7			5	7
Tremor	1	11	1	2		9
Trigeminal nerve paresis	1	1			1	1
Troponin increased	1	1	1	1		
Underdose		3		3		

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	5
			1
		1	1
			1
	1		
	3		4
1	4	1	7
		2	10
		4	20
		1	1
	5	1	10
	1		1
			3
	1		
	1	2	2
	4	2	8
	1		4
		7	7
1	1	2	3
		1	1
		6	9
		2	12
			1
			1
		1	4
			1
			1
		5	7
1	2		9
		1	1
1	1		
	3		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Unresponsive to stimuli	1	2			1	2
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract congestion		1		1		
Upper respiratory tract infection		1				1
Urinary retention		1				1
Urinary tract infection	3	8	1	4	2	4
Urine output decreased		2				2
Urosepsis		1				1
Urticaria	4	35		13	4	22
Uterine inflammation		1		1		
Vaccination failure	4	5			4	5
Vaccination site bruising	1	2	1	1		1
Vaccination site discolouration		1				1
Vaccination site discomfort		1				1
Vaccination site erythema	2	33	1	21	1	12
Vaccination site haematoma		2				2
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		2		2		
Vaccination site induration	1	4	1	3		1
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy		1				1
Vaccination site mass		1		1		
Vaccination site movement impairment	1	7	1	6		1
Vaccination site nodule		1		1		
Vaccination site pain	5	106	5	82		24
Vaccination site paraesthesia		1		1		
Vaccination site phlebitis		1		1		
Vaccination site pruritus		9		6		3
Vaccination site rash		1				1
Vaccination site reaction		4		2		2
Vaccination site swelling	4	38	4	26		12
Vaccination site thrombosis		1				1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria		1		1		
Vaccination site warmth	1	10	1	9		1
Vaginal haemorrhage		1				1
Vascular dementia		1				1
Vasculitis		1				1
Vasodilatation	1	1	1	1		
Venous thrombosis		1				1
Ventricular hypokinesia	1	1			1	1
Vertigo	1	2			1	2
Vertigo positional		1		1		
Vision blurred	1	7		1	1	6
Visual field defect		3				3
Visual impairment	3	9		1	3	8
Vomiting	14	54	3	12	11	42
Weight decreased		2		1		1
Wheezing	2	6	1	1	1	5
White blood cell count increased	1	2	1	2		
Wound	1	2		1	1	1
	712	3,885	141	1428	571	2457

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1				1
Abdominal pain		2		1		1
Abnormal behaviour		3		1		2
Abnormal dreams	1	1	1	1		
Acute kidney injury	1	2			1	2
Acute myocardial infarction	2	3			2	3
Agitation	1	2			1	2
Akinesia		1				1
Allergy to vaccine		1				1
Altered state of consciousness	1	1			1	1
Amnesia	2	2			2	2
Anaphylactic reaction	2	3			2	3
Anaphylactic shock	1	1			1	1
Anaphylactoid reaction	1	1			1	1
Angina pectoris	2	3			2	3
Angioedema		2				2
Anxiety	2	7			2	7
Apathy	1	1			1	1
Apnoea		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia		6		3		3
Arthritis		2				2
Ascites		1				1
Asthenia	5	8	2	3	3	5
Asthenopia		1				1
Atrial f brillation	3	6			3	6
Atrioventricular block complete		1				1
Axillary pain		1				1
Back pain	1	2		1	1	1
Balance disorder	2	5			2	5
Blepharospasm		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatinine increased	1	2	1	2		
Blood fibrinogen decreased	1	1			1	1
Blood lactate dehydrogenase increased	1	1			1	1
Blood pressure decreased	1	5	1	1		4
Blood pressure diastolic decreased		1		1		
Blood pressure increased		2		1		1
Body temperature increased		2		1		1
Bradycardia	1	1			1	1
Brain herniation	1	1			1	1
Brain stem syndrome		1				1
Bronchial haemorrhage		1				1
Bronchitis		1				1
Bundle branch block left		1				1
Bundle branch block right		1				1
Bursitis	1	1			1	1
Cardiac arrest	7	11			7	11
Cardiac death	1	1			1	1
Cardiac discomfort	1	1			1	1
Cardiac failure	2	6			2	6
Cardiac failure acute		1				1
Cardiac fibrillation		1				1
Cardiogenic shock	1	1			1	1
Catheter site haemorrhage		1		1		
Cerebellar haemorrhage	1	1			1	1
Cerebellar syndrome		1				1
Cerebral artery embolism		1				1
Cerebral haemorrhage	3	5			3	5
Cerebral infarction	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident	4	9			4	9
Chest discomfort	2	4	1	2	1	2
Chest pain	2	6			2	6

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Gender

**MALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	7	3	7
		1	1
			1
		1	4
		1	1
		1	1
		1	2
	1	1	1
		1	6
	2		
			1
		1	1
1	4		3
1	1	2	5
	2		1
		1	11
	1	1	2
	1		
2		2	3
2		2	4
1		1	1
			1
2		2	12
			1
1		1	1
	1		1
			1
2	6	1	4
1	1		
			1
	1		1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disorientation		1				1
Dizziness	5	20	2	5	3	15
Dizziness exertional	1	1			1	1
Drug ineffective		2				2
Dysgeusia	1	1			1	1
Dysphagia	2	6		3	2	3
Dysphonia	1	1			1	1
Dyspnoea	6	29		3	6	26
Dysstasia		1				1
Dystonia	1	1			1	1
Eating disorder	1	1			1	1
Eczema		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Embolic cerebral infarction	1	1			1	1
Energy increased	1	1			1	1
Epilepsy	1	1			1	1
Epistaxis	3	4		1	3	3
Erysipelas	2	2			2	2
Erythema		1		1		
Escherichia infection		1				1
Escherichia sepsis		1				1
Extrasystoles	1	1			1	1
Eye disorder		1				1
Eye haemorrhage	2	2			2	2
Eye irritation		1				1
Eye pain		2		1		1
Face injury		1				1
Facial pain		1				1
Facial paralysis		5				5
Facial paresis	2	5			2	5
Fall	3	8	1	1	2	7
Fatigue	10	43	5	23	5	20

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fear of death	1	1
Feeling abnormal		1
Feeling hot		2
Fluid intake reduced		1
Fluid retention	1	1
Gait disturbance		1
Gastric haemorrhage	1	1
Gastrointestinal haemorrhage	1	1
General physical health deterioration	5	10
Goitre		1
Gout		1
Graft versus host disease		1
Haematemesis	2	4
Haematoma	1	1
Haematuria	1	1
Haemolytic anaemia		1
Haemoptysis	1	2
Haemorrhage	3	3
Hallucination		2
Headache	6	27
Head discomfort		1
Head injury	2	3
Heart rate increased		3
Heart rate irregular		2
Helplessness	1	1
Herpes ophthalmic	1	1
Herpes zoster	1	3
Hiccups		1
Hip fracture		1
Horner's syndrome	1	1
Hydrothorax		1
Hyperglycaemia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
	1		1
			1
		1	1
			1
		1	1
		1	1
2	3	3	7
			1
			1
			1
		2	4
		1	1
		1	1
			1
		1	2
		3	3
			2
3	16	3	11
	1		
1	1	1	2
	1		2
	2		
		1	1
		1	1
	1	1	2
			1
		1	1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	5	1	3		2
Hypersensitivity	1	4			1	4
Hypersomnia	1	1			1	1
Hypertension	3	3	1	1	2	2
Hypoacusis		1				1
Hypoaesthesia	2	13		2	2	11
Hypoaesthesia oral		1				1
Hypoglycaemia		1				1
Hypokinesia		1				1
Hypoperfusion	1	1			1	1
Hypophagia		1				1
Hypotension	2	6			2	6
Hypothermia		1				1
Idiopathic pulmonary fibrosis		1				1
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration	2	2	2	2		
Incontinence		1		1		
Incorrect route of product administration	1	2	1	2		
Infection	2	5			2	5
Influenza like illness		1		1		
Insomnia		3		2		1
International normalised ratio increased	1	1			1	1
Intestinal haemorrhage		1				1
Intestinal ischaemia		1				1
Ischaemic stroke	1	1			1	1
Joint stiffness		1				1
Lacrimation increased		1				1
Lactic acidosis		1				1
Lethargy	1	1	1	1		
Loose tooth	1	1			1	1
Loss of consciousness	1	3			1	3
Lung disorder	1	2			1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung transplant rejection		1				1
Malaise		8		3		5
Mental fatigue	1	1			1	1
Metastasis	1	1			1	1
Motor dysfunction		1				1
Muscle spasms	1	2	1	1		1
Muscle twitching		1				1
Muscular weakness	1	2			1	2
Musculoskeletal stiffness	2	9		1	2	8
Myalgia	2	17		6	2	11
Myelitis		1				1
Myocardial infarction	1	4			1	4
Myocarditis	2	2			2	2
Nasal congestion	1	2	1	1		1
Nasopharyngitis		1				1
Nausea	4	19	2	7	2	12
Neck pain	2	4		1	2	3
Neoplasm progression		1				1
Nephrolithiasis	1	1			1	1
Nightmare	1	1	1	1		
Obstructive airways disorder		1				1
Ocular discomfort		2		1		1
Off label use	2	2	2	2		
Oral mucosal blistering	1	1			1	1
Oropharyngeal pain		6		4		2
Orthostatic hypotension		1				1
Oxygen saturation decreased		8		2		6
Pain	4	11	2	4	2	7
Painful respiration	1	1	1	1		
Pain in extremity	3	12	2	10	1	2
Pain in jaw		1		1		
Pallor		1				1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Palpitations	2	5
Paraesthesia	1	5
Paralysis		1
Parosmia	1	1
Pemphigoid		2
Penile haemorrhage	1	1
Periorbital discomfort		1
Peripheral swelling	5	7
Petechiae	2	2
Petit mal epilepsy		1
Pharyngeal mass	1	1
Pharyngeal swelling		1
Platelet count decreased	1	1
Pneumonia	1	8
Pneumonia aspiration	1	2
Pneumonia bacterial		1
Pneumonia pneumococcal		1
Pneumonia streptococcal		1
Poor quality product administered		4
Poor quality sleep	1	1
Product colour issue		2
Productive cough		2
Product preparation issue		1
Product storage error		1
Pruritus	1	5
Psoriasis		1
Psychotic disorder	1	1
Pulmonary embolism	14	18
Pulmonary hypertension	1	1
Pulmonary oedema	1	4
Pulmonary thrombosis	1	2
Pyrexia	11	42

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	2	4
1	1		4
			1
		1	1
			2
		1	1
			1
	1	5	6
		2	2
			1
		1	1
			1
		1	1
		1	8
		1	2
			1
			1
	4		
1	1		
	2		
			2
	1		
	1		
		1	5
	1		
		1	1
		14	18
		1	1
		1	4
		1	2
4	17	7	25

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	1	3		1	1	2
Rash erythematous		2				2
Rash pruritic		1				1
Renal failure	1	1			1	1
Renal haemorrhage	1	1			1	1
Respiration abnormal		1				1
Respiratory arrest		2				2
Respiratory distress		4				4
Respiratory rate increased		3		1		2
Retinal artery occlusion	1	1			1	1
Retinal vein occlusion	1	1			1	1
Rhinitis		1		1		
Rhinorrhoea		3		3		
Screaming	1	1	1	1		
Seizure	3	5			3	5
Sense of oppression		1				1
Sepsis	1	5			1	5
Sinus tachycardia		1				1
Skin disorder	1	1			1	1
Skin tightness	1	1			1	1
Skin wound	1	1			1	1
Sleep paralysis	1	1	1	1		
Slow speech		1				1
Solar dermatitis	1	1			1	1
Somnolence	1	3	1	1		2
Speech disorder		2		1		1
Spleen disorder	1	1			1	1
Status epilepticus	1	1			1	1
Streptococcal bacteraemia		1				1
Stress	1	2	1	2		
Subarachnoid haemorrhage	1	1			1	1
Subdural haematoma	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death	1	1			1	1
Supraventricular tachycardia		1				1
Suspected COVID-19		1				1
Swelling	1	2	1	1		1
Swelling face		3		1		2
Swollen tongue		2		1		1
Syncope	3	7			3	7
Systemic inflammatory response syndrome		1				1
Tachycardia		2				2
Tachypnoea	1	3		1	1	2
Tenosynovitis		1				1
Throat irritation		1				1
Throat tightness		1				1
Thrombocytopenia	7	7			7	7
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	1	3			1	3
Tinnitus	1	4			1	4
Tongue discomfort		1		1		
Tracheal haemorrhage		1				1
Transient ischaemic attack	1	2			1	2
Tremor		2				2
Underdose		2		2		
Unresponsive to stimuli		1				1
Upper respiratory tract infection		2				2
Urinary incontinence		1				1
Urinary tract infection		2		1		1
Urosepsis		2				2
Urticaria	2	4	1	1	1	3
Vaccination failure	1	2			1	2
Vaccination site erythema	1	1			1	1
Vaccination site induration		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site infection		1					1
Vaccination site pain	9	25	7	22	2	3	
Vaccination site pruritus		1		1			
Vaccination site swelling	1	3		2	1	1	
Vaccination site warmth		1		1			
Ventricular fibrillation	2	2			2	2	
Ventricular tachycardia		1					1
Vertigo		3		2			1
Vision blurred		1					1
Visual field defect	1	1			1	1	
Visual impairment		1					1
Vomiting	2	11	1	4	1	7	
Wheezing	1	4		2	1	2	
White blood cells urine positive		1		1			
Wound necrosis		1					1
	323	986	63	260	260	726	

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Circumstance or information capable of leading to medication error		29		29		
COVID-19		19		18		1
Death		2				2
Diarrhoea	1	1	1	1		
Facial paresis		1				1
Gastrointestinal pain	1	1	1	1		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Incorrect route of product administration		2		2		
Myalgia		2		2		
Poor quality product administered		28		28		
Product colour issue		29		29		
Pyrexia		3		3		
Vaccination site joint movement impairment		2		2		
Vaccination site pain		2		2		
	4	125	4	119		6

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**SWITZERLAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	1	2			1	2
Abdominal pain lower		1				1
Acute kidney injury	2	2			2	2
Acute myocardial infarction	1	2			1	2
Acute pulmonary oedema	1	2			1	2
Acute stress disorder		2				2
Ageusia		1		1		
Alanine aminotransferase increased		1		1		
Alopecia	1	1			1	1
Altered state of consciousness		1				1
Amnesia	1	2	1	2		
Anaemia		1				1
Anaphylactic reaction	3	12			3	12
Anaphylactic shock		1				1
Angina pectoris		1				1
Angioedema	4	7			4	7
Aphasia		1				1
Aphthous ulcer	1	1			1	1
Arrhythmia	2	4			2	4
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	5	8	2	2	3	6
Ascites		1				1
Asthenia	6	8			6	8
Asthma		3				3
Atrial f brillation	4	4			4	4
Atrophy		1				1
Axillary lymphadenectomy	1	1			1	1
Back pain		1		1		
Blindness transient		1				1
Blister		1		1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood alkaline phosphatase increased		1		1			
Blood glucose increased		1		1			
Blood pressure decreased		1		1			
Blood pressure increased	2	5		1	2	4	
Body temperature increased		1		1			
Bone pain	1	1	1	1			
Breast haematoma	1	1			1	1	
Breast pain	1	1			1	1	
Cardiac arrest	1	2			1	2	
Cardiac failure	3	4			3	4	
Cardiac failure acute	1	1			1	1	
Cardiac failure chronic		1				1	
Cardiac failure congestive	1	1			1	1	
Cardiovascular disorder	1	1			1	1	
Cerebral infarction		1				1	
Cerebrovascular accident	1	4			1	4	
Chest discomfort	3	5			3	5	
Chest pain	3	4			3	4	
Chills	8	16	1	3	7	13	
Cholecystitis acute	1	1			1	1	
Cholestasis	1	2			1	2	
Chronic obstructive pulmonary disease		2				2	
Circulatory collapse	2	2			2	2	
Coma		1				1	
Condition aggravated	2	2			2	2	
Confusional state	1	2			1	2	
Conjunctivitis bacterial		1				1	
Cough	2	5		1	2	4	
COVID-19	5	13			5	13	
COVID-19 pneumonia	1	1			1	1	
C-reactive protein increased		1				1	
Cystitis	1	1			1	1	

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
	1	1	2
		1	2
		1	2
		1	2
			1
1	1		
	1		
			1
			1
1	3	6	9
		1	1
1	1		1
		3	3
			1
			1
		2	3
4	4	4	10
		1	1
		2	5
	1		
		1	2
			1
	1		
8	2	7	13
		1	1
			1
1		1	1
	1		
			4
2		2	2
2	2	1	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Gender

**FEMALE**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
			2
			2
2	2	2	2
2	4	1	3
11	14	3	8
			1
			1
2	4	2	3
1	1	1	1
			2
			2
			1
1	1	1	1
2	2		
2	2	2	2
			1
2	3	1	2
1	1	1	1
1	1	1	1
1	1		1
1	1	1	1
13	27	1	20
			1
			1
			1
1	1	1	1
9	11	9	11
1	1		1

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	4			1	4
Hypersensitivity	9	19	3	4	6	15
Hypertension	7	15		1	7	14
Hypertensive crisis		2				2
Hypertensive emergency		1				1
Hyperthermia		1		1		
Hyperventilation	2	4			2	4
Hypoaesthesia oral	1	1	1	1		
Hypoglycaemic coma		1				1
Hypotension	3	5		1	3	4
Immunisation anxiety related reaction	2	2			2	2
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	4	6	4	6		
Inflammation		2				2
Influenza like illness	1	3	1	1		2
Insomnia		1		1		
Ischaemic cerebral infarction		2				2
Joint swelling		1				1
Lethargy		1		1		
Lip oedema		1				1
Lip swelling	1	1			1	1
Liver disorder	1	1			1	1
Loss of consciousness	1	1			1	1
Lung disorder	1	1			1	1
Lymphadenopathy	2	3		1	2	2
Lymphangiectasia	1	1			1	1
Lymph node pain	1	1			1	1
Lymphopenia		1				1
Malaise	8	15	1	2	7	13
Meningioma	1	1			1	1
Metabolic syndrome		1				1
Migraine	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Monocytosis		1		1			
Monoplegia	1	1		1		1	
Muscle spasms		3					3
Muscular weakness	1	2			1		2
Musculoskeletal stiffness		1					1
Myalgia	6	13	2	4	4		9
Myelitis	1	1			1		1
Nasopharyngitis	1	1			1		1
Nausea	10	19	3	5	7		14
Neuralgia	2	2			2		2
Neuralgic amyotrophy	1	1			1		1
Obstructive airways disorder		1					1
Odynophagia		1					1
Oedema peripheral	1	2			1		2
Off label use	1	1	1	1			
Ophthalmic herpes zoster	2	2			2		2
Oropharyngeal oedema	1	1			1		1
Oropharyngeal pain		1		1			
Oxygen saturation decreased	1	2			1		2
Pain	6	7	1	2	5		5
Pain in extremity	8	9	3	4	5		5
Pallor		1					1
Palpitations	2	4			2		4
Paraesthesia	2	6	1	2	1		4
Paraesthesia oral	2	3	1	1	1		2
Paranoia		1					1
Parotitis	1	1			1		1
Peak expiratory flow rate decreased	1	1			1		1
Peripheral coldness		2					2
Peripheral swelling		1					1
Peripheral vascular disorder		1					1
Pharyngeal paraesthesia	1	1			1		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia	1	1			1	1
Platelet count increased		1		1		
Pleural effusion		1		1		
Pneumonia	2	3			2	3
Pneumonia pneumococcal		1				1
Polyneuropathy		1				1
Presyncope	4	7			4	7
Pruritus	3	11		3	3	8
Pulmonary embolism	2	2			2	2
Pulmonary fibrosis	1	1			1	1
Pulmonary oedema	1	1			1	1
Purpura	1	1			1	1
Pyrexia	17	34	3	6	14	28
Rash	5	11	4	6	1	5
Rash erythematous		2				2
Rash maculo-papular	1	2		1	1	1
Rash pustular		1				1
Renal failure		1				1
Renal impairment	1	1			1	1
Respiratory depression		1				1
Respiratory distress	1	2			1	2
Respiratory failure	1	3			1	3
Respiratory paralysis		1				1
Respiratory tract infection		1				1
Rheumatoid arthritis		2				2
Rhinitis		1		1		
Road traffic accident	1	1			1	1
Salivary hypersecretion		1				1
Scratch	1	2	1	2		
Sedation	1	1			1	1
Sense of oppression		2				2
Sensory disturbance	2	3			2	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sepsis		1					1
Sickle cell anaemia with crisis	1	1			1		1
Sinus tachycardia	1	1			1		1
Skin reaction	1	1			1		1
Somnolence		1					1
Speech disorder		1					1
Stress cardiomyopathy	1	1			1		1
Sudden death		2					2
Swelling face	1	2	1	2			
Swelling of eyelid	1	1			1		1
Swollen tongue		1					1
Syncope	3	5			3		5
Tachycardia	6	11	1	2	5		9
Tachypnoea	1	1			1		1
Tendon pain	1	1	1	1			
Throat irritation	1	1			1		1
Throat tightness	1	2			1		2
Thrombocytopenia	1	2			1		2
Tongue oedema		1					1
Transient ischaemic attack		2					2
Tremor		3					3
Trigeminal neuralgia	1	1			1		1
Tumour marker increased	2	2	2	2			
Type I hypersensitivity		1					1
Type II hypersensitivity	1	1			1		1
Underdose		1		1			
Urinary tract infection	1	1			1		1
Urinary tract infection bacterial		1					1
Urogenital haemorrhage		1					1
Urticaria	2	4		1	2		3
Vaccination failure	3	3			3		3
Vaccination site erythema	1	6		3	1		3

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\* AE=Adverse Event

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site haematoma		1				1	
Vaccination site induration		1				1	
Vaccination site lymphadenopathy	1	1			1	1	
Vaccination site oedema		1		1			
Vaccination site pain	4	10	1	5	3	5	
Vaccination site pruritus		1		1			
Vaccination site rash		1		1			
Vaccination site reaction	1	1			1	1	
Vaccination site swelling		1				1	
Vaccination site urticaria		1				1	
Vaccination site warmth		2		1		1	
Varicella zoster virus infection	1	1			1	1	
Vascular encephalopathy		1				1	
Vertigo positional		1				1	
Viral infection	1	1	1	1			
Visual impairment	2	3			2	3	
Vomiting	8	18		3	8	15	
Weight decreased	1	1	1	1			
White matter lesion		1		1			
Wrong technique in product usage process		1		1			
	371	767	58	147	313	620	

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal infection		1				1
Abdominal pain	2	4		1	2	3
Acute kidney injury		1				1
Agitation		1				1
Anal haemorrhage		1		1		
Anaphylactic reaction		1				1
Angioedema		2				2
Anti-myelin-associated glycoprotein ant bodies positive		1				1
Aphasia		3				3
Apnoea	1	1			1	1
Appendicitis		1				1
Arthralgia	2	3	1	1	1	2
Asthenia	5	8	2	3	3	5
Asymptomatic COVID-19	1	1	1	1		
Back pain	1	2		1	1	1
Blood pressure decreased		1				1
Bone formation increased		1		1		
Brain hypoxia		1				1
Cardiac failure		1				1
Cardiac failure acute	1	1			1	1
Cardiac fibrillation		1				1
Cardio-respiratory arrest		1				1
Cardiovascular disorder	1	1			1	1
Central nervous system lesion		1				1
Cheilitis		1		1		
Chills	1	4		1	1	3
Circulatory collapse	1	1			1	1
Cold sweat	1	1			1	1
Coma		1				1
Confusional state		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	2		1	1	1
COVID-19	3	7		1	3	6
Craniocerebral injury	1	1			1	1
C-reactive protein increased	1	3	1	1		2
CSF test abnormal		1				1
Deafness unilateral		1				1
Death		4				4
Deep vein thrombosis	1	1			1	1
Delirium	1	2			1	2
Disorientation		1				1
Disturbance in attention		1		1		
Dizziness	5	7	1	1	4	6
Drug ineffective	1	2			1	2
Dysarthria	1	1			1	1
Dysgeusia		1		1		
Dyspnoea	1	2	1	2		
Ear pain		1				1
Embolic stroke		1				1
Encephalitis		1				1
Encephalopathy		1				1
Epilepsy	1	2			1	2
Epistaxis		1		1		
Erysipeloid		1				1
Erythema	1	1			1	1
Eyelids pruritus		1		1		
Eye pain	1	1	1	1		
Facial paresis	2	2			2	2
Fall	2	2			2	2
Fatigue	7	10	4	5	3	5
Feeding disorder	1	1	1	1		
Feeling cold	1	2	1	2		
Gait disturbance		2		1		1

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Gender

**MALE**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
1	2		3
			1
			1
	1		
3	4		1
			1
		4	7
		2	3
		1	2
		1	1
		2	2
	1		
			1
1	1		
			1
	1		
			1
1		1	1
1	1		
		1	1
		1	1
			1
		1	2
		1	1
	1		2
1		1	1
		1	1
1	1		

Gastrointestinal disorder 1  
 Generalised tonic-clonic seizure 1  
 General physical health deterioration 1 5  
 Glomerulonephritis minimal lesion 1  
 Gout 1  
 Hair growth abnormal 1  
 Headache 3 5  
 Heart rate decreased 1  
 Herpes zoster 4 7  
 Hypersensitivity 2 3  
 Hypertension 1 2  
 Hypoaesthesia oral 1 1  
 Hypotension 2 2  
 Illusion 1  
 Immune thrombocytopenia 1  
 Impaired work ability 1 1  
 Incorrect route of product administration 1  
 Infection 1  
 Inflammation 1  
 Influenza 1 1  
 Influenza like illness 1 1  
 Insomnia 1 1  
 Ischaemic cerebral infarction 1 1  
 Joint dislocation 1 1  
 Joint range of motion decreased 1  
 Liver injury 1  
 Loss of consciousness 1 2  
 Lymphadenopathy 1 1  
 Malaise 3  
 Meniere's disease 1 1  
 Middle insomnia 1  
 Mobility decreased 1 1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscle disorder		1				1	
Musculoskeletal pain	1	1	1	1			
Myalgia	5	7	2	3	3	4	
Myocardial infarction	1	1			1	1	
Nausea		1				1	
Neck pain		1				1	
Nervous system disorder		1				1	
Neuralgia	1	1			1	1	
Neuralgic amyotrophy	1	1			1	1	
Neutrophilia		1				1	
NIH stroke scale score decreased	1	1			1	1	
Oedema peripheral		1		1			
Oesophageal perforation		1				1	
Oral herpes	1	1			1	1	
Oropharyngeal pain		1				1	
Oxygen saturation decreased		1				1	
Pain		1		1			
Pain in extremity	1	2		1	1	1	
Pallor	1	1			1	1	
Pancreatitis		1				1	
Paraesthesia	1	1			1	1	
Performance status decreased	1	1			1	1	
Pericardial effusion	1	1			1	1	
Pleocytosis		1				1	
Pleural effusion	1	1			1	1	
Pneumonia		1				1	
Pneumonia bacterial		1				1	
Pruritus	1	3			1	3	
Pulmonary embolism	3	3			3	3	
Pyrexia	7	14	4	5	3	9	
Rash		1				1	
Rash papular	1	1			1	1	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic	1	1			1	1
Renal failure		1				1
SARS-CoV-2 ant body test negative		1		1		
Seizure		1				1
Sepsis		1				1
Septic shock		1				1
Skin disorder	1	1			1	1
Skin lesion		1				1
Skull fracture	1	1			1	1
Sleep disorder		1		1		
Somnolence		3				3
Spinal cord ischaemia	1	1			1	1
Subdural haematoma	1	1			1	1
Sudden death	2	2			2	2
Sudden hearing loss		1				1
Syncope	3	3			3	3
Tachycardia	1	2			1	2
Tachypnoea		1				1
Tendon rupture	1	1			1	1
Therapeutic response unexpected		2		2		
Tinnitus		1				1
Urinary incontinence		1				1
Urinary tract infection		1				1
Urticaria		2				2
Vaccination failure	1	1			1	1
Vaccination site pain	3	5	2	3	1	2
Vaccination site pruritus		1				1
Vaccination site swelling	1	1			1	1
Ventricular fibrillation		1				1
Vertigo	2	4	1	1	1	3
Vomiting		1				1
	122	272	33	67	89	205

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Dizziness		2				2
Dysgeusia		1		1		
Dyspnoea		2				2
Headache		1		1		
Hypertension		1		1		
Malaise	1	3		1	1	2
Nausea		2		1		1
Pruritus		1		1		
Pyrexia		1		1		
Tachycardia	1	2			1	2
Underdose		1		1		
Vomiting		2				2
Wrong product administered		1		1		
	2	21		9	2	12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**TUNISIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	2	2	2	2
Chills	1	1	1	1
Cough	1	1	1	1
COVID-19	1	1	1	1
Dizziness	1	1	1	1
Fatigue	2	2	2	2
Headache	1	1	1	1
Influenza like illness	1	1	1	1
Injection site pain	1	1	1	1
Joint range of motion decreased	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
Pyrexia	1	1	1	1
Vaccination site pain	2	2	2	2
Vertigo	1	1	1	1
	19	19	19	19

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Dysgeusia	1	1	1	1
Hypertension	1	1	1	1
Paraesthesia	1	1	1	1
	4	4	4	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**TURKEY**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Arthralgia	1	1	1	1		
Cough	1	1	1	1		
COVID-19	3	3	2	2	1	1
Dizziness	2	2	2	2		
Drug ineffective	1	1			1	1
Dyspnoea	1	1	1	1		
Fatigue	1	1	1	1		
Headache	3	3	3	3		
Incorrect dose administered	1	1	1	1		
Invasive ductal breast carcinoma	1	1			1	1
Maternal exposure during pregnancy	1	1	1	1		
Product preparation error	1	1	1	1		
Pyrexia	1	1	1	1		
Toothache	1	1	1	1		
Vaccination site pain	2	2	2	2		
	23	23	19	19	4	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	2	2	2		
Back pain	1	1	1	1		
Chills	1	1	1	1		
COVID-19	1	1	1	1		
Dry skin	1	1	1	1		
Erythema	2	2	2	2		
Fatigue	1	1	1	1		
Headache	2	2	2	2		
Herpes zoster	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Malaise	1	1	1	1		
Meningitis	1	1			1	1
Nausea	1	1	1	1		
Off label use	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	2	2	2	2		
Swelling face	1	1	1	1		
Tonsillar hypertrophy	1	1	1	1		
Toothache	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vomiting	1	1	1	1		
	28	28	27	27	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Overdose	1	1	1	1
Product preparation error	1	1	1	1
Vaccination site pain	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative  
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Country Where Event Occurred  
**TURKS AND CAICOS ISLANDS**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Haemorrhagic stroke	1	1			1	1
Myalgia		1		1		
Nodule		1		1		
Seizure		1				1
	1	6		3	1	3

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UKRAINE**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**UNITED ARAB EMIRATES**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	4	1	4		
Arthralgia		1		1		
Asthenia	1	1	1	1		
Babesiosis		1				1
Back pain	1	1	1	1		
Bone pain	1	1	1	1		
Chest discomfort		1		1		
Chest pain		1				1
Chills	2	3	2	3		
COVID-19	1	2	1	1		1
Depressed level of consciousness		1				1
Depressed mood		1				1
Dizziness		3		2		1
Drug ineffective	1	2			1	2
Dysgeusia	2	2	2	2		
Facial paralysis		1				1
Fatigue	3	5	3	5		
Feeling abnormal		2		2		
Fibromyalgia		1		1		
Headache	2	4	2	3		1
Hyperhidrosis	1	1	1	1		
Hypertension		1				1
Hypoacusis		1				1
Hypoaesthesia		1				1
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Lyme disease		1				1
Lymphadenopathy		1		1		
Maternal exposure timing unspecified		1		1		
Muscle fatigue		1		1		
Myalgia	2	2	2	2		
Nausea	1	6	1	5		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia		1		1		
Neurotoxicity		1				1
Off label use		1		1		
Pain	1	2	1	2		
Pain in extremity	1	1	1	1		
Paraesthesia		1		1		
Product use issue		1		1		
Pruritus		1		1		
Pyrexia	4	7	4	7		
Rash		1		1		
Respiratory tract irritation		1		1		
SARS-CoV-2 ant body test negative		2		2		
Sciatica		1		1		
Skin irritation		1		1		
Sleep deficit		1		1		
Somnolence		1		1		
Suspected COVID-19	1	1			1	1
Swelling		1				1
Tremor	1	1	1	1		
Vaccination site pain	2	5	2	5		
Vision blurred		1		1		
Vomiting		2		2		
	29	91	27	73	2	18

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Back pain		2		2		
Blindness unilateral	1	1			1	1
Blood pressure decreased		1				1
Chest pain	1	1			1	1
Cough		1		1		
COVID-19		5				5
Death		1				1
Decreased appetite		1		1		
Dizziness		1		1		
Drug ineffective		4				4
Dyspnoea		2		1		1
Erectile dysfunction		1				1
Erythropeia		1				1
Facial paralysis	1	1			1	1
Fatigue		2		2		
Gait disturbance		1		1		
Headache	1	3	1	3		
Head injury	1	1			1	1
Hypertension		1		1		
Hypoxia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Ocular vascular disorder	1	1			1	1
Ophthalmic herpes zoster	1	1			1	1
Pain		1		1		
Pyrexia		4		4		
Rash	1	2	1	1		1
Rectal haemorrhage		1				1
SARS-CoV-2 ant body test negative		1		1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sciatica		1		1		
Sudden death		1				1
Tachypnoea		1		1		
Thrombosis	2	2			2	2
Urticaria		1				1
Vaccination site pain	1	2	1	2		
Vision blurred		1		1		
	15	57	6	29	9	28

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	3	1	1	1	2
Drug ineffective		1				1
Nasopharyngitis		1		1		
Pneumonia	1	1			1	1
Vaccination failure	1	1			1	1
	4	7	1	2	3	5

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Country Where Event Occurred

**UNITED KINGDOM**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions	1	1					1	1
Abdominal discomfort	49	177	1	3	23	55	26	122
Abdominal distension	32	85			12	27	20	58
Abdominal lymphadenopathy		1						1
Abdominal mass	1	1					1	1
Abdominal migraine	1	1					1	1
Abdominal pain	102	334			33	103	69	231
Abdominal pain lower	7	24			1	5	6	19
Abdominal pain upper	143	526		1	55	144	88	382
Abdominal rigidity		5				2		3
Abdominal symptom		1						1
Abdominal tenderness	3	8			1	3	2	5
Abnormal behaviour	2	4				1	2	3
Abnormal dreams	11	40			7	22	4	18
Abnormal faeces	3	6			2	4	1	2
Abnormal loss of weight		1						1
Abnormal sensation in eye	3	11			2	5	1	6
Abnormal weight gain		1						1
Abortion missed		1						1
Abortion spontaneous	25	52					25	52
Abscess	2	5				2	2	3
Abscess jaw		1						1
Abscess oral	1	3			1	1		2
Accident		1				1		
Accidental exposure to product		3				2		1
Accidental overdose		2				2		
Achenbach syndrome		1				1		
Acidosis		1				1		
Acne	7	8			3	4	4	4
Acne pustular		1				1		
Acoustic neuroma	1	1					1	1
Acrochordon		1						1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Activated partial thromboplastin time prolonged	4	4
Activated partial thromboplastin time shortened	2	2
Acute abdomen		2
Acute cardiac event		1
Acute coronary syndrome	2	2
Acute disseminated encephalomyelitis	1	1
Acute febrile neutrophilic dermatosis		1
Acute kidney injury	6	19
Acute motor axonal neuropathy		1
Acute myocardial infarction	1	9
Acute respiratory failure		1
Acute vestibular syndrome		1
Addison's disease		1
Administration site joint movement impairment		2
Adnexa uteri pain		4
Adrenocortical insufficiency acute	3	7
Adverse drug reaction	9	29
Adverse reaction		
Aerophagia		2
Affective disorder	1	1
Affect lability	1	3
African trypanosomiasis	1	2
Age-related macular degeneration		1
Ageusia	37	120
Aggression	2	5
Agitated depression		1
Agitation	8	34
Airway burns		1
Airway secretion clearance therapy		1
Akathisia		1
Alanine aminotransferase increased	3	10
Alcohol interaction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	4
				2	2
					2
					1
				2	2
				1	1
					1
				6	19
					1
				1	9
					1
			1		
					1
					2
					4
				3	7
		3	16	6	13
	1				
			1		1
				1	1
				1	3
				1	2
					1
	1	20	49	17	71
			1	2	4
					1
		2	9	6	25
					1
					1
			2	3	8
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Alcohol intolerance	2	2
Alcohol poisoning		1
Allergic cough	2	4
Allergic oedema	1	2
Allergic reaction to excipient		4
Allergy to arthropod bite	1	1
Allergy to arthropod sting	1	1
Allergy to vaccine	7	45
Allodynia	2	3
Alopecia	11	23
Alopecia areata	2	2
Alopecia totalis	1	1
Altered state of consciousness	4	8
Alveolitis	1	1
Amblyopia	1	2
Amenorrhoea	6	13
Amnesia	10	28
Amylase increased	1	1
Anaemia	8	17
Anaemia vitamin B12 deficiency		1
Anal fissure		1
Analgesic drug level		1
Anal haemorrhage	1	5
Anal incontinence		3
Anal pruritus		1
Anal sphincter atony		1
Anaphylactic reaction	30	223
Anaphylactic shock		12
Anaphylactoid reaction	2	13
Anaphylactoid shock	1	1
Anaphylaxis prophylaxis	1	1
Aneurysm	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
				2	4
		1	1		1
					4
		1	1		
				1	1
		4	20	3	25
				2	3
			3	11	20
				2	2
				1	1
				4	8
				1	1
			1	1	1
			2	6	11
		1	4	9	24
		1	1		
			2	8	15
					1
					1
					1
				1	5
	1		1		2
			1		
					1
				30	223
					12
				2	13
				1	1
				1	1
				1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anger	1	3
Angina bullosa haemorrhagica	1	1
Angina pectoris	12	24
Angina unstable		1
Angioedema	18	87
Angular cheilitis	1	1
Anisocytosis		2
Anisomastia		1
Ankle fracture	2	2
Ankylosing spondylitis	1	4
Anorectal discomfort	1	1
Anorectal swelling		1
Anorgasmia		1
Anosmia	14	49
Anovulatory cycle		1
Antibody test positive		1
Anticholinergic syndrome		1
Anticoagulation drug level increased		1
Antiphospholipid syndrome	1	2
Antisynthetase syndrome		1
Anti-thyroid antibody positive	1	1
Anuria	1	3
Anxiety	48	178
Aortic arteriosclerosis		1
Aortic embolus	3	3
Aortic stenosis		2
Apathy	2	9
Aphasia	9	20
Aphonia	5	23
Aphthous ulcer	6	11
Apnoea	1	2
Appendicitis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
				1	1
				12	24
					1
				18	87
				1	1
					2
			1		
				2	2
				1	4
		1	1		
					1
					1
		5	21	9	28
					1
			1		
					1
				1	2
			1		
				1	1
				1	3
		19	64	29	114
					1
				3	3
					2
		2	4		5
		3	6	6	14
1	1	4	6	1	17
		3	3	3	8
				1	2
				2	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Appendicitis perforated	1	1
Appetite disorder	2	7
Apraxia		1
Aptyalism	1	1
Areflexia		2
Arrhythmia	5	18
Arrhythmia supraventricular		3
Arterial disorder	1	1
Arterial occlusive disease	1	1
Arterial stenosis		1
Arterial thrombosis	1	2
Arteriosclerosis coronary artery		1
Arteritis		1
Arthralgia	829	2,713
Arthritis	18	59
Arthritis reactive	2	8
Arthritis viral	1	1
Arthropathy	3	11
Arthropod bite	1	2
Arthropod sting	1	1
Ascites		2
Aspiration		3
Asthenia	192	722
Asthenopia	13	53
Asthma	22	112
Asthma prophylaxis		1
Asymptomatic COVID-19	3	7
Ataxia	1	2
Atelectasis		1
Atonic seizures		3
Atopy		1
Atrial fibrillation	11	55

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1	2	6
			1		
		1	1		
					2
				5	18
			1		2
				1	1
				1	1
					1
				1	2
					1
					1
2	15	308	818	521	1895
		4	8	14	51
				2	8
				1	1
		1	4	2	7
		1	1		1
		1	1		
					2
					3
	1	65	219	127	503
		4	14	9	39
		4	20	18	92
					1
				3	7
				1	2
					1
					3
					1
				11	55

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atrial flutter		1
Atrial tachycardia		1
Atrioventricular block	2	2
Attention deficit hyperactivity disorder	1	1
Atypical femur fracture		1
Auditory disorder	2	5
Aura	4	10
Auricular swelling		2
Autoimmune disorder	3	13
Autoimmune haemolytic anaemia	1	2
Autonomic nervous system imbalance	1	3
Autoscopy	2	3
Axillary lymphadenectomy	1	1
Axillary mass	36	75
Axillary pain	285	600
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation	2	6
Back injury	1	1
Back pain	189	690
Bacterial diarrhoea		1
Balance disorder	37	121
Basal cell carcinoma	1	1
Basedow's disease	1	1
Bed rest	1	1
Bedridden	7	16
Behcet's syndrome	2	5
Biliary colic		1
Binocular eye movement disorder		1
Bipolar disorder		1
Bipolar I disorder	1	1
Bladder discomfort		1
Bladder disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				2	2
				1	1
					1
				2	5
		1	5	3	5
					2
				3	13
				1	2
				1	3
		1	1	1	2
				1	1
		8	26	28	49
		64	174	221	426
					1
			2	2	4
				1	1
	1	73	215	116	475
					1
		9	25	28	96
				1	1
				1	1
		1	3	6	13
				2	5
					1
					1
				1	1
			1		
				1	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder dysfunction		1
Bladder irritation		1
Bladder pain	1	6
Bleeding time abnormal		1
Blepharitis	1	2
Blepharospasm	5	13
Blindness	9	21
Blindness transient	1	7
Blindness unilateral	3	5
Blister	27	80
Blister rupture		1
Blood alkaline phosphatase increased	1	4
Blood blister	3	9
Blood cholesterol increased		2
Blood count abnormal	1	1
Blood creatine phosphokinase increased	1	2
Blood creatinine increased		2
Blood fibrinogen decreased	1	1
Blood folate decreased	1	1
Blood glucose	1	1
Blood glucose abnormal		2
Blood glucose decreased	5	12
Blood glucose fluctuation	2	11
Blood glucose increased	8	39
Blood immunoglobulin G increased		1
Blood immunoglobulin M abnormal	1	1
Blood immunoglobulin M increased		1
Blood iron decreased	1	1
Blood iron increased	1	1
Blood ketone body increased		1
Blood ketone body present		1
Blood lactate dehydrogenase increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	6
					1
			1	1	1
		2	2	3	11
				9	21
				1	7
				3	5
		10	28	17	52
			1		
			1	1	3
		1	1	2	8
					2
				1	1
			1	1	2
			1		1
		1	1	1	1
			1		
			1	1	1
			2	5	10
		1	4	1	7
		1	10	7	29
			1		
				1	1
			1		
		1	1		
		1	1		
					1
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood lactic acid increased		2
Blood luteinising hormone abnormal		1
Blood magnesium decreased		1
Blood oestrogen increased		1
Blood pH	1	2
Blood pH increased	1	3
Blood phosphorus decreased	1	1
Blood potassium abnormal		1
Blood potassium decreased	1	3
Blood potassium increased	2	2
Blood pressure abnormal	3	6
Blood pressure decreased	10	32
Blood pressure diastolic decreased	1	1
Blood pressure fluctuation	1	8
Blood pressure increased	34	153
Blood pressure orthostatic abnormal		1
Blood pressure orthostatic decreased		1
Blood pressure systolic decreased		2
Blood pressure systolic increased		5
Blood prolactin increased		1
Blood sodium decreased	1	4
Blood test abnormal	4	6
Blood testosterone increased		1
Blood thyroid stimulating hormone increased		1
Blood urea increased		1
Blood urine		1
Blood urine present	3	11
Bloody discharge	1	1
Blue toe syndrome	1	4
Body fat disorder	1	1
Body temperature	11	19
Body temperature abnormal	17	59

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			1		
			1		
					1
				1	2
		1	2		1
				1	1
					1
		1	1		2
		1	1	1	1
		2	4	1	2
		3	10	7	22
		1	1		
			2	1	6
		14	68	20	85
					1
					1
					2
			2		3
			1		
		1	1		3
				4	6
			1		
			1		
					1
					1
		2	5	1	6
				1	1
		1	2		2
		1	1		
		7	10	4	9
		5	19	12	40

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Body temperature decreased	6	26
Body temperature fluctuation	8	21
Body temperature increased	70	204
Bone contusion		1
Bone disorder	1	1
Bone neoplasm	1	2
Bone pain	49	155
Bone swelling	3	8
Bowel movement irregularity		3
Brachial plexus injury	1	1
Bradycardia	4	19
Bradykinesia	2	6
Bradyphrenia	5	10
Brain injury		2
Brain neoplasm	1	1
Brain oedema		2
Brain stem stroke	1	1
Breast abscess		1
Breast cancer	5	9
Breast cancer stage III	1	1
Breast cellulitis	1	1
Breast cyst	1	2
Breast discomfort	3	6
Breast disorder	1	1
Breast engorgement	1	1
Breast enlargement	1	3
Breast inflammation	2	2
Breast mass	9	19
Breast milk discolouration		1
Breast oedema	1	1
Breast pain	55	126
Breast prosthesis user	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6	3	20
		5	8	3	13
	2	37	88	33	116
			1		
				1	1
		1	1		1
		18	47	31	108
		1	4	2	4
			1		2
				1	1
				4	19
		1	1	1	5
		1	2	4	8
					2
				1	1
					2
				1	1
					1
				5	9
				1	1
				1	1
		1	1		1
		2	3	1	3
				1	1
				1	1
				1	3
				2	2
		2	4	7	15
			1		
				1	1
		7	25	48	101
		1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast swelling	20	44
Breast tenderness	9	17
Breath odour	3	7
Breath sounds abnormal	1	1
Bronchial disorder		1
Bronchial secretion retention	1	1
Bronchiectasis	2	4
Bronchitis		5
Bronchopulmonary aspergillosis		1
Bronchospasm	3	7
Bruxism	1	2
Burning feet syndrome		1
Burning sensation	59	163
Burn oesophageal		1
Burn oral cavity		1
Burns second degree	1	3
Bursitis	4	10
Butterfly rash	1	3
Candida infection	2	6
Cardiac arrest	5	24
Cardiac discomfort	1	2
Cardiac disorder		5
Cardiac failure	4	13
Cardiac failure congestive		4
Cardiac flutter	9	34
Cardiac murmur	3	6
Cardiogenic shock	1	1
Cardiomyopathy	1	1
Cardiopulmonary failure		1
Cardiovascular disorder		2
Carotid artery occlusion	1	1
Carpal tunnel syndrome	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	16	14	28
		3	4	6	13
		2	4	1	3
		1	1		
					1
		1	1		
				2	4
			1		4
					1
		1	2	2	5
				1	2
					1
		21	47	38	116
					1
					1
		1	2		1
				4	10
			1	1	2
			2	2	4
				5	24
			1	1	1
					5
				4	13
					4
				9	34
			1	3	5
				1	1
				1	1
					1
					2
				1	1
		1	1	1	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cataplexy	1	2
Catarrh		4
Cavernous sinus thrombosis	1	1
Cells in urine	1	1
Cellulitis	25	86
Central nervous system vasculitis	1	1
Cerebellar stroke		3
Cerebral artery occlusion	1	1
Cerebral artery thrombosis	2	2
Cerebral disorder		2
Cerebral haemorrhage	5	16
Cerebral infarction	7	12
Cerebral thrombosis	5	9
Cerebral venous sinus thrombosis	6	9
Cerebral venous thrombosis	1	1
Cerebrospinal fluid leakage		1
Cerebrovascular accident	56	120
Cervical dysplasia	1	1
Cervical radiculopathy	1	1
Cervicobrachial syndrome		1
Cervicogenic headache	1	1
Chalazion	1	2
Change of bowel habit	1	1
Chapped lips	2	7
Charles Bonnet syndrome		1
Cheilitis	2	8
Chest crushing	1	2
Chest discomfort	91	397
Chest injury	2	3
Chest pain	164	572
Chest X-ray abnormal		1
Chillblains	16	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			2		2
				1	1
				1	1
				25	86
				1	1
					3
				1	1
				2	2
			2		
				5	16
				7	12
				5	9
				6	9
				1	1
					1
				56	120
				1	1
				1	1
					1
		1	1		
				1	2
		1	1		
		1	3	1	4
					1
		2	5		3
				1	2
	1	36	115	55	282
				2	3
	2	41	123	123	449
			1		
		13	14	3	6

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Chills	851	3,057
Choking	1	6
Choking sensation	1	4
Cholecystitis infective		1
Cholelithiasis	2	3
Chorea		1
Chorioretinopathy	1	1
Choroidal neovascularisation		3
Chromatopsia	1	1
Chromaturia	4	16
Chronic fatigue syndrome	15	28
Chronic gastritis	1	1
Chronic kidney disease	1	5
Chronic lymphocytic leukaemia	1	1
Chronic obstructive pulmonary disease	1	5
Chronic spontaneous urticaria		1
Circulatory collapse	1	23
Circumoral swelling		1
Circumstance or information capable of leading to medication error		2
Clavicle fracture	1	2
Clonic convulsion		1
Clostridium difficile colitis		1
Clostridium difficile infection		1
Clot retraction		1
Clumsiness	1	3
Cluster headache	18	56
Coagulation time prolonged		1
Coagulopathy	3	8
Coccydynia	1	2
Coeliac disease	1	4
Cognitive disorder	4	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
4	17	383	1082	468	1975
				1	6
			1	1	3
					1
				2	3
					1
				1	1
					3
		1	1		
		2	8	2	8
			1	15	27
				1	1
				1	5
				1	1
				1	5
					1
				1	23
			1		
			2		
				1	2
					1
					1
					1
				1	3
		7	15	11	41
					1
			1	3	7
		1	2		
				1	4
			1	4	21

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cold-stimulus headache	2	3
Cold sweat	56	209
Cold urticaria	1	1
Colitis	6	8
Colitis ischaemic	1	1
Colitis microscopic	1	2
Colitis ulcerative	6	14
Colon cancer	1	1
Coma	1	2
Communication disorder		4
Condition aggravated	76	216
Confusional arousal		1
Confusional state	65	232
Congenital cystic lung		1
Congestive cardiomyopathy		1
Congestive hepatopathy		1
Conjunctival haemorrhage	5	13
Conjunctival hyperaemia	1	1
Conjunctival oedema	1	2
Conjunctivitis	3	16
Conjunctivitis bacterial		2
Conjunctivitis viral	1	1
Consciousness fluctuating		4
Constipation	20	50
Constricted affect		1
Contraindicated product administered		2
Contrast media reaction		1
Contusion	89	189
Coordination abnormal	8	22
Corneal abrasion		1
Corneal disorder		1
Corneal erosion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
		17	67	39	142
		1	1		
		1	1	5	7
				1	1
				1	2
				6	14
				1	1
				1	2
			1		3
		21	50	55	166
					1
	1	13	44	52	188
					1
					1
				5	13
				1	1
				1	2
		3	4		12
					2
		1	1		
					4
		6	10	14	40
					1
			1		1
					1
	1	31	70	58	119
		3	6	5	16
					1
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Corneal reflex decreased	1	1
Coronary artery disease	1	3
Coronary artery occlusion		1
Coronary artery stenosis		1
Coronavirus infection	1	2
Cor pulmonale		1
Cortisol decreased		1
Costochondritis	6	16
Costovertebral angle tenderness		1
Cough	151	592
COVID-19	86	326
COVID-19 immunisation	2	2
COVID-19 pneumonia	3	16
Cranial nerve disorder		1
Cranial nerve palsies multiple	1	1
C-reactive protein abnormal	1	1
C-reactive protein increased	7	14
Creutzfeldt-Jakob disease	1	1
Crohn's disease	3	11
Crying	4	29
CT hypotension complex		1
Culture negative		1
Cutaneous sarcoidosis	1	2
Cutaneous symptom		1
Cutaneous vasculitis	1	1
Cyanosis	9	21
Cyanosis central		1
Cyclic vomiting syndrome		1
Cyclothymic disorder		1
Cyst	2	3
Cystitis	9	19
Cystitis interstitial	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	3
					1
			1	1	1
					1
			1	6	15
			1		
1	3	65	186	86	406
2	3	26	82	60	244
				2	2
				3	16
					1
				1	1
			1	7	13
				1	1
				3	11
			6	4	23
					1
					1
				1	2
					1
		6	7	3	14
					1
		1	1	1	2
		2	5	7	14
				1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cystitis-like symptom		1
Cytomegalovirus infection reactivation		1
Dairy intolerance	1	1
Deafness	22	45
Deafness bilateral	1	2
Deafness neurosensory	4	8
Deafness transitory	1	2
Deafness unilateral	10	13
Death	5	47
Decreased activity	2	2
Decreased appetite	138	532
Decreased embryo viability	1	1
Decreased immune responsiveness		2
Decreased interest	3	7
Decubitus ulcer	2	2
Deep vein thrombosis	30	52
Defaecation urgency	1	7
Deficiency anaemia	1	1
Dehydration	15	56
Delayed recovery from anaesthesia	2	2
Delirium	8	29
Delusion	2	3
Delusional perception		1
Dementia	2	5
Dementia Alzheimer's type	1	1
Demyelination	1	2
Dental caries	1	1
Depersonalisation/derealisation disorder		2
Depressed level of consciousness	6	16
Depressed mood	20	76
Depression	13	47
Depression suicidal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
				22	45
				1	2
				4	8
				1	2
				10	13
				5	47
		1	1	1	1
	3	53	166	85	366
				1	1
					2
		1	3	2	4
				2	2
	1			30	52
				1	7
		1	1		
		6	18	9	38
		1	1	1	1
				8	29
		1	1	1	2
					1
				2	5
				1	1
				1	2
			1		1
				6	16
		5	15	15	61
		1	2	12	45
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Derealisation		4
Dermal cyst		1
Dermal filler injection	1	1
Dermatitis	7	27
Dermatitis allergic	12	47
Dermatitis atopic	1	6
Dermatitis bullous	1	5
Dermatitis contact	1	1
Dermatitis diaper	1	1
Dermatitis exfoliative		1
Dermatitis exfoliative generalised	1	1
Dermatitis infected		2
Dermatomyositis		3
Device related infection	1	1
Device stimulation issue		1
Diabetes mellitus	5	10
Diabetes mellitus inadequate control	1	5
Diabetic complication	1	2
Diabetic diet		1
Diabetic eye disease		1
Diabetic ketoacidosis		5
Diaphragmalgia	2	4
Diarrhoea	343	1,311
Diarrhoea haemorrhagic	3	9
Diastolic hypertension		1
Diplegia	3	5
Diplopia	20	39
Discharge		2
Discoloured vomit		4
Discomfort	33	115
Disease progression	1	2
Disease recurrence	51	161

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		3
					1
		1	1		
		3	11	4	16
		5	15	7	32
			1	1	5
				1	5
				1	1
		1	1		
					1
				1	1
					2
					3
				1	1
			1		
				5	10
				1	5
				1	2
					1
			1		
					5
		1	1	1	3
2	6	154	385	189	926
				3	9
					1
				3	5
		7	13	13	26
					2
			2		2
	1	10	37	23	78
				1	2
1	1	3	17	48	144

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Disorganised speech		3
Disorientation	21	82
Disseminated intravascular coagulation	1	1
Dissociation	4	16
Dissociative amnesia	1	1
Disturbance in attention	46	136
Diverticulitis	1	4
Dizziness	690	2,487
Dizziness exertional	6	15
Dizziness postural	67	226
Dose calculation error		1
Dreamy state		1
Drooling	1	5
Drooping shoulder syndrome		1
Drug eruption	2	4
Drug hypersensitivity	3	15
Drug-induced liver injury		1
Drug ineffective	67	324
Drug interaction	4	8
Drug level decreased		1
Drug level fluctuating	1	1
Drug withdrawal syndrome		1
Dry eye	4	29
Dry mouth	37	150
Dry skin	21	47
Dry throat	16	55
Duodenal ulcer haemorrhage	1	1
Duodenogastric reflux	1	2
Dysaesthesia	1	2
Dysarthria	13	51
Dyschezia		1
Dyschromatopsia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		6	15	15	67
				1	1
		1	8	3	8
		1	1		
		12	34	34	102
				1	4
	12	293	800	397	1687
		1	2	5	13
	1	26	65	41	161
			1		
			1		
				1	5
			1		
		1	1	1	3
			3	3	12
					1
2	2			67	324
			2	4	6
					1
				1	1
					1
			11	4	18
	1	19	51	18	99
		11	22	10	25
1	2	13	26	3	29
				1	1
		1	1		1
		1	1		1
		2	11	11	40
					1
		1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysfunctional uterine bleeding		1
Dysgeusia	83	311
Dysgraphia		1
Dyshidrotic eczema		4
Dyskinesia	14	28
Dysmenorrhoea	11	29
Dysmorphism		1
Dyspepsia	22	74
Dysphagia	33	105
Dysphemia	2	3
Dysphonia	13	50
Dysphoria	1	1
Dyspnoea	268	1,010
Dyspnoea at rest		3
Dyspnoea exertional	6	42
Dysstasia	14	46
Dystonia	2	6
Dysuria	5	16
Ear canal erythema	1	1
Ear congestion	1	3
Ear discomfort	10	36
Ear disorder	3	9
Ear haemorrhage	1	1
Ear infection	14	23
Ear infection bacterial		1
Ear pain	72	231
Ear pruritus		6
Ear swelling	5	11
Eating disorder	7	20
Eating disorder symptom		1
Eczema	11	34
Eczema asteatotic	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	51	156	32	155
					1
					4
		4	8	10	20
		3	11	8	18
					1
		9	23	13	51
		14	37	19	68
				2	3
		7	18	6	32
				1	1
	1	76	215	192	795
					3
			11	6	31
		3	15	11	31
				2	6
		1	4	4	12
		1	1		
				1	3
		3	14	7	22
		1	4	2	5
				1	1
		3	6	11	17
					1
		24	63	48	168
			2		4
		1	2	4	9
			1	7	19
					1
			6	11	28
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eczema eyelids	1	2
Eczema herpeticum		1
Eczema weeping		1
Ehlers-Danlos syndrome		1
Electric shock	1	2
Electrocardiogram abnormal	3	5
Electrocardiogram change		1
Electrocardiogram ST segment elevation		1
Embolic stroke	2	4
Embolism	22	24
Emotional disorder	7	18
Emotional distress	4	14
Emphysema		1
Encephalitis	3	5
Encephalopathy		1
Endometriosis	2	4
Energy increased	2	2
Enlarged uvula		3
Enteritis	1	2
Enthesopathy		1
Enuresis	2	4
Eosinophil count increased	1	3
Eosinophilia		1
Ephelides	1	1
Epicondylitis	1	3
Epigastric discomfort		7
Epiglottitis	1	1
Epilepsy	10	41
Epileptic aura		1
Epileptic encephalopathy		1
Epinephrine increased		1
Epiphyses premature fusion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
					1
			1		
					1
				1	2
		1	1	2	4
			1		
					1
				2	4
				22	24
		5	7	2	11
			3	4	11
					1
				3	5
					1
		1	1	1	3
		1	1	1	1
			2		1
				1	2
					1
			1	2	3
			1	1	2
			1		
		1	1		
		1	1		2
			2		5
				1	1
				10	41
					1
					1
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Episcleritis	1	4
Epistaxis	61	143
Epstein-Barr virus infection		2
Erectile dysfunction	2	3
Eructation	4	14
Erythema	193	642
Erythema annulare	1	2
Erythema multiforme	2	14
Erythema nodosum	2	4
Erythema of eyelid		2
Essential hypertension		1
Essential thrombocythaemia		1
Euphoric mood	5	10
Eustachian tube disorder		1
Eustachian tube dysfunction		2
Excessive cerumen production	2	2
Excessive granulation tissue		1
Exercise tolerance decreased	5	7
Exertional headache	1	3
Exfoliative rash	1	6
Exophthalmos		1
Expired product administered	1	2
Exposure during pregnancy	14	32
Exposure keratitis		1
Exposure to extreme temperature	1	1
Exposure to SARS-CoV-2		3
Exposure via breast milk	6	10
Extensive swelling of vaccinated limb	3	8
Extensor plantar response		1
External ear cellulitis		1
External ear pain	1	4
Extraocular muscle disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
		20	47	41	96
					2
				2	3
			1	4	13
	1	122	324	71	318
				1	2
				2	14
				2	4
					2
					1
					1
		3	5	2	5
					1
					2
				2	2
					1
		1	1	4	6
		1	2		1
				1	6
					1
			1	1	1
1	1	9	26	5	6
			1		
				1	1
			1		2
		3	4	3	6
		1	6	2	2
					1
					1
		1	3		1
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Extraocular muscle paresis		1
Extrasystoles	3	14
Eye abscess		1
Eye allergy	1	2
Eye colour change		1
Eye complication associated with device		1
Eye contusion	1	9
Eye discharge	2	9
Eye disorder	5	22
Eye haematoma		1
Eye haemorrhage	1	7
Eye infection	3	6
Eye inflammation	3	9
Eye injury		2
Eye irritation	12	36
Eyelid bleeding	1	1
Eyelid cyst		1
Eyelid disorder		2
Eyelid exfoliation		1
Eyelid function disorder		2
Eyelid irritation		2
Eyelid margin crusting		1
Eyelid oedema	1	4
Eyelid pain		6
Eyelid ptosis	3	11
Eyelid rash	2	5
Eyelids pruritus	2	7
Eye movement disorder	1	6
Eye oedema	2	4
Eye pain	79	285
Eye paraesthesia		1
Eye pruritus	25	76

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			3	3	11
					1
		1	1		1
					1
					1
	1	1	4		5
		1	1	1	8
		1	8	4	14
					1
				1	7
				3	6
		2	3	1	6
					2
		3	8	9	28
				1	1
					1
			1		1
			1		1
			1		1
			2	1	2
			1		5
		2	7	1	4
		2	2		3
			2	2	5
			1	1	5
		2	3		1
		28	76	51	209
			1		
	2	13	32	12	44

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye swelling	40	149
Eye symptom	1	1
Face crushing		1
Face injury	2	3
Face oedema	3	9
Facial discomfort		8
Facial nerve disorder	1	1
Facial neuralgia	1	7
Facial pain	23	94
Facial paralysis	68	248
Facial paresis	7	32
Facial spasm	2	8
Factitious disorder	1	1
Faecal calprotectin		1
Faeces discoloured	1	9
Faeces hard	1	1
Faeces pale		2
Faeces soft	1	2
Failed in vitro fertilisation	1	1
Fall	30	98
False positive investigation result	1	1
Familial hemiplegic migraine		1
Familial periodic paralysis		1
Fatigue	1,768	6,240
Fear	4	13
Fear of falling	1	1
Fear of injection		1
Febrile convulsion	6	8
Feeding disorder	4	37
Feeling abnormal	182	607
Feeling cold	137	510
Feeling drunk	5	30

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	20	44	20	105
				1	1
					1
			1	2	2
		1	3	2	6
			2		6
		1	1		
		1	3		4
		8	27	15	67
	2			68	248
		4	11	3	21
		1	5	1	3
				1	1
					1
			4	1	5
				1	1
					2
				1	2
				1	1
		9	29	21	69
				1	1
					1
10	54	742	2036	1026	4204
			3	4	10
				1	1
			1		
		5	6	1	2
		1	16	3	21
1	1	70	206	112	401
1	4	58	189	79	321
		3	10	2	20

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling hot	136	527
Feeling jittery	3	16
Feeling of body temperature change	47	165
Feeling of despair	3	4
Feeling of relaxation	1	1
Femoral neck fracture	1	2
Femur fracture		1
Fibrin D dimer increased	6	9
Fibromyalgia	9	30
Fine motor skill dysfunction	3	6
Finger deformity	1	1
Flank pain	5	12
Flashback	1	1
Flat affect	1	3
Flatulence	12	40
Fluid imbalance	2	2
Fluid intake reduced		2
Fluid retention	4	9
Flushing	42	186
Focal dyscognitive seizures	1	1
Foetal death	2	2
Foetal exposure during pregnancy	1	1
Folliculitis		3
Food allergy	1	5
Food aversion	1	4
Food craving		3
Food intolerance	2	2
Food poisoning		2
Food refusal		2
Forced expiratory volume increased		1
Foreign body sensation in eyes	5	12
Formication	5	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		75	253	61	274
		2	5	1	11
		16	58	31	107
				3	4
				1	1
				1	2
					1
		1	1	5	8
		2	4	7	26
		1	1	2	5
		1	1		
		4	9	1	3
				1	1
		1	2		1
		4	11	8	29
		1	1	1	1
					2
		1	2	3	7
	1	24	75	18	111
				1	1
				2	2
		1	1		
			1		2
			1	1	4
				1	4
			1		2
		1	1	1	1
					2
					2
					1
		3	5	2	7
		2	4	3	11

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fracture		1
Fracture blisters		1
Freezing phenomenon	1	2
Frequent bowel movements	3	15
Frustration tolerance decreased		1
Full blood count abnormal		1
Functional gastrointestinal disorder	1	1
Fungal infection	1	1
Fungal skin infection		1
Furuncle	3	6
Gait disturbance	49	158
Gait inability	18	53
Galactorrhoea	2	3
Gal bladder disorder	1	1
Gamma-glutamyltransferase increased	1	2
Gastric antral vascular ectasia	1	2
Gastric dilatation		2
Gastric disorder	4	12
Gastric ulcer	1	2
Gastritis	3	12
Gastroenteritis	3	8
Gastroenteritis norovirus	1	1
Gastroenteritis rotavirus	1	1
Gastroenteritis viral		5
Gastrointestinal disorder	3	7
Gastrointestinal haemorrhage	1	3
Gastrointestinal motility disorder		1
Gastrointestinal pain	13	35
Gastrointestinal sounds abnormal	4	11
Gastrointestinal stoma complication		1
Gastrointestinal surgery	1	1
Gastrointestinal wall thickening		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
				1	2
		1	3	2	12
			1		
					1
				1	1
				1	1
					1
			1	3	5
	1	7	27	42	131
	1	3	8	15	45
				2	3
				1	1
				1	2
				1	2
					2
		1	6	3	6
				1	2
			1	3	11
		1	1	2	7
				1	1
				1	1
			2		3
		1	3	2	4
				1	3
			1		
		3	4	10	31
		2	3	2	8
					1
				1	1
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastroesophageal reflux disease	9	30
Generalised oedema	2	2
Generalised tonic-clonic seizure	3	24
General physical health deterioration	3	10
Genital haemorrhage		1
Genital herpes	2	4
Genital tract inflammation		1
Genital ulceration		1
Gestational diabetes	1	1
Giant cell arteritis	1	4
Gingival abscess		1
Gingival bleeding	4	9
Gingival blister		1
Gingival discomfort		2
Gingival disorder		2
Gingival erythema		1
Gingival pain	9	32
Gingival pruritus	1	1
Gingival swelling	4	7
Gingivitis	1	3
Gingivitis ulcerative		2
Glaucoma	1	2
Glomerulonephritis minimal lesion	1	2
Glossitis		5
Glossodynia	22	71
Glucose tolerance impaired		1
Glycopenia	1	1
Goitre	3	5
Gout		6
Granuloma skin	1	1
Granulomatous lymphadenitis		2
Grief reaction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5	6	25
		1	1	1	1
				3	24
		1	3	2	7
					1
		1	2	1	2
			1		
					1
				1	1
				1	4
					1
		3	4	1	5
			1		
			1		1
			1		1
					1
		3	8	6	24
				1	1
		1	2	3	5
			2	1	1
					2
				1	2
				1	2
			3		2
		11	30	11	41
			1		
		1	1		
		1	2	2	3
					6
		1	1		
					2
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Grip strength		1
Grip strength decreased	6	17
Groin pain	9	39
Guillain-Barre syndrome	5	14
Guttate psoriasis	1	1
Habit cough	3	3
Haemarthrosis	3	3
Haematemesis	2	14
Haematochezia	4	14
Haematocrit increased		1
Haematoma	2	8
Haematospermia	1	1
Haematuria	5	12
Haemoglobin decreased	2	7
Haemoglobin increased		2
Haemolysis	1	2
Haemolytic anaemia		1
Haemoperitoneum	1	1
Haemoptysis	6	14
Haemorrhage	29	53
Haemorrhage in pregnancy	1	1
Haemorrhage intracranial		2
Haemorrhage subcutaneous	2	4
Haemorrhage urinary tract	1	5
Haemorrhagic diathesis	1	2
Haemorrhagic stroke	3	5
Haemorrhoids	1	7
Hair colour changes		1
Hair disorder	1	1
Hair texture abnormal	1	1
Hallucination	20	72
Hallucination, auditory	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	5	4	12
		2	14	7	25
				5	14
				1	1
		1	1	2	2
				3	3
				2	14
				4	14
					1
			1	2	7
				1	1
			2	5	10
			2	2	5
					2
				1	2
					1
				1	1
		2	2	4	12
1	1		1	29	52
				1	1
					2
				2	4
			1	1	4
				1	2
				3	5
				1	7
			1		
		1	1		
				1	1
				20	72
				1	4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hallucination, olfactory	1	3
Hallucinations, mixed		1
Hallucination, tactile		1
Hallucination, visual	2	6
Halo vision		1
Hand-arm vibration syndrome		1
Hand deformity	2	2
Hangover	1	16
Haptoglobin decreased		1
Headache	2,125	7,463
Head banging	2	3
Head discomfort	42	106
Head injury	3	21
Head titubation	1	1
Heart disease congenital		1
Heart injury		3
Heart rate	5	10
Heart rate abnormal	8	24
Heart rate decreased	6	21
Heart rate increased	72	299
Heart rate irregular	6	25
Heat illness		1
Heat oedema	1	4
Heat stroke		1
Hemianopia		1
Hemianopia homonymous	1	1
Hemiparaesthesia		1
Hemiparesis	3	13
Hemiplegia	4	12
Hemiplegic migraine	2	5
Hepatic enzyme increased	1	1
Hepatic function abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
					1
				2	6
					1
					1
				2	2
			3	1	13
					1
3	33	955	2623	1170	4840
		1	2	1	1
		12	33	30	73
		1	9	2	12
				1	1
					1
					3
		2	3	3	7
	1	2	7	6	17
		1	3	5	18
		32	99	40	200
			2	6	23
					1
			1	1	3
			1		
					1
				1	1
					1
				3	13
				4	12
				2	5
		1	1		
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hepatic lesion		1
Hepatic pain	1	6
Hepatitis	2	5
Hepatitis A	1	1
Hepatitis viral	1	1
Hepatomegaly	1	1
Hereditary neuropathy with liability to pressure palsies	1	1
Herpes ophthalmic		1
Herpes simplex	3	7
Herpes simplex reactivation		1
Herpes virus infection		2
Herpes zoster	51	241
Herpes zoster meningoencephalitis	1	1
Herpes zoster oticus	1	2
Herpes zoster reactivation	1	4
Hiccups		1
Hidradenitis		1
Hip fracture		2
Histamine intolerance		1
Hordeolum	1	3
Hormone level abnormal		2
Hot flush	95	270
Humerus fracture	1	1
Hunger	2	6
Hyperactive pharyngeal reflex		1
Hyperacusis	7	23
Hyperaesthesia	19	46
Hyperaesthesia teeth	2	5
Hyperchlorhydria		6
Hypergeusia		1
Hyperglycaemia	7	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	6
				2	5
				1	1
				1	1
				1	1
				1	1
					1
		1	3	2	4
					1
					2
		4	74	47	167
				1	1
				1	2
				1	4
					1
					1
					2
			1	1	2
					2
		51	104	44	166
				1	1
		2	4		2
					1
		2	8	5	15
		6	18	13	28
		2	2		3
			1		5
					1
		2	5	5	20

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperhidrosis	176	612
Hyperphagia		1
Hyperpyrexia		4
Hyperreflexia		1
Hypersensitivity	51	232
Hypersomnia	36	111
Hypertension	50	232
Hypertensive crisis	3	4
Hypertensive heart disease		2
Hypertensive urgency	1	1
Hyperthermia		1
Hyperthyroidism	3	6
Hypertonia		2
Hypertonic bladder		2
Hyperventilation	3	8
Hypervigilance		1
Hypervolaemia		1
Hyphaema		1
Hypnagogic hallucination		1
Hypoacusis	12	30
Hypoaesthesia	192	623
Hypoaesthesia eye	1	5
Hypoaesthesia oral	33	154
Hypoaesthesia teeth		1
Hypocalcaemia	1	2
Hypoglycaemia	3	23
Hypokalaemic syndrome		2
Hypokinesia	28	45
Hypomania		1
Hypomenorrhoea	3	9
Hyponatraemia	1	5
Hyponatraemic syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		61	186	115	426
					1
					4
					1
		20	61	31	171
		15	40	21	71
	1	15	65	35	167
				3	4
					2
				1	1
					1
				3	6
					2
			2		
		2	5	1	3
					1
					1
					1
		6	12	6	18
	3	87	225	105	398
			1	1	4
		21	71	12	83
			1		
				1	2
		1	4	2	19
					2
		7	12	21	33
					1
		2	6	1	3
				1	5
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoperfusion		1
Hypophagia	5	10
Hypopnoea	10	26
Hyporeflexia		3
Hyporesponsive to stimuli		1
Hyposmia		3
Hyposomnia		1
Hypotension	33	133
Hypothermia	3	11
Hypothyroidism	6	9
Hypotonia	1	5
Hypoventilation	1	1
Hypovitaminosis	1	2
Hypoxia	3	10
Idiopathic intracranial hypertension	1	2
Illrd nerve disorder	1	2
Illrd nerve paralysis	1	1
Ileus paralytic	1	1
Illness	183	544
Illusion		1
Immediate post-injection reaction		1
Immobile	1	1
Immune-mediated adverse reaction		1
Immune-mediated hepatic disorder	1	1
Immune system disorder	2	9
Immune thrombocytopenia	11	25
Immunisation		1
Immunisation anxiety related reaction		1
Immunisation reaction	1	1
Immunodeficiency		2
Immunodeficiency common variable	1	1
Immunology test	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				5	10
			1	10	25
			1		2
					1
			1		2
					1
		11	33	22	100
				3	11
				6	9
			1	1	4
				1	1
		1	1		1
				3	10
				1	2
				1	2
				1	1
1	2	71	152	112	392
			1		
			1		
				1	1
					1
				1	1
				2	9
				11	25
					1
					1
				1	1
					2
				1	1
		1	1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Impaired driving ability	5	11
Impaired gastric emptying		1
Impaired healing		1
Impaired quality of life	2	2
Impaired self-care		1
Impaired work ability	8	15
Impetigo		1
Implant site pain		1
Inability to crawl	1	1
Inappropriate affect	1	1
Inappropriate schedule of product administration	313	400
Incision site pain	1	2
Incoherent	2	5
Incomplete course of vaccination		1
Incontinence	4	13
Incorrect dose administered	3	6
Incorrect route of product administration	2	35
Increased appetite	1	2
Increased insulin requirement		1
Increased tendency to bruise	2	7
Increased upper airway secretion	1	4
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion	1	3
Indifference	1	2
Induration	1	5
Infantile vomiting		1
Infant irritability	1	1
Infarction	1	2
Infected dermal cyst		1
Infected skin ulcer		1
Infection	22	49

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	3	7
					1
					1
		1	1	1	1
			1		
		2	5	6	10
					1
					1
				1	1
				1	1
1	1	301	385	12	15
				1	2
		1	2	1	3
			1		
			1	4	12
		2	5	1	1
		2	34		1
		1	1		1
					1
			4	2	3
			1	1	3
					1
				1	2
		1	2		3
					1
		1	1		
				1	2
					1
					1
		7	14	15	35

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infectious mononucleosis		2
Infectious pleural effusion		1
Infertility		1
Inflammation	29	89
Inflammatory bowel disease	1	1
Inflammatory marker increased		4
Inflammatory pain		2
Influenza	139	401
Influenza like illness	228	852
Infusion related reaction		1
Inguinal mass		1
Initial insomnia	2	5
Injected limb mobility decreased	4	12
Injection related reaction	5	14
Injection site erythema	7	14
Injection site joint movement impairment		1
Injection site mass	2	3
Injection site muscle weakness	1	1
Injection site oedema	1	1
Injection site pain	26	47
Injection site pruritus	2	4
Injection site pustule	1	1
Injection site rash		1
Injection site reaction		2
Injection site swelling	8	11
Injection site urticaria		1
Injection site warmth	1	3
Injury	2	3
Injury associated with device		1
Injury corneal		1
Inner ear disorder	2	4
Insomnia	133	445

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
		13	32	16	57
				1	1
			1		3
			1		1
1	2	47	111	92	290
	4	84	286	144	566
					1
					1
		1	2	1	3
		2	4	2	8
		1	3	4	11
		6	13	1	1
					1
			1	2	2
				1	1
		1	1		
		22	31	4	16
		1	3	1	1
				1	1
					1
			1	1	2
				2	3
			1		
					1
				2	4
		40	143	93	302

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Insulin resistance		2
Intentional self-injury	1	3
International normalised ratio abnormal	2	3
International normalised ratio decreased	5	8
International normalised ratio fluctuation		1
International normalised ratio increased	2	14
Interstitial lung disease	1	1
Intervertebral disc compression	1	1
Intervertebral disc protrusion	1	2
Intestinal infarction	1	1
Intestinal mass		1
Intestinal obstruction	2	2
Intestinal perforation		1
Intracranial aneurysm	1	1
Intracranial pressure increased	1	1
Intranasal hypoesthesia		1
Intranasal paraesthesia	1	2
Intraocular pressure increased		1
Intravascular haemolysis		1
Intrusive thoughts	1	1
Iodine uptake increased		1
Iridocyclitis		4
Iritis		1
Iron deficiency	2	3
Iron deficiency anaemia	1	2
Irregular breathing		7
Irregular sleep wake rhythm disorder	1	1
Irritability	13	33
Irritable bowel syndrome	4	23
Ischaemia	1	1
Ischaemic stroke	8	17
Itching scar	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	3
		1	1	1	2
		1	1	4	7
					1
			5	2	9
				1	1
				1	1
		1	1		1
				1	1
					1
				2	2
					1
				1	1
				1	1
					1
		1	2		
					1
					1
		1	1		
					1
					4
			1		
				2	3
		1	1		1
					7
		1	1		
		7	10	6	23
		2	4	2	19
				1	1
				8	17
		1	4		2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Jaundice	2	5
Jaw clicking		2
Joint destruction		1
Joint effusion	1	8
Joint injury	2	4
Joint laxity	1	1
Joint lock		2
Joint microhaemorrhage		1
Joint noise	3	5
Joint range of motion decreased	33	92
Joint stiffness	23	85
Joint swelling	45	132
Joint vibration		1
Joint warmth	2	6
Jugular vein thrombosis	1	2
Keratitis		2
Ketoacidosis		1
Kidney infection	3	8
Kidney small		1
Labile blood pressure		2
Labyrinthitis	11	27
Lack of spontaneous speech		2
Lacrimal disorder		1
Lacrimation increased	9	49
Lactation disorder	1	2
Lactose intolerance		1
Lacunar infarction		1
Lacunar stroke		1
Lagophthalmos		1
Language disorder	2	2
Laryngeal disorder		1
Laryngeal pain		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	4
			1		1
					1
		1	3		5
		1	2	1	2
				1	1
					2
					1
			1	3	4
		6	20	27	72
		6	16	17	69
		14	30	31	102
					1
			3	2	3
		1	1		1
			2		
					1
				3	8
					1
					2
		3	5	8	22
			1		1
					1
		4	13	5	36
				1	2
			1		
					1
					1
					1
				2	2
					1
			1		2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngitis		3
Left ventricular dysfunction	1	2
Left ventricular failure		1
Lennox-Gastaut syndrome		1
Lethargy	202	678
Leukaemia		1
Leukopenia	2	2
Lhermitte's sign	1	1
L bido increased		1
Lichenoid keratosis	1	2
Ligament sprain	1	5
Limbal swelling	1	1
Limb discomfort	141	484
Limb immobilisation	1	3
Limb injury	10	17
Limb mass	3	21
Limb operation	1	1
Lip blister	3	12
Lip discolouration		1
Lip disorder		4
Lip dry	6	19
Lip erythema		3
Lip exfoliation		1
Lip haemorrhage		1
Lip oedema		2
Lipoma	1	1
Lip pain	8	23
Lip pruritus	2	4
Lip scab		1
Lip swelling	61	236
Lip ulceration	2	3
Listless	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				1	2
					1
					1
1	6	90	237	112	441
					1
				2	2
				1	1
			1		
				1	2
				1	5
				1	1
	1	69	204	72	280
			2	1	1
		2	3	8	14
			8	3	13
				1	1
		2	2	1	10
					1
			2		2
		3	9	3	10
			2		1
					1
					2
		1	1		
		2	9	6	14
		2	4		
					1
	1	31	73	30	163
		2	2		1
				2	5

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Livedo reticularis	3	16
Liver function test abnormal	2	6
Liver function test increased	4	7
Liver injury	2	5
Liver tenderness	1	1
Localised infection	3	13
Localised oedema	3	9
Local reaction	7	20
Locked-in syndrome		1
Loss of bladder sensation		2
Loss of consciousness	43	174
Loss of control of legs	1	6
Loss of libido	1	1
Loss of personal independence in daily activities	42	102
Lower limb fracture		2
Lower respiratory tract congestion	1	1
Lower respiratory tract infection	15	58
Lung consolidation	1	1
Lung disorder	3	6
Lung infiltration	1	1
Lung neoplasm malignant		1
Lung opacity	1	1
Lupus-like syndrome		1
Lymphadenitis	17	35
Lymphadenopathy	825	2,013
Lymphangioma		1
Lymphangiopathy	1	1
Lymphangitis	2	4
Lymphatic disorder	1	2
Lymph gland infection	3	5
Lymph node pain	172	420
Lymph node palpable	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	1	12
			1	2	5
			2	4	5
				2	5
				1	1
			2	3	11
		3	4		5
		6	9	1	11
					1
					2
				43	174
				1	6
				1	1
		11	30	31	72
					2
		1	1		
				15	58
				1	1
		1	1	2	5
				1	1
					1
				1	1
					1
		5	11	12	24
1	3	268	676	557	1337
					1
				1	1
				2	4
			1	1	1
			1	3	4
	1	33	109	139	311
		1	4		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymph nodes scan abnormal		1
Lymphocyte count decreased	1	1
Lymphocytosis	1	2
Lymphoedema	19	43
Lymphoma	1	6
Lymphopenia		1
Macular degeneration	1	2
Macular hole	1	1
Macular oedema	1	1
Macular rupture	1	1
Macule	1	4
Maculopathy	1	2
MAGIC syndrome		1
Magnetic resonance imaging abnormal	1	1
Magnetic resonance imaging brain abnormal	1	1
Major depression	2	2
Malaise	559	2,186
Malignant hypertension	2	2
Mallory-Weiss syndrome		2
Malnutrition		1
Mania	1	3
Mass	6	13
Mass excision		1
Mast cell activation syndrome		4
Mastication disorder	1	4
Mastitis	8	17
Mastocytosis		1
Maternal exposure before pregnancy	1	2
Maternal exposure during breast feeding	8	14
Maternal exposure during pregnancy	23	87
Maternal exposure timing unspecified	1	3
Mean cell volume decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	2
	1	2	10	17	33
			1	1	6
			1		
				1	2
				1	1
				1	1
		1	2		2
				1	2
					1
				1	1
				1	1
				2	2
2	7	219	707	340	1479
				2	2
					2
					1
				1	3
		1	3	5	10
			1		
					4
				1	4
				8	17
					1
				1	2
		3	6	5	8
3	3	14	63	9	24
		1	3		
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Measles	2	2
Mechanical urticaria		1
Medial tibial stress syndrome		1
Medication error		2
Melaena	1	4
Melanocytic naevus		1
Memory impairment	13	42
Meniere's disease	3	6
Meningitis	2	4
Meningitis aseptic		1
Meningitis bacterial		1
Meningitis viral	1	2
Menopausal symptoms	2	4
Menopause	1	1
Menorrhagia	33	68
Menstrual discomfort	1	1
Menstrual disorder	8	18
Menstruation delayed	14	41
Menstruation irregular	18	29
Mental disorder	3	5
Mental fatigue	11	53
Mental impairment	2	14
Mesenteric vein thrombosis	1	1
Metabolic acidosis		1
Metamorphopsia	2	7
Metastases to lymph nodes		2
Metastasis		1
Metastatic neoplasm	1	1
Metrorrhagia	6	9
Microvascular coronary artery disease	1	1
Micturition disorder		3
Micturition urgency	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
			1		
					1
			2		
				1	4
					1
		4	12	9	30
				3	6
				2	4
					1
				1	2
			2	2	2
				1	1
1	1	12	21	21	47
				1	1
1	1	3	8	5	10
		4	13	10	28
1	1	4	9	14	20
		2	3	1	2
		3	10	8	43
	1			2	14
				1	1
					1
			1	2	6
					2
					1
				1	1
		2	4	4	5
				1	1
			1		2
		1	1	2	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle ear effusion		1
Middle ear inflammation		1
Middle insomnia	9	34
Migraine	220	711
Migraine prophylaxis	1	1
Migraine with aura	17	56
Migraine without aura	2	3
Miliaria	10	25
Mini mental status examination abnormal		1
Miosis		2
Misophonia	1	1
Mitral valve incompetence	1	1
Moaning		2
Mobility decreased	33	143
Monocytosis		1
Monoparesis	5	18
Monoplegia	4	25
Mood altered	2	9
Mood disorder due to a general medical condition		1
Mood swings		7
Morning sickness		8
Morton's neuralgia		1
Motion sickness	9	20
Motor dysfunction	1	3
Mouth breathing		3
Mouth cyst	1	3
Mouth haemorrhage	4	6
Mouth injury		1
Mouth swelling	8	37
Mouth ulceration	26	90
Movement disorder	20	60

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		3	12	6	22
3	5	50	160	170	551
	1	3	14	14	42
				2	3
		6	10	4	15
					1
					2
				1	1
				1	1
					2
		6	38	27	105
			1		
			2	5	16
				4	25
			3	2	6
					1
			2		5
					8
					1
		3	8	6	12
			1	1	2
					3
			2	1	1
		2	3	2	3
					1
		2	9	6	28
		7	23	19	67
		4	11	16	49

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mucosal haemorrhage		2
Mucous stools	2	2
Multiple allergies		1
Multiple organ dysfunction syndrome	1	2
Multiple sclerosis	1	15
Multiple sclerosis relapse	4	19
Multiple sclerosis relapse prophylaxis	1	1
Mumps	1	2
Muscle atrophy	2	3
Muscle contractions involuntary		4
Muscle discomfort	1	1
Muscle disorder	1	1
Muscle fatigue	25	97
Muscle injury		1
Muscle rigidity		5
Muscle rupture	1	2
Muscle spasms	70	232
Muscle spasticity		2
Muscle strain	4	10
Muscle swelling	4	11
Muscle tightness	6	33
Muscle tone disorder		1
Muscle twitching	10	63
Muscular weakness	88	302
Musculoskeletal chest pain	19	78
Musculoskeletal deformity		1
Musculoskeletal discomfort	13	48
Musculoskeletal disorder	4	19
Musculoskeletal pain	5	24
Musculoskeletal stiffness	121	388
Mutism	2	5
Myalgia	932	3,243

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				2	2
					1
				1	2
				1	15
				4	19
				1	1
				1	2
		1	1	1	2
			2		2
		1	1		
		1	1		
		12	23	13	74
					1
			1		4
				1	2
1	1	18	60	52	172
					2
		1	1	3	9
		2	4	2	7
		2	12	4	21
					1
		6	29	4	34
		27	78	61	224
		4	14	15	64
					1
		4	18	9	30
			3	4	16
		2	7	3	17
		50	125	71	263
		1	3	1	2
6	22	435	1149	497	2094

\* I=Interval, C=Cumulative

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myalgia intercostal	1	1
Myasthenia gravis	2	4
Myasthenia gravis crisis		1
Mydriasis	2	4
Myelitis	1	3
Myelitis transverse	3	15
Myocardial infarction	19	42
Myocardial ischaemia		5
Myocardial oedema		1
Myocarditis	3	12
Myoclonus	2	5
Myofascial pain syndrome		3
Myositis	2	4
Nail avulsion		1
Nail discolouration	1	5
Nail ridging	1	1
Narcolepsy		1
Nasal congestion	22	68
Nasal discharge discolouration		1
Nasal discomfort	6	19
Nasal disorder		1
Nasal dryness	3	4
Nasal herpes	1	2
Nasal obstruction		3
Nasal odour		2
Nasal oedema		3
Nasal pruritus	1	4
Nasopharyngitis	72	226
Natural killer T cell count increased		1
Nausea	1,106	4,183
Near death experience	1	1
Neck mass	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	4
					1
		1	1	1	3
				1	3
				3	15
				19	42
					5
					1
				3	12
			1	2	4
			1		2
			1	2	3
			1		
		1	2		3
				1	1
					1
		7	22	15	46
			1		
		1	7	5	12
			1		
		1	1	2	3
		1	2		
			2		1
			1		1
					3
			1	1	3
		31	86	41	140
			1		
	17	525	1418	581	2765
			5	2	8

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neck pain	197	661
Necrotising fasciitis	1	1
Needle issue		2
Negative thoughts		2
Neoplasm	3	4
Neoplasm malignant	2	4
Nephrotic syndrome	1	4
Nerve compression	4	11
Nerve injury	4	16
Nervousness	26	88
Nervous system disorder	2	4
Neuralgia	42	104
Neuritis	1	1
Neurogenic bladder		1
Neurogenic shock		7
Neurological symptom	3	11
Neurologic neglect syndrome		1
Neuromuscular pain	1	1
Neuropathy peripheral	7	29
Neuropsychiatric symptoms		1
Neutropenia	5	18
Neutropenic sepsis		2
Neutrophil count decreased	2	4
Neutrophil count increased		1
New daily persistent headache		1
Nightmare	6	36
Night sweats	48	150
Nipple exudate bloody	1	1
Nipple pain	3	7
Nipple swelling		1
No adverse event	1	1
Nocturia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	75	219	122	442
				1	1
			1		1
					2
			1	3	3
				2	4
				1	4
		2	4	2	7
		2	5	2	11
		14	25	12	63
		2	3		1
		8	28	34	76
		1	1		
					1
					7
			1	3	10
					1
				1	1
				7	29
			1		
				5	18
					2
		1	2	1	2
			1		
			1		
		3	15	3	21
	2	23	56	25	94
				1	1
		1	2	2	5
			1		
		1	1		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nocturnal dyspnoea		2
Nodule	4	8
Non-cardiac chest pain		4
Non-Hodgkin's lymphoma	1	1
Noninfective gingivitis	1	3
Noninfective sialoadenitis	1	1
Non-tobacco user	1	1
No reaction on previous exposure to drug	1	1
Nuchal rigidity		3
Numb chin syndrome		1
Nystagmus	2	3
Obstructive airways disorder		2
Obstructive pancreatitis	1	1
Occipital neuralgia	2	4
Occupational exposure to product		2
Ocular discomfort	5	13
Ocular hyperaemia	20	62
Ocular myasthenia	1	1
Odynophagia	7	21
Oedema	2	10
Oedema mouth	1	4
Oedema peripheral	10	28
Oesophageal pain	1	4
Oesophageal spasm		2
Oesophageal varices haemorrhage		1
Oesophagitis	1	1
Off label use	357	771
Oligodendroglioma	1	1
Oligohydramnios		1
Oligomenorrhoea	2	3
Oliguria	1	1
Onychoclasia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		2	4	2	4
			1		3
				1	1
				1	3
				1	1
		1	1		
		1	1		
					3
					1
				2	3
					2
				1	1
				2	4
			2		
		2	6	3	7
		12	22	8	40
				1	1
		3	9	4	12
			2	2	8
			1	1	3
		3	9	7	19
			2	1	2
			1		1
					1
		1	1		
1	1	337	730	20	41
				1	1
					1
				2	3
				1	1
		1	1	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmic herpes zoster		3
Ophthalmological examination abnormal	1	1
Ophthalmoplegia		2
Optic ischaemic neuropathy	1	1
Optic nerve disorder		1
Optic neuritis	4	9
Oral allergy syndrome		1
Oral blood blister		4
Oral candidiasis	3	13
Oral discharge		1
Oral discomfort	4	27
Oral disorder	4	8
Oral dysaesthesia		1
Oral herpes	18	52
Oral lichen planus	2	2
Oral mucosal blistering	2	14
Oral mucosal discolouration		1
Oral mucosal eruption	3	4
Oral mucosal erythema	2	4
Oral mucosal exfoliation	2	5
Oral mucosal roughening	1	2
Oral pain	15	51
Oral papule		1
Oral pruritus	5	10
Oral purpura	1	1
Orbital oedema	1	1
Oropharyngeal blistering		10
Oropharyngeal discomfort	11	37
Oropharyngeal oedema		1
Oropharyngeal pain	190	684
Orthostatic hypertension		1
Orthostatic hypotension	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	1		
					2
				1	1
				4	9
					1
			2		2
		1	4	2	9
			1		
		2	8	2	19
			2	4	6
					1
	1	8	22	10	30
				2	2
		2	8		6
					1
		2	2	1	2
		1	1	1	3
		1	3	1	2
				1	2
		10	18	5	33
					1
		2	4	3	6
				1	1
				1	1
					10
		5	13	6	24
					1
1	4	98	241	92	443
					1
		2	3		5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oscillopsia		1
Osteitis	1	1
Osteoarthritis	3	12
Osteonecrosis of jaw	1	1
Otitis externa		1
Overdose	5	18
Overflow diarrhoea		1
Oversensing	3	6
Ovulation pain		1
Oxygen saturation	1	1
Oxygen saturation decreased	2	39
Pain	808	2,473
Painful respiration	8	28
Pain in extremity	1,077	3,545
Pain in jaw	27	97
Pain of skin	34	107
Palatal oedema		2
Palatal swelling		3
Palatal ulcer		1
Palindromic rheumatism	1	1
Pallor	16	88
Palmar erythema	1	1
Palpitations	165	583
Pancreatic carcinoma	2	2
Pancreatic disorder		1
Pancreatitis		2
Pancreatitis acute	1	1
Pancytopenia	1	3
Panic attack	10	24
Panic disorder	1	3
Panic reaction	2	10
Papilloedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			1	3	11
				1	1
					1
		5	17		1
			1		
		1	1	2	5
					1
				1	1
		1	6	1	33
1	6	344	926	464	1547
			4	8	24
4	28	492	1350	585	2195
		6	25	21	72
		12	30	22	77
					2
					3
					1
				1	1
		9	30	7	58
				1	1
	1	52	155	113	428
				2	2
					1
					2
				1	1
				1	3
		4	7	6	17
		1	1		2
			1	2	9
					2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Papule	4	16
Paraesthesia	273	907
Paraesthesia oral	105	438
Parainfluenzae viral laryngotracheobronchitis	1	1
Paralysis	15	33
Paramnesia	1	1
Paranasal sinus discomfort	2	10
Paranasal sinus hypersecretion	1	1
Paranasal sinus inflammation		1
Paranoia		3
Paresis	1	2
Parkinson's disease		3
Parophthalmia	1	1
Parosmia	17	44
Parotid gland enlargement	1	3
Parotitis		5
Partial seizures	2	9
Peak expiratory flow rate	1	1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased	1	2
Pelvic haemorrhage		3
Pelvic pain	5	19
Pelvic venous thrombosis		1
Pemphigoid	1	4
Pemphigus		1
Peptic ulcer haemorrhage	1	2
Periarthritis	6	20
Pericardial effusion	2	5
Pericarditis	1	7
Perioral dermatitis	1	1
Periorbital cellulitis	1	1
Periorbital haematoma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	3	11
	3	127	351	146	556
	1	72	216	33	222
				1	1
	1			15	33
				1	1
		1	4	1	6
				1	1
					1
					3
				1	2
					3
				1	1
		7	15	10	29
			1	1	2
			2		3
				2	9
				1	1
					1
				1	2
					3
		2	5	3	14
					1
				1	4
					1
				1	2
		1	3	5	17
				2	5
				1	7
		1	1		
				1	1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Periorbital oedema		6
Periorbital pain	1	2
Periorbital swelling	11	38
Peripheral circulatory failure		3
Peripheral coldness	37	128
Peripheral embolism		1
Peripheral ischaemia	3	5
Peripheral sensory neuropathy	1	4
Peripheral swelling	288	803
Peripheral vein stenosis	1	1
Peroneal nerve palsy	1	4
Persistent postural-perceptual dizziness		3
Petechiae	11	24
Petit mal epilepsy	2	11
Phantom limb syndrome		2
Pharyngeal disorder		1
Pharyngeal enanthema		1
Pharyngeal erythema	3	5
Pharyngeal haemorrhage		1
Pharyngeal hypoaesthesia	3	8
Pharyngeal inflammation		6
Pharyngeal oedema	2	7
Pharyngeal paraesthesia	9	28
Pharyngeal pustule	1	1
Pharyngeal swelling	20	100
Pharyngeal ulceration	1	5
Pharyngitis	3	7
Pharyngitis streptococcal		2
Phlebitis	6	10
Phobia	1	1
Phonophobia		1
Photophobia	30	132

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		5
			1	1	1
		5	11	6	27
					3
		13	40	24	88
					1
		2	2	1	3
		1	1		3
1	3	94	256	194	547
				1	1
			1	1	3
			1		2
		7	10	4	14
				2	11
					2
					1
					1
		2	2	1	3
					1
		2	5	1	3
			1		5
				2	7
		7	11	2	17
		1	1		
		9	23	11	77
			1	1	4
			2	3	5
					2
		5	5	1	5
				1	1
			1		
		8	33	22	99

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Photopsia	9	30
Photosensitivity reaction	6	23
pH urine		1
pH urine increased		1
Physical deconditioning		1
Physical disability		1
Pigmentation disorder	3	4
Piloerection	2	7
Pityriasis	1	5
Pityriasis lichenoides et varioliformis acuta	1	1
Pityriasis rosea	5	8
Plantar fasciitis	1	3
Plasma viscosity abnormal	1	1
Platelet anisocytosis		1
Platelet count decreased	15	19
Platelet count increased	2	2
Pleural effusion	4	8
Pleurisy		11
Pleuritic pain	1	7
Plicated tongue		2
Pneumonia	5	24
Pneumonia aspiration		1
Pneumonia bacterial		1
Pneumonia fungal		1
Pneumonia staphylococcal		1
Pneumonitis	2	8
Poisoning	1	3
Pollakiuria	5	17
Polyarthrits	1	4
Polychondritis	1	2
Polychromasia	1	2
Polydipsia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	9	4	21
		1	5	5	18
					1
					1
					1
		1	2	2	2
				2	7
		1	3		2
		1	1		
		2	3	3	5
				1	3
				1	1
					1
		3	3	12	16
				2	2
				4	8
					11
				1	7
			1		1
				5	24
					1
					1
					1
			1	2	7
				1	3
		2	4	3	13
				1	4
				1	2
				1	2
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Polymenorrhoea	3	9
Polymerase chain reaction positive	1	4
Polymyalgia rheumatica	5	17
Polymyositis		1
Polyp	1	1
Polyuria		1
Poor feeding infant	1	1
Poor peripheral circulation		2
Poor quality product administered		1
Poor quality sleep	21	76
Portal vein thrombosis	1	1
Post herpetic neuralgia		3
Postictal state		1
Post laminectomy syndrome		1
Post lumbar puncture syndrome		1
Postmenopausal haemorrhage	5	7
Postprandial hypoglycaemia		1
Post procedural complication		1
Post stroke seizure		1
Post-traumatic stress disorder	1	2
Postural orthostatic tachycardia syndrome	1	7
Posture abnormal	1	1
Post viral fatigue syndrome	14	31
Pouchitis		1
Pre-existing condition improved		2
Pregnancy	1	3
Pregnancy test positive	1	1
Pregnancy with contraceptive device	1	1
Prehypertension	1	1
Premature delivery		1
Premature menarche	1	1
Premature menopause		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	2	5
		1	3		1
				5	17
					1
				1	1
					1
		1	1		
			2		
			1		
	1	10	26	11	50
				1	1
			2		1
					1
					1
				5	7
					1
					1
					1
				1	2
			1	1	6
		1	1		
			1	14	30
					1
			2		
			2	1	1
		1	1		
		1	1	1	1
					1
		1	1		
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Premenstrual syndrome	1	1
Pressure of speech		1
Presyncope	27	161
Preterm premature rupture of membranes		2
Primary cough headache		3
Procedural dizziness	2	3
Procedural nausea		3
Proctalgia		3
Proctitis ulcerative		1
Product administered at inappropriate site	4	21
Product administered to patient of inappropriate age	5	24
Product administration error	1	2
Product complaint		1
Product dose omission issue		2
Productive cough	9	42
Product preparation error	3	6
Product preparation issue		1
Product residue present	1	1
Product taste abnormal		1
Product use issue	52	394
Prolapse	1	1
Prophylaxis of nausea and vomiting		1
Proteinuria	1	2
Pruritus	314	1,024
Pseudofolliculitis		1
Pseudolymphoma		1
Psoriasis	11	22
Psoriatic arthropathy	4	9
Psychiatric symptom		1
Psychogenic seizure	1	5
Psychomotor hyperactivity	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
	1	15	67	12	94
					2
			1		2
		1	1	1	2
					3
			2		1
					1
		4	17		4
		5	22		2
			1	1	1
					1
			1		1
		2	11	7	31
		3	6		
			1		
				1	1
			1		
		44	368	8	26
				1	1
					1
			1	1	1
		161	453	153	571
					1
					1
		2	7	9	15
				4	9
					1
			1	1	4
		2	2	3	6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psychotic disorder	1	5
Psychotic symptom		2
Pulmonary artery dilatation		1
Pulmonary congestion		2
Pulmonary embolism	44	83
Pulmonary f brosis	1	1
Pulmonary function test	1	1
Pulmonary hypertension		2
Pulmonary infarction	1	2
Pulmonary oedema	3	8
Pulmonary pain	8	35
Pulmonary sepsis		1
Pulmonary thrombosis	5	8
Pulpitis dental		1
Pulse abnormal	2	5
Pulseless electrical activity		2
Puncture site bruise	1	1
Puncture site discharge		1
Puncture site swelling	1	1
Pupil fixed	1	1
Pupillary disorder		1
Pupillary reflex impaired	1	2
Pupils unequal	1	3
Purging	1	1
Purple glove syndrome	1	1
Purpura	7	16
Pustular psoriasis		1
Pustule	1	3
Pyelonephritis		1
Pyrexia	1,071	4,187
Q fever	1	5
Quadrantanopia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	4
					2
					1
					2
				44	83
				1	1
				1	1
					2
				1	2
				3	8
		3	7	5	28
					1
				5	8
					1
		1	2	1	3
					2
				1	1
					1
		1	1		1
				1	1
				1	3
				1	1
				1	1
		5	7	2	9
					1
		1	1		2
					1
4	21	496	1476	575	2711
				1	5
				1	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Quality of life decreased	1	2
Radiculitis brachial		2
Radiculopathy	1	2
Radioisotope uptake increased		1
Rales		2
Rash	314	939
Rash erythematous	89	307
Rash macular	36	144
Rash maculo-papular	4	16
Rash morbilliform	3	7
Rash papular	29	78
Rash pruritic	86	277
Rash pustular		2
Rash vesicular	3	17
Raynaud's phenomenon	6	19
Reaction to excipient	1	3
Reaction to preservatives		2
Reaction to previous exposure to any vaccine		1
Reading disorder		1
Rectal haemorrhage	8	24
Rectal injury	1	1
Rectal spasm		1
Red blood cell sedimentation rate increased	2	5
Reduced facial expression	2	2
Reflux gastritis	1	2
Relapsing fever	1	1
Renal cancer		1
Renal colic	1	1
Renal disorder	1	2
Renal failure	2	7
Renal haemorrhage	1	2
Renal impairment	4	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		1
				1	2
					1
					2
		171	421	143	518
1	1	46	128	43	179
		22	73	14	71
		2	6	2	10
		1	3	2	4
		15	35	14	43
		42	103	44	174
					2
		1	6	2	11
		2	7	4	12
				1	3
					2
					1
				8	24
				1	1
			1		
				2	5
		1	1	1	1
			1	1	1
				1	1
					1
		1	1		
				1	2
				2	7
				1	2
				4	6

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Renal pain	17	61
Repetitive speech		1
Respiration abnormal	3	17
Respiratory acidosis		1
Respiratory arrest	2	8
Respiratory depression		1
Respiratory disorder	3	16
Respiratory distress	2	8
Respiratory failure		3
Respiratory rate decreased	1	3
Respiratory rate increased	6	24
Respiratory symptom		1
Respiratory tract infection	1	3
Respiratory tract irritation	1	4
Respiratory tract oedema		1
Restless legs syndrome	8	21
Restlessness	22	57
Retching	6	40
Reticulocyte count decreased	1	1
Retinal artery occlusion	1	1
Retinal artery thrombosis		1
Retinal exudates	2	2
Retinal haemorrhage		2
Retinal migraine	2	5
Retinal tear	1	1
Retinal toxicity		1
Retinal vasculitis	1	1
Retinal vein occlusion	3	5
Retinopathy	1	1
Retroperitoneal haemorrhage		1
Reversed hot-cold sensation		1
Reversible airways obstruction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	21	10	40
					1
		2	5	1	12
					1
	1			2	8
					1
			4	3	12
				2	8
					3
				1	3
		2	6	4	18
	1				1
				1	3
			2	1	2
					1
		2	6	6	15
		6	16	16	41
		4	16	2	24
				1	1
				1	1
					1
				2	2
					2
			1	2	4
				1	1
					1
				1	1
				3	5
				1	1
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Revers ble cerebral vasoconstriction syndrome		1
Rhabdomyolysis		2
Rheumatoid arthritis	20	50
Rheumatoid factor increased		1
Rhinalgia	3	7
Rhinitis	3	16
Rhinitis allergic		2
Rhinorrhoea	43	166
Right ventricular enlargement		1
Right ventricular failure		1
Road traffic accident		1
Rosacea		2
Rotator cuff syndrome	3	5
Rubber sensitivity		1
Sacroiliitis	1	2
Salivary gland enlargement	2	4
Salivary gland pain	2	4
Salivary hypersecretion	2	16
Salt craving		1
Sarcoidosis	3	6
Sarcoma		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative	2	8
SARS-CoV-2 ant body test positive		2
SARS-CoV-2 test		1
SARS-CoV-2 test negative	1	3
SARS-CoV-2 test positive	7	33
Scab	2	3
Scalloped tongue	1	1
Scar	1	4
Scarlet fever	1	1
Scar pain	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
	1			20	50
					1
		2	3	1	4
		1	8	2	8
					2
2	5	19	55	24	111
			1		
					1
					1
			1		1
				3	5
					1
			1	1	1
				2	4
				2	4
		1	8	1	8
					1
				3	6
					1
			1		
			4	2	4
			1		1
					1
			2	1	1
		4	10	3	23
		2	3		
				1	1
				1	4
				1	1
			2	1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sciatica	1	13
Sciatic nerve neuropathy		1
Scintillating scotoma	1	1
Scleral discolouration		1
Scleritis	1	2
Scleroderma associated digital ulcer		1
Scratch	1	6
Screaming		2
Seasonal allergy	5	9
Secondary transmission	1	1
Secretion discharge		3
Sedation	1	3
Sedation complication	1	1
Seizure	37	124
Seizure cluster		3
Seizure like phenomena		1
Self-injurious ideation	1	2
Semen discolouration	1	1
Senile dementia		1
Sensation of blood flow		1
Sensation of foreign body	6	23
Sense of a foreshortened future		1
Sensitisation	1	2
Sensitive skin	21	56
Sensitivity to weather change	1	1
Sensory disturbance	9	34
Sensory loss	15	26
Sepsis	7	16
Septic pulmonary embolism		1
Serositis	1	2
Serum ferritin decreased	1	1
Serum ferritin increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	10
				1	1
			1		
				1	2
					1
			2	1	4
			1		1
		3	4	2	5
				1	1
					3
			1	1	2
				1	1
				37	124
					3
					1
				1	2
				1	1
					1
					1
		4	6	2	17
					1
				1	2
		12	26	9	30
				1	1
		4	17	5	17
		6	9	9	17
				7	16
					1
				1	2
				1	1
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Serum sickness		1
Serum sickness-like reaction		1
Shock	1	11
Shock symptom	1	1
Shoulder injury related to vaccine administration		3
Sialoadenitis		1
Sight disability		1
Sigmoidoscopy abnormal	1	1
Sinonasal obstruction		1
Sinus arrest	2	2
Sinus bradycardia		1
Sinus congestion	2	11
Sinus disorder	1	5
Sinus headache	32	89
Sinusitis	7	23
Sinus node dysfunction		1
Sinus pain	17	50
Sinus tachycardia	1	20
Sitting disability	1	2
Sjogren's syndrome	1	4
Skin abrasion	2	7
Skin burning sensation	16	61
Skin depigmentation		1
Skin discharge		1
Skin discolouration	9	35
Skin disorder	4	9
Skin erosion	2	6
Skin exfoliation	9	23
Skin fissures		1
Skin haemorrhage	4	4
Skin hypertrophy		1
Skin induration		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	11
				1	1
					3
					1
					1
				1	1
					1
				2	2
					1
		1	3	1	8
				1	5
	1	16	32	16	57
		1	2	6	21
					1
		4	12	13	38
			9	1	11
		1	1		1
				1	4
		2	3		4
	1	4	17	12	44
					1
					1
		4	9	5	26
		1	2	3	7
		1	2	1	4
		7	9	2	14
			1		
		2	2	2	2
			1		
			2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin infection	5	6
Skin irritation	14	35
Skin laceration		1
Skin laxity		1
Skin lesion	4	12
Skin mass		6
Skin odour abnormal	1	2
Skin reaction	11	25
Skin sensitisation	6	10
Skin swelling	8	26
Skin temperature	3	5
Skin tightness	4	22
Skin ulcer	2	6
Skin warm	17	71
Skin weeping	1	2
Skull fracture		1
Sleep apnoea syndrome	2	3
Sleep attacks		1
Sleep deficit	1	4
Sleep disorder	57	152
Sleep disorder due to a general medical condition	2	10
Sleep disorder due to general medical condition, insomnia type	6	22
Sleep paralysis		1
Sleep terror	2	5
Slow response to stimuli		1
Slow speech	2	2
Sluggishness	2	10
Small intestinal haemorrhage		1
Sneezing	15	69
Snoring		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	3	3
		5	10	9	25
					1
					1
		3	6	1	6
			1		5
		1	2		
		6	13	5	12
		1	2	5	8
		5	15	3	11
		1	1	2	4
		1	10	3	12
				2	6
		8	29	9	42
				1	2
					1
				2	3
					1
			1	1	3
		27	65	30	87
		2	7		3
		1	8	5	14
			1		
			1	2	4
					1
				2	2
		1	3	1	7
					1
	1	7	30	8	39
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Social avoidant behaviour		1
Social fear		1
Soft tissue infection		1
Soft tissue injury	1	1
Soft tissue swelling	4	4
Solar lentigo	1	1
Somatic symptom disorder		1
Somnolence	84	329
Speech disorder	14	36
Spinal column injury		1
Spinal cord disorder		1
Spinal disorder		2
Spinal fracture	2	2
Spinal osteoarthritis		1
Spinal pain	7	22
Spinal stenosis	1	1
Spleen atrophy		1
Splenic artery embolisation	1	1
Splenic rupture	2	2
Splenomegaly		2
Spondylitis	1	1
Sputum abnormal		1
Sputum discoloured	1	4
Sputum increased		1
Staphylococcal abscess	1	1
Staphylococcal infection	1	3
Staphylococcal sepsis	1	1
Staring	2	3
Status epilepticus	10	21
Steatorrhoea	1	1
Stereotypy		1
Stevens-Johnson syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
				1	1
		2	2	2	2
				1	1
					1
	1	37	109	47	220
	1	5	10	9	26
					1
					1
			1		1
				2	2
					1
		2	6	5	16
				1	1
					1
				1	1
				2	2
					2
				1	1
					1
			1	1	
				1	3
				1	1
				2	3
				10	21
		1	1		
					1
					2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stiff leg syndrome		1
Stiff tongue	1	2
Stillbirth	1	1
Stomatitis	7	20
Strabismus	1	1
Streptococcal abscess	1	1
Stress	10	20
Stress cardiomyopathy	1	2
Stridor	2	7
Subacute inflammatory demyelinating polyneuropathy	1	1
Subarachnoid haemorrhage	1	5
Subclavian vein thrombosis		2
Subcutaneous abscess		1
Subcutaneous haematoma	1	1
Subdural haematoma	1	2
Subdural haemorrhage	1	1
Submaxillary gland enlargement	1	2
Sudden death	2	8
Sudden hearing loss	2	7
Sudden visual loss	1	1
Suffocation feeling		1
Suicidal ideation	5	10
Suicide attempt	2	3
Sunburn	1	3
Superior sagittal sinus thrombosis		1
Suppressed lactation		2
Suprapubic pain		1
Supraventricular tachycardia	3	17
Suspected COVID-19	61	301
Sweating fever	9	41
Swelling	287	659

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		1
				1	1
	1	4	8	3	12
		1	1		
				1	1
		3	7	7	13
				1	2
		1	1	1	6
				1	1
				1	5
					2
					1
		1	1		
				1	2
				1	1
		1	2		
				2	8
				2	7
				1	1
			1		
				5	10
				2	3
		1	1		2
					1
					2
			1		
		1	4	2	13
		31	114	30	187
				9	41
		113	262	174	397

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Swelling face	79	292
Swelling of eyelid	16	47
Swollen joint count increased		1
Swollen tongue	43	207
Symphysiolysis		1
Symptom recurrence	1	2
Syncope	102	435
Synovial cyst		3
Synovitis		2
Syringe issue		1
Systemic candida		1
Systemic immune activation	1	1
Systemic inflammatory response syndrome		2
Systemic lupus erythematosus	5	11
Systemic lupus erythematosus rash	1	4
Systolic hypertension		1
Tachycardia	53	290
Tachyphrenia		2
Tachypnoea	1	15
Tardive dyskinesia	1	1
Taste disorder	28	81
Tearfulness	7	20
Teething		2
Telangiectasia	1	1
Temperature difference of extremities	1	3
Temperature intolerance	5	7
Temperature perception test increased		1
Temperature regulation disorder	1	6
Temporal lobe epilepsy		1
Temporomandibular joint syndrome	1	4
Tenderness	54	129
Tendon injury	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	26	76	53	216
		6	16	10	31
					1
		18	59	25	148
					1
			1	1	1
	1			102	435
					3
					2
			1		
					1
				1	1
					2
	1			5	11
			1	1	3
					1
		24	91	29	199
					2
		1	4		11
				1	1
		14	38	14	43
		2	6	5	14
			1		1
				1	1
				1	3
		1	1	4	6
					1
			2	1	4
					1
			3	1	1
	2	35	80	19	49
				1	3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tendonitis	6	9
Tendon pain		1
Tenosynovitis stenosaurs	1	2
Tension	2	5
Tension headache	41	125
Terminal insomnia	1	3
Testicular pain	1	1
Tetany		2
Therapeutic procedure	1	1
Therapeutic product effect increased		1
Therapeutic product ineffective		1
Therapeutic response unexpected	8	17
Thermal burn	4	7
Thermal burns of eye	1	4
Thinking abnormal	4	14
Thirst	31	101
Throat clearing		4
Throat irritation	17	86
Throat tightness	22	132
Thrombocytopenia	26	39
Thrombocytosis		1
Thrombophlebitis	3	7
Thrombophlebitis superficial	1	4
Thrombosis	37	66
Thrombosis in device	1	2
Thrombotic stroke	1	1
Thrombotic thrombocytopenic purpura	3	4
Thunderclap headache		1
Thyroid disorder	1	1
Thyroid function test abnormal		1
Thyroiditis subacute		1
Thyroid pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	6	8
					1
				1	2
		1	3	1	2
		16	40	25	85
		1	1		2
				1	1
			1		1
		1	1		
					1
					1
		6	10	2	7
		1	2	3	5
				1	4
		1	3	3	11
		9	33	22	68
					4
		8	24	9	62
		11	37	11	95
				26	39
			1		
		1	1	2	6
		1	1		3
	1			37	66
				1	2
				1	1
				3	4
					1
				1	1
			1		
			1		
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thyroxine free increased	1	1
Tinnitus	116	267
Tongue blistering	2	6
Tongue coated	1	4
Tongue cyst	1	1
Tongue discolouration	5	9
Tongue discomfort	7	17
Tongue disorder	3	23
Tongue dry		5
Tongue eruption	1	5
Tongue erythema		1
Tongue haemorrhage	1	1
Tongue injury		1
Tongue movement disturbance	1	3
Tongue oedema	2	12
Tongue paralysis		1
Tongue pruritus	2	5
Tongue rough		1
Tongue spasm	1	2
Tongue ulceration	4	12
Tonic clonic movements	1	3
Tonic convulsion		6
Tonsillar disorder		1
Tonsillar erythema	1	2
Tonsillar hypertrophy	5	14
Tonsillar inflammation	1	3
Tonsillitis	4	15
Tonsillitis bacterial	1	2
Toothache	14	33
Tooth disorder		1
Tooth extraction	1	1
Tooth fracture	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		26	55	90	212
			1	2	5
		1	2		2
				1	1
		2	4	3	5
		3	6	4	11
			3	3	20
			2		3
		1	2		3
			1		
		1	1		
					1
			1	1	2
		1	2	1	10
					1
		1	2	1	3
			1		
				1	2
		2	6	2	6
				1	3
					6
					1
		1	1		1
		4	6	1	8
		1	2		1
1	1	1	3	3	12
				1	2
		4	10	10	23
			1		
				1	1
				1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Torticollis		1
Toxic epidermal necrolysis		1
Toxicity to various agents	1	2
Toxic skin eruption		1
Tracheal inflammation		1
Tracheal pain		1
Tracheitis	1	2
Transferrin decreased	1	1
Transient global amnesia		2
Transient ischaemic attack	26	45
Traumatic haemorrhage		1
Tremor	135	553
Trichodynia		1
Trigeminal neuralgia	4	10
Trigger finger	1	3
Tri-iodothyronine		1
Tri-iodothyronine decreased		2
Triple negative breast cancer	1	1
Trismus	5	9
Troponin increased	1	6
Tubulointerstitial nephritis		1
Tumefactive multiple sclerosis	1	1
Tunnel vision	2	4
Tympanic membrane hyperaemia	1	1
Type 1 diabetes mellitus	2	7
Type 2 diabetes mellitus	2	3
Type I hypersensitivity		1
Type IV hypersensitivity reaction	1	4
Typical aura without headache	1	1
Ulcer	1	4
Ulcerative keratitis		4
Ulnar nerve injury		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	2
					1
			1		
			1		
		1	1		1
		1	1		
					2
				26	45
					1
	3	62	160	73	393
					1
		1	1	3	9
			1	1	2
			1		
					2
				1	1
		1	1	4	8
				1	6
					1
				1	1
				2	4
				1	1
				2	7
				2	3
					1
		1	1		3
				1	1
				1	4
					4
					3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ulnar neuritis	1	1
Underdose		6
Underweight	2	2
Unresponsive to stimuli	2	22
Upper-airway cough syndrome	1	5
Upper airway obstruction		2
Upper limb fracture	1	5
Upper respiratory tract congestion	1	2
Upper respiratory tract infection	1	3
Urinary incontinence	4	23
Urinary retention	2	17
Urinary tract disorder		1
Urinary tract infection	14	56
Urinary tract infection bacterial		1
Urinary tract pain		1
Urine abnormality		1
Urine analysis abnormal		2
Urine flow decreased	1	2
Urine odour abnormal		4
Urine output	1	2
Urine output decreased	2	4
Urine output increased		1
Urosepsis		1
Urticaria	118	392
Urticaria chronic	3	4
Urticaria papular	1	1
Urticaria thermal	1	1
Uterine contractions abnormal		1
Uterine haemorrhage	3	3
Uterine pain		2
Uterine spasm		1
Uveitis	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			6		
				2	2
				2	22
			2	1	3
					2
				1	5
				1	2
				1	3
		1	5	3	18
				2	17
					1
1	1	2	7	12	49
					1
			1		1
			1		1
				1	2
			1		3
		1	1		1
		1	2	1	2
			1		
					1
		74	157	44	235
				3	4
		1	1		
		1	1		
					1
				3	3
					2
			1		
				1	7

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Uvulitis	1	1
Vaccination complication	8	18
Vaccination error		1
Vaccination failure	1	6
Vaccination site abscess	2	5
Vaccination site bruising	29	86
Vaccination site calcification	1	1
Vaccination site cellulitis	2	23
Vaccination site coldness		1
Vaccination site discharge		1
Vaccination site discolouration	1	8
Vaccination site discomfort	15	57
Vaccination site dryness		2
Vaccination site eczema	1	1
Vaccination site erythema	165	584
Vaccination site haematoma		2
Vaccination site haemorrhage	5	18
Vaccination site hyperaesthesia		5
Vaccination site hypersensitivity	2	4
Vaccination site hypoaesthesia	3	17
Vaccination site induration	23	68
Vaccination site infection	6	22
Vaccination site inflammation	19	55
Vaccination site irritation	3	8
Vaccination site joint discomfort	1	1
Vaccination site joint erythema	2	3
Vaccination site joint movement impairment		14
Vaccination site joint pain		9
Vaccination site joint swelling	1	1
Vaccination site joint warmth	1	1
Vaccination site lymphadenopathy	7	21
Vaccination site macule		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	7	4	11
			1		
				1	6
		2	3		2
		16	42	13	44
				1	1
		1	5	1	18
					1
					1
		1	4		4
		9	31	6	26
			1		1
		1	1		
		107	328	58	256
					2
		2	5	3	13
			2		3
		2	2		2
		1	6	2	11
		16	42	7	26
		3	7	3	15
		14	31	5	24
		1	3	2	5
		1	1		
		2	2		1
			6		8
			3		6
		1	1		
		1	1		
		1	7	6	14
			2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site mass	64	210
Vaccination site movement impairment	18	64
Vaccination site necrosis	1	2
Vaccination site nodule		1
Vaccination site oedema	3	9
Vaccination site pain	633	2,324
Vaccination site papule		1
Vaccination site paraesthesia	3	28
Vaccination site pruritus	70	226
Vaccination site rash	31	117
Vaccination site reaction	8	42
Vaccination site scab		1
Vaccination site scar		2
Vaccination site swelling	167	618
Vaccination site urticaria	2	14
Vaccination site vesicles	3	8
Vaccination site warmth	66	296
Vaccine breakthrough infection	4	4
Vaginal cyst	1	2
Vaginal discharge		2
Vaginal disorder	1	2
Vaginal haemorrhage	20	50
Vaginal ulceration	1	1
Varicella	4	5
Varicose vein	2	5
Vascular dementia	1	3
Vascular headache	1	7
Vascular injury	2	3
Vascular pain	1	2
Vascular stent thrombosis	1	1
Vasculitic rash	2	6
Vasculitis	11	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	32	95	32	115
		6	26	12	38
				1	2
					1
		2	4	1	5
1	8	360	1088	273	1236
					1
		2	13	1	15
		50	133	20	93
		19	60	12	57
		2	20	6	22
					1
			1		1
		100	298	67	320
		1	8	1	6
		1	1	2	7
		42	146	24	150
				4	4
				1	2
			1		1
			1	1	1
		6	12	14	38
				1	1
		1	2	3	3
			2	2	3
				1	3
		1	3		4
				2	3
			1	1	1
				1	1
		1	2	1	4
		5	6	6	15

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vasodilatation	3	9
Vasospasm		1
Vein discolouration	1	1
Vein disorder	1	4
Vein rupture		2
Venous haemorrhage		1
Venous injury	2	2
Venous thrombosis	3	3
Ventricular arrhythmia		2
Ventricular extrasystoles		4
Ventricular fibrillation		3
Ventricular hypertrophy		1
Ventricular tachycardia	1	2
Vertebral lesion	1	1
Vertigo	106	296
Vertigo labyrinthine	1	3
Vertigo positional	7	20
Vestibular disorder	1	3
Vestibular migraine	2	6
Vestibular neuritis	1	4
Viral infection	5	10
Viral labyrinthitis	2	4
Viral pharyngitis		4
Viral rash	2	10
Viral test		1
Viral tonsillitis		1
Vision blurred	73	243
Visual acuity reduced	4	7
Visual brightness		1
Visual field defect	3	9
Visual impairment	35	101
Vital capacity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	2	7
			1		
		1	1		
				1	4
					2
					1
				2	2
				3	3
					2
					4
					3
					1
				1	2
				1	1
	1	25	55	81	241
				1	3
		2	2	5	18
			1	1	2
			1	2	5
				1	4
		1	3	4	7
			2	2	2
					4
		1	4	1	6
					1
					1
		22	70	51	173
		1	2	3	5
			1		
			2	3	7
		11	34	24	67
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vitamin B12 decreased	1	1
Vitamin D	1	1
Vitamin D deficiency		1
Vlth nerve paralysis	1	3
Vitreous detachment	4	7
Vitreous floaters	3	14
Vitreous haemorrhage	1	1
Vocal cord disorder		1
Vomiting	313	1,182
Vomiting projectile	7	25
Vomiting psychogenic		1
Vth nerve injury		1
Vulval abscess		1
Vulval haemorrhage	2	4
Vulval oedema		1
Vulval ulceration	1	1
Vulvovaginal burning sensation	1	1
Vulvovaginal candidiasis	3	9
Vulvovaginal pain	1	5
Vulvovaginal pruritus		1
Vulvovaginal rash		1
Vulvovaginal swelling		1
Vulvovaginal ulceration	2	3
Water pollution	1	1
Weight bearing difficulty	2	5
Weight decreased	10	28
Weight increased	1	2
Weight loss diet		1
Wheat-free diet	1	1
Wheezing	25	138
White blood cell count abnormal	1	1
White blood cell count decreased	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
					1
				1	3
				4	7
			5	3	9
				1	1
					1
1	5	104	343	209	839
		3	6	4	19
					1
					1
				2	4
			1		
		1	1		
				1	1
		1	2	2	7
			2	1	3
			1		
			1		
					1
				2	3
				1	1
		1	3	1	2
		2	6	8	22
		1	1		1
					1
				1	1
		13	39	12	99
				1	1
		1	1	3	6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased	4	11			1	4	3	7
Withdrawal syndrome		1						1
Wound	1	4				2	1	2
Wound complication		2				1		1
Wound haemorrhage		1						1
Wound secretion		1						1
Wrist fracture		1						1
Writer's cramp		1						1
Wrong product administered	2	3			2	3		
Wrong technique in product usage process		2				1		1
Yawning	3	8			1	1	2	7
Yellow skin		5				3		2
	2	15			2	15		
	31,240	104,999	76	397	12646	35112	18594	69887

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions		1					1	
Abdominal discomfort	10	47			2	10	8	37
Abdominal distension	5	20			3	9	2	11
Abdominal infection	1	1					1	1
Abdominal lymphadenopathy	1	1					1	1
Abdominal pain	22	83		2	5	19	17	64
Abdominal pain lower	2	8			1	2	1	6
Abdominal pain upper	17	102			4	23	13	79
Abdominal rigidity		1						1
Abnormal behaviour	2	3				1	2	2
Abnormal dreams	6	17			5	10	1	7
Abnormal faeces		1						1
Abnormal loss of weight		1						1
Abnormal sensation in eye	1	2				1	1	1
Abnormal weight gain		2						2
Abscess	1	1					1	1
Acarodermatitis	1	1					1	1
Accidental overdose		1				1		
Acidosis	1	2					1	2
Acne	2	5					2	5
Acoustic neuroma		1						1
Acquired haemophilia		1						1
Activated partial thromboplastin time prolonged	1	1					1	1
Acute abdomen	2	2					2	2
Acute cardiac event		2						2
Acute coronary syndrome	2	2					2	2
Acute disseminated encephalomyelitis	1	1					1	1
Acute kidney injury	3	14					3	14
Acute leukaemia		1						1
Acute myocardial infarction	4	10					4	10
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		1						1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute respiratory failure		1
Administration site discomfort	1	1
Adrenocortical insufficiency acute		1
Adverse drug reaction		4
Affect lability	1	1
Ageusia	11	32
Aggression	1	4
Agitation	3	10
Alanine aminotransferase increased	1	3
A buminuria	1	1
Alcoholic hangover		1
Alcohol interaction		1
Alexia		1
Alexithymia		1
Allergic cough		1
Allergic oedema		2
Allergic sinusitis		1
Allergy to vaccine		6
Allodynia		2
Alopecia	1	4
Altered state of consciousness		1
Amegakaryocytic thrombocytopenia		1
Ammonia abnormal		1
Amnesia	9	19
Anaemia		5
Anaemia megaloblastic	1	1
Anaemia vitamin B12 deficiency	1	1
Anal haemorrhage	1	2
Anal incontinence	1	6
Anal pruritus	1	1
Anaphylactic reaction	1	36
Anaphylactic shock	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
			4		1
		1	1		
		2	8	9	24
			1	1	3
		1	4	2	6
				1	3
				1	1
					1
					1
			1		
			1		
					1
					2
					1
			4		2
					2
			1	1	3
					1
					1
			1		
			4	8	15
					5
				1	1
		1	1		
				1	2
			1	1	5
				1	1
				1	36
				3	5

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactoid reaction		1
Anaphylactoid shock		2
Anger		2
Angina pectoris	6	15
Angioedema	2	16
Ankylosing spondylitis		2
Anorectal discomfort		1
Anosmia	6	27
Anticoagulation drug level below therapeutic	1	1
Anxiety	10	42
Aortic aneurysm		1
Aortic aneurysm rupture		1
Aortic dissection		1
Apathy	1	7
Aphasia	4	10
Aphonia	1	3
Aphthous ulcer		2
Apparent death		1
Appendicitis	1	5
Appendicitis perforated	1	1
Appetite disorder		1
Application site vesicles	1	1
Arrhythmia	2	10
Arrhythmia supraventricular		3
Arterial occlusive disease		1
Arterial rupture		1
Arterial thrombosis	1	1
Arteriospasm coronary		1
Arthralgia	170	677
Arthritis	8	20
Arthritis bacterial		1
Arthritis reactive	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
			2		
				6	15
				2	16
					2
					1
		1	7	5	20
				1	1
		1	6	9	36
					1
					1
					1
			1	1	6
				4	10
				1	3
					2
					1
				1	5
				1	1
					1
				1	1
				2	10
					3
					1
					1
				1	1
					1
1	8	65	186	105	491
		1	2	7	18
					1
				1	6

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthritis viral		1
Arthropathy	1	5
Ascites		1
Aspartate aminotransferase increased		2
Aspiration		2
Asthenia	42	202
Asthenopia	5	11
Asthma	3	20
Asthma late onset		1
Asymptomatic COVID-19	4	6
Ataxia	2	3
Atonic seizures	1	1
Atrial fibrillation	16	49
Atrial flutter	2	4
Atrial tachycardia		2
Atrioventricular block	1	1
Atrioventricular block complete	2	2
Attention deficit hyperactivity disorder	1	1
Auditory disorder		1
Aura		1
Auricular swelling		2
Autoimmune disorder	1	2
Autoimmune haemolytic anaemia	1	1
Autoimmune neutropenia	2	2
Autoscopy	2	2
Axillary mass	2	9
Axillary pain	15	48
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation		1
Back pain	44	177
Bacterial infection	1	2
Balance disorder	20	64

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	5
					1
					2
					2
	1	12	54	30	148
		3	3	2	8
			2	3	18
					1
			2	4	4
				2	3
				1	1
1	1			16	49
				2	4
			1		1
				1	1
				2	2
				1	1
			1		
					1
					2
				1	2
				1	1
				2	2
				2	2
		1	3	1	6
		5	24	10	24
					1
			1		
	1	13	45	31	132
				1	2
	1	3	10	17	54

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Basal cell carcinoma		1
B-cell lymphoma		1
Bedridden		5
Behaviour disorder		3
Bile duct stone		1
Biliary sepsis		1
Binge eating		1
Bite		1
Bladder disorder		2
Bladder neoplasm	1	1
Bladder pain		1
Blepharitis		1
Blepharospasm	1	3
Blindness	8	16
Blindness transient		1
Blindness unilateral	1	2
Blister	10	26
Blister infected		1
Blood albumin decreased		1
Blood blister	3	4
Blood cholesterol increased	2	2
Blood count abnormal	2	2
Blood creatine phosphokinase increased		2
Blood electrolytes increased		1
Blood glucose		1
Blood glucose abnormal		3
Blood glucose decreased	1	8
Blood glucose fluctuation	1	4
Blood glucose increased	4	25
Blood growth hormone abnormal		1
Blood heavy metal increased		1
Blood immunoglobulin E increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					5
					3
					1
					1
					1
					1
					2
				1	1
					1
					1
		1	1		2
				8	16
					1
				1	2
		3	5	7	21
			1		
					1
				3	4
				2	2
				2	2
			1		1
			1		
					1
			1		2
			3	1	5
				1	4
			8	4	17
			1		
			1		
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood iron increased	1	1
Blood lactic acid increased	1	2
Blood pH increased		1
Blood phosphorus decreased		1
Blood potassium decreased		2
Blood pressure abnormal		1
Blood pressure decreased	4	14
Blood pressure diastolic decreased		1
Blood pressure diastolic increased		3
Blood pressure fluctuation	2	2
Blood pressure increased	11	36
Blood pressure systolic decreased	1	2
Blood pressure systolic increased		1
Blood sodium decreased	1	2
Blood test abnormal	1	2
Blood thrombin	1	1
Blood urea increased		1
Blood urine present	3	6
Blood viscosity increased		1
Blue toe syndrome	1	1
Body temperature	2	2
Body temperature abnormal	2	7
Body temperature decreased	1	5
Body temperature fluctuation	2	10
Body temperature increased	7	44
Bone pain	4	34
Bone swelling		1
Bradycardia	1	7
Bradyphrenia		2
Brain hypoxia		1
Brain neoplasm		1
Brain stem stroke		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		1
					1
					1
					2
					1
		2	3	2	11
			1		
					3
				2	2
			6	11	30
				1	2
			1		
			1	1	1
				1	2
				1	1
			1		
				3	6
			1		
				1	1
		2	2		
			2	2	5
			1	1	4
			3	2	7
		4	23	3	21
2	3	1	9	3	25
			1		
				1	7
					2
					1
					1
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Brain stem syndrome		2
Breast mass	1	1
Breath odour		4
Breath sounds abnormal		1
Bronchiectasis		1
Bruxism	1	2
Bulbar palsy	1	1
Bulimia nervosa		1
Bundle branch block	1	1
Bundle branch block right		3
Burning sensation	8	20
Bursitis	2	3
Cachexia		1
Cardiac arrest	3	37
Cardiac discomfort		1
Cardiac disorder	2	3
Cardiac failure	1	5
Cardiac failure acute	2	2
Cardiac failure chronic	1	1
Cardiac flutter	2	11
Cardiac valve disease		1
Cardiogenic shock		1
Cardiomegaly		1
Cardio-respiratory arrest		1
Cardiovascular disorder	1	1
Carotid artery disease	1	1
Carotid artery dissection		1
Carpal tunnel syndrome	3	3
Cataract	1	1
Catarrh	1	2
Catatonia		1
Cellulitis	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
			2		2
					1
					1
				1	2
				1	1
					1
				1	1
			1		2
		3	6	5	14
		1	1	1	2
					1
				3	37
					1
		1	2	1	1
				1	5
				2	2
				1	1
				2	11
					1
					1
			1		
					1
				1	1
				1	1
					1
		1	1	2	2
				1	1
		1	2		
					1
				5	8

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Central nervous system lesion	1	1
Central venous pressure abnormal	1	1
Central vision loss		1
Cerebellar infarction		2
Cerebral artery embolism	1	1
Cerebral artery thrombosis	1	1
Cerebral disorder		1
Cerebral haemorrhage	5	8
Cerebral infarction	6	12
Cerebral thrombosis	5	6
Cerebral venous sinus thrombosis	7	7
Cerebral venous thrombosis	1	1
Cerebrovascular accident	30	70
Cervicobrachial syndrome		1
Cervicogenic headache		1
Change of bowel habit	1	1
Chest discomfort	18	79
Chest pain	54	179
Chillblains	8	9
Chills	140	741
Choking	2	4
Choking sensation		1
Cholangitis	1	1
Chondritis		1
Chorea		1
Chromaturia	3	7
Chronic fatigue syndrome	2	4
Chronic kidney disease	1	1
Chronic obstructive pulmonary disease	4	9
Circulatory collapse	7	28
Clonic convulsion		1
Clostridium test positive	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
					1
					2
				1	1
				1	1
					1
				5	8
				6	12
				5	6
				7	7
				1	1
				30	70
					1
					1
				1	1
		8	19	10	60
	1	12	33	42	146
		7	7	1	2
	3	70	235	70	506
				2	4
					1
				1	1
					1
					1
		2	4	1	3
1	1			2	4
				1	1
				4	9
				7	28
					1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clumsiness	1	2
Cluster headache	4	11
Coagulation time prolonged		1
Coeliac disease		1
Cognitive disorder	3	14
Cold-stimulus headache	1	2
Cold sweat	10	57
Colitis	1	4
Colitis ulcerative	3	5
Coma	1	2
Coma scale abnormal		3
Communication disorder	2	3
Concussion		1
Condition aggravated	16	55
Confusional state	31	111
Conjunctival haemorrhage	1	4
Conjunctival hyperaemia		1
Conjunctivitis	2	6
Constipation	7	26
Contraindicated product prescribed	1	1
Contusion	17	34
Conversion disorder	1	1
Coordination abnormal	4	12
Corneal reflex decreased		1
Coronary artery disease	1	3
Coronary artery thrombosis	1	1
Coronavirus test positive		1
Cortisol decreased		1
Costochondritis		2
Cough	40	155
Cough decreased	1	1
COVID-19	32	167

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	2	3	9
					1
			1	3	13
		1	1		1
		5	16	5	41
				1	4
1	1			3	5
				1	2
					3
			1	2	2
			1		
1	1	6	14	10	41
		5	20	26	91
				1	4
					1
		1	2	1	4
		2	6	5	20
		1	1		
	1	7	13	10	21
				1	1
				4	12
			1		
				1	3
				1	1
			1		
					1
					2
		15	54	25	101
			1		
		9	28	23	139

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19 immunisation	1	2
COVID-19 pneumonia	2	11
Cranial nerve disorder		1
C-reactive protein increased	4	13
Creutzfeldt-Jakob disease		1
Crohn's disease	1	5
Crying	3	6
Crystal arthropathy		1
CT hypotension complex		1
Cutaneous vasculitis		1
Cyanopsia		1
Cyanosis	2	4
Cystitis		2
Dark circles under eyes	1	1
Deafness	7	20
Deafness neurosensory		3
Deafness unilateral		4
Death	6	53
Decreased appetite	26	156
Decreased insulin requirement	1	1
Decreased interest		1
Deep vein thrombosis	26	41
Dehydration	5	19
Deja vu	1	1
Delirium	7	31
Delusion	1	2
Dementia		5
Dementia with Lewy bodies		1
Demyelination	2	2
Dental discomfort		1
Depersonalisation/derealisation disorder	1	1
Depressed level of consciousness	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
				2	11
					1
		1	5	3	8
					1
				1	5
		2	3	1	3
					1
					1
					1
			2	2	2
					2
				1	1
				7	20
					3
					4
				6	53
	1	6	38	20	118
				1	1
					1
				26	41
		2	6	3	13
				1	1
				7	31
			1	1	1
					5
					1
				2	2
					1
				1	1
				1	7

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depressed mood	5	15
Depression	9	22
Depression suicidal		1
Derealisation	1	1
Dermatitis	6	9
Dermatitis acneiform		1
Dermatitis allergic	2	11
Dermatitis atopic	1	2
Dermatitis bullous		2
Dermatitis contact	1	1
Dermatitis exfoliative		1
Dermatitis infected		1
Dermatosis		1
Device infusion issue		1
Device pacing issue	1	1
Diabetes mellitus	3	10
Diabetes mellitus inadequate control	1	3
Diabetic coma	1	1
Diabetic ketoacidosis	1	3
Diarrhoea	74	331
Diarrhoea haemorrhagic	1	2
Diplegia		1
Diplopia	5	19
Discoloured vomit	1	1
Discomfort	7	26
Disease progression		1
Disease recurrence	19	62
Disorganised speech		1
Disorientation	10	28
Disseminated varicella zoster virus infection		1
Dissociation	1	2
Dissociative disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	4	14
		2	2	7	20
					1
				1	1
		1	3	5	6
					1
		1	3	1	8
				1	2
					2
				1	1
					1
			1		
			1		
					1
				1	1
				3	10
				1	3
				1	1
				1	3
	1	21	70	53	261
				1	2
					1
		3	5	2	14
				1	1
		2	14	5	12
					1
			6	19	56
					1
		2	5	8	23
					1
		1	1		1
			1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Disturbance in attention	12	38
Diverticulum		1
Diverticulum intestinal	1	1
Dizziness	138	520
Dizziness exertional	2	7
Dizziness postural	9	36
Dreamy state		1
Drooling	3	4
Drug eruption		2
Drug hypersensitivity		1
Drug-induced liver injury	1	1
Drug ineffective	34	167
Drug interaction		1
Dry eye	1	8
Dry mouth	1	25
Dry skin	7	11
Dry throat	6	10
Duodenal ulcer perforation		1
Dupuytren's contracture	1	1
Dysarthria	6	24
Dyschezia	1	2
Dysdiadochokinesis	1	1
Dysentery		1
Dysgeusia	13	49
Dysgraphia		1
Dyskinesia	3	7
Dyspepsia	7	19
Dysphagia	5	21
Dysphemia	1	1
Dysphonia	3	12
Dyspnoea	79	300
Dyspnoea at rest	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	3	11	9	27
			1		
				1	1
	2	64	153	74	367
				2	7
		3	6	6	30
					1
		1	2	2	2
			1		1
					1
				1	1
				34	167
			1		
		1	3		5
			9	1	16
			2	7	9
		3	3	3	7
					1
				1	1
			2	6	22
		1	2		
				1	1
					1
		8	29	5	20
					1
			1	3	6
		1	4	6	15
			2	5	19
		1	1		
			1	3	11
		10	47	69	253
				1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea exertional	1	15
Dyssomnia	1	1
Dysstasia	8	17
Dystonia		2
Dysuria	8	16
Ear congestion		1
Ear discomfort		6
Ear disorder		2
Ear haemorrhage	1	1
Ear infection	2	5
Ear pain	8	39
Ear pruritus		2
Ear swelling	1	4
Eating disorder		4
Eating disorder symptom		1
Eczema	3	12
Eczema eyelids		1
Eczema herpeticum	1	1
Eczema nummular		1
Electric shock		1
Electrocardiogram abnormal		1
Electrocardiogram ST segment abnormal		1
Electrocardiogram ST segment elevation		2
Embolic cerebral infarction	1	1
Embolism	15	17
Emotional disorder	1	3
Emotional distress	1	4
Emphysema		1
Encephalitis	1	2
Encephalitis viral	2	2
Encephalopathy		1
Energy increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6	1	9
		1	1		
		1	3	7	14
					2
		3	6	5	10
			1		
			2		4
			1		1
				1	1
			2	2	3
		1	11	7	28
			1		1
				1	4
			3		1
					1
	1	1	4	2	8
			1		
				1	1
			1		
			1		
					1
					1
					2
				1	1
				15	17
				1	3
		1	2		2
					1
				1	2
				2	2
					1
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Enlarged uvula	1	4
Enteritis	1	2
Enuresis		1
Epididymitis		2
Epigastric discomfort	1	1
Epiglottic oedema		1
Epiglottitis	1	1
Epilepsy	10	25
Epistaxis	26	55
Erectile dysfunction	3	12
Erection increased	1	2
Eructation		5
Erythema	35	82
Erythema multiforme	3	4
Erythema nodosum	2	2
Erythema of eyelid	1	2
Erythroplasia		2
Essential hypertension		1
Essential tremor		1
Euphoric mood	1	3
Evans syndrome	1	1
Exercise tolerance decreased	2	3
Exertional headache		1
Expired product administered	1	2
Exploding head syndrome		1
Exposure via breast milk	4	9
Extensive swelling of vaccinated limb		1
External ear inflammation		1
Extrasystoles	1	8
Extremity necrosis	1	1
Eye contusion	1	1
Eye disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		3
			1	1	1
					1
					2
				1	1
					1
				1	1
				10	25
		10	15	16	40
				3	12
				1	2
			2		3
		17	30	18	52
				3	4
		1	1	1	1
			1	1	1
			1		1
					1
					1
				1	3
				1	1
		2	2		1
					1
			1	1	1
					1
		1	2	3	7
					1
					1
				1	8
				1	1
		1	1		
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eye haemorrhage	3	3
Eye infection		2
Eye inflammation		1
Eye irritation	1	7
Eyelid disorder		2
Eyelid function disorder	1	2
Eyelid pain		1
Eyelid ptosis	1	3
Eye movement disorder	1	4
Eye pain	12	64
Eye pruritus	1	12
Eye swelling	6	19
Eye ulcer	1	1
Face injury		1
Face oedema		3
Facial asymmetry		1
Facial discomfort		2
Facial nerve disorder		1
Facial neuralgia		1
Facial pain	8	19
Facial paralysis	34	105
Facial paresis	1	8
Facial spasm		4
Faecal calprotectin increased	1	1
Faecaloma		2
Faeces discoloured	1	8
Faeces hard	1	1
Faeces pale		2
Fall	16	49
Fatigue	299	1,359
Fear	1	2
Fear of falling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
					2
					1
			2	1	5
			1		1
				1	2
			1		
			2	1	1
				1	4
		2	12	10	52
		1	3		9
		3	5	3	14
		1	1		
					1
			1		2
			1		
			1		1
		1	6	7	13
				34	105
			4	1	4
			1		3
				1	1
					2
			4	1	4
				1	1
			2		
		4	11	12	38
5	25	120	402	179	957
			1	1	1
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeding disorder	2	13
Feeling abnormal	33	111
Feeling cold	27	134
Feeling drunk	4	10
Feeling hot	12	79
Feeling jittery	1	2
Feeling of body temperature change	10	25
Feeling of despair		1
Fibrin D dimer increased	3	4
Fibromyalgia		2
Fixed eruption		1
Flank pain	2	8
Flashback		1
Flatulence	7	24
Fluid retention		2
Flushing	3	22
Foaming at mouth	1	1
Folliculitis		1
Food poisoning	1	1
Food refusal		1
Forced expiratory volume increased		1
Foreign body sensation in eyes		3
Formication		2
Foveal reflex abnormal	1	1
Fractured skull depressed		1
Freezing phenomenon		1
Frequent bowel movements		4
Full blood count increased		1
Functional gastrointestinal disorder	1	1
Furuncle		6
Gait disturbance	32	77
Gait inability	5	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			7	2	6
	2	7	26	26	85
		8	42	19	92
		2	3	2	7
		7	35	5	44
				1	2
		4	9	6	16
					1
		1	2	2	2
			1		1
			1		
			1	2	7
					1
		2	7	5	17
					2
		3	11		11
				1	1
			1		
				1	1
					1
					3
					2
				1	1
					1
					1
					4
					1
				1	1
			1		5
		4	16	28	61
		2	6	3	25

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric cancer		1
Gastric dilatation		1
Gastric disorder		2
Gastric haemorrhage		2
Gastric varices haemorrhage		1
Gastritis		3
Gastroenteritis		8
Gastroenteritis viral		1
Gastrointestinal carcinoma	1	1
Gastrointestinal disorder	3	5
Gastrointestinal haemorrhage	1	2
Gastrointestinal pain	2	8
Gastrointestinal sounds abnormal		1
Gastrooesophageal reflux disease		8
Gastroschisis	1	1
Generalised tonic-clonic seizure	4	8
General physical health deterioration	2	3
Genital herpes	1	2
Genital pain		1
Genitourinary symptom		1
Giant cell arteritis		1
Gingival bleeding	2	2
Gingival blister	1	1
Gingival discomfort	1	1
Gingival disorder		2
Gingival pain		5
Gingival swelling		2
Glassy eyes		1
Glaucoma	1	2
Gliososis		1
Glomerulonephritis		1
Glomerulonephritis minimal lesion	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					2
					2
					1
			1		2
			1		7
					1
				1	1
			2	3	3
				1	2
		1	1	1	7
					1
					8
				1	1
				4	8
				2	3
				1	2
					1
					1
					1
				2	2
		1	1		
				1	1
			1		1
					5
					2
					1
				1	2
					1
					1
				1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glomerulonephritis rapidly progressive		1
Glossodynia	4	10
Glucose urine present		1
Gonorrhoea		1
Gout	7	20
Gouty tophus	1	1
Graft versus host disease	1	1
Grip strength decreased	2	5
Groin pain	5	10
Guillain-Barre syndrome	6	12
Guttate psoriasis	1	1
Haemangioma		1
Haemarthrosis	1	1
Haematemesis		4
Haematochezia		5
Haematoma	1	5
Haematuria	3	6
Haemodynamic instability		1
Haemoglobin decreased		3
Haemoptysis	2	6
Haemorrhage	9	17
Haemorrhage intracranial	1	3
Haemorrhage subcutaneous	1	1
Haemorrhage urinary tract	1	3
Haemorrhagic stroke	1	1
Haemorrhoids	1	2
Hair texture abnormal	2	2
Hallucination	2	13
Hallucination, auditory		1
Hallucination, olfactory		1
Hallucinations, mixed		1
Hallucination, visual	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	4	3	6
					1
					1
				7	20
				1	1
				1	1
		2	2		3
		2	2	3	8
				6	12
				1	1
			1		
				1	1
					4
					5
		1	3		2
		1	1	2	5
					1
			2		1
		1	1	1	5
	1			9	17
				1	3
				1	1
				1	3
				1	1
				1	2
		1	1	1	1
				2	13
					1
					1
					1
				1	4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hand-arm vibration syndrome		1
Hand-eye coordination impaired		1
Hand fracture		1
Hangover	3	9
Headache	352	1,525
Head discomfort	7	16
Head injury	4	13
Heart disease congenital		1
Heart injury	1	4
Heart rate	1	2
Heart rate abnormal	1	5
Heart rate decreased	4	14
Heart rate increased	16	58
Heart rate irregular	5	12
Heart sounds abnormal	1	1
Heat stroke		1
Hemianopia homonymous	1	1
Hemiparesis	3	8
Hemiplegia	2	2
Hepatic artery embolism		1
Hepatic cirrhosis		1
Hepatic enzyme increased	1	3
Hepatic failure		1
Hepatic pain		2
Hepatitis	1	1
Hepatitis viral	1	2
Herpes ophthalmic		1
Herpes simplex		1
Herpes simplex encephalitis		1
Herpes simplex reactivation	1	1
Herpes virus infection	1	4
Herpes zoster	15	93

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
		1	2	2	7
2	8	161	494	191	1031
		1	4	6	12
			2	4	11
					1
				1	4
				1	2
				1	5
			2	4	12
		5	15	11	43
		1	1	4	11
				1	1
					1
				1	1
				3	8
				2	2
					1
					1
			2	1	1
					1
					2
				1	1
				1	2
					1
					1
		1	1		
		1	1		3
			23	15	70

\* I=Interval, C=Cumulative

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster oticus		2
Herpes zoster reactivation		1
Hiccups		1
Hordeolum		2
Horner's syndrome		1
Hot flush	10	46
Hyperacusis	2	5
Hyperaesthesia	2	10
Hypercoagulation	1	1
Hyperglycaemia	4	15
Hyperhidrosis	35	193
Hyperkalaemia		2
Hypersensitivity	10	36
Hypersensitivity pneumonitis		1
Hypersomnia	5	27
Hypertension	21	57
Hypertensive crisis	1	1
Hypertensive heart disease		1
Hyperthermia		3
Hyperthyroidism	2	2
Hypertonic bladder		1
Hypertrophic cardiomyopathy		1
Hyperventilation		5
Hypnagogic hallucination		1
Hypoacusis	8	12
Hypoaesthesia	40	108
Hypoaesthesia oral	3	11
Hypocalcaemia		1
Hypogeusia		1
Hypoglycaemia	2	14
Hypoglycaemic coma		1
Hypokalaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
					2
					1
		2	15	8	31
				2	5
		1	7	1	3
				1	1
				4	15
	1	11	59	24	134
					2
		1	8	9	28
					1
		2	9	3	18
		6	8	15	49
				1	1
					1
					3
				2	2
			1		
					1
			2		3
					1
		3	5	5	7
	1	13	28	27	80
		3	5		6
					1
					1
			2	2	12
					1
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypokinesia	6	8
Hyponatraemia		1
Hypophagia	3	5
Hypopnoea		5
Hyporeflexia		2
Hyposmia		2
Hypotension	8	37
Hypothermia	1	10
Hypothyroidism		1
Hypoventilation	1	1
Hypovitaminosis	1	1
Hypovolaemia		1
Hypovolaemic shock	1	1
Hypoxia	1	9
IgA nephropathy	1	1
Illrd nerve paralysis		3
Illness	26	98
Immobile	1	5
Immune-mediated adverse reaction		1
Immune system disorder	3	6
Immune thrombocytopenia	7	12
Immunisation	1	1
Immunodeficiency		1
Impaired driving ability	1	6
Impaired healing	1	1
Impaired quality of life	1	1
Impaired work ability	1	3
Inadequate analgesia	1	1
Inappropriate affect		1
Inappropriate schedule of product administration	64	83
Incision site pain		1
Incoherent	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	5	7
					1
				3	5
			1		4
			1		1
			1		1
		2	8	6	29
				1	10
					1
				1	1
				1	1
					1
				1	1
					3
		10	25	16	73
				1	5
		1	1	2	5
				7	12
				1	1
					1
		1	3		3
				1	1
				1	1
				1	3
				1	1
					1
		63	82	1	1
					1
			1	1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incontinence	1	6
Incorrect route of product administration	3	8
Increased bronchial secretion		1
Increased upper airway secretion		2
Increased viscosity of upper respiratory secretion	1	2
Indifference		2
Infant irritability		1
Infarction	3	4
Infection	9	24
Infectious mononucleosis	1	1
Inflammation	6	13
Inflammatory marker increased		3
Influenza	27	99
Influenza like illness	55	224
Infusion related reaction	1	2
Inhibitory drug interaction		1
Initial insomnia		3
Injected limb mobility decreased		1
Injection related reaction		6
Injection site cellulitis	1	1
Injection site erythema	2	2
Injection site pain	4	9
Injection site reaction		1
Injection site swelling	1	1
Injury	2	2
Inner ear inflammation		1
Insomnia	28	145
Insulin resistance		1
Internal haemorrhage		1
Internal hernia	1	1
International normalised ratio decreased	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		4
		3	8		
					1
			1		1
			1	1	1
			1		1
				3	4
		1	4	8	20
				1	1
		2	3	4	10
					3
	2	9	24	18	75
		22	73	33	151
				1	2
					1
			2		1
			1		
			2		4
				1	1
		1	1	1	1
		3	6	1	3
			1		
				1	1
				2	2
					1
		9	55	19	90
					1
					1
				1	1
			1	1	4

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
International normalised ratio increased	2	19
Interstitial lung disease	1	1
Intestinal haemorrhage	1	1
Intestinal ischaemia	1	3
Intestinal obstruction	1	4
Intestinal perforation	1	1
Intestinal pseudo-obstruction		1
Intranasal paraesthesia		1
Intrusive thoughts	1	1
Iridocyclitis		2
Iritis	1	1
Irregular breathing	1	2
Irritability	2	9
Irritable bowel syndrome		4
Ischaemia	1	1
Ischaemic stroke	1	9
IVth nerve paralysis		1
Jaundice	2	3
Jaw disorder	1	1
Joint dislocation		1
Joint effusion		4
Joint injury	1	3
Joint laxity		1
Joint lock	1	3
Joint noise		2
Joint range of motion decreased	4	19
Joint stiffness	5	22
Joint swelling	19	53
Jugular vein thrombosis	1	1
Keratitis		1
Ketoacidosis		2
Kidney infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	2	16
				1	1
				1	1
				1	3
				1	4
				1	1
					1
			1		
				1	1
					2
		1	2		
		1	4	1	5
					4
				1	1
				1	9
					1
				2	3
				1	1
					1
					4
			1	1	2
					1
				1	3
					2
	1	1	6	3	13
			4	5	18
		3	15	16	38
				1	1
					1
					2
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Kidney transplant rejection	1	1
Labyrinthitis	3	8
Lack of spontaneous speech	1	2
Lacrimation increased	2	15
Lacunar infarction		1
Lagophthalmos	1	1
Laryngeal obstruction		1
Laryngospasm		1
Latent autoimmune diabetes in adults		1
Lateral medullary syndrome	1	1
Laziness		1
Learning disability		1
Left ventricular dysfunction	1	1
Left ventricular failure		1
Lethargy	40	175
L bido decreased		1
Ligament disorder	1	1
Ligamentitis	1	1
Limb discomfort	20	70
Limb immobilisation		2
Limb injury		2
Limb mass		1
Lip disorder		2
Lip dry	1	5
Lip erythema		1
Lip exfoliation		2
Lip pain		5
Lip pruritus	1	1
Lip swelling	6	28
Lip ulceration		1
Listless		2
Liver function test abnormal	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				3	8
				1	2
		1	5	1	10
					1
		1	1		
					1
					1
					1
				1	1
					1
					1
				1	1
					1
		17	55	23	120
					1
				1	1
1	3	11	35	9	35
			2		
			1		1
					1
			2		
			2	1	3
					1
			1		1
			4		1
				1	1
		4	13	2	15
					1
					2
		1	2	1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver function test increased		3
Localised infection		2
Localised oedema		1
Local reaction		3
Logorrhoea		2
Long thoracic nerve palsy		1
Loss of consciousness	11	62
Loss of control of legs	1	1
Loss of libido		1
Loss of personal independence in daily activities	7	24
Lower respiratory tract infection	11	32
Lower respiratory tract infection viral		1
Lung consolidation		1
Lung disorder	1	3
Lung infiltration	1	1
Lung neoplasm malignant	2	2
Lymphadenitis	6	14
Lymphadenopathy	70	220
Lymph gland infection	1	1
Lymph node abscess		1
Lymph node pain	11	36
Lymphocyte count decreased	1	1
Lymphocyte count increased		1
Lymphocytosis	1	1
Lymphoedema		5
Lymphoma	1	3
Lymphopenia	1	3
Macular oedema		1
Madarosis		1
Magnetic resonance imaging brain abnormal	1	1
Major depression	1	1
Malaise	112	501

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					2
					1
			1		2
			1		2
				11	62
				1	1
					1
		2	9	5	15
				11	32
					1
					1
			1	1	2
		1	1		
				2	2
		3	7	3	7
		35	84	35	136
		1	1		
					1
		2	13	9	23
				1	1
					1
			2		3
				1	3
			1	1	2
					1
					1
				1	1
				1	1
1	2	48	164	64	337

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mandibular mass		1
Mania		1
Mass	1	6
Maternal exposure during breast feeding	1	1
Medication error	1	3
Medication overuse headache		1
Melaena		1
Memory impairment	4	14
Meniere's disease	1	2
Meningitis pneumococcal		1
Meniscus injury		1
Menorrhagia	1	2
Mental disorder	3	5
Mental fatigue	3	9
Mental impairment	3	5
Mesenteric vein thrombosis	2	2
Metabolic acidosis		1
Metamorphopsia	1	2
Metastases to lymph nodes		1
Microembolism	1	1
Microvascular coronary artery disease		1
Micturition urgency	4	7
Middle insomnia	1	9
Migraine	28	91
Migraine with aura	5	10
Migraine without aura	1	1
Miliaria	3	7
Mitral valve prolapse		1
Moaning		1
Mobility decreased	7	30
Mononeuropathy		1
Monoparesis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1	1	5
				1	1
				1	3
					1
					1
		1	3	3	11
				1	2
					1
			1		
				1	2
		1	2	2	3
		1	2	2	7
				3	5
				2	2
					1
				1	2
					1
				1	1
					1
				4	7
			5	1	4
		3	13	25	78
		1	2	4	8
				1	1
		1	3	2	4
					1
					1
		2	7	5	23
					1
				2	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Monoplegia		3
Mood altered		1
Mood swings		3
Morose		3
Motion sickness	1	3
Motor dysfunction	1	3
Mouth haemorrhage	1	1
Mouth swelling	1	4
Mouth ulceration	7	19
Movement disorder	3	14
Mucous stools		1
Multiple injuries		1
Multiple organ dysfunction syndrome		3
Multiple sclerosis	1	1
Multiple sclerosis relapse	1	3
Mumps		1
Muscle atrophy	4	4
Muscle contractions involuntary		4
Muscle discomfort		1
Muscle disorder		3
Muscle fatigue	9	24
Muscle injury		2
Muscle mass	1	1
Muscle rigidity		4
Muscle rupture		1
Muscle spasms	11	43
Muscle strain	1	3
Muscle tightness	4	10
Muscle twitching	5	16
Muscular weakness	29	107
Musculoskeletal chest pain	4	8
Musculoskeletal discomfort	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
			1		2
			2		1
		1	2		1
				1	3
				1	1
		1	2		2
		3	10	4	9
		1	3	2	11
					1
					1
					3
				1	1
				1	3
					1
		1	1	3	3
			1		3
					1
			1		2
		3	5	6	19
			1		1
				1	1
					4
					1
		2	10	9	33
			1	1	2
			2	4	8
			1	5	15
		9	30	20	77
		1	2	3	6
		1	3	1	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal pain	1	6
Musculoskeletal stiffness	24	87
Myalgia	208	894
Myasthenia gravis crisis	1	1
Myelitis transverse		2
Myelodysplastic syndrome		1
Myocardial fibrosis		1
Myocardial haemorrhage		1
Myocardial infarction	13	43
Myocardial ischaemia		5
Myocardial oedema		1
Myocarditis	1	3
Myoclonus	1	2
Myofascial pain syndrome		2
Myositis	3	6
Nail pigmentation	1	1
Narcolepsy		1
Nasal congestion	4	22
Nasal discomfort	2	7
Nasal dryness	1	3
Nasal injury		1
Nasal odour	1	1
Nasal oedema	1	2
Nasal pruritus		1
Nasopharyngitis	16	50
Nausea	147	630
Neck injury		1
Neck pain	27	101
Necrotising fasciitis		1
Neoplasm skin		1
Nephritis		1
Nephrolithiasis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	5
	2	8	24	16	63
2	5	108	315	100	579
				1	1
					2
					1
					1
					1
				13	43
					5
					1
				1	3
			1	1	1
			1		1
		1	2	2	4
				1	1
					1
	1	2	9	2	13
			2	2	5
		1	2		1
					1
				1	1
		1	2		
					1
	1	8	16	8	34
	4	56	184	91	446
					1
		9	25	18	76
					1
					1
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nephrotic syndrome	1	5
Nerve degeneration		1
Nerve injury	3	3
Nervousness	5	19
Nervous system disorder	3	5
Neuralgia	10	34
Neuritis		1
Neurogenic shock		6
Neurological symptom	1	3
Neurologic neglect syndrome		1
Neuromyelitis optica spectrum disorder	1	1
Neuromyopathy		1
Neuropathy peripheral	5	13
Neutropenia	2	5
Neutrophil count abnormal	1	1
Neutrophilia		1
Nightmare	5	15
Night sweats	13	62
Nipple pain	1	3
Nipple swelling	2	3
Nodule	2	3
Noninfective encephalitis		1
No reaction on previous exposure to drug	1	1
Nystagmus	2	4
Obsessive-compulsive symptom		1
Obstructive pancreatitis		1
Occupational exposure to SARS-CoV-2		1
Ocular discomfort	3	7
Ocular hyperaemia	7	20
Ocular hypertension		1
Ocular sarcoidosis		1
Ocular vascular disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
					1
		1	1	2	2
		2	6	3	13
				3	5
		2	6	8	28
					1
					6
				1	3
					1
				1	1
					1
				5	13
				2	5
				1	1
					1
		2	5	3	10
	1	7	29	6	33
			1	1	2
			1	2	2
				2	3
					1
		1	1		
				2	4
					1
			1		
		2	4	1	3
		3	6	4	14
					1
					1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Odynophagia		2
Oedema	5	5
Oedema peripheral	1	5
Oesophageal discomfort		1
Oesophageal stenosis		1
Off label use	73	153
Oligomenorrhoea	1	1
Oliguria		1
Ophthalmic herpes zoster	1	4
Ophthalmoplegia	1	1
Ophthalmoplegic migraine	1	1
Optic neuritis		1
Optic neuropathy		1
Oral blood blister	1	1
Oral discomfort	1	4
Oral disorder	1	2
Oral herpes	1	18
Oral mucosa erosion		1
Oral mucosal blistering	1	1
Oral mucosal eruption		1
Oral mucosal exfoliation	1	1
Oral pain	2	10
Oral pruritus		2
Orchitis		3
Oropharyngeal discomfort		1
Oropharyngeal pain	16	100
Oropharyngeal spasm		1
Orthopnoea		2
Orthostatic hypotension		2
Osmophobia		1
Osteoarthritis	2	3
Osteochondritis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		3	3	2	2
			1	1	4
			1		
					1
		71	149	2	4
				1	1
					1
				1	4
				1	1
		1	1		
					1
					1
		1	1		
			1	1	3
			1	1	1
			5	1	13
			1		
			1		
				1	1
			2	2	8
					2
					3
			1		
		5	25	11	75
					1
			1		1
		1	1	1	2
		1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Osteoporosis		1
Otorrhoea		1
Ovarian cyst	1	1
Overdose	1	3
Oversensing		1
Overweight		1
Oxygen consumption decreased	1	1
Oxygen saturation decreased	3	18
Pain	144	482
Painful respiration	2	4
Pain in extremity	190	676
Pain in jaw	4	21
Pain of skin	3	13
Pallor	6	28
Palpitations	18	83
Pancreatic carcinoma		1
Pancreatitis		1
Pancreatitis acute	1	3
Pancreatitis necrotising		1
Panic attack	3	7
Panic disorder		1
Panic reaction	1	3
Paraesthesia	34	128
Paraesthesia oral	8	28
Paralysis	3	9
Paramnesia		1
Paranasal sinus discomfort	1	1
Paranoia	1	5
Paraparesis		1
Parkinsonism		3
Parkinson's disease	1	3
Parosmia	2	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		1	1		
		1	3		
					1
					1
		1	1		
			1	3	17
1	4	63	185	81	297
			1	2	3
1	11	82	239	108	437
		2	6	2	15
		2	3	1	10
		3	13	3	15
		4	18	14	65
					1
					1
				1	3
					1
				3	7
					1
		1	2		1
		18	47	16	81
		7	15	1	13
				3	9
					1
		1	1		
		1	2		3
					1
			1		2
				1	3
			7	2	9

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Paroxysmal arrhythmia		1
Partial seizures		1
Patellofemoral pain syndrome	1	1
Paternal exposure before pregnancy	1	1
Patient elopement	1	1
Peak expiratory flow rate decreased	1	1
Pelvic discomfort		1
Pelvic pain		1
Pelvic venous thrombosis		1
Pemphigoid		4
Pemphigus		1
Penile swelling		2
Periarthritis	1	3
Pericardial effusion		1
Pericardial haemorrhage	1	2
Pericarditis	2	8
Perineal pain	1	1
Periorbital cellulitis		1
Periorbital oedema		2
Periorbital pain	1	1
Periorbital swelling	1	8
Peripheral coldness	5	24
Peripheral sensory neuropathy		1
Peripheral swelling	44	118
Peripheral vascular disorder		1
Peripheral vein thrombus extension	1	1
Peritonitis		1
Peroneal nerve palsy	1	3
Personality change		4
Petechiae	3	11
Petit mal epilepsy	1	4
Pharyngeal hypoaesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
				1	1
				1	1
				1	1
					1
					1
					1
					4
					1
					2
	1			1	3
					1
	1			1	2
	2			2	8
	1	1	1		
					1
					2
	1			1	1
	1		1	1	7
	5	1	7	3	17
			1		
		14	34	30	84
			1		
	1			1	1
					1
	1	1	1		2
			1		3
	3	2	4	1	7
	1			1	4
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pharyngeal inflammation		2
Pharyngeal oedema		2
Pharyngeal paraesthesia	1	2
Pharyngeal swelling	1	14
Pharyngeal ulceration		2
Pharyngitis		1
Phlebitis	1	2
Photophobia	6	18
Photopsia	3	8
Photosensitivity reaction		5
Piloerection		1
Pineal gland cyst	1	1
Pityriasis rosea	1	3
Plantar fasciitis	1	3
Plasma cell myeloma		1
Platelet count abnormal	1	1
Platelet count decreased	17	21
Platelet count increased		1
Platelet disorder	1	1
Pleural effusion	1	2
Pleurisy	1	2
Pleuritic pain	2	3
Pneumonia	8	29
Pneumonia aspiration		6
Pneumonitis	1	5
Pneumothorax	1	1
Pneumothorax spontaneous		1
Pollakiuria	1	7
Polyarthritits	2	3
Polydipsia	1	2
Polymyalgia rheumatica	6	9
Polyuria		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		1
		1	1		1
		1	3		11
					2
					1
				1	2
		1	3	5	15
			1	3	7
			1		4
					1
				1	1
		1	2		1
		1	1		2
		4	5	13	16
					1
				1	1
				1	2
				1	2
				2	3
				8	29
					6
				1	5
				1	1
					1
			2	1	5
				2	3
			1	1	1
				6	9
			1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Poor quality product administered		1
Poor quality sleep	5	17
Posterior reversible encephalopathy syndrome		1
Post herpetic neuralgia	1	2
Postictal paralysis	1	1
Postoperative ileus		1
Post procedural complication		2
Post procedural constipation	1	1
Posture abnormal		1
Post viral fatigue syndrome	1	4
Potentiating drug interaction	1	1
Pre-existing condition improved	1	2
Presyncope	5	35
Primary gastrointestinal follicular lymphoma		1
Primary headache associated with sexual activity		1
Prion disease		1
Procedural dizziness		1
Proctalgia	2	3
Proctitis	1	1
Product administered at inappropriate site	2	4
Product administered to patient of inappropriate age	2	4
Product complaint	1	2
Productive cough	7	22
Product quality issue		1
Product use issue	6	75
Prostatic abscess	1	1
Prostatic disorder	1	1
Prostatic pain	1	1
Prostatic specific antigen increased		1
Prostatitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	8	3	9
					1
				1	2
				1	1
					1
					2
		1	1		
					1
1	1			1	4
				1	1
			1	1	1
		2	12	3	23
					1
					1
					1
		1	1	1	2
		1	1		
		2	4		
		2	4		
			1	1	1
		2	7	5	15
			1		
		6	72		3
				1	1
		1	1		
				1	1
			1		
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Prostatomegaly	1	3
Proteinuria		1
Prothrombin time prolonged	1	1
Pruritus	42	144
Pruritus genital		1
Psoriasis	3	9
Psoriatic arthropathy	1	3
Psychiatric symptom	1	2
Psychomotor hyperactivity		1
Psychotic behaviour		1
Psychotic disorder		3
Pulmonary artery thrombosis		1
Pulmonary congestion		1
Pulmonary embolism	33	63
Pulmonary f brosis	1	1
Pulmonary haemorrhage	1	1
Pulmonary infarction		2
Pulmonary oedema	3	8
Pulmonary pain	1	5
Pulmonary sarcoidosis		2
Pulmonary thrombosis	1	6
Pulmonary tuberculosis	1	1
Pulse abnormal	1	3
Pulseless electrical activity		1
Puncture site bruise		1
Purpura		2
Pustule		1
Pylorospasm		1
Pyrexia	212	1,133
Q fever		2
Radial pulse abnormal		1
Rash	78	210

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
					1
				1	1
		18	49	24	95
			1		
			2	3	7
				1	3
		1	1		1
			1		
					1
					3
					1
					1
				33	63
				1	1
				1	1
					2
				3	8
			2	1	3
			1		1
	1			1	6
				1	1
				1	3
					1
			1		1
	1	116	380	96	753
					2
					1
		30	80	48	130

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash erythematous	20	65
Rash macular	9	25
Rash maculo-papular	2	8
Rash morbilliform		1
Rash papular	4	13
Rash pruritic	11	49
Rash pustular	1	1
Rash vesicular	3	11
Raynaud's phenomenon	1	2
Reaction to colouring	1	1
Reaction to excipient		1
Reaction to preservatives		1
Rectal abscess	1	1
Rectal discharge		1
Rectal haemorrhage	1	5
Red blood cell sedimentation rate abnormal	1	1
Red blood cell sedimentation rate increased		1
Red man syndrome		1
Reduced facial expression		2
Regurgitation		1
Renal cancer	1	1
Renal cyst	2	2
Renal disorder	1	2
Renal failure	1	3
Renal impairment	3	6
Renal pain	6	21
Renal vasculitis		1
Respiration abnormal	1	7
Respiratory arrest	1	5
Respiratory disorder		8
Respiratory distress		1
Respiratory failure		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	5	26	15	39
		5	15	4	10
		2	3		5
					1
		2	5	2	8
		3	14	8	35
				1	1
			3	3	8
				1	2
				1	1
			1		
					1
				1	1
			1		
				1	5
				1	1
					1
			2		
					1
				1	1
				2	2
				1	2
				1	3
				3	6
			2	6	19
					1
			2	1	5
				1	5
			2		6
					1
					4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory muscle weakness		1
Respiratory rate decreased		1
Respiratory rate increased		5
Respiratory symptom	1	2
Respiratory tract congestion		1
Respiratory tract oedema		2
Restless legs syndrome	1	7
Restlessness	6	16
Retching	1	11
Retinal aneurysm	1	1
Retinal artery occlusion		1
Retinal detachment	1	1
Retinal disorder	1	1
Retinal fovea disorder	1	1
Retinal injury	1	1
Retinal migraine		4
Retinal vein occlusion	2	3
Retinal vein thrombosis	1	1
Retinitis pigmentosa		1
Rhabdomyolysis		3
Rheumatoid arthritis	6	9
Rhinalgia	1	1
Rhinitis		5
Rhinorrhoea	10	39
Rib fracture		1
Road traffic accident	2	3
Rosacea	1	1
Rotator cuff syndrome	2	2
Sacroiliitis	1	2
Salivary duct obstruction		1
Salivary gland disorder		1
Salivary gland pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					5
				1	2
					1
					2
			1	1	6
			2	6	14
		1	4		7
				1	1
					1
				1	1
		1	1		
				1	1
			1		3
				2	3
				1	1
					1
					3
				6	9
		1	1		
			2		3
		3	12	7	27
					1
		1	1	1	2
				1	1
				2	2
				1	2
					1
					1
					1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Salivary hypersecretion	1	4
Sarcoidosis		3
SARS-CoV-2 ant body test negative		5
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	6	12
Scab	2	3
Schizophrenia	1	1
Sciatica	3	7
Scleral discolouration		3
Scratch		1
Screaming	2	2
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain	1	4
Scrotal swelling		3
Seasonal allergy		2
Seborrhoea	1	1
Second primary malignancy		1
Secretion discharge	1	2
Sedation		1
Seizure	14	63
Seizure cluster		1
Sensation of blood flow		1
Sensation of foreign body	3	4
Sense of a foreshortened future		3
Sensitive skin	6	12
Sensitivity to weather change		1
Sensory disturbance	2	5
Sensory loss	3	8
Sepsis	3	11
Sepsis syndrome		1
Septic shock	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
					3
			4		1
			1		
		1	1	5	11
			1	2	2
				1	1
		2	2	1	5
			1		2
					1
		1	1	1	1
					1
					1
		1	2		2
					3
			1		1
				1	1
					1
		1	1		1
					1
				14	63
					1
					1
				3	4
			2		1
		3	3	3	9
					1
		1	1	1	4
		1	4	2	4
				3	11
					1
				2	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Serotonin syndrome		1
Serum sickness-like reaction		1
Severe acute respiratory syndrome	1	1
Shock	1	2
Sinonasal obstruction	1	4
Sinus congestion	2	6
Sinus headache	7	19
Sinusitis	3	6
Sinus pain		4
Sinus tachycardia	1	4
Skin abrasion		1
Skin burning sensation	2	7
Skin cancer		1
Skin depigmentation		1
Skin discharge	1	1
Skin discolouration	9	21
Skin disorder	3	6
Skin erosion		2
Skin exfoliation	5	13
Skin fissures	2	2
Skin haemorrhage	1	1
Skin induration	1	1
Skin infection	1	2
Skin injury		1
Skin irritation	3	7
Skin laceration		4
Skin lesion	1	8
Skin mass		2
Skin plaque	1	1
Skin reaction	1	3
Skin swelling	3	5
Skin temperature	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
				1	2
		1	2		2
			2	2	4
		1	5	6	14
			1	3	5
			2		2
		1	1		3
			1		
	1		2	2	5
					1
					1
				1	1
		4	8	5	13
		1	1	2	5
					2
			2	5	11
				2	2
				1	1
				1	1
		1	1		1
			1		
		1	2	2	5
			2		2
			2	1	6
			2		
				1	1
			1	1	2
		2	2	1	3
		1	1		1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin tightness	1	3
Skin warm	1	12
Skin weeping	1	3
Skin wrinkling	2	2
Sleep apnoea syndrome		1
Sleep attacks		1
Sleep deficit		2
Sleep disorder	8	43
Sleep disorder due to a general medical condition	1	5
Sleep disorder due to general medical condition, insomnia type	2	4
Sleep paralysis		2
Sleep talking	1	1
Sleep terror	1	1
Slow response to stimuli		1
Slow speech		1
Sluggishness	1	1
Small intestinal haemorrhage		1
Small intestinal obstruction	1	2
Sneezing	7	31
Snoring		1
Somatic symptom disorder		1
Somnolence	26	87
Speech disorder	4	14
Spinal disorder	1	1
Spinal pain	2	8
Splenomegaly	1	1
Splinter haemorrhages		1
Sputum abnormal		1
Sputum purulent		1
Steatorrhoea		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		2
	1		3	1	9
				1	3
		1	1	1	1
					1
			1		1
		4	22	4	21
		1	2		3
			1	2	3
			1		1
		1	1		
				1	1
					1
				1	1
					1
				1	2
		4	11	3	20
			1		
					1
		12	30	14	57
		1	2	3	12
				1	1
			1	2	7
				1	1
					1
					1
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stevens-Johnson syndrome		1
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage		1
Stomatitis	1	4
Strabismus	1	1
Stress	2	6
Stridor		5
Stupor	1	1
Subarachnoid haemorrhage	1	2
Subcutaneous abscess		1
Sudden death	2	13
Sudden hearing loss	2	5
Suicidal behaviour	1	1
Suicidal ideation	2	4
Suicide attempt		1
Superficial injury of eye		1
Superficial vein prominence		1
Supraventricular extrasystoles	1	1
Supraventricular tachycardia	2	3
Suspected COVID-19	17	78
Sweating fever		12
Swelling	27	74
Swelling face	10	45
Swelling of eyelid	3	6
Swollen tongue	5	18
Syncope	21	92
Synovial cyst	2	4
Synovial rupture		1
Synovitis		2
Systemic immune activation		1
Systemic lupus erythematosus rash	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
					1
		1	3		1
				1	1
		1	1	1	5
					5
				1	1
				1	2
			1		
				2	13
				2	5
				1	1
				2	4
					1
			1		1
				1	1
		1	1	1	2
		8	24	9	54
					12
		9	29	18	45
		5	13	5	32
			1	3	5
		3	8	2	10
				21	92
			1	2	3
			1		
					2
					1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Systolic hypertension		1
Tachycardia	13	57
Tachypnoea	1	7
Taste disorder	7	18
Tearfulness	1	2
Temperature difference of extremities		1
Temperature intolerance	3	6
Temperature regulation disorder		3
TEMPI syndrome		1
Tenderness	14	26
Tendon injury		2
Tendonitis	2	7
Tendon pain	1	3
Tenosynovitis		1
Tension	1	3
Tension headache	9	27
Terminal insomnia	1	1
Testicular pain	3	7
Testicular swelling	2	5
Testicular torsion		1
Testis discomfort	1	2
Therapeutic product effect delayed	1	1
Therapeutic response unexpected	6	9
Thermal burn	1	2
Thermal burns of eye		1
Thinking abnormal	2	2
Thirst	4	16
Throat irritation	6	13
Throat tightness	1	15
Thrombocytopenia	15	24
Thrombocytosis		1
Thrombophlebitis	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
1	1	3	9	10	48
			2	1	5
		4	8	3	10
				1	2
					1
				3	6
			1		2
					1
		12	16	2	10
					2
		1	1	1	6
		1	2		1
					1
			1	1	2
	1	2	7	7	20
				1	1
		2	3	1	4
		2	3		2
					1
		1	1		1
				1	1
		4	7	2	2
		1	1		1
					1
		1	1	1	1
		3	5	1	11
		3	6	3	7
			2	1	13
				15	24
					1
		2	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombophlebitis superficial	2	2
Thrombosis	24	43
Thrombotic microangiopathy	1	1
Thrombotic thrombocytopenic purpura	1	1
Thunderclap headache		1
Thyroxine free increased	1	1
Tinnitus	33	69
Tongue biting		1
Tongue blistering	2	2
Tongue coated		1
Tongue discolouration		1
Tongue discomfort	1	2
Tongue disorder	1	2
Tongue dry		1
Tongue erythema	1	3
Tongue pruritus	1	3
Tongue ulceration	1	2
Tonic convulsion	1	3
Tonsillar cyst	1	1
Tonsillar haemorrhage		1
Tonsillar hypertrophy	1	4
Tonsillar inflammation		1
Tonsillar ulcer		1
Tonsillitis	4	5
Tonsillitis bacterial		1
Tooth abscess		1
Toothache	3	9
Tooth infection	1	1
Toxic epidermal necrolysis		1
Toxicity to various agents		
Tracheitis	1	1
Transient global amnesia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
				24	43
				1	1
				1	1
					1
				1	1
		4	13	29	56
					1
		1	1	1	1
			1		
			1		
		1	1		1
			1	1	1
			1		
			1	1	2
				1	3
				1	2
				1	3
		1	1		
					1
		1	1		3
			1		
					1
		1	1	3	4
					1
					1
			1	3	8
				1	1
					1
	1				
				1	1
				2	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Transient ischaemic attack	16	31
Traumatic intracranial haemorrhage		1
Treatment noncompliance		1
Tremor	20	129
Trigeminal nerve disorder		1
Trigeminal neuralgia	1	4
Trigger finger		1
Trismus		1
Troponin increased	1	2
Tunnel vision		2
Type 1 diabetes mellitus		1
Type 2 diabetes mellitus		1
Type III immune complex mediated reaction	1	1
Type IV hypersensitivity reaction	1	2
Typical aura without headache		1
Ulcer		1
Ulnar nerve injury		1
Underdose		1
Unresponsive to stimuli	2	14
Upper gastrointestinal haemorrhage		2
Upper limb fracture		1
Upper respiratory tract congestion	1	3
Upper respiratory tract infection	2	3
Ureteric stenosis		1
Urethral stenosis		1
Urinary bladder haemorrhage	1	1
Urinary incontinence	5	16
Urinary retention	2	10
Urinary tract infection	5	15
Urine abnormality	3	3
Urine analysis abnormal		1
Urine flow decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				16	31
					1
					1
		6	24	14	105
			1		
			1	1	3
					1
					1
				1	2
					2
					1
					1
				1	1
				1	2
					1
			1		
					1
			1		
				2	14
					2
					1
			1	1	2
		2	3		
					1
					1
				1	1
		2	3	3	13
				2	10
		2	3	3	12
		2	2	1	1
					1
		1	1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Urine ketone body present	1	1
Urine odour abnormal		1
Urine output		1
Urine output decreased		2
Urine output increased		1
Urosepsis		1
Urticaria	18	60
Urticaria papular		1
Uveitis		3
Vaccination complication		5
Vaccination site bruising	5	20
Vaccination site cellulitis		1
Vaccination site coldness	1	1
Vaccination site cyst		1
Vaccination site discolouration		3
Vaccination site discomfort	3	17
Vaccination site erythema	13	49
Vaccination site haemorrhage	1	4
Vaccination site hypoaesthesia		5
Vaccination site induration	1	2
Vaccination site infection	1	3
Vaccination site inflammation	3	5
Vaccination site joint discomfort		1
Vaccination site joint movement impairment		2
Vaccination site joint pain	1	4
Vaccination site lymphadenopathy		3
Vaccination site mass	5	21
Vaccination site movement impairment	7	19
Vaccination site oedema		3
Vaccination site pain	131	551
Vaccination site paraesthesia		1
Vaccination site pruritus	4	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
					1
					2
					1
					1
		9	28	9	32
					1
					3
			2		3
		2	10	3	10
			1		
				1	1
					1
			1		2
		1	10	2	7
		6	18	7	31
				1	4
					2
		1	1		1
				1	3
		2	3	1	2
					1
			1		
		1	3		1
			2		1
		2	12	3	9
		2	8	5	11
					3
	1	82	287	49	264
			1		
		4	8		5

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site pustule	1	1
Vaccination site rash	6	12
Vaccination site reaction	1	11
Vaccination site scab		2
Vaccination site swelling	20	74
Vaccination site ulcer		1
Vaccination site urticaria	1	1
Vaccination site vesicles	1	3
Vaccination site warmth	3	21
Vaccine breakthrough infection	7	7
Varicella		1
Varicella zoster virus infection		1
Varicose vein		1
Vascular dementia		1
Vascular pain	1	2
Vasculitic rash		1
Vasculitis	2	5
Vasoconstriction		1
Vein disorder	2	3
Vena cava embolism		1
Vena cava thrombosis		1
Venous injury	1	1
Venous thrombosis	1	2
Venous thrombosis limb	1	1
Ventricular extrasystoles	1	7
Ventricular fibrillation		3
Ventricular hypertrophy	1	1
Ventricular tachycardia	2	2
Vertebral artery stenosis	1	1
Vertigo	28	75
Vertigo positional	4	8
Vestibular migraine	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	3	4	9
			3	1	8
					2
		14	36	6	38
					1
		1	1		
		1	2		1
		2	7	1	14
				7	7
					1
					1
					1
					1
		1	1		1
					1
				2	5
					1
		1	2	1	1
					1
					1
				1	1
				1	2
				1	1
			1	1	6
					3
				1	1
				2	2
				1	1
		2	9	26	66
			1	4	7
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vestibular neuritis	1	4
Viral infection	3	4
Viral labyrinthitis		1
Viral pericarditis		1
Viral rash		1
Viral upper respiratory tract infection		1
Virologic failure		1
Visceral pain		1
Vision blurred	19	67
Visual acuity reduced	1	2
Visual impairment	14	32
Visual snow syndrome	1	1
Vitamin D deficiency	1	1
Vitiligo	1	1
Vitreous detachment	1	3
Vitreous floaters	1	2
Vitreous haemorrhage	1	1
Vomiting	46	213
Vomiting projectile		3
Walking aid user	1	1
Weight bearing difficulty		3
Weight decreased	5	15
Weight increased		3
Weight loss poor	1	1
Wheezing	8	30
White blood cell count decreased	1	1
White blood cell count increased	2	4
White blood cell disorder	2	2
Withdrawal syndrome	1	2
Wound	1	2
Wound infection	1	1
Wound secretion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
				3	4
			1		
					1
					1
					1
			1		
		2	16	17	51
				1	2
		6	9	8	23
				1	1
				1	1
				1	3
			1	1	1
				1	1
		13	45	33	168
					3
		1	1		
					3
			3	5	12
					3
				1	1
		1	3	7	27
				1	1
				2	4
				2	2
		1	2		
				1	2
				1	1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wrong product administered	3	3			2	2	1	1
Yawning		1				1		
Yellow skin		2				2		
	1	4			1	4		
	6,448	24,281	22	118	2212	6930	4236	17351

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	3	7			2	3	1	4
Abdominal distension	1	3				1	1	2
Abdominal pain	5	17			1	7	4	10
Abdominal pain lower	1	1			1	1		
Abdominal pain upper	13	28			4	8	9	20
Abnormal dreams	2	2			2	2		
Abnormal faeces		2				1		1
Abscess		2						2
Abscess drainage		1						1
Accidental overdose		15				15		
Acne pustular		1						1
Acute kidney injury	1	1					1	1
Adjustment disorder with depressed mood	1	1					1	1
Adnexa uteri pain		1						1
Adverse drug reaction		1				1		
Adverse event	1	1			1	1		
Ageusia		3						3
Agitation		2						2
Alanine aminotransferase increased	1	1					1	1
Allergic oedema	1	1					1	1
Alopecia	1	1					1	1
Anaphylactic reaction	3	9					3	9
Anaphylactic shock	1	2					1	2
Androgenetic alopecia	1	1					1	1
Angina pectoris		1						1
Angioedema	1	4					1	4
Anosmia		3						3
Anxiety	4	11			1	2	3	9
Aphasia		2				1		1
Aphthous ulcer		1				1		
Arrhythmia	1	2					1	2
Arrhythmia supraventricular	1	1					1	1

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthralgia	53	140
Arthritis	3	8
Arthropathy		1
Asthenia	5	34
Asthenopia	1	3
Asthma	2	5
Asymptomatic COVID-19		6
Atrial fibrillation	3	4
Autoimmune anaemia	1	1
Autoimmune uveitis		1
Autoscopy	1	1
Axillary mass		2
Axillary pain	9	16
Back pain	15	43
Balance disorder	7	12
Bladder disorder		1
Blepharitis		1
Blepharospasm		1
Blindness	1	2
Blister	1	2
Blood glucose increased	1	2
Blood growth hormone abnormal	1	1
Blood lactic acid increased		1
Blood potassium decreased		1
Blood pressure decreased		1
Blood pressure increased	2	6
Blood thyroid stimulating hormone increased		1
Blood urine		1
Blue toe syndrome	1	1
Body temperature	4	4
Body temperature abnormal	1	1
Body temperature decreased		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		19	54	34	86
				3	8
			1		
			11	5	23
		1	2		1
			1	2	4
					6
				3	4
				1	1
					1
				1	1
					2
		1	4	8	12
		5	17	10	26
			1	7	11
					1
					1
				1	2
				1	2
			1	1	1
		1	1		
					1
			1		
					1
		1	2	1	4
					1
				1	1
		4	4		
		1	1		
			1		2

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Body temperature fluctuation	1	1
Body temperature increased	5	12
Bone pain	2	4
Bradycardia	1	1
Bradyphrenia		1
Breast cancer	1	1
Breast mass	1	1
Breast pain	2	2
Bronchospasm		1
Burning sensation	2	4
Bursitis	1	1
Candida infection	1	1
Cardiac disorder		2
Cardiac failure	1	2
Cardiac flutter	2	3
Cellulitis	1	4
Central vision loss	1	1
Cerebellar haemorrhage	1	1
Cerebrovascular accident	1	5
Chest crushing	1	1
Chest discomfort	11	25
Chest pain	7	22
Chills	49	170
Circumstance or information capable of leading to medication error		3
Cluster headache		1
Cognitive disorder		1
Cold sweat	1	6
Colitis ulcerative	1	1
Condition aggravated	2	9
Confusional state	3	7
Congenital multiplex arthrogryposis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		4	7	1	5
			2	2	2
				1	1
			1		
				1	1
				1	1
		1	1	1	1
					1
			1	2	3
				1	1
				1	1
					2
				1	2
				2	3
				1	4
				1	1
				1	1
				1	5
				1	1
		3	7	8	18
		3	8	4	14
	1	17	76	32	94
			3		
					1
					1
		1	3		3
				1	1
				2	9
				3	7
				1	1

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Conjunctivitis		1
Constipation	1	4
Contusion	2	9
Coordination abnormal		2
Coronavirus infection		1
Cough	12	38
COVID-19	21	99
Crying		2
Deafness	3	3
Death	3	6
Decreased appetite	5	17
Deep vein thrombosis	3	5
Defaecation urgency	1	1
Dehydration	1	2
Delirium		1
Depressed mood		1
Depression		4
Dermatitis	1	2
Diabetes mellitus	1	1
Diaphragmatic disorder	1	1
Diarrhoea	22	69
Diplopia	2	3
Discomfort	6	10
Disease recurrence	1	2
Disorientation	1	2
Disturbance in attention	4	8
Dizziness	30	113
Dizziness exertional		1
Dizziness postural	2	7
Drug eruption		1
Drug ineffective	14	98
Dry eye	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	4
		2	5		4
					2
					1
		5	15	7	23
		5	9	16	90
					2
				3	3
				3	6
		3	7	2	10
				3	5
				1	1
				1	2
					1
			1		
					4
				1	2
				1	1
				1	1
		7	22	15	47
				2	3
		4	6	2	4
				1	2
				1	2
		2	3	2	5
		12	45	18	68
					1
		2	5		2
					1
				14	98
			1	2	3

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dry mouth	1	9
Dry skin	1	1
Dry throat		1
Dysarthria	2	3
Dysgeusia	6	20
Dyskinesia	2	2
Dyspepsia	1	4
Dysphagia	3	3
Dysphonia	1	1
Dyspnoea	16	47
Dysstasia	1	4
Ear discomfort	1	2
Ear haemorrhage		1
Ear infection		1
Ear pain	9	17
Eczema	1	1
Electric shock		1
Encephalitis	1	1
Enuresis		1
Epicondylitis	1	1
Epilepsy	1	1
Epistaxis	4	7
Eructation		1
Erythema	9	23
Essential hypertension		1
Expired product administered	1	3
Exposure during pregnancy		1
Exposure via breast milk	29	82
Extrasystoles	1	1
Eye disorder		1
Eye haemorrhage		1
Eye irritation	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		4
		1	1		
					1
				2	3
		4	14	2	6
				2	2
		1	2		2
				3	3
				1	1
		4	11	12	36
		1	3		1
				1	2
					1
					1
		2	7	7	10
		1	1		
			1		
				1	1
			1		
				1	1
		2	2	2	5
					1
		6	14	3	9
					1
		1	3		
			1		
		22	69	7	13
				1	1
					1
				1	4

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eyelid ptosis	1	1
Eye oedema	1	1
Eye pain	7	15
Eye pruritus		1
Eye swelling	1	2
Facial discomfort	1	1
Facial pain	1	5
Facial paralysis	5	14
Fall	2	5
Fatigue	113	325
Fear		1
Fear of injection		1
Feeding disorder		2
Feeling abnormal	10	27
Feeling cold	6	19
Feeling drunk	1	1
Feeling hot	7	25
Feeling of body temperature change		3
Fibromyalgia	1	1
Flank pain		1
Flatulence	2	5
Flushing	1	6
Foetal exposure during pregnancy	1	1
Foetal malformation	1	1
Food allergy	1	1
Food aversion	1	1
Food intolerance	1	1
Food refusal	1	1
Foreign body in gastrointestinal tract	1	1
Foreign body in mouth	1	1
Foreign body sensation in eyes		1
Functional gastrointestinal disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		1	3	6	12
			1		
			1	1	1
		1	1		
		1	3		2
				5	14
			1	2	4
	2	56	131	57	194
			1		
			1		
			1		1
		3	10	7	17
			3	6	16
				1	1
		4	15	3	10
			1		2
				1	1
					1
		1	1	1	4
		1	3		3
				1	1
				1	1
				1	1
				1	1
		1	1		
				1	1
				1	1
					1
					1

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait disturbance	1	3
Gait inability		1
Gastric disorder	1	1
Gastritis	1	1
Gastrointestinal pain		3
Gastrointestinal sounds abnormal		1
Gastroesophageal reflux disease		1
Generalised tonic-clonic seizure	1	1
Genital pain		1
Gingival pain		1
Glossodynia	2	3
Gout	1	2
Groin pain	1	1
Haematochezia	1	2
Haemophilia		1
Haemoptysis	1	1
Haemorrhage		2
Haemorrhage urinary tract	1	1
Haemorrhoids		1
Hallucination	1	2
Headache	141	389
Head discomfort	2	7
Head injury	1	2
Heart rate abnormal		1
Heart rate decreased		1
Heart rate increased	4	17
Heart rate irregular	1	2
Hepatic pain	1	1
Herpes zoster	1	12
Histamine level increased		1
Hot flush	4	13
Hunger		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
					1
				1	1
				1	1
			1		2
					1
					1
				1	1
					1
					1
		2	2		1
				1	2
				1	1
				1	2
					1
				1	1
					2
				1	1
					1
		70	172	71	217
		1	4	1	3
			1	1	1
			1		
					1
			3	4	14
				1	2
		1	1		
			4	1	8
			1		
		3	8	1	5
			1		1

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperacusis	1	1
Hypercapnia		1
Hyperglycaemia		1
Hyperhidrosis	10	22
Hyperintensity in brain deep nuclei	1	1
Hyperoxia	1	1
Hypersensitivity	4	15
Hypersomnia	1	5
Hypertension	7	12
Hypoacusis	1	1
Hypoaesthesia	8	27
Hypoaesthesia oral	1	6
Hypokinesia		1
Hypopnoea	1	2
Hypotension	2	5
Hypothermia		1
Illness	7	17
Immobile		1
Impaired gastric emptying	1	1
Inappropriate schedule of product administration	11	13
Incorrect dose administered	1	2
Incorrect route of product administration	1	2
Increased tendency to bruise		1
Infection	2	2
Inflammation	4	6
Inflammatory pain	1	1
Influenza	9	30
Influenza like illness	18	46
Injection site erythema		1
Injection site pain	3	5
Insomnia	5	25
Intentional product misuse		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
		4	7	6	15
				1	1
				1	1
		1	5	3	10
		1	3		2
		2	4	5	8
				1	1
		1	11	7	16
			2	1	4
			1		
				1	2
		1	2	1	3
					1
		3	5	4	12
					1
				1	1
		11	13		
		1	2		
		1	2		
					1
		2	2		
		2	2	2	4
		1	1		
		3	8	6	22
		9	22	9	24
			1		
		3	4		1
		1	6	4	19
			1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intentional product use issue		1
International normalised ratio decreased		1
International normalised ratio increased		1
Iritis		1
Iron deficiency anaemia		1
Irregular breathing		1
Irritability	1	5
Irritable bowel syndrome	1	3
Joint effusion		2
Joint prosthesis user		1
Joint range of motion decreased	4	5
Joint stiffness	1	3
Joint swelling	6	11
Labyrinthitis		2
Lacrimation increased	1	6
Lethargy	14	42
Limb crushing injury	1	1
Limb discomfort	6	16
Limb mass		1
Lip dry	1	1
Lip oedema		1
Lip pain		1
Lip swelling	1	6
Liquid product physical issue		2
Listless	1	1
Liver function test abnormal		1
Localised infection		1
Local reaction		1
Loss of consciousness	3	6
Loss of libido		1
Loss of personal independence in daily activities		5
Loss of proprioception		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
					1
				1	5
				1	3
			1		1
					1
		2	3	2	2
				1	3
		1	1	5	10
					2
				1	6
		8	26	6	16
				1	1
		3	7	3	9
			1		
				1	1
					1
					1
			2	1	4
			2		
				1	1
					1
			1		
			1		
				3	6
					1
			2		3
					1

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\* AE=Adverse Event

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lower respiratory tract infection	1	1
Lymphadenitis	3	5
Lymphadenopathy	36	94
Lymph node pain	5	12
Lymphoma		2
Malaise	24	86
Maternal exposure during pregnancy	1	4
Medication error		1
Melaena		1
Memory impairment	2	2
Menorrhagia		1
Menstrual disorder	1	1
Menstruation delayed		1
Mental fatigue	1	1
Mental impairment	1	1
Mental status changes		1
Metastases to lymph nodes		4
Metrorrhagia		1
Migraine	15	37
Migraine with aura	2	3
Miliaria	1	1
Mobility decreased	3	12
Monoplegia	1	1
Mood altered		1
Motion sickness	1	3
Mouth ulceration	2	5
Movement disorder		3
Mucous stools	1	1
Multiple sclerosis	1	1
Muscle contractions involuntary	1	1
Muscle fatigue	3	5
Muscle spasms	7	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1	3	4
	1	16	42	20	52
		2	7	3	5
					2
	1	11	30	13	56
				1	4
			1		
		1	1	1	1
					1
		1	1		
					1
				1	1
				1	1
					4
					1
		2	9	13	28
		1	1	1	2
		1	1		
		2	6	1	6
				1	1
					1
				1	3
		1	3	1	2
					3
				1	1
				1	1
				1	1
				3	5
		2	7	5	8

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle spasticity		1
Muscle strain	1	2
Muscle twitching	1	5
Muscular weakness	4	16
Musculoskeletal chest pain	1	4
Musculoskeletal discomfort	1	2
Musculoskeletal pain		1
Musculoskeletal stiffness	6	22
Myalgia	57	170
Myasthenia gravis	1	1
Myelitis transverse		1
Myelosuppression		1
Myocardial infarction	1	1
Myocardial necrosis marker increased	1	1
Myoclonus		1
Nasal congestion	3	6
Nasal disorder	1	2
Nasopharyngitis	8	13
Nausea	61	187
Neck mass		1
Neck pain	12	35
Neonatal pneumothorax		1
Neonatal respiratory distress		1
Nerve compression	1	1
Nervousness		4
Neuralgia	1	2
Neurogenic shock		2
Neurological symptom	1	1
Neuropathy peripheral	1	1
Nightmare	4	4
Night sweats		5
No adverse event	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
		1	2		3
		1	3	3	13
		1	2		2
				1	2
					1
		2	6	4	16
	1	29	83	28	87
				1	1
					1
					1
				1	1
				1	1
					1
		1	2	2	4
			1	1	1
		4	5	4	8
		25	73	36	114
					1
		4	14	8	21
					1
					1
				1	1
			1		3
			1	1	1
					2
				1	1
				1	1
				4	4
			2		3
		2	7		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ocular hyperaemia	2	4
Oedema	1	1
Off label use	13	23
Oral candidiasis	1	1
Oral discomfort		1
Oral mucosal blistering	1	1
Oral pain		3
Oral pruritus		1
Oropharyngeal discomfort		1
Oropharyngeal pain	11	36
Orthopnoea		2
Osteoarthritis	1	2
Osteonecrosis of jaw	1	1
Overdose		3
Oxygen saturation decreased		3
Pain	42	118
Pain in extremity	60	176
Pain in jaw	5	10
Pain of skin	2	6
Pallor		3
Palmar erythema		2
Palpitations	6	30
Panic reaction		1
Papule		1
Paraesthesia	8	36
Paraesthesia oral	4	11
Paralysis		1
Parkinsonism	1	1
Parkinson's disease	1	1
Parosmia	2	2
Peau d'orange		1
Pelvic pain	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		2
				1	1
		13	22		1
			1	1	1
		1	1		
			1		2
			1		
			1		
		4	15	7	21
					2
			1	1	1
				1	1
			3		
					3
		24	60	18	58
	1	22	77	38	99
		2	3	3	7
		1	3	1	3
			2		1
			1		1
		2	8	4	22
			1		
			1		
		3	12	5	24
		2	7	2	4
					1
				1	1
				1	1
				2	2
			1		
			1	2	2

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Periarthritis	2	4
Periorbital swelling	1	2
Peripheral coldness		8
Peripheral swelling	14	33
Pharyngeal hypoaesthesia		1
Pharyngeal leukoplakia		1
Pharyngeal swelling		5
Pharyngitis		1
Pharyngitis streptococcal		1
Phlebitis		1
Photophobia	1	4
Pityriasis rosea		1
Plantar erythema	1	1
Pleuritic pain		1
Pneumonia	1	1
Pollakiuria	1	2
Polymyalgia rheumatica	1	1
Poor feeding infant	1	1
Poor quality product administered	5	87
Poor quality sleep		2
Post viral fatigue syndrome		1
Premature baby		3
Presyncope	1	6
Primary biliary cholangitis		1
Product administered to patient of inappropriate age		2
Product contamination		1
Product contamination physical	1	1
Productive cough	3	4
Product label confusion		1
Product packaging quantity issue		4
Product preparation error		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	3
				1	2
			4		4
		4	9	10	24
					1
			1		
			2		3
			1		
					1
					1
			1	1	3
			1		
				1	1
				1	2
				1	1
				1	1
		5	87		
			1		1
					1
					3
		1	3		3
					1
			2		
			1		
		1	1		
				3	4
			1		
			4		
			4		

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product preparation issue		2
Product quality issue		1
Product storage error	1	8
Product supply issue		1
Product temperature excursion issue	3	71
Product use issue		9
Pruritus	13	46
Pulmonary congestion	1	1
Pulmonary embolism	2	6
Pulmonary pain	1	2
Pyrexia	72	228
Rales		1
Rash	15	38
Rash erythematous	2	8
Rash macular	3	6
Rash papular	1	4
Rash pruritic	2	5
Raynaud's phenomenon		1
Reflux gastritis		1
Renal pain	2	6
Respiratory rate increased	1	1
Respiratory tract infection	1	1
Restless legs syndrome		1
Restlessness	1	1
Retching		3
Retinal injury	1	1
Rheumatic disorder	1	1
Rheumatoid arthritis	1	2
Rhinitis	1	1
Rhinitis allergic		1
Rhinorrhoea	4	12
SARS-CoV-2 ant body test negative		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
		1	8		
			1		
		3	71		
			8		1
		7	23	6	23
				1	1
				2	6
			1	1	1
		33	118	39	110
					1
		5	17	10	21
		2	6		2
		2	4	1	2
				1	4
			2	2	3
					1
			1		
		1	2	1	4
				1	1
				1	1
			1		
				1	1
				1	2
				1	1
			1		
		1	3	3	9
			2		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test positive		3
Scar	1	1
Sciatica		1
Seasonal allergy	1	1
Seizure		1
Sensitive skin		1
Sepsis		1
Sialoadenitis	1	1
Sinus congestion	1	1
Sinus disorder	1	1
Sinus headache	2	5
Sinusitis		2
Sinus pain		1
Sinus tachycardia		1
Skin infection		1
Skin lesion		2
Skin odour abnormal		1
Skin sensitisation	1	1
Skin warm		7
Sleep apnoea syndrome		1
Sleep disorder	1	6
Sluggishness		1
Small intestinal haemorrhage		1
Sneezing	1	5
Somnolence	5	15
Speech disorder		1
Spinal pain		2
Status epilepticus	1	1
Stomatitis	2	3
Sudden visual loss		1
Suspected COVID-19	2	15
Sweating fever	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	1		
					1
				1	1
					1
			1		
					1
				1	1
				1	1
				1	1
		2	4		1
			1		1
			1		
					1
			1		
			2		
					1
		1	1		
			2		5
					1
			2	1	4
			1		
					1
		1	2		3
		1	6	4	9
					1
			1		1
				1	1
				2	3
					1
		2	7		8
				1	1

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Swelling	13	26
Swelling face	5	9
Swelling of eyelid	1	2
Swollen tongue	1	7
Syncope	2	16
Tachycardia	3	13
Taste disorder	2	4
Teething		1
Temperature regulation disorder	2	2
Tenderness	3	8
Tension headache	3	6
Therapeutic response unexpected	1	1
Thirst		3
Throat irritation		4
Throat tightness	1	6
Thrombocytopenia		1
Thrombosis	2	3
Tic	1	1
Tinnitus	8	11
Tongue coated		
Tongue discomfort		1
Tongue disorder	2	2
Tongue eruption		1
Tongue oedema		1
Tonsillar disorder		1
Tonsillar hypertrophy	1	3
Tooth erosion	1	1
Transient ischaemic attack	2	2
Tremor	4	21
Trigeminal neuralgia	1	1
Underdose	1	5
Upper respiratory tract infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	16	7	10
		2	2	3	7
				1	2
			2	1	5
				2	16
		1	6	2	7
		1	3	1	1
			1		
		1	1	1	1
	1	2	6	1	2
	1	2	2	1	4
				1	1
					3
			4		
		1	3		3
					1
				2	3
				1	1
		1	2	7	9
	1				
					1
		2	2		
					1
					1
			1		
		1	2		1
		1	1		
				2	2
		1	3	3	18
		1	1		
		1	5		
				1	1

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Urinary retention		1
Urinary tract infection		5
Urine odour abnormal		1
Urticaria	3	13
Urticaria thermal		1
Vaccination complication	1	1
Vaccination failure	2	2
Vaccination site bruising	2	4
Vaccination site cellulitis		2
Vaccination site discomfort	1	2
Vaccination site erythema	5	19
Vaccination site haemorrhage		1
Vaccination site hypoaesthesia		1
Vaccination site induration		2
Vaccination site inflammation	1	2
Vaccination site joint erythema	1	1
Vaccination site joint swelling		1
Vaccination site mass	3	10
Vaccination site movement impairment	1	4
Vaccination site necrosis		1
Vaccination site pain	29	105
Vaccination site paraesthesia		2
Vaccination site pruritus	1	9
Vaccination site rash		1
Vaccination site reaction	1	1
Vaccination site swelling	6	22
Vaccination site urticaria		1
Vaccination site warmth	2	10
Vaccine breakthrough infection	6	6
Vaginal haemorrhage		1
Vasoconstriction		1
Vertigo	7	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					5
			1		
		1	6	2	7
			1		
				1	1
		1	1	1	1
		2	2		2
			1		1
		1	1		1
		4	14	1	5
					1
			1		
			2		
		1	2		
				1	1
					1
		1	5	2	5
		1	3		1
					1
		23	71	6	34
			1		1
		1	6		3
					1
		1	1		
		4	14	2	8
			1		
		2	9		1
				6	6
					1
					1
		1	1	6	11

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vertigo positional	1	1					1	1
Viral infection		2				2		
Vision blurred	5	13			2	3	3	10
Visual impairment	4	8			1	1	3	7
Visual perseveration	1	1					1	1
Vitamin D deficiency		1						1
Vlth nerve paralysis		1						1
Vomiting	11	39			5	11	6	28
Vomiting projectile	1	1					1	1
Weight decreased	2	2					2	2
Wheezing	2	5				1	2	4
Wrong technique in product usage process		3				3		
	1	3			1	3		
	1,754	5,363		10	707	2239	1047	3124

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Country Where Event Occurred  
**UNITED STATES**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal discomfort	45	180			45	175		5
Abdominal distension	10	43			10	42		1
Abdominal infection	2	2					2	2
Abdominal pain	35	180			28	154	7	26
Abdominal pain lower	4	20			3	14	1	6
Abdominal pain upper	75	244			64	224	11	20
Abdominal rigidity	2	5			2	4		1
Abdominal symptom		1				1		
Abdominal wall haematoma		1						1
Abdominal wall haemorrhage		1						1
Abnormal behaviour	4	8			3	6	1	2
Abnormal clotting factor		1						1
Abnormal dreams	5	22			5	21		1
Abnormal faeces		3				2		1
Abnormal sensation in eye	2	6			2	6		
Abnormal withdrawal bleeding		1				1		
Abortion	1	1					1	1
Abortion induced		1						1
Abortion missed		1						1
Abortion spontaneous	8	30					8	30
Acarodermatitis		2				1		1
Accident	2	2			1	1	1	1
Accidental exposure to product	2	28			2	28		
Accidental overdose	1	20			1	18		2
Accidental underdose		2				2		
Acetonaemia		1				1		
Achlorhydria	1	1			1	1		
Acidosis	1	1					1	1
Acne	4	15			4	14		1
Acoustic neuritis		1				1		
Activated partial thromboplastin time prolonged		1				1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute coronary syndrome		1
Acute disseminated encephalomyelitis		2
Acute febrile neutrophilic dermatosis	1	1
Acute hepatic failure		2
Acute kidney injury	1	7
Acute myeloid leukaemia		4
Acute myocardial infarction	1	3
Acute pulmonary oedema		1
Acute respiratory failure	1	2
Adenoma benign		1
Adhesion		1
Administration site erythema		1
Administration site irritation	1	1
Administration site reaction		1
Adnexa uteri pain		1
Adrenal disorder	1	3
Adrenal insufficiency		2
Adrenergic syndrome		1
Adrenocortical insufficiency acute		1
Adverse drug reaction		1
Adverse event	2	5
Adverse event following immunisation	1	1
Affective disorder	1	2
Affect lability	2	2
Ageusia	25	133
Aggression		3
Agitation	7	18
Alanine aminotransferase abnormal		1
Alanine aminotransferase decreased		1
Alanine aminotransferase increased	1	5
A bumin globulin ratio decreased		1
Allergic cough	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
				1	1
				1	7
					4
				1	3
					1
				1	2
			1		
			1		
		1	1		
			1		
			1		
		1	2		1
					2
			1		
			1		
		2	5		
		1	1		
		1	2		
				2	2
		22	120	3	13
			2		1
		7	17		1
			1		
					1
		1	4		1
			1		
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergic reaction to excipient		2
Allergic respiratory disease		1
Allergic sinusitis		1
Allergy test positive		1
Allergy to arthropod sting		1
Allergy to chemicals	1	1
Allergy to vaccine	6	52
Allodynia		1
Alopecia	12	27
Alopecia areata		1
Altered state of consciousness	2	6
Altered visual depth perception	1	1
Amenorrhoea	1	1
Ammonia increased		1
Amnesia	14	32
Amniotic cavity infection	1	1
Amyloidosis		1
Anaemia		3
Anaemia vitamin B12 deficiency	1	1
Anaesthesia	1	2
Anal haemorrhage	1	2
Anal incontinence	5	9
Anal infection		1
Anal pruritus	1	1
Anal skin tags		1
Anaphylactic reaction	100	274
Anaphylactic shock	6	16
Anaphylactoid reaction		5
Aneurysm		1
Anger		5
Angina pectoris	15	29
Angina unstable		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
			1		
			1		
			1		
		1	1		
		2	34	4	18
			1		
		11	22	1	5
			1		
				2	6
		1	1		
		1	1		
					1
		9	23	5	9
				1	1
					1
			3		
		1	1		
		1	2		
		1	2		
		4	8	1	1
			1		
		1	1		
			1		
		1	1	99	273
				6	16
					5
					1
			3		2
				15	29
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angioedema	14	54
Angiopathy	1	5
Angle closure glaucoma	1	1
Angular cheilitis		1
Animal bite	1	2
Anion gap abnormal		1
Anion gap decreased		1
Ankle fracture	2	2
Anomalous pulmonary venous connection		1
Anorectal discomfort	1	2
Anosmia	19	113
Antibody test abnormal	1	3
Antibody test negative		3
Anti Kell antibody test positive	1	1
Antinuclear antibody positive		1
Anxiety	47	193
Anxiety disorder		1
Aortic arteriosclerosis	1	1
Apathy	1	4
Aphasia	11	22
Aphonia	9	18
Aphthous ulcer	2	4
Apnoea	1	1
Appendicitis	15	33
Appendicitis perforated	5	6
Appendix disorder	1	1
Appetite disorder		3
Application site erythema	1	1
Application site swelling	1	1
Aptyalism		2
Arachnoid cyst		1
Arrhythmia	11	34

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	12	52
			4	1	1
			1	1	1
			1		
		1	2		
			1		
			1		
				2	2
					1
		1	2		
		17	100	2	13
		1	3		
			3		
		1	1		
			1		
		39	169	8	24
					1
		1	1		
		1	4		
		5	10	6	12
		7	10	2	8
		2	4		
				1	1
				15	33
				5	6
				1	1
			3		
		1	1		
		1	1		
			2		
					1
				11	34

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arrhythmia supraventricular		1
Arterial occlusive disease	1	1
Arterial thrombosis		1
Arteriosclerosis		1
Arteriosclerosis coronary artery	1	1
Arteriospasm coronary	1	2
Arthralgia	256	1,333
Arthritis	11	46
Arthritis allergic		1
Arthropathy	8	19
Arthropod bite	2	6
Arthropod infestation		1
Arthropod sting	3	4
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased	1	4
Aspiration		1
Asthenia	204	817
Asthenopia	8	23
Asthma	19	61
Asthma exercise induced		1
Asymptomatic COVID-19	9	33
Ataxia	1	3
Atelectasis	1	3
Atrial fibrillation	22	73
Atrial flutter	3	3
Atrioventricular block complete	1	1
Atypical pneumonia		1
Aura	1	2
Auricular swelling		1
Autoimmune disorder	6	17
Autoimmune thyroid disorder	1	1
Autoimmune thyroiditis	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
					1
		1	1		
				1	2
1	1	236	1251	20	82
		11	43		3
			1		
		8	18		1
		2	6		
					1
		3	4		
			1		
		1	4		
					1
		168	704	36	113
		7	21	1	2
		14	46	5	15
			1		
		1	1		2
			1	22	72
		2	2	1	1
				1	1
					1
			1	1	1
			1		
				6	17
				1	1
				1	5

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Autonomic nervous system imbalance	1	4
Autoscopy	1	3
Avulsion fracture	1	1
Axillary mass	5	18
Axillary pain	23	115
Back disorder	1	5
Back injury	1	3
Back pain	120	435
Bacteraemia		2
Bacterial infection	2	3
Bacterial pyelonephritis	1	1
Bacterial test positive		1
Bacterial vaginosis	2	2
Bacteriuria		1
Balance disorder	30	98
Band neutrophil count increased		1
Barrett's oesophagus	1	1
Basal cell carcinoma		1
Basal ganglia infarction	1	1
Basal ganglia stroke		2
Basedow's disease	2	2
Basophil count abnormal		1
Basophil count increased		1
Bed rest	1	1
Bedridden	8	21
Biliary tract disorder	1	1
Binocular eye movement disorder	1	1
Bipolar disorder	1	1
Bladder discomfort		3
Bladder disorder	1	4
Bladder dysfunction		1
Bladder pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
		1	2		1
		1	1		
		5	15		3
		20	110	3	5
		1	5		
		1	3		
		100	377	20	58
					2
		1	2	1	1
				1	1
			1		
		2	2		
					1
		18	75	12	23
					1
				1	1
					2
				2	2
			1		
			1		
		1	1		
		6	16	2	5
		1	1		
				1	1
				1	1
			3		
		1	4		
			1		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder spasm		1
Blast cell count increased		1
Blepharitis		1
Blepharospasm	2	8
Blindness	7	20
Blindness transient	1	5
Blindness unilateral		3
Blister	16	54
Blood albumin decreased		2
Blood bilirubin decreased		1
Blood bilirubin increased		2
Blood blister	2	4
Blood calcium decreased		1
Blood calcium increased		2
Blood chloride decreased		2
Blood chloride increased		3
Blood cholesterol	1	1
Blood cholesterol abnormal	2	2
Blood cholesterol increased	2	5
Blood chromium increased	1	1
Blood copper increased	1	2
Blood count abnormal	1	4
Blood creatine increased		1
Blood creatine phosphokinase abnormal	1	1
Blood creatine phosphokinase increased	1	3
Blood creatinine abnormal	1	1
Blood creatinine decreased		1
Blood creatinine increased	2	8
Blood disorder	1	4
Blood folate decreased		1
Blood folate increased	1	1
Blood follicle stimulating hormone increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
		2	8		
				7	20
				1	5
					3
		12	44	4	10
			2		
			1		
			1		1
		1	1	1	3
			1		
			2		
			1		1
			3		
		1	1		
		2	2		
		2	5		
				1	1
		1	2		
		1	4		
			1		
		1	1		
			1	1	2
				1	1
			1		
		2	6		2
		1	3		1
			1		
		1	1		
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood glucose abnormal	1	4
Blood glucose decreased	5	20
Blood glucose fluctuation		2
Blood glucose increased	5	45
Blood iron decreased	1	3
Blood iron increased		1
Blood lactic acid increased	1	3
Blood magnesium decreased		2
Blood potassium decreased	5	15
Blood potassium increased		1
Blood pressure abnormal	5	21
Blood pressure decreased	12	46
Blood pressure diastolic decreased		3
Blood pressure diastolic increased		1
Blood pressure fluctuation	5	20
Blood pressure increased	57	262
Blood pressure measurement	1	1
Blood pressure systolic increased	2	12
Blood sodium decreased	2	4
Blood test abnormal	4	6
Blood testosterone decreased		1
Blood thyroid stimulating hormone decreased		1
Blood thyroid stimulating hormone increased	1	4
Blood triglycerides abnormal	1	1
Blood triglycerides increased	1	2
Blood urea increased		2
Blood uric acid increased		1
Blood urine present	5	15
Blue toe syndrome	1	1
Body height decreased	3	20
Body temperature		2
Body temperature abnormal	2	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	1
		2	13	3	7
			2		
		3	37	2	8
			2	1	1
			1		
			1	1	2
					2
		3	8	2	7
			1		
		4	15	1	6
		4	25	8	21
			3		
					1
		5	14		6
		30	153	27	109
		1	1		
		1	5	1	7
		2	3		1
		3	5	1	1
			1		
					1
		1	3		1
		1	1		
		1	1		1
			2		
					1
		4	12	1	3
				1	1
		3	20		
			2		
		2	17		3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Body temperature decreased	8	18
Body temperature fluctuation	1	5
Body temperature increased	19	93
Body tinea		1
Bone density abnormal	1	1
Bone development abnormal	1	1
Bone disorder	2	5
Bone neoplasm	1	2
Bone pain	27	91
Bone swelling		7
Booster dose missed		3
Bowel movement irregularity	2	11
Brachial plexopathy		2
Bradycardia	5	5
Bradykinesia	2	5
Bradyphrenia	1	5
Brain cancer metastatic	1	1
Brain death		1
Brain injury	2	6
Brain oedema	1	3
Brain stem haemorrhage		1
Brain stem infarction	1	1
Brain stem stroke	1	1
Brain stem syndrome		1
Breast cancer		2
Breast cancer metastatic		1
Breast discharge		4
Breast discomfort		4
Breast disorder	2	4
Breast induration		1
Breast mass	4	8
Breast milk discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	15	2	3
		1	5		
		19	91		2
			1		
		1	1		
		1	1		
		1	4	1	1
			1	1	1
		24	80	3	11
			5		2
			3		
		2	11		
			1		1
				5	5
		2	5		
		1	2		3
				1	1
					1
				2	6
				1	3
					1
				1	1
				1	1
					1
					2
					1
			4		
			3		1
		2	4		
			1		
		3	7	1	1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast pain	19	55
Breast swelling	6	12
Breast tenderness	2	8
Breathing-related sleep disorder	1	1
Breath odour		1
Breath sounds abnormal	4	4
Bronchial disorder	1	1
Bronchial oedema	1	1
Bronchitis	8	19
Bronchospasm	4	24
Bruxism		1
Bundle branch block left	1	1
Burning mouth syndrome		1
Burning sensation	59	204
Burning sensation mucosal		1
Burn oral cavity		1
Bursitis	2	5
Butterfly rash		1
Caffeine consumption	1	1
Candida infection		3
Capillary fragility	1	1
Capillary nail refill test abnormal	1	2
Carbohydrate antigen 125 increased		1
Cardiac arrest	10	17
Cardiac discomfort	1	4
Cardiac disorder	13	33
Cardiac failure		2
Cardiac failure congestive	2	7
Cardiac fibrillation		1
Cardiac flutter	16	33
Cardiac murmur		1
Cardiac neoplasm unspecified		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		17	52	2	3
		6	12		
		2	7		1
		1	1		
					1
		4	4		
		1	1		
				1	1
		5	14	3	5
		2	14	2	10
			1		
				1	1
			1		
		49	172	10	32
			1		
					1
		1	4	1	1
					1
		1	1		
			3		
		1	1		
		1	2		
			1		
				10	17
		1	4		
		10	24	3	9
					2
				2	7
					1
				16	33
					1
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac valve sclerosis		1
Cardiac valve vegetation		1
Cardiogenic shock		3
Cardiomyopathy	1	1
Cardio-respiratory arrest		1
Cardiospasm	3	3
Cardiovascular disorder	2	4
Carpal tunnel syndrome	2	3
Cartilage injury		1
Cataract	3	6
Catatonia		1
Cellulitis	14	30
Central nervous system lesion		2
Cerebellar ataxia		1
Cerebellar stroke	1	2
Cerebral artery embolism	1	1
Cerebral disorder	2	7
Cerebral haemorrhage	2	6
Cerebral infarction		2
Cerebral palsy	2	2
Cerebral thrombosis	2	4
Cerebral venous sinus thrombosis	3	3
Cerebrospinal fluid leakage	1	1
Cerebrovascular accident	45	98
Cerumen impaction	1	1
Cervical radiculopathy	1	1
Chalazion		1
Change in sustained attention	1	1
Chapped lips	2	5
Cheilitis		3
Chest discomfort	92	354
Chest injury	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					3
				1	1
					1
		2	2	1	1
		2	3		1
		1	2	1	1
			1		
			1	3	5
			1		
				14	30
			1		1
			1		
				1	2
				1	1
		2	7		
				2	6
					2
				2	2
				2	4
				3	3
				1	1
				45	98
		1	1		
				1	1
			1		
		1	1		
		2	5		
			2		1
		74	256	18	98
				1	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Chest pain	78	338
Chest X-ray abnormal		1
Chillblains	2	6
Chills	486	2,846
Choking	5	15
Choking sensation	4	10
Cholecystitis		1
Cholecystitis infective	1	1
Cholelithiasis	1	1
Cholestasis	1	3
Chondritis		1
Chromatopsia		1
Chromaturia	1	9
Chronic fatigue syndrome	1	1
Chronic kidney disease	1	2
Chronic lymphocytic leukaemia	1	1
Chronic obstructive pulmonary disease	3	9
Ciliary muscle spasm		1
Circadian rhythm sleep disorder	1	1
Circulatory collapse	1	6
Circumoral swelling	2	3
Circumstance or information capable of leading to device use error		2
Circumstance or information capable of leading to medication error	42	248
Clostridium difficile colitis	1	1
Clostridium difficile infection	1	1
Clumsiness	2	2
Cluster headache		2
Coagulation time prolonged		1
Coagulopathy	2	4
Coccidioidomycosis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		54	248	24	90
					1
		2	5		1
		452	2675	34	171
1	1			5	15
		3	6	1	4
					1
				1	1
				1	1
				1	3
			1		
			1		
		1	9		
		1	1		
				1	2
				1	1
1	1	1	4	2	5
			1		
		1	1		
				1	6
		2	3		
			2		
		42	248		
				1	1
				1	1
		1	1	1	1
			2		
			1		
			1	2	3
					2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coccydynia	1	1
Cognitive disorder	4	24
Cold sweat	18	72
Cold urticaria		1
Colitis	6	8
Colitis ischaemic	3	3
Colitis ulcerative	3	6
Colon cancer		1
Communication disorder		3
Complex regional pain syndrome		1
Complicated appendicitis	1	1
Concussion	4	10
Condition aggravated	71	239
Conductive deafness		1
Confusional state	28	96
Congestive cardiomyopathy		1
Conjunctival haemorrhage	4	6
Conjunctival hyperaemia		1
Conjunctivitis	2	9
Conjunctivitis allergic		3
Conjunctivitis viral		1
Consciousness fluctuating	1	1
Constipation	11	34
Contraceptive diaphragm	1	1
Contraindicated product administered		1
Contraindication to vaccination		2
Contrast media allergy		1
Contusion	31	96
Conversion disorder	1	1
Coombs negative haemolytic anaemia		1
Coordination abnormal	2	5
Corneal infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	16		8
		13	61	5	11
			1		
		4	5	2	3
				3	3
				3	6
					1
			2		1
			1		
				1	1
		1	3	3	7
		49	180	22	59
					1
		21	72	7	24
					1
				4	6
					1
		2	9		
			3		
			1		
				1	1
		10	32	1	2
		1	1		
			1		
			2		
			1		
		25	84	6	12
		1	1		
					1
			2	2	3
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Corneal oedema		1
Corneal reflex decreased		1
Coronary artery disease		1
Coronary artery occlusion		1
Coronavirus infection		1
Coronavirus test positive	1	2
Cor pulmonale acute	1	1
Costochondritis	1	3
Costovertebral angle tenderness		1
Cough	124	517
COVID-19	466	1,175
COVID-19 immunisation		1
COVID-19 pneumonia	5	21
Cranial nerve disorder		1
Cranial nerve paralysis		1
C-reactive protein increased		12
Crohn's disease	2	5
Crying	5	30
Crystal urine		1
Culture urine positive		1
Cutaneous lupus erythematosus		1
Cutaneous vasculitis	1	1
Cyanosis	6	19
Cyst		3
Cystitis	6	14
Cystitis bacterial	1	1
Cyst rupture		1
Cytokine storm		1
Daydreaming	1	3
Deafness	21	50
Deafness bilateral	1	2
Deafness neurosensory	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
			1		
				1	2
				1	1
			1	1	2
			1		
1	1	105	438	19	79
1	3	173	338	293	837
			1		
				5	21
					1
			8		4
				2	5
		4	27	1	3
			1		
			1		
					1
		1	1		
		4	13	2	6
			3		
		5	10	1	4
		1	1		
			1		
					1
		1	3		
		1	1	20	49
				1	2
				2	6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deafness transitory		2
Deafness unilateral	8	26
Death	17	48
Decreased activity		1
Decreased appetite	67	292
Decreased embryo viability	1	1
Decreased interest		1
Deep vein thrombosis	22	35
Defaecation urgency	1	3
Degenerative bone disease		1
Dehydration	14	73
Delirium	8	20
Delusion	2	4
Delusional perception	1	3
Dementia	3	12
Demyelinating polyneuropathy		2
Dental caries	1	1
Dental discomfort	1	5
Dental paraesthesia	1	3
Dental restoration failure		1
Depersonalisation/derealisation disorder	1	3
Depressed level of consciousness	1	11
Depressed mood	6	22
Depression	6	19
Derealisation		1
Dermatitis	4	15
Dermatitis acneiform		2
Dermatitis allergic	1	5
Dermatitis atopic	1	1
Dermatitis contact	1	5
Dermatitis diaper		1
Dermatitis exfoliative		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				8	26
				17	48
			1		
		59	262	8	30
		1	1		
			1		
		1	1	21	34
		1	3		
			1		
		5	43	9	30
				8	20
			1	2	3
		1	2		1
				3	12
					2
		1	1		
		1	5		
		1	3		
			1		
		1	3		
				1	11
	1	6	20		2
		4	14	2	5
			1		
		2	13	2	2
			2		
		1	4		1
		1	1		
		1	5		
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dermatomyositis	1	3
Dermatophytosis of nail	1	1
Dermo-hypodermatitis	1	1
Dermoid cyst		1
Device breakage		1
Device leakage	1	1
Diabetes mellitus	2	9
Diabetes mellitus inadequate control		4
Diabetic foot infection		1
Diabetic neuropathy		1
Diaphragmatic disorder	1	2
Diaphragmatic paralysis		1
Diarrhoea	198	824
Diarrhoea haemorrhagic	3	11
Diastolic hypotension		1
Diet refusal		1
Diffuse alopecia	1	1
Dilatation ventricular		1
Diplegia	1	1
Diplopia	8	17
Disability		1
Discomfort	23	107
Discouragement	1	1
Disease progression		2
Disease recurrence	18	82
Disorganised speech	1	1
Disorientation	20	52
Disseminated intravascular coagulation	1	2
Dissociation		3
Disturbance in attention	9	51
Disturbance in social behaviour		2
Diverticulitis	8	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
		1	1		
		1	1		
					1
					1
		1	1		
				2	9
					4
			1		
			1		
		1	2		
					1
		173	755	25	69
				3	11
					1
					1
				1	1
					1
		6	12	2	5
					1
		23	99		8
		1	1		
			2		
		6	50	12	32
				1	1
		10	33	10	19
				1	2
			2		1
		5	42	4	9
			2		
				8	15

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diverticulum intestinal		1
Dizziness	375	1,759
Dizziness exertional		1
Dizziness postural	4	22
Drainage	1	1
Dreamy state	1	1
Drooling		3
Dropped head syndrome		1
Drug effective for unapproved indication	1	1
Drug eruption	1	3
Drug hypersensitivity	9	37
Drug ineffective	258	887
Drug interaction	4	15
Drug screen positive	1	1
Dry eye	4	19
Dry mouth	19	89
Dry skin	5	20
Dry throat	4	27
Dumping syndrome	1	1
Duodenogastric reflux	1	2
Dupuytren's contracture		1
Dysaesthesia	1	6
Dysarthria	10	27
Dyschromatopsia		1
Dysentery		1
Dysgeusia	33	209
Dysgraphia	1	2
Dyskinesia	12	32
Dyslipidaemia		1
Dysmenorrhoea	6	12
Dyspareunia		1
Dyspepsia	18	55

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
1	1	298	1484	77	275
			1		
		3	19	1	3
		1	1		
		1	1		
			3		
					1
		1	1		
			2	1	1
		8	32	1	5
1	3		1	258	886
		2	10	2	5
		1	1		
		4	19		
		16	77	3	12
		5	18		2
		4	23		4
		1	1		
		1	2		
					1
		1	5		1
		8	16	2	11
			1		
					1
		32	199	1	10
			1	1	1
		8	24	4	8
			1		
		5	11	1	1
			1		
		18	55		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysphagia	40	152
Dysphemia	1	7
Dysphonia	25	101
Dyspnoea	239	841
Dyspnoea at rest	2	3
Dyspnoea exertional	2	16
Dysstasia	14	55
Dystonia	5	7
Dysuria	4	14
Ear congestion	1	5
Ear discomfort	20	67
Ear disorder	3	13
Ear haemorrhage		1
Ear infection	6	18
Ear infection viral	1	1
Ear neoplasm		1
Ear pain	28	133
Ear pruritus	8	17
Ear swelling	1	15
Eating disorder	10	37
Ebola disease		1
Eczema	5	10
Ejection fraction decreased		1
Electrocardiogram abnormal	2	9
Electrocardiogram PR shortened	1	1
Electrocardiogram QT prolonged		2
Electrocardiogram ST segment depression	1	1
Electrocardiogram T wave abnormal	1	1
Electrocardiogram T wave peaked		1
Embolic stroke		1
Emotional disorder	3	15
Emotional distress	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		28	101	12	51
		1	5		2
		18	67	7	34
		142	521	97	320
				2	3
		1	12	1	4
		10	35	4	20
		1	1	4	6
		3	12	1	2
			2	1	3
		18	63	2	4
		3	10		3
			1		
		5	14	1	4
		1	1		
			1		
		24	120	4	13
		7	16	1	1
		1	13		2
		9	31	1	6
					1
		5	9		1
					1
		2	7		2
				1	1
					2
				1	1
		1	1		
			1		
					1
		3	14		1
		2	3		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Emphysema	1	1
Enanthema		1
Encephalitis		2
Encephalopathy		2
Endocarditis		1
Endocrine ophthalmopathy	1	2
Endometriosis	1	1
Energy increased	3	7
Enlarged uvula	3	10
Eosinophil count increased		3
Eosinophilia		1
Eosinophilic oesophagitis	1	1
Epicondylitis		2
Epilepsy	2	2
Epinephrine increased		1
Episcleritis		2
Epistaxis	23	71
Epstein-Barr virus infection reactivation		1
Erosive oesophagitis		1
Eructation	3	9
Erythema	99	445
Erythema multiforme	2	3
Erythema nodosum	1	1
Erythema of eyelid	2	10
Escherichia infection		1
Essential hypertension	1	1
Euphoric mood	5	8
Eustachian tube disorder		1
Eustachian tube dysfunction		1
Exaggerated startle response	1	1
Excessive cerumen production	2	3
Excessive ocular convergence	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
					2
					2
					1
				1	2
				1	1
		3	7		
		2	6	1	4
			1		2
			1		
		1	1		
			2		
				2	2
			1		
			2		
		14	52	9	19
					1
					1
		3	9		
		84	375	15	70
				2	3
		1	1		
		1	7	1	3
					1
		1	1		
		5	7		1
			1		
					1
		1	1		
		2	3		
				1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Exercise lack of		1
Exercise tolerance decreased		2
Exophthalmos	1	2
Expired product administered	3	7
Exposure during pregnancy	15	47
Exposure to SARS-CoV-2	32	71
Exposure via breast milk	3	9
Exposure via eye contact		1
Exposure via skin contact	2	24
Extensive swelling of vaccinated limb		1
External ear disorder		1
External ear pain		1
Extra dose administered		2
Extraocular muscle disorder	1	1
Extraocular muscle paresis	2	3
Extrasystoles	3	7
Extremity contracture		1
Eye allergy		1
Eye contusion	2	9
Eye discharge	4	13
Eye disorder	15	40
Eye haemorrhage	14	27
Eye infection		5
Eye inflammation	1	6
Eye injury	1	1
Eye irritation	6	40
Eyelid disorder		3
Eyelid function disorder	1	2
Eyelid haematoma		1
Eyelid irritation	1	3
Eyelid oedema	1	2
Eyelid pain	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
				1	2
		3	7		
		13	42	2	5
		30	61	2	10
		3	8		1
			1		
		2	24		
			1		
			1		
			2		
		1	1		
				2	3
		3	6		1
			1		
			1		
		2	9		
		4	13		
		13	34	2	6
				14	27
			5		
		1	4		2
				1	1
		6	38		2
			3		
			1	1	1
			1		
			2	1	1
		1	2		
		4	9		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid ptosis	3	11
Eyelid sensory disorder	1	2
Eyelids pruritus	3	7
Eye movement disorder	3	8
Eye oedema	1	6
Eye pain	21	106
Eye paraesthesia		2
Eye pruritus	10	58
Eye swelling	21	111
Eye ulcer		1
Face injury	3	7
Face oedema	1	4
Facial bones fracture	2	3
Facial discomfort	2	11
Facial nerve disorder	1	4
Facial neuralgia	1	2
Facial pain	13	57
Facial paralysis	63	199
Facial paresis	3	10
Facial spasm	1	3
Faecaloma	1	1
Faeces discoloured	9	16
Faeces pale	1	1
Faeces soft	2	4
Fall	46	135
False negative investigation result	1	1
Fatigue	668	3,204
Fear	5	29
Febrile convulsion		1
Feeding disorder	11	34
Feeling abnormal	203	768
Feeling cold	25	202

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6	1	5
		1	2		
		2	5	1	2
		3	6		2
		1	6		
		19	96	2	10
			1		1
		9	48	1	10
		14	83	7	28
			1		
		1	4	2	3
			2	1	2
				2	3
		2	11		
			1	1	3
		1	1		1
		10	50	3	7
			2	63	197
		3	6		4
			1	1	2
				1	1
		8	14	1	2
		1	1		
		1	2	1	2
		25	79	21	56
				1	1
1	2	625	3036	43	168
		5	27		2
					1
		10	28	1	6
		184	704	19	64
		20	180	5	22

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling drunk	2	12
Feeling hot	74	404
Feeling jittery	4	26
Feeling of body temperature change	13	57
Feeling of relaxation	1	1
Femur fracture	1	2
Fibrin D dimer increased	4	9
Fibromyalgia	3	8
Fine motor skill dysfunction		4
Finger deformity		2
Flank pain	1	14
Flatulence	8	32
Fluid imbalance		1
Fluid intake reduced	1	4
Fluid retention	4	7
Flushing	31	262
Foaming at mouth	2	2
Foetal death	2	3
Foetal hypokinesia	1	1
Folliculitis	1	3
Food allergy	3	4
Food aversion	1	3
Food intolerance	1	1
Food poisoning	1	3
Foot deformity	1	3
Foot fracture	3	3
Foreign body aspiration		1
Foreign body in eye		1
Foreign body in throat	2	4
Formication	5	10
Fracture		1
Freezing phenomenon		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	11		1
		60	345	14	59
		4	21		5
		12	54	1	3
		1	1		
				1	2
		1	5	3	4
		3	7		1
			3		1
			2		
		1	12		2
		8	31		1
					1
		1	3		1
		4	7		
		27	205	4	57
		2	2		
				2	3
				1	1
		1	3		
		2	3	1	1
		1	3		
		1	1		
		1	3		
		1	1	2	2
					1
			1		
				2	4
		5	9		1
					1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Frequent bowel movements	1	7
Frostbite		1
Frustration tolerance decreased	2	8
Full blood count abnormal		2
Functional gastrointestinal disorder	3	4
Fungal infection	2	7
Fungal skin infection	1	1
Furuncle		2
Gait disturbance	55	208
Gait inability	15	58
Gal bladder disorder	2	7
Gal bladder polyp		1
Gastric dilatation	1	1
Gastric disorder	7	14
Gastric infection		1
Gastric pH decreased		1
Gastric ulcer		1
Gastritis	1	2
Gastritis bacterial		1
Gastroenteritis	1	1
Gastroenteritis viral	3	9
Gastrointestinal disorder	10	37
Gastrointestinal haemorrhage	3	8
Gastrointestinal hypomotility	1	1
Gastrointestinal infection		1
Gastrointestinal injury	1	1
Gastrointestinal motility disorder		1
Gastrointestinal pain	11	23
Gastrointestinal sounds abnormal	1	6
Gastrointestinal stoma complication		1
Gastrointestinal viral infection		1
Gastrooesophageal reflux disease	8	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	7		
			1		
		2	7		1
			2		
		3	4		
		2	6		1
		1	1		
			2		
		38	154	17	54
		7	33	8	25
			3	2	4
			1		
		1	1		
		6	13	1	1
					1
			1		
					1
		1	2		
					1
		1	1		
		1	5	2	4
		10	34		3
				3	8
		1	1		
			1		
		1	1		
			1		
		9	21	2	2
		1	6		
			1		
			1		
		8	30		2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Generalised anxiety disorder	1	2
Generalised tonic-clonic seizure	3	4
General physical health deterioration	2	5
Genital herpes	2	5
Genital herpes simplex		2
Genital lesion		1
Genital swelling	1	1
Genital ulceration		1
Gingival bleeding	2	6
Gingival blister		2
Gingival discomfort	1	2
Gingival disorder		1
Gingival erythema		3
Gingival pain		9
Gingival recession		1
Gingival swelling	2	9
Gingival ulceration		1
Gingivitis		1
Glare		1
Glassy eyes		4
Glaucoma	1	5
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	3	6
Glomerulonephritis minimal lesion	1	1
Glossitis		5
Glossodynia	6	29
Glycosylated haemoglobin increased	1	1
Goitre	1	4
Gout	1	4
Granulocytes abnormal	1	1
Granuloma skin		1
Grip strength decreased	6	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
				3	4
		2	2		3
		1	4	1	1
			2		
			1		
		1	1		
			1		
		1	5	1	1
			1		1
		1	1		1
			1		
			3		
			8		1
			1		
		2	9		
			1		
			1		
			1		
			4		
				1	5
			1		
		1	4	2	2
				1	1
			5		
		6	27		2
				1	1
		1	3		1
		1	4		
		1	1		
					1
		6	11		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Groin pain		3
Growing pains		1
Grunting	1	6
Guillain-Barre syndrome	4	15
Haemangioma		1
Haematemesis	2	5
Haematochezia	7	23
Haematocrit decreased		3
Haematocrit increased		1
Haematoma	5	9
Haematuria		3
Haemoglobin abnormal		1
Haemoglobin decreased	1	12
Haemoglobin increased		1
Haemolysis	1	1
Haemolytic anaemia	2	2
Haemophagocytic lymphohistiocytosis		1
Haemoptysis	5	17
Haemorrhage	21	44
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		2
Haemorrhagic stroke		2
Haemorrhagic urticaria	1	1
Haemorrhagic varicella syndrome		1
Haemorrhoidal haemorrhage		1
Haemorrhoids	4	6
Hair injury		1
Hallucination	13	29
Hallucination, auditory	2	9
Hallucination, visual	3	11
Hand-eye coordination impaired		1
Hand fracture		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
			1		
		1	5		1
			1	4	14
					1
				2	5
				7	23
			3		
			1		
		5	8		1
			2		1
					1
			6	1	6
			1		
				1	1
				2	2
					1
		2	10	3	7
				21	44
					1
					2
					2
				1	1
					1
			1		
		3	4	1	2
			1		
				13	29
				2	9
				3	11
					1
					4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hangover	1	12
Headache	785	4,056
Head banging		1
Head discomfort	26	110
Head injury	11	26
Head titubation	1	1
Heart injury	1	3
Heart rate abnormal	10	24
Heart rate decreased	6	17
Heart rate increased	97	520
Heart rate irregular	12	37
Heart valve incompetence	2	2
Heat illness	1	1
Helicobacter infection		1
Hemiparesis	6	10
Hemiplegia		4
Henoch-Schonlein purpura	1	1
Heparin-induced thrombocytopenia		1
Hepatic cirrhosis		1
Hepatic cyst		1
Hepatic enzyme abnormal	1	1
Hepatic enzyme increased	4	6
Hepatic function abnormal	1	1
Hepatic lesion		1
Hepatic necrosis		1
Hepatic pain		2
Hepatitis		1
Hepatitis acute		1
Hepatitis D	1	1
Hepatomegaly		1
Hernia repair	1	1
Herpes simplex	2	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	10		2
		716	3785	69	271
			1		
		23	95	3	15
		7	13	4	13
		1	1		
				1	3
		8	20	2	4
		3	9	3	8
		71	398	26	122
		8	28	4	9
		1	1	1	1
		1	1		
					1
		1	1	5	9
					4
				1	1
					1
			1		
				1	1
		2	4	2	2
				1	1
					1
			1		1
					1
				1	1
			1		
		1	1		
		2	10		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Herpes simplex reactivation		2
Herpes virus infection	3	11
Herpes zoster	55	148
Herpes zoster oticus	1	1
Heterophoria	1	1
Hiccups		1
Hidradenitis		2
Hip fracture	2	5
Histamine level increased		3
HIV test false positive		1
HIV test negative	1	1
Hordeolum	1	6
Hormone level abnormal		2
Hot flush	21	132
Hunger		7
Huntington's disease	1	1
Hydrophobia		1
Hyperacusis	6	17
Hyperaemia		1
Hyperaesthesia	3	21
Hyperaesthesia teeth		2
Hyperbilirubinaemia	1	1
Hypercholesterolaemia		1
Hyperglycaemia	1	3
Hyperhidrosis	86	390
Hyperlipidaemia		1
Hypermetropia		1
Hyperparathyroidism		1
Hyperphagia		1
Hyperpyrexia	6	9
Hyperreflexia		1
Hypersensitivity	82	259

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		2	10	1	1
		49	126	6	22
				1	1
			1		
			2		
				2	5
			2		1
			1		
				1	1
		1	5		1
			1		1
		19	118	2	14
			7		
		1	1		
			1		
		5	15	1	2
			1		
		3	20		1
			2		
				1	1
			1		
			1	1	2
		75	344	11	46
					1
			1		
			1		
			1		
				6	9
			1		
		61	178	21	81

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypersensitivity vasculitis	3	3
Hypersomnia	19	81
Hypertension	50	223
Hypertensive crisis		3
Hypertensive emergency		3
Hyperthyroidism	1	1
Hypertonia		1
Hypertrichosis		1
Hyperventilation	2	16
Hypervigilance	1	1
Hypoacusis	11	43
Hypoaesthesia	142	619
Hypoaesthesia eye	2	6
Hypoaesthesia oral	34	186
Hypoaesthesia teeth		1
Hypocalcaemia		1
Hypogeusia		6
Hypoglycaemia	1	8
Hypokalaemia	1	4
Hypokalaemic syndrome	1	1
Hypokinesia	5	18
Hypomagnesaemia		1
Hyponatraemic syndrome	1	1
Hypophagia	1	5
Hypopnoea	3	9
Hyporeflexia		1
Hyporesponsive to stimuli		2
Hyposmia		4
Hypotension	18	65
Hypothermia	1	4
Hypothyroidism	1	5
Hypotonia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
		16	74	3	7
1	1	22	119	28	104
					3
				1	1
			1		
			1		
		2	11		5
		1	1		
		8	37	3	6
		99	483	43	136
		2	6		
		28	146	6	40
			1		
			6		
			4	1	4
				1	4
		1	1		
		4	15	1	3
					1
		1	1		
		1	2		3
		3	7		2
					1
			1		1
			4		
		6	33	12	32
				1	4
			1	1	4
		1	2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypovolaemic shock	1	2
Hypoxia	4	6
Hysterectomy	1	1
Idiopathic intracranial hypertension	1	1
Idiosyncratic drug reaction		1
Illrd nerve paralysis		1
Ileus		1
Iliot bial band syndrome		1
Ill-defined disorder	1	3
Illness	129	339
Illness anxiety disorder		1
Immobile	3	4
Immune-mediated arthritis		1
Immune system disorder	9	21
Immune thrombocytopenia	1	9
Immunisation	1	2
Immunisation reaction	1	1
Immunodeficiency	1	4
Immunosuppression		1
Impaired driving ability	1	12
Impaired gastric emptying	1	1
Impaired healing	1	3
Impaired quality of life		1
Impaired work ability	2	12
Impulsive behaviour		1
Inappropriate affect	1	1
Inappropriate schedule of product administration	92	525
Incoherent	1	7
Incomplete course of vaccination	3	10
Incontinence		2
Incorrect dosage administered	1	2
Incorrect dose administered	4	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				4	6
				1	1
				1	1
			1		
					1
					1
			1		
		1	3		
		111	307	18	32
			1		
				3	4
					1
		6	14	3	7
				1	9
		1	2		
				1	1
				1	4
					1
			9	1	3
				1	1
		1	2		1
					1
		1	10	1	2
			1		
		1	1		
		91	524	1	1
		1	3		4
		3	10		
			2		
		1	2		
		4	22		2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incorrect dose administered by device	1	1
Incorrect route of product administration	16	89
Increased appetite	1	3
Increased tendency to bruise		2
Increased upper airway secretion	1	8
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion	2	3
Induration		6
Infant irritability		1
Infection	7	19
Infection parasitic		1
Infectious mononucleosis	1	2
Infertility female	1	1
Inflammation	19	67
Inflammatory marker increased		1
Inflammatory pain		2
Influenza	23	78
Influenza B virus test positive		1
Influenza like illness	73	268
Initial insomnia	1	4
Injected limb mobility decreased	2	8
Injection site bruising	2	4
Injection site discolouration		1
Injection site discomfort	1	2
Injection site erythema	9	39
Injection site extravasation	1	3
Injection site haematoma		1
Injection site haemorrhage	1	4
Injection site indentation		1
Injection site induration		2
Injection site inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		14	85	2	4
		1	3		
			2		
			5	1	3
					1
		2	2		1
			6		
			1		
		4	14	3	5
			1		
		1	2		
				1	1
		17	60	2	7
			1		
			2		
		22	75	1	3
			1		
		67	254	6	14
		1	4		
		2	8		
		2	4		
			1		
		1	2		
		9	39		
		1	3		
					1
		1	4		
			1		
			2		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site mass		5
Injection site nodule		1
Injection site oedema		1
Injection site pain	15	129
Injection site papule		1
Injection site pruritus	2	12
Injection site rash		10
Injection site reaction	1	5
Injection site swelling	7	35
Injection site urticaria		2
Injection site warmth	1	8
Injury	4	8
Inner ear disorder	1	3
Insomnia	64	288
Instillation site pain		1
Intentional dose omission		2
Intentional overdose		1
Intentional product misuse		1
Intercepted medication error		2
Internal haemorrhage	4	5
International normalised ratio decreased	1	2
International normalised ratio increased		5
Intervertebral disc protrusion	1	3
Intestinal haemorrhage	2	2
Intestinal ischaemia		1
Intestinal obstruction		1
Intestinal perforation		1
Intra-abdominal haematoma		1
Intracardiac thrombus	1	1
Intracranial aneurysm	1	3
Intracranial pressure increased	3	4
Intranasal hypoaesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		
			1		
			1		
		15	127		2
			1		
		2	12		
			10		
		1	5		
		7	35		
			2		
		1	8		
		4	5		3
		1	2		1
		57	264	7	24
			1		
			2		
			1		
			1		
			2		
				4	5
			1	1	1
			1		4
			1	1	2
				2	2
					1
					1
					1
				1	1
				1	3
				3	4
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intranasal paraesthesia		3
Intraocular pressure increased	1	3
Intraocular pressure test abnormal		1
Iridocyclitis	2	2
Iron deficiency	1	1
Irregular breathing	1	1
Irregular sleep wake rhythm disorder		2
Irritability	3	20
Irritability postvaccinal		1
Irritable bowel syndrome	4	6
Ischaemic cerebral infarction	1	1
Ischaemic stroke	2	7
IVth nerve paralysis		1
Jaundice	3	7
Jaw clicking	1	3
Jaw cyst		1
Jaw disorder	1	6
Joint dislocation		7
Joint effusion		2
Joint injury	2	8
Joint instability		4
Joint lock	4	6
Joint noise	1	2
Joint range of motion decreased	12	51
Joint stiffness	5	31
Joint swelling	22	92
Joint warmth		1
Keratitis		1
Kidney infection	5	10
Labile hypertension		1
Laboratory test abnormal	1	2
Labyrinthitis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		1	2		1
			1		
				2	2
		1	1		
		1	1		
			2		
		3	18		2
			1		
		3	5	1	1
				1	1
				2	7
					1
			2	3	5
		1	3		
			1		
		1	5		1
			1		6
			2		
		2	7		1
			1		3
		4	6		
		1	2		
		9	44	3	7
		5	28		3
		19	83	3	9
			1		
					1
				5	10
			1		
			1	1	1
					3

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lack of spontaneous speech	1	2
Lacrimation decreased		1
Lacrimation increased	8	47
Lactic acidosis		1
Large intestinal obstruction		1
Large intestine infection	1	1
Large intestine perforation	1	1
Large intestine polyp		1
Laryngeal discomfort		1
Laryngeal oedema		4
Laryngeal pain	1	2
Laryngitis	3	9
Laryngospasm		4
Latent autoimmune diabetes in adults		1
Laziness		2
Lethargy	36	154
Leukaemia		3
Leukocytosis		2
Lichenoid keratosis		1
Lichen planus		1
Ligament disorder		1
Ligament injury		2
Ligament rupture	1	2
Ligament sprain	2	6
Limb deformity		1
Limb discomfort	42	164
Limb injury	2	22
Limb mass	5	11
Lipase decreased		1
Lipase increased	1	2
Lip blister	2	10
Lip discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
		8	44		3
					1
				1	1
			1		
			1		
					4
		1	2		
		2	7	1	2
			1		3
					1
			2		
		33	142	3	12
			1		2
			1		1
					1
			1		
			1		
			2		
			1	1	1
		2	6		
			1		
		34	144	8	20
		2	22		
		5	11		
			1		
			1	1	1
		1	7	1	3
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lip disorder	2	8
Lip dry		1
Lip erythema	1	6
Lip exfoliation		1
Lip haemorrhage	1	1
Lipids increased		1
Lip infection		1
Lip injury	3	5
Lip oedema		6
Lip pain		4
Lip pruritus		11
Lip swelling	30	144
Lip ulceration		1
Liquid product physical issue		4
Listless	1	2
Livedo reticularis		6
Liver disorder	1	5
Liver function test abnormal		2
Liver injury		1
Liver tenderness		1
Local anaesthesia		1
Localised infection	2	6
Localised oedema	1	3
Local reaction		1
Loose body in joint	1	1
Loss of consciousness	90	225
Loss of control of legs	1	2
Loss of personal independence in daily activities	27	92
Loss of proprioception		1
Low density lipoprotein increased	1	1
Lower limb fracture	2	2
Lower respiratory tract congestion		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	8		
			1		
		1	5		1
			1		
				1	1
			1		
			1		
		3	4		1
			4		2
			4		
			6		5
		24	102	6	42
			1		
			4		
		1	2		
			3		3
			3	1	2
			1		1
					1
			1		
			1		
		1	5	1	1
		1	3		
			1		
				1	1
		1	2	89	223
				1	2
		20	76	7	16
					1
		1	1		
				2	2
			2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lower respiratory tract infection	3	8
Lumbar radiculopathy		1
Lung carcinoma cell type unspecified stage I		1
Lung disorder	3	10
Lung hyperinflation		1
Lung infiltration	1	1
Lung neoplasm malignant	1	2
Lung opacity		1
Lupus myositis	1	1
Lyme disease	1	3
Lymphadenitis	1	13
Lymphadenopathy	154	815
Lymph gland infection		2
Lymph node pain	27	170
Lymph node palpable	1	3
Lymphocyte count abnormal		2
Lymphocyte count decreased		4
Lymphocytosis		1
Lymphoedema		13
Lymphoma	1	3
Lymphopenia		1
Macroglossia	1	2
Macular degeneration		5
Macular hole		1
Macule		3
Major depression	1	3
Malaise	210	1,035
Malignant hypertension		1
Mammogram abnormal	1	1
Mania		2
Mass	10	35
Mastication disorder	3	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	8
			1		
					1
	1	2	8	1	2
			1		
				1	1
				1	2
					1
				1	1
				1	3
		1	12		1
		145	765	9	50
			2		
		24	159	3	11
		1	3		
			1		1
			4		
			1		
			13		
				1	3
					1
				1	2
					5
					1
			3		
				1	3
		197	971	13	64
					1
		1	1		
			1		1
		9	31	1	4
		3	7		2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mastitis	2	5
Mastoid disorder	1	2
Maternal exposure before pregnancy		1
Maternal exposure during pregnancy	17	117
Maternal exposure timing unspecified		4
May-Thurner syndrome		1
Mean cell volume increased		1
Mean platelet volume decreased		1
Measles	2	2
Mechanical urticaria		1
Medication error	1	3
Melaena	1	2
Memory impairment	19	52
Meniere's disease	3	5
Meningeal disorder		1
Meningism		1
Meningitis	1	2
Meningitis aseptic		1
Meningitis viral		4
Menopausal symptoms		1
Menopause	1	1
Menorrhagia	22	33
Menstrual discomfort	1	1
Menstrual disorder	9	24
Menstruation delayed	2	4
Menstruation irregular	10	24
Mental disorder	3	16
Mental impairment	4	36
Mental status changes	2	5
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Metabolic function test abnormal		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
		1	1		1
			1		
		17	115		2
			4		
					1
			1		
			1		
				2	2
			1		
		1	3		
				1	2
		18	41	1	11
				3	5
					1
			1		
				1	2
					1
			1		
		1	1		
		20	29	2	4
		1	1		
		7	22	2	2
		2	3		1
		10	24		
		3	13		3
				4	36
		2	4		1
					1
			2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Metamyelocyte count increased		1
Metastases to meninges		1
Methylenetetrahydrofolate reductase gene mutation	1	1
Metrorrhagia	4	13
Microangiopathic haemolytic anaemia	1	1
Microembolism		2
Micturition disorder		2
Micturition urgency	2	6
Middle ear effusion		1
Middle insomnia	4	34
Migraine	62	255
Migraine with aura	4	12
Migraine without aura	1	1
Miliaria		3
Miosis		1
Mitral valve disease	1	1
Mitral valve prolapse		1
Mixed connective tissue disease		1
Moaning	1	1
Mobility decreased	17	68
Monocyte count abnormal		1
Monocyte count increased		3
Mononeuropathy		1
Monoparesis		1
Monoplegia		6
Mood altered	1	2
Mood swings	1	3
Morning sickness	1	1
Motion sickness	1	7
Motor dysfunction	4	9
Mouth haemorrhage	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	1		
		3	11	1	2
				1	1
			1		2
			1		1
		1	4	1	2
			1		
		4	32		2
		50	223	12	32
		4	11		1
		1	1		
			3		
			1		
				1	1
					1
					1
		1	1		
		14	55	3	13
			1		
			2		1
					1
					1
					6
		1	2		
		1	1		2
				1	1
			6	1	1
		1	3	3	6
			3	1	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mouth injury		2
Mouth swelling	5	31
Mouth ulceration	4	12
Movement disorder	16	78
Mucosal disorder		5
Mucosal dryness		1
Mucosal inflammation		1
Mucosa vesicle		1
Mucous stools	1	2
Multi-organ disorder	1	1
Multiple allergies	1	1
Multiple organ dysfunction syndrome		1
Multiple sclerosis	3	8
Multiple sclerosis relapse	5	7
Muscle atrophy		2
Muscle contractions involuntary	3	6
Muscle contracture		1
Muscle discomfort	3	16
Muscle disorder	6	14
Muscle fatigue	6	15
Muscle injury	1	1
Muscle mass		1
Muscle rigidity	1	4
Muscle rupture		1
Muscle spasms	58	219
Muscle spasticity	1	3
Muscle strain	2	12
Muscle swelling	4	9
Muscle tightness	12	75
Muscle twitching	11	51
Muscular weakness	49	196
Musculoskeletal chest pain	7	42

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		4	20	1	11
		4	11		1
		13	68	3	10
			4		1
			1		
			1		
					1
		1	2		
				1	1
		1	1		
					1
				3	8
				5	7
			2		
		3	5		1
			1		
		3	16		
		6	13		1
		6	15		
		1	1		
			1		
		1	2		2
					1
		44	183	14	36
		1	2		1
		1	10	1	2
		3	7	1	2
		10	66	2	9
		10	43	1	8
		35	152	14	44
		5	37	2	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal discomfort	16	54
Musculoskeletal disorder	6	13
Musculoskeletal pain	6	16
Musculoskeletal stiffness	50	212
Mutism		1
Myalgia	198	1,340
Myasthenia gravis		2
Mydriasis	4	6
Myelitis transverse	4	7
Myelocyte count increased		1
Myelopathy		1
Myocardial infarction	17	55
Myocardial necrosis marker increased		4
Myocardial strain	1	1
Myocarditis	1	6
Myoclonus		2
Myopia		1
Myositis		2
Nail discolouration	1	2
Narcolepsy	1	2
Nasal congestion	56	231
Nasal crusting		1
Nasal discharge discolouration		1
Nasal discomfort	5	17
Nasal disorder	2	4
Nasal dryness	1	2
Nasal injury		3
Nasal oedema	5	17
Nasal pruritus	2	4
Nasopharyngitis	56	189
Nausea	444	2,230
Near death experience	10	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		15	50	1	4
		5	9	1	4
		5	14	1	2
		47	197	3	15
					1
		185	1267	13	73
					2
		4	6		
				4	7
					1
					1
				17	55
					4
				1	1
				1	6
					2
			1		
					2
		1	1		1
				1	2
		52	212	4	19
			1		
			1		
		5	14		3
		1	3	1	1
		1	2		
			3		
		4	12	1	5
		1	3	1	1
		53	183	3	6
		381	2013	63	217
		1	1	9	21

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neck injury	1	2
Neck mass	2	12
Neck pain	79	382
Needle issue	1	2
Neoplasm	1	2
Neoplasm malignant	3	5
Neoplasm progression	1	3
Neoplasm skin	1	3
Nephrolithiasis	6	12
Nephropathy	2	3
Nephrotic syndrome	1	1
Nerve compression	3	15
Nerve injury	5	13
Nervousness	26	103
Nervous system disorder	5	18
Neuralgia	21	68
Neuralgic amyotrophy		3
Neuritis		3
Neurological symptom	2	7
Neuromyelitis optica spectrum disorder	1	1
Neuropathy peripheral	24	57
Neutropenia	1	3
Neutrophil count abnormal		2
Neutrophil count decreased		3
Neutrophil count increased		3
Nightmare	6	32
Night sweats	8	79
Nipple exudate bloody		1
Nipple pain	1	6
Nipple swelling		2
Nitrite urine present		1
No adverse event	25	52

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		2	12		
		67	344	12	38
		1	2		
		1	2		
				3	5
			1	1	2
		1	3		
				6	12
			1	2	2
				1	1
		2	14	1	1
		4	9	1	4
		24	97	2	6
		3	12	2	6
		14	57	7	11
			1		2
			3		
			4	2	3
				1	1
			2	24	55
				1	3
					2
			1		2
			2		1
		6	29		3
		7	75	1	4
			1		
		1	6		
			2		
			1		
		25	52		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nocturia		1
Nocturnal dyspnoea	1	1
Nodule	5	11
Non-Hodgkin's lymphoma		2
Noninfective encephalitis		3
Noninfective gingivitis		2
Non-pitting oedema	1	1
Normocytic anaemia		1
Nuchal rigidity		3
Nystagmus	1	4
Obesity		1
Obsessive thoughts		1
Obstructive airways disorder	1	6
Occipital neuralgia	1	2
Occupational exposure to product	2	4
Occupational exposure to SARS-CoV-2		5
Ocular discomfort	10	27
Ocular hyperaemia	11	59
Ocular icterus		1
Ocular vascular disorder	2	2
Odynophagia	3	16
Oedema	1	11
Oedema mouth		1
Oedema peripheral	3	13
Oesophageal achalasia	1	1
Oesophageal disorder		2
Oesophageal pain		3
Oesophageal stenosis	1	1
Oesophagitis	1	1
Off label use	72	480
Oligodipsia		1
Oligomenorrhoea		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
		5	11		
					2
			2		3
				1	1
			1		
			2		1
		1	2		2
			1		
					1
			1	1	5
		1	1		1
		2	4		
			5		
		10	23		4
		10	51	1	8
			1		
		1	1	1	1
		3	13		3
		1	9		2
					1
		3	11		2
		1	1		
			1		1
			3		
				1	1
		1	1		
		69	471	3	9
					1
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oliguria		1
Omphalitis	1	1
On and off phenomenon		1
Onychoclasia	1	1
Ophthalmic herpes simplex		1
Optic ischaemic neuropathy	2	2
Optic nerve disorder	1	1
Optic neuritis	3	7
Oral blood blister		1
Oral candidiasis	2	6
Oral discomfort	5	29
Oral disorder	2	13
Oral fungal infection		2
Oral herpes	11	45
Oral lichen planus	1	1
Oral mucosal blistering	2	7
Oral mucosal eruption		5
Oral mucosal erythema		4
Oral mucosal exfoliation		1
Oral mucosal roughening	1	1
Oral pain	9	26
Oral pruritus	4	21
Oral viral infection		2
Orbital oedema	1	2
Oromandibular dystonia		1
Oropharyngeal blistering	1	3
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	14	50
Oropharyngeal pain	90	412
Oropharyngeal spasm		2
Orthopnoea		1
Orthostatic heart rate response increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			1		
		1	1		
					1
				2	2
				1	1
				3	7
					1
		2	6		
		4	26	1	3
		2	11		2
			2		
		9	42	2	3
		1	1		
		1	6	1	1
			5		
			3		1
			1		
		1	1		
		8	24	1	2
		3	14	1	7
			2		
				1	2
			1		
				1	3
			1		
		11	40	3	10
		85	384	5	28
					2
					1
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orthostatic hypotension	1	5
Orthostatic intolerance	1	1
Osteoarthritis		5
Osteochondritis		1
Osteomyelitis		3
Osteopenia		1
Osteoporosis		1
Otitis media	2	2
Otorrhoea		1
Ovarian cancer		1
Ovarian cyst	1	1
Ovarian disorder	1	1
Ovarian enlargement	1	1
Overdose	8	52
Overweight		2
Oxygen saturation abnormal		5
Oxygen saturation decreased	10	40
Pain	500	2,531
Painful respiration	1	9
Pain in extremity	573	2,326
Pain in jaw	17	75
Pain of skin	8	36
Palatal disorder		2
Palatal swelling	2	9
Pallor	10	49
Palmar erythema		7
Palpitations	72	379
Pancreatic disorder	2	2
Pancreatitis	2	7
Pancreatitis acute	1	3
Pancytopenia		3
Panic attack	7	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	3
		1	1		
			5		
			1		
					3
			1		
			1		
		2	2		
			1		
					1
				1	1
		1	1		
		8	50		2
			2		
			5		
		4	18	6	22
		455	2374	45	157
		1	6		3
1	1	539	2226	34	100
		15	63	2	12
		7	33	1	3
			1		1
		2	7		2
		7	35	3	14
			6		1
		52	285	20	94
		1	1	1	1
				2	7
				1	3
					3
		6	15	1	4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Panic disorder	2	5
Panic reaction	3	13
Papule		2
Paraesthesia	132	691
Paraesthesia ear		1
Paraesthesia mucosal		1
Paraesthesia oral	29	235
Paralysis	7	25
Paranasal sinus discomfort	3	23
Paranasal sinus hypersecretion		3
Paranasal sinus hyopsecretion		1
Paranoia	1	6
Paraplegia	1	1
Parkinson's disease	1	2
Parosmia	9	43
Patient elopement		1
Pelvic inflammatory disease		1
Pelvic mass	2	2
Pelvic pain	3	9
Periarthritis		3
Pericardial effusion	1	7
Pericarditis	3	11
Periodontitis		1
Periorbital cellulitis		1
Periorbital discomfort		1
Periorbital oedema		2
Periorbital pain		2
Periorbital swelling	3	25
Peripheral artery thrombosis	1	1
Peripheral coldness	16	73
Peripheral ischaemia		1
Peripheral nerve injury		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		
		3	12		1
			2		
		107	582	25	109
			1		
			1		
		24	187	5	48
				7	25
		3	23		
			3		
			1		
		1	6		
				1	1
				1	2
		6	39	3	4
			1		
					1
				2	2
		2	8	1	1
			2		1
				1	7
				3	11
			1		
					1
			1		
			1		1
		2	21	1	4
		1	1		
		13	65	3	8
					1
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Peripheral sensory neuropathy		2
Peripheral swelling	95	381
Peripheral vascular disorder		2
Peripheral venous disease	2	3
Perivascular dermatitis		1
Peroneal nerve palsy	1	2
Personality change	1	2
Pertussis		1
Petechiae	3	24
Pharyngeal disorder	1	6
Pharyngeal enanthema		2
Pharyngeal erythema	5	13
Pharyngeal haemorrhage	2	2
Pharyngeal hypoaesthesia	3	13
Pharyngeal inflammation	1	2
Pharyngeal mass	1	5
Pharyngeal oedema	2	6
Pharyngeal paraesthesia	4	25
Pharyngeal swelling	35	146
Pharyngeal ulceration		1
Pharyngitis	5	9
Pharyngitis streptococcal		5
Phlebitis	1	3
Phlebitis superficial	2	2
Photophobia	9	41
Photopsia	2	8
Photosensitivity reaction	4	17
Phrenic nerve injury		1
Physical deconditioning		1
Physical examination abnormal		1
Pigmentation disorder		2
Piloerection	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		83	340	12	41
			2		
		2	3		
			1		
		1	2		
				1	2
					1
		1	15	2	9
			5	1	1
			2		
		5	13		
				2	2
		3	10		3
		1	2		
		1	4		1
		1	1	1	5
		3	18	1	7
		17	78	18	68
			1		
		4	7	1	2
			5		
		1	3		
		2	2		
		7	38	2	3
		1	5	1	3
		1	13	3	4
					1
			1		
					1
			1		1
		1	5		1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pituitary tumour benign		1
Pityriasis		1
Pityriasis rosea	1	2
Plantar erythema		1
Plantar fasciitis	1	2
Platelet count decreased	9	31
Platelet count increased	1	5
Platelet disorder	1	2
Pleural effusion	4	10
Pleurisy		2
Pleuritic pain		5
Plicated tongue		1
Pneumocystis jirovecii pneumonia		1
Pneumonia	20	61
Pneumonia aspiration		2
Pneumonia staphylococcal	1	1
Pneumonia viral	1	1
Pneumonitis	1	3
Pneumothorax	2	2
PO2 decreased		2
Poisoning	1	2
Pollakiuria	3	17
Polychondritis		1
Polydipsia		2
Polymenorrhoea	1	2
Polymyalgia rheumatica		4
Polymyositis		1
Polyneuropathy	1	2
Polyserositis		1
Polyuria	4	6
Poor peripheral circulation	2	7
Poor quality product administered	16	38

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		1	2		
			1		
		1	2		
		3	12	6	19
		1	3		2
		1	1		1
		1	2	3	8
			1		1
			5		
			1		
					1
				20	61
					2
				1	1
				1	1
			1	1	2
				2	2
			1		1
				1	2
		3	17		
					1
			2		
		1	2		
					4
					1
				1	2
					1
		3	4	1	2
		2	5		2
		16	38		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Poor quality sleep	6	32
Porphyria acute		1
Portal vein thrombosis	3	3
Post herpetic neuralgia		1
Postictal state		1
Postmenopausal haemorrhage	6	7
Postoperative wound infection		1
Post procedural complication		
Post-traumatic neck syndrome		3
Post-traumatic neuralgia		1
Post-traumatic stress disorder		2
Postural orthostatic tachycardia syndrome	2	6
Posture abnormal		1
Post viral fatigue syndrome	1	1
Potentiating drug interaction	1	7
Pre-existing condition improved		3
Premature delivery		1
Premature labour	1	2
Premature rupture of membranes		1
Premenstrual syndrome	1	5
Pressure of speech		1
Presyncope	35	136
Prinzmetal angina	1	2
Procedural haemorrhage		1
Procedural pain		2
Procedural site reaction		1
Proctalgia		1
Product administered at inappropriate site	17	60
Product administered to patient of inappropriate age	3	8
Product administration error		11
Product colour issue		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	32		
					1
				3	3
			1		
			1		
				6	7
					1
	1				
					3
			1		
			2		
1	1	1	2	1	4
			1		
		1	1		
		1	7		
			3		
					1
				1	2
					1
		1	5		
			1		
		27	104	8	32
				1	2
					1
			1		1
			1		
		16	58	1	2
		3	8		
			10		1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product communication issue		1
Product complaint		1
Product confusion		2
Product container issue		1
Product dose omission in error		1
Product dose omission issue	21	37
Product formulation issue		1
Productive cough	9	34
Product leakage		8
Product lot number issue		1
Product odour abnormal		1
Product preparation error	3	28
Product preparation issue	1	25
Product prescribing error		2
Product quality issue	1	2
Product storage error	9	17
Product supply issue	7	13
Product temperature excursion issue	8	12
Product use in unapproved indication	1	1
Product use issue	19	331
Protein total decreased		1
Proteinuria	1	2
Protein urine present	1	1
Prothrombin time prolonged		2
Pruritus	170	808
Pruritus genital		1
Pseudofolliculitis		1
Pseudomonas infection	1	1
Psoriasis	1	4
Psoriatic arthropathy	1	3
Psychiatric symptom		2
Psychomotor hyperactivity	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			2		
			1		
			1		
		21	37		
					1
		9	32		2
			8		
			1		
			1		
		3	26		2
		1	22		3
			2		
		1	2		
		9	17		
		7	13		
		8	12		
		1	1		
		18	324	1	7
			1		
		1	1		1
		1	1		
			1		1
		148	702	22	106
					1
			1		
				1	1
		1	4		
				1	3
			2		
		1	2	1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Psychotic disorder	3	3
Pulmonary artery occlusion	1	1
Pulmonary congestion	9	17
Pulmonary embolism	28	39
Pulmonary fibrosis	1	2
Pulmonary hypertension		1
Pulmonary mass	1	4
Pulmonary oedema	5	12
Pulmonary pain	4	19
Pulmonary thrombosis	12	18
Pulmonary venous thrombosis	1	1
Pulse abnormal	1	12
Pulse absent	2	3
Pulseless electrical activity	1	1
Pulse pressure decreased	1	1
Pulse volume decreased	1	1
Pupil fixed	1	1
Pupillary disorder	1	2
Pupils unequal	1	1
Purpura	1	3
Pustule		5
Pyrexia	507	2,762
Quality of life decreased	1	3
Radial nerve palsy	1	1
Radiculitis brachial		2
Rash	197	793
Rash erythematous	22	128
Rash macular	22	106
Rash maculo-papular	1	9
Rash morbilliform	4	8
Rash papular	10	47
Rash pruritic	23	119

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
				1	1
				9	17
				28	39
				1	2
					1
		1	2		2
				5	12
		3	15	1	4
				12	18
				1	1
		1	7		5
				2	3
				1	1
		1	1	1	1
		1	2		
				1	1
		1	3		
			3		2
		468	2572	39	190
			2	1	1
		1	1		
					2
		168	662	29	131
		18	103	4	25
		18	91	4	15
		1	9		
		4	6		2
		8	43	2	4
		19	105	4	14

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash pustular		2
Rash vesicular	3	13
Raynaud's phenomenon	3	7
Reaction to excipient	2	10
Reaction to preservatives	2	2
Reading disorder		1
Rectal discharge		1
Rectal haemorrhage	3	9
Rectal tenesmus		1
Red blood cell abnormality	1	1
Red blood cell count abnormal	1	2
Red blood cell count decreased	2	7
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased		5
Red cell distribution width decreased		1
Red cell distribution width increased		1
Red ear syndrome		1
Reduced facial expression	1	3
Regurgitation		1
Renal cyst		1
Renal disorder	2	7
Renal failure		2
Renal impairment	3	7
Renal infarct	1	1
Renal pain	2	16
Renal tubular disorder	1	1
Renal tubular injury		1
Respiration abnormal	2	4
Respiratory arrest	2	10
Respiratory disorder	7	28
Respiratory distress	7	39
Respiratory failure		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		3	11		2
		3	6		1
		2	7		3
		2	2		
					1
			1		
				3	9
			1		
				1	1
		1	2		
			3	2	4
			1		
			2		3
			1		
					1
			1		
			1	1	2
			1		
			1		
		1	5	1	2
					2
				3	7
				1	1
		1	13	1	3
				1	1
					1
		2	4		
				2	10
		4	17	3	11
				7	39
					4

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Respiratory rate decreased	3	5
Respiratory rate increased	3	18
Respiratory symptom	2	3
Respiratory tract congestion	7	28
Respiratory tract infection	1	3
Respiratory tract irritation	1	2
Respiratory tract oedema	1	5
Restless legs syndrome	5	11
Restlessness	8	31
Restrictive pulmonary disease		1
Retching	5	39
Retinal detachment		1
Retinal disorder		1
Retinal haemorrhage	1	1
Retinal tear		1
Retinal vein occlusion	2	3
Retinitis		1
Rhabdomyolysis		1
Rheumatic disorder		1
Rheumatoid arthritis	17	33
Rhinalgia	2	7
Rhinitis		2
Rhinitis allergic		2
Rhinorrhoea	56	241
Rhinovirus infection		2
Rib fracture	2	3
Right ventricular dysfunction		1
Road traffic accident	3	5
Root canal infection	1	1
Rosacea		3
Rotator cuff syndrome		2
Rubber sensitivity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	2
			7	3	11
		1	1	1	2
		4	25	3	3
			1	1	3
			1	1	1
				1	5
		4	10	1	1
		7	27	1	4
					1
1	1	4	33	1	6
					1
			1		
				1	1
					1
				2	3
					1
					1
			1		
2	2		1	17	32
		1	6	1	1
			2		
			1		1
		53	227	3	14
			2		
				2	3
					1
		1	2	2	3
		1	1		
			3		
			1		1
			1		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ruptured cerebral aneurysm		2
Sacroiliitis	1	1
Saliva discolouration		1
Salivary gland disorder		1
Salivary gland enlargement		2
Salivary gland pain		1
Salivary hypersecretion	3	7
Sarcoidosis	2	2
SARS-CoV-1 test positive	1	1
SARS-CoV-2 ant body test negative	7	33
SARS-CoV-2 ant body test positive	1	9
SARS-CoV-2 test		1
SARS-CoV-2 test false positive	1	1
SARS-CoV-2 test negative		1
SARS-CoV-2 test positive	33	175
Scab	1	7
Scar	2	5
Sciatica	4	7
Scleral discolouration		1
Scleral haemorrhage	1	1
Scleritis	1	3
Scleroderma	2	2
Scratch	3	10
Screaming	1	5
Seasonal allergy	6	13
Secretion discharge	4	9
Sedation		6
Seizure	41	77
Seizure like phenomena	2	4
Self-injurious ideation	1	1
Sensation of blood flow		2
Sensation of foreign body	3	38

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
					1
			1		
			2		
			1		
		1	5	2	2
				2	2
		1	1		
		6	30	1	3
			8	1	1
					1
		1	1		
			1		
		11	36	22	139
		1	6		1
		2	3		2
		4	6		1
			1		
				1	1
				1	3
				2	2
		3	8		2
			3	1	2
		6	13		
		4	8		1
			5		1
		1	1	40	76
				2	4
		1	1		
					2
		3	28		10

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sensitisation		2
Sensitive skin	3	16
Sensitivity to weather change	1	4
Sensorimotor disorder		1
Sensory disturbance	4	20
Sensory level abnormal		1
Sensory loss	6	14
Sepsis	2	10
Seronegative arthritis		2
Serum ferritin decreased		1
Serum sickness	1	2
Shock	3	12
Shock symptom		4
Shoulder injury related to vaccine administration		1
Sialoadenitis		2
Sickle cell anaemia with crisis	2	2
Sinus bradycardia		3
Sinus congestion	6	22
Sinus disorder	12	37
Sinus headache	8	22
Sinusitis	26	55
Sinusitis bacterial		2
Sinus pain	3	10
Sinus rhythm		1
Sinus tachycardia		9
Sitting disability		4
Sjogren's syndrome	1	4
Skeletal injury		1
Skin abrasion		1
Skin bacterial infection	1	1
Skin burning sensation	7	37
Skin depigmentation	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		3	16		
		1	4		
					1
		3	18	1	2
			1		
		5	10	1	4
				2	10
					2
		1	1		1
		1	1	2	11
					4
			1		
					2
				2	2
			1		2
		6	22		
		11	34	1	3
		8	22		
		23	52	3	3
					2
		3	10		
			1		
			4		5
			3		1
				1	4
			1		
			1		
				1	1
		7	36		1
		1	3		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin discolouration	18	53
Skin discomfort		1
Skin disorder	9	38
Skin erosion	1	1
Skin exfoliation	5	18
Skin fissures	1	2
Skin haemorrhage	2	3
Skin hyperpigmentation		1
Skin indentation	1	2
Skin injury		2
Skin irritation	1	12
Skin laceration	2	11
Skin laxity		1
Skin lesion	3	13
Skin mass	2	4
Skin reaction		7
Skin sensitisation	1	2
Skin swelling	2	9
Skin tightness	3	6
Skin turgor decreased	1	1
Skin ulcer		2
Skin warm	3	8
Skin wrinkling	1	1
Sleep apnoea syndrome	1	1
Sleep attacks	1	1
Sleep deficit	2	3
Sleep disorder	21	65
Sleep disorder due to a general medical condition		5
Sleep disorder due to general medical condition, insomnia type		3
Sleep paralysis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	40	4	13
			1		
		9	33		5
		1	1		
		5	17		1
		1	1		1
		1	2	1	1
			1		
		1	2		
			2		
		1	12		
		1	6	1	5
			1		
		3	12		1
		2	4		
			5		2
		1	2		
		1	8	1	1
		2	4	1	2
				1	1
			2		
		3	8		
		1	1		
				1	1
		1	1		
		2	3		
		21	64		1
			5		
			3		
			2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep talking	1	1
Sleep terror		1
Slow speech		2
Sluggishness	6	16
Small fibre neuropathy		1
Small intestinal obstruction	1	2
Sneezing	23	88
Snoring		2
Soft tissue disorder		1
Soft tissue swelling	1	1
Solar lentigo		1
Somatic symptom disorder	1	1
Somnambulism	1	1
Somnolence	45	222
Speech disorder	21	93
Speech sound disorder	1	1
Spinal compression fracture	1	1
Spinal cord disorder		2
Spinal disorder	1	3
Spinal fusion surgery		1
Spinal osteoarthritis		1
Spinal pain	2	25
Spinal stenosis		1
Splenic vein thrombosis		1
Splenomegaly		2
Splinter	1	1
Splinter haemorrhages		1
Spondylitis		1
Sputum discoloured	3	6
Staphylococcal infection	2	3
Staring		2
Status asthmaticus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
			2		
		5	15	1	1
					1
				1	2
		20	85	3	3
			1		1
			1		
		1	1		
					1
		1	1		
		41	201	4	21
		13	59	8	34
		1	1		
				1	1
					2
			2	1	1
					1
			1		
		2	22		3
			1		
					1
			1		1
		1	1		
			1		
					1
		2	4	1	2
				2	3
					2
					1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Stenosis		1
Stevens-Johnson syndrome		2
Sticky skin	1	1
Stiff tongue		1
Stomatitis	5	26
Strabismus	1	3
Strawberry tongue		1
Streptococcal infection		3
Streptococcus test positive		2
Stress	6	32
Stress urinary incontinence	1	1
Stridor	1	8
Subarachnoid haemorrhage		3
Subcutaneous abscess	1	3
Sudden death		1
Sudden hearing loss	2	5
Sudden visual loss	1	1
Suffocation feeling		1
Suicidal ideation	2	9
Suicide attempt		1
Sunburn	1	4
Superficial vein prominence	1	2
Suppressed lactation		1
Supraventricular extrasystoles	1	4
Supraventricular tachycardia		5
Suspected COVID-19	20	66
Suture related complication		1
Swelling	65	279
Swelling face	66	261
Swelling of eyelid	8	32
Swollen tongue	40	148
Syncope	95	224

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
		1	1		
					1
		4	22	1	4
				1	3
			1		
			2		1
			1		1
		6	31		1
		1	1		
		1	3		5
					3
			1	1	2
					1
				2	5
				1	1
			1		
				2	9
					1
		1	4		
			1	1	1
			1		
		1	3		1
			1		4
		8	25	12	41
					1
		57	236	8	43
		52	196	14	65
		5	28	3	4
		18	81	22	67
		1	4	94	220

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Syringe issue	1	1
Systemic immune activation		1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	6	10
Systemic scleroderma		1
Tachycardia	21	238
Tachyphrenia		4
Tachypnoea	1	26
Tardive dyskinesia	1	1
Taste disorder	17	62
Tearfulness	1	2
Teeth brittle	1	1
Temperature intolerance	1	6
Temperature regulation disorder		3
Temporomandibular joint syndrome	1	3
Tenderness	13	45
Tendon discomfort		1
Tendonitis	1	4
Tendon pain		3
Tenosynovitis		1
Tension		3
Tension headache	4	10
Terminal insomnia		3
Tetany		2
Thalamic infarction		1
Thanatophobia		1
Therapeutic product effect incomplete		1
Therapeutic product effect prolonged		1
Therapeutic response unexpected	16	37
Thermal burn		2
Thinking abnormal	6	25
Thirst	11	42

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
		1	1	5	9
					1
		7	146	14	92
			4		
			16	1	10
				1	1
		15	56	2	6
		1	2		
		1	1		
		1	5		1
			3		
			1	1	2
		12	43	1	2
			1		
			4		
			3		
			1		
			3		
		3	9	1	1
			3		
					2
					1
			1		
			1		
		16	37		
			1		1
		5	23	1	2
		10	39	1	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thirst decreased		1
Thoracic outlet syndrome		1
Thoracic vertebral fracture		1
Throat clearing	2	8
Throat irritation	38	181
Throat tightness	55	219
Thrombocytopenia	6	17
Thrombophlebitis	2	2
Thrombophlebitis superficial	4	7
Thrombosis	72	105
Thrombotic microangiopathy	1	1
Thrombotic stroke	2	2
Thunderclap headache		1
Thyroid cancer	1	1
Thyroid disorder	4	8
Thyroidectomy	1	1
Thyroid function test abnormal	1	3
Thyroid hormones increased	1	1
Thyroiditis	1	3
Thyroiditis acute		1
Thyroiditis subacute	1	2
Thyroid mass	2	3
Thyroid pain	2	4
Thyrotoxic crisis	3	3
Thyroxine decreased		1
Tic		2
Tinnitus	83	204
T-lymphocyte count increased		1
Tongue biting	1	2
Tongue blistering	3	7
Tongue coated		2
Tongue discolouration	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
		1	4	1	4
		28	139	10	42
		37	114	18	105
				6	17
		2	2		
		4	6		1
1	1	1	2	71	103
				1	1
				2	2
					1
				1	1
		3	7	1	1
		1	1		
		1	3		
					1
			1	1	1
		1	2	1	1
		2	4		
				3	3
			1		
			2		
		60	152	23	52
			1		
		1	1		1
		2	6	1	1
			2		
		1	5		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tongue discomfort	7	30
Tongue disorder	4	25
Tongue dry		6
Tongue eruption	1	2
Tongue erythema	1	5
Tongue fungal infection	1	1
Tongue haematoma		1
Tongue haemorrhage		1
Tongue injury		1
Tongue movement disturbance	2	3
Tongue oedema		2
Tongue pruritus	3	15
Tongue ulceration	1	5
Tonsillar disorder		2
Tonsillar erythema		1
Tonsillar hypertrophy		7
Tonsillar ulcer		1
Tonsillolith		1
Tooth abscess	3	4
Toothache	12	41
Tooth discolouration	1	1
Tooth disorder	2	6
Tooth extraction	1	1
Tooth fracture	3	3
Tooth infection	4	8
Tooth injury	2	3
Tooth loss		1
Torticollis		1
Tourette's disorder	1	1
Tracheitis		1
Tracheomalacia		1
Transaminases increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	26	2	4
		3	20	1	5
			6		
		1	1		1
		1	5		
		1	1		
			1		
			1		
			1		
		2	2		1
			1		1
		2	11	1	4
		1	4		1
			1		1
			1		
			7		
			1		
			1		
		3	3		1
		10	34	2	7
		1	1		
		2	5		1
		1	1		
		3	3		
		3	7	1	1
		2	2		1
					1
			1		
				1	1
			1		
					1
			1		1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Transient global amnesia	1	1
Transient ischaemic attack	8	19
Transverse sinus stenosis	1	1
Tremor	84	336
Tricuspid valve incompetence	1	1
Trigeminal nerve disorder	1	3
Trigeminal neuralgia	1	10
Trigeminal neuritis		1
Trigger finger	5	5
Tri-iodothyronine decreased		1
Trismus	4	9
Troponin	1	1
Troponin increased	5	15
Tryptase decreased		1
Tryptase increased		1
Tuberculosis		2
Tumour marker abnormal		1
Tunnel vision	5	12
Type 1 diabetes mellitus	1	2
Type 2 diabetes mellitus		1
Type III immune complex mediated reaction		1
Type IV hypersensitivity reaction		1
Type V hyperlipidaemia	1	1
Ulcer		3
Ulcer haemorrhage		1
Underdose	12	74
Undifferentiated connective tissue disease		1
Unresponsive to stimuli	3	13
Upper-airway cough syndrome	4	13
Upper airway obstruction	1	2
Upper limb fracture	3	5
Upper respiratory tract congestion	4	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				8	19
				1	1
	1	71	271	13	65
				1	1
		1	1		2
		1	6		4
			1		
		5	5		
			1		
		2	6	2	3
				1	1
		2	4	3	11
			1		
			1		
					2
					1
				5	12
				1	2
					1
					1
			1		
				1	1
			3		
					1
		12	73		1
					1
				3	13
		4	11		2
				1	2
				3	5
		3	29	1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Upper respiratory tract infection		5
Ureteric stenosis		1
Urethral disorder		1
Urge incontinence		1
Urinary incontinence	6	21
Urinary retention		3
Urinary tract infection	20	58
Urinary tract infection bacterial		2
Urine abnormality		1
Urine analysis abnormal	3	7
Urine leukocyte esterase positive	1	2
Urine odour abnormal		1
Urine output decreased	2	2
Urine output increased		3
Urobilinogen urine increased		1
Urosepsis		1
Urticaria	92	512
Urticaria chronic	1	1
Urticaria thermal		1
Use of accessory respiratory muscles		5
Uterine contractions during pregnancy		2
Uterine disorder		1
Uterine haemorrhage	1	2
Uterine inflammation		1
Uterine pain	1	1
Uveitis		1
Vaccination complication	1	1
Vaccination error	2	2
Vaccination failure	51	80
Vaccination site bruising	9	54
Vaccination site cellulitis	2	15
Vaccination site coldness	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		
					1
			1		
			1		
		4	16	2	5
					3
		14	43	6	15
					2
			1		
		3	7		
		1	2		
					1
		2	2		
			3		
			1		
					1
		69	401	23	111
		1	1		
			1		
			4		1
			1		1
			1		
				1	2
					1
				1	1
					1
1	1	1	1		
		2	2		
				51	80
		9	52		2
			4	2	11
		1	3		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site discharge	1	2
Vaccination site discolouration	5	18
Vaccination site discomfort	8	37
Vaccination site dryness	1	1
Vaccination site erythema	64	425
Vaccination site exfoliation	1	1
Vaccination site extravasation	3	8
Vaccination site haemorrhage	12	40
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity		3
Vaccination site hypoaesthesia	7	25
Vaccination site induration	4	42
Vaccination site infection		6
Vaccination site inflammation	3	16
Vaccination site injury		4
Vaccination site irritation	4	7
Vaccination site joint erythema		1
Vaccination site joint movement impairment	2	12
Vaccination site joint pain	1	7
Vaccination site joint swelling	1	1
Vaccination site lymphadenopathy	4	15
Vaccination site macule		5
Vaccination site mass	20	94
Vaccination site movement impairment	3	42
Vaccination site nodule	1	12
Vaccination site oedema		4
Vaccination site pain	274	1,803
Vaccination site pallor		1
Vaccination site papule		3
Vaccination site paraesthesia	3	24
Vaccination site pruritus	46	220
Vaccination site pustule	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		5	17		1
		8	35		2
		1	1		
		63	408	1	17
		1	1		
		3	8		
		12	38		2
			1		
			3		
		6	23	1	2
		4	41		1
			6		
		3	14		2
			4		
		4	7		
			1		
		2	9		3
		1	6		1
		1	1		
		4	14		1
			5		
		19	89	1	5
		3	41		1
		1	11		1
			3		1
2	2	268	1756	6	47
			1		
			3		
		3	21		3
		45	210	1	10
		1	2		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site rash	26	98
Vaccination site reaction	4	24
Vaccination site scab		3
Vaccination site scar	1	1
Vaccination site streaking	1	1
Vaccination site swelling	65	400
Vaccination site thrombosis	1	1
Vaccination site urticaria	5	41
Vaccination site vesicles	1	11
Vaccination site warmth	20	191
Vaginal discharge		2
Vaginal disorder		1
Vaginal haemorrhage	11	24
Vaginal infection		2
Vaginal lesion		1
Vagus nerve disorder	1	1
Varicella	1	3
Varicella zoster virus infection		1
Varicose vein	1	2
Vascular occlusion	1	1
Vascular pain	1	2
Vascular rupture	1	1
Vasculitic rash		1
Vasculitis	1	2
Vasodilatation		1
Vein discolouration		3
Vein disorder	2	5
Vein rupture	1	1
Ventricular extrasystoles	4	17
Ventricular tachycardia		2
Vertebral artery dissection	1	1
Vertigo	61	199

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		24	92	2	6
		3	22	1	2
			3		
		1	1		
		1	1		
		63	383	2	17
				1	1
		4	37	1	4
		1	11		
		20	182		9
			2		
			1		
		7	16	4	8
			2		
			1		
				1	1
		1	3		
			1		
		1	2		
				1	1
		1	2		
		1	1		
			1		
		1	2		
			1		
			3		
		1	4	1	1
				1	1
		3	10	1	7
					2
				1	1
		42	162	19	37

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo positional	4	7
Vestibular disorder	2	3
Vestibular migraine	1	1
Vestibular neuritis	1	3
VIIIth nerve lesion		1
Viral infection	1	4
Viral myocarditis		1
Viral rash		1
Viral upper respiratory tract infection		2
Vision blurred	38	141
Visual acuity reduced	3	6
Visual field defect	2	7
Visual impairment	22	83
Vitamin B12 decreased	1	2
Vitamin B12 increased	1	1
Vitamin D decreased	4	5
Vitamin D deficiency	2	2
VIth nerve paralysis		1
Vitreous degeneration		2
Vitreous detachment	1	2
Vitreous floaters	1	5
Vocal cord disorder		2
Vocal cord paralysis		1
Volvulus		1
Vomiting	189	736
Vomiting projectile	3	10
Vulval disorder		1
Vulvovaginal burning sensation	1	2
Vulvovaginal mycotic infection	1	3
Vulvovaginal pain	2	2
Vulvovaginal pruritus		1
Vulvovaginal rash		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4	1	3
		1	2	1	1
		1	1		
			1	1	2
					1
		1	2		2
					1
			1		
			1		1
		24	104	14	37
		3	5		1
		1	6	1	1
		16	65	6	18
				1	2
		1	1		
		3	4	1	1
		1	1	1	1
					1
					2
				1	2
			3	1	2
					2
					1
					1
		138	611	51	125
		3	10		
			1		
		1	2		
		1	3		
		1	1	1	1
					1
					1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vulvovaginal swelling		2				1			1
Walking aid user	3	4			2	3	1		1
Walking disability	1	1			1	1			
Water pollution		1				1			
Weight bearing difficulty		1							1
Weight decreased	16	58			9	42	7		16
Weight fluctuation	3	5			3	5			
Weight increased	9	17			8	16	1		1
Wheezing	28	88			19	58	9		30
White blood cell count abnormal	1	1			1	1			
White blood cell count decreased	4	13			3	9	1		4
White blood cell count increased	4	23			2	14	2		9
White blood cells urine		1				1			
White blood cells urine positive	1	2			1	2			
White matter lesion		1							1
Winged scapula		1				1			
Withdrawal bleed		1				1			
Wound	3	6			2	4	1		2
Wound closure		1				1			
Wound complication	1	1			1	1			
Wound haemorrhage	1	4			1	2			2
Wound secretion		1							1
Wrist fracture		1							1
Wrong product administered	5	19			5	19			
Wrong schedule		2				2			
Wrong technique in device usage process		2				2			
Wrong technique in product usage process	4	34			4	32			2
Xanthopsia		1				1			
	2	4			2	4			
	17,051	73,555	18	27	12806	59770	4245		13785

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	17	50			14	43	3	7
Abdominal distension	6	14			5	11	1	3
Abdominal pain	12	45			5	29	7	16
Abdominal pain lower	1	4			1	4		
Abdominal pain upper	22	73			19	59	3	14
Abdominal rigidity	1	2			1	2		
Abdominal tenderness	1	1			1	1		
Abnormal behaviour	1	3				1	1	2
Abnormal clotting factor	1	1					1	1
Abnormal dreams	4	12			2	9	2	3
Abnormal faeces	1	4				3	1	1
Abnormal sensation in eye		1				1		
Abscess	1	1					1	1
Accident	2	4				1	2	3
Accidental exposure to product	1	7			1	7		
Accidental overdose		5				4		1
Accidental underdose		2				2		
Acne	3	5			3	5		
Acoustic neuritis		1						1
Activated partial thromboplastin time prolonged		1						1
Acute coronary syndrome	1	1					1	1
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury		2						2
Acute myocardial infarction	2	4					2	4
Acute respiratory distress syndrome		2						2
Adrenocortical insufficiency acute		1						1
Adverse event	1	1			1	1		
Ageusia	17	51			16	47	1	4
Aggression	2	2			1	1	1	1
Agitation	1	6			1	6		
Alanine aminotransferase increased		1				1		
Allergy to arthropod sting	1	1			1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergy to vaccine	3	13
Alopecia	1	3
Alopecia areata		1
Alopecia universalis		1
Amaurosis fugax		1
Amnesia	3	8
Anaemia	2	6
Anal haemorrhage	1	1
Anal incontinence	1	1
Anaphylactic reaction	11	22
Anaphylactic shock	5	7
Aneurysm ruptured		1
Anger	1	3
Angina pectoris	2	4
Angioedema	2	6
Angiokeratoma	1	1
Anion gap increased		1
Ankle fracture	1	1
Ankylosing spondylitis		1
Anorectal discomfort		1
Anosmia	15	48
Anterior chamber cell		1
Antibody test abnormal		3
Antibody test negative		2
Anxiety	18	48
Anxiety disorder	1	1
Aortic disorder	1	1
Aortic valve disease		1
Aortitis		1
Apathy	2	2
Aphasia	5	13
Aphonia		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	9	1	4
		1	3		
			1		
			1		
					1
		3	5		3
		1	1	1	5
				1	1
		1	1		
			1	11	21
				5	7
					1
		1	2		1
				2	4
				2	6
		1	1		
			1		
				1	1
					1
			1		
		12	41	3	7
					1
			3		
			2		
		17	43	1	5
		1	1		
				1	1
					1
		1	1	1	1
		1	6	4	7
			4		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aphthous ulcer	1	5
Apnoea		1
Appendicitis	5	10
Appendicitis perforated	1	1
Appetite disorder		3
Application site haemorrhage		1
Areflexia	1	2
Arrhythmia	7	19
Arteriosclerosis		1
Arteriospasm coronary		1
Arthralgia	113	416
Arthritis	3	15
Arthritis reactive	1	1
Arthropathy	2	11
Arthropod bite	1	3
Aspartate aminotransferase increased		1
Aspiration	1	1
Asthenia	86	297
Asthenopia		1
Asthma	7	17
Asymptomatic COVID-19	6	13
Ataxia		2
Atelectasis	1	2
Atrial fibrillation	17	43
Atrial flutter	2	3
Atrioventricular block	1	1
Auricular swelling	1	1
Autoimmune disorder	3	5
Autoimmune haemolytic anaemia	1	2
Autoimmune thyroiditis	1	1
Autoscopy		1
Axillary mass		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		
					1
				5	10
				1	1
			3		
					1
		1	1		1
				7	19
					1
					1
		98	384	15	32
		2	13	1	2
				1	1
		2	11		
		1	3		
			1		
				1	1
		70	250	16	47
			1		
		3	11	4	6
		2	5	4	8
					2
				1	2
				17	43
				2	3
				1	1
				1	1
				3	5
				1	2
				1	1
			1		
			4		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Axillary pain	4	26
Back disorder	2	6
Back injury	1	3
Back pain	44	146
Bacterial infection	1	2
Balance disorder	15	43
Basal ganglia haemorrhage		3
Bed rest	1	1
Bedridden	1	6
Behaviour disorder		1
Belligerence		1
Biliary tract disorder	1	1
Bilirubin urine present		1
Bladder discomfort	1	1
Bladder pain		1
Blast cell crisis		1
Blepharochalasis		1
Blepharospasm	1	2
Blindness	5	12
Blindness transient	2	6
Blindness unilateral	4	7
Blister	5	19
Blood bilirubin abnormal	1	1
Blood bilirubin increased	1	3
Blood calcium increased		1
Blood chloride decreased		1
Blood cholesterol increased		2
Blood count abnormal		2
Blood creatine increased		2
Blood creatine phosphokinase increased	1	3
Blood creatinine increased		1
Blood disorder	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	26		
		2	6		
		1	2		1
		31	123	13	23
		1	1		1
		10	34	5	9
					3
		1	1		
		1	6		
					1
					1
				1	1
			1		
				1	1
			1		
			1		
		1	2		
				5	12
				2	6
				4	7
		3	14	2	5
				1	1
		1	3		
					1
			1		
			2		
			1		1
			1		1
			1	1	2
			1		
		2	2		1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood electrolytes decreased	1	1
Blood fibrinogen decreased		1
Blood glucose abnormal		3
Blood glucose decreased	4	11
Blood glucose fluctuation		1
Blood glucose increased	11	36
Blood immunoglobulin E increased		1
Blood immunoglobulin G decreased		1
Blood insulin increased	1	1
Blood iron decreased		3
Blood ketone body increased		1
Blood lactic acid increased	1	1
Blood phosphorus decreased	1	1
Blood potassium decreased	1	2
Blood potassium increased	1	3
Blood pressure abnormal		4
Blood pressure decreased	11	18
Blood pressure diastolic increased		2
Blood pressure fluctuation	2	11
Blood pressure increased	11	52
Blood pressure orthostatic increased	1	1
Blood pressure systolic increased		1
Blood sodium decreased	1	2
Blood test abnormal	3	3
Blood triglycerides increased		2
Blood urine present	3	11
Blue toe syndrome	1	1
Body height decreased	2	9
Body temperature	1	1
Body temperature abnormal		2
Body temperature decreased	2	8
Body temperature fluctuation	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			2		1
		3	6	1	5
			1		
		7	24	4	12
					1
			1		
		1	1		
			1		2
					1
				1	1
				1	1
			1	1	1
				1	3
			3		1
		7	12	4	6
			2		
		1	9	1	2
		8	35	3	17
		1	1		
					1
				1	2
		2	2	1	1
			1		1
		2	8		1
		1	1		
			2		
		2	8		
		2	2		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Body temperature increased	7	39
Bone disorder		1
Bone pain	8	20
Bone swelling		1
Bowel movement irregularity	3	5
Brachial plexopathy		1
Bradycardia		2
Bradyphrenia	1	3
Brain death		1
Brain oedema		1
Brain stem syndrome		1
Breast pain	1	1
Breath odour		2
Bronchitis	4	10
Bronchospasm		1
Burning sensation	5	30
Burn oesophageal	1	1
Bursitis	2	3
Butterfly rash		1
Candida infection	1	1
Capillary disorder	1	1
Carbon dioxide increased		1
Cardiac arrest	5	20
Cardiac disorder	10	21
Cardiac failure	1	3
Cardiac failure chronic		1
Cardiac failure congestive		3
Cardiac fibrillation	1	1
Cardiac flutter	2	3
Cardiac pacemaker insertion		1
Cardiac valve disease		2
Cardiomyopathy		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	36	1	3
			1		
		8	20		
			1		
		3	5		
					1
					2
		1	3		
					1
					1
					1
		1	1		
			2		
		2	7	2	3
			1		
		5	24		6
		1	1		
		1	1	1	2
			1		
		1	1		
		1	1		
			1		
				5	20
		4	8	6	13
				1	3
					1
					3
				1	1
				2	3
			1		
			1		1
					4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardio-respiratory arrest	1	3
Cardiospasm	1	1
Cardiovascular disorder		1
Carotid artery occlusion	1	1
Carpal tunnel syndrome		1
Cataract	1	1
Cataract nuclear		1
Cell marker decreased	1	1
Cellulitis	2	8
Cellulitis gangrenous		1
Cerebellar stroke	1	1
Cerebral artery occlusion	2	2
Cerebral haemorrhage	4	8
Cerebral infarction		1
Cerebral thrombosis	4	4
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	28	69
Cheilitis	1	1
Chest discomfort	18	54
Chest injury		1
Chest pain	38	95
Chillblains	1	1
Chills	213	953
Choking	4	5
Choking sensation	1	1
Cholecystitis	1	1
Cholestasis		1
Chorea		1
Chromatopsia		2
Chromaturia	3	7
Chronic inflammatory demyelinating polyradiculoneuropathy	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
		1	1		
			1		
				1	1
			1		
				1	1
					1
				1	1
				2	8
					1
				1	1
				2	2
				4	8
					1
				4	4
				1	1
				28	69
		1	1		
		12	37	6	17
					1
		16	49	22	46
		1	1		
		191	896	22	57
				4	5
		1	1		
				1	1
					1
			2		
		3	7		
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Chronic kidney disease	1	3
Chronic lymphocytic leukaemia	1	1
Chronic myeloid leukaemia recurrent		1
Chronic obstructive pulmonary disease	1	3
Circadian rhythm sleep disorder	1	2
Circumstance or information capable of leading to device use error		1
Circumstance or information capable of leading to medication error	14	102
Claustrophobia		1
Clonus	1	1
Clumsiness		2
Cluster headache	1	2
Coagulopathy	3	5
Coccydynia	1	1
Cognitive disorder	1	6
Cold sweat	8	38
Colitis	1	2
Colitis microscopic		1
Colitis ulcerative	1	1
Coma		4
Communication disorder		2
Completed suicide	1	1
Complication associated with device		2
Computerised tomogram normal		1
Concussion	1	3
Condition aggravated	23	81
Confusional state	14	40
Conjunctival haemorrhage	2	4
Conjunctival irritation		1
Conjunctival oedema		1
Conjunctivitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	1
					1
				1	3
		1	2		
			1		
		14	102		
			1		
		1	1		
			2		
		1	2		
		2	2	1	3
		1	1		
		1	2		4
		8	36		2
		1	2		
					1
				1	1
					4
					2
				1	1
					2
			1		
			2	1	1
		16	60	7	21
		6	20	8	20
				2	4
			1		
			1		
			1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Constipation	8	23
Contraindicated product administered		3
Contraindication to medical treatment		1
Contraindication to vaccination		1
Contusion	6	27
Coordination abnormal		2
Corneal disorder		1
Corneal graft rejection		1
Corneal infiltrates		1
Corneal reflex decreased		1
Costochondritis		1
Cough	47	168
COVID-19	339	716
COVID-19 pneumonia	6	21
C-reactive protein increased	1	5
Crohn's disease		1
Crying	1	3
CSF protein increased		1
Cyanosis	1	1
Cystitis		4
Cystitis escherichia	1	1
Deafness	13	32
Deafness neurosensory	1	6
Deafness transitory	2	2
Deafness unilateral	6	11
Death	14	49
Decreased appetite	23	92
Deep vein thrombosis	22	31
Defaecation disorder	1	1
Defaecation urgency	1	2
Dehydration	15	39
Delirium	4	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	20	2	3
			3		
			1		
			1		
		6	26		1
			1		1
					1
					1
			1		
			1		
		42	149	5	19
2	2	94	183	245	533
				6	21
			3	1	2
			1		
			1	1	2
					1
				1	1
			2		2
				1	1
			1	13	31
				1	6
				2	2
				6	11
1	1			14	49
		16	80	7	12
				22	31
		1	1		
		1	2		
		7	23	8	16
				4	12

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Gender

**MALE**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Delirium febrile	1	1
Dementia		5
Dementia Alzheimer's type	1	2
Demyelinating polyneuropathy		1
Dental discomfort		4
Dental restoration failure		1
Depressed level of consciousness	2	2
Depressed mood	3	5
Depression	3	8
Dermatitis	2	6
Dermatitis acneiform		1
Dermatitis allergic		1
Diabetes mellitus		6
Diabetic coma	1	1
Diabetic ketoacidosis		1
Diabetic wound		1
Diaphragmalgia		1
Diarrhoea	49	218
Diarrhoea haemorrhagic	2	5
Differential white blood cell count abnormal		1
Diplegia		1
Diplopia	10	17
Discharge		1
Discomfort	11	46
Disease progression		1
Disease recurrence	8	32
Disorganised speech	1	1
Disorientation	8	27
Disseminated varicella zoster virus infection	1	1
Dissociation		1
Disturbance in attention	5	16
Diverticulitis	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					5
				1	2
					1
			4		
			1		
				2	2
		3	5		
		3	7		1
		1	5	1	1
			1		
					1
					6
				1	1
					1
					1
			1		
		41	195	8	23
				2	5
					1
					1
					1
		9	14	1	3
			1		
		10	43	1	3
					1
		3	12	5	20
				1	1
		4	16	4	11
				1	1
			1		
		4	12	1	4
				4	8

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dizziness	127	445
Dizziness exertional		1
Dizziness postural	2	12
Drainage		1
Drooling	2	4
Drowning	1	1
Drug hypersensitivity		8
Drug ineffective	216	534
Drug interaction	3	10
Dry eye		3
Dry mouth	11	31
Dry skin	1	5
Dry throat	4	10
Ductus arteriosus premature closure		1
Dysaesthesia		1
Dysarthria	5	15
Dysentery	1	3
Dysgeusia	15	37
Dysgraphia	1	1
Dyskinesia	1	1
Dyslexia		1
Dyspepsia	4	20
Dysphagia	5	17
Dysphemia		2
Dysphonia	6	20
Dyspnoea	86	228
Dyspnoea exertional	1	8
Dysstasia	13	28
Dystonia	1	1
Dysuria	2	7
Ear congestion	2	3
Ear discomfort	4	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		106	395	21	50
			1		
		2	11		1
			1		
		2	3		1
				1	1
			8		
1	1			216	534
		2	7	1	3
			2		1
		7	26	4	5
		1	4		1
		4	9		1
					1
			1		
		2	8	3	7
				1	3
		13	33	2	4
		1	1		
		1	1		
			1		
		1	16	3	4
1	1	3	11	2	6
			1		1
		4	15	2	5
2	2	47	142	39	86
		1	6		2
		6	16	7	12
				1	1
			5	2	2
		2	3		
		2	10	2	4

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ear disorder	2	6
Ear infection	1	1
Ear injury	1	1
Ear pain	14	19
Ear pruritus		1
Ear swelling	2	3
Eating disorder	6	11
Ecchymosis		1
Eczema		1
Ejection fraction abnormal		1
Ejection fraction decreased	1	3
Electrocardiogram abnormal	1	2
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment elevation	1	1
Electrolyte imbalance		1
Embolic stroke		1
Embolism		2
Emotional distress	2	2
Encephalitis	1	4
Endocarditis		1
Energy increased	2	5
Enteritis		1
Eosinophil count decreased		1
Eosinophil count increased	1	2
Epigastric discomfort	1	1
Epistaxis	11	31
Erectile dysfunction	4	11
Eructation	1	4
Erythema	20	75
Erythema marginatum		1
Erythema multiforme		4
Erythema nodosum		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		
		1	1		
		1	1		
		10	15	4	4
			1		
		1	2	1	1
		4	8	2	3
			1		
			1		
			1		
				1	3
		1	2		
					1
				1	1
					1
					1
					2
		1	1	1	1
				1	4
					1
		2	5		
					1
					1
		1	1		1
		1	1		
		10	26	1	5
				4	11
			3	1	1
		15	66	5	9
			1		
					4
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema of eyelid		1
Escherichia bacteraemia	1	1
Escherichia urinary tract infection	1	1
Euphoric mood	1	1
Eustachian tube dysfunction	1	1
Excessive cerumen production	1	1
Exercise electrocardiogram abnormal	1	1
Exercise tolerance decreased		1
Exophthalmos	1	1
Expired product administered	3	4
Exposure during pregnancy	1	1
Exposure to SARS-CoV-2	9	22
Exposure via breast milk	3	16
Exposure via skin contact	1	5
External ear pain	1	1
Extra dose administered		1
Extrasystoles	1	5
Eye allergy		1
Eye contusion		1
Eye discharge		1
Eye disorder	5	12
Eye haemorrhage	4	8
Eye infection		1
Eye inflammation		3
Eye irritation	1	9
Eyelid disorder	3	3
Eyelid function disorder		1
Eyelid infection		1
Eyelid oedema		1
Eyelid pain	1	2
Eyelid ptosis	2	3
Eye movement disorder	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
				1	1
		1	1		
		1	1		
		1	1		
				1	1
			1		
				1	1
		3	4		
				1	1
		9	18		4
		2	15	1	1
		1	5		
		1	1		
			1		
		1	5		
			1		
			1		
		4	9	1	3
				4	8
			1		
			2		1
		1	7		2
		2	2	1	1
			1		
			1		
		1	2		
		1	2	1	1
			1	1	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye oedema		2
Eye pain	9	29
Eye pruritus	1	7
Eye swelling	9	27
Face injury		2
Face oedema		2
Facet joint syndrome		1
Facial bones fracture	1	1
Facial discomfort	1	1
Facial nerve disorder		1
Facial neuralgia		1
Facial pain		11
Facial paralysis	49	126
Facial paresis	2	6
Factor V Leiden mutation	1	1
Faeces discoloured	1	1
Faeces soft	1	3
Fall	27	68
False positive investigation result		1
Fasciitis		2
Fatigue	257	943
Fear	1	3
Fear of death	2	2
Fear of falling		1
Fear of injection	1	1
Febrile convulsion		1
Feeding disorder	6	16
Feeling abnormal	85	229
Feeling cold	23	57
Feeling drunk	3	11
Feeling hot	25	74
Feeling jittery		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		8	26	1	3
		1	7		
		7	22	2	5
			1		1
			1		1
			1		
				1	1
		1	1		
			1		
			1		
			9		2
		1	1	48	125
		2	4		2
				1	1
		1	1		
		1	2		1
		14	36	13	32
			1		
					2
1	1	230	888	27	55
		1	3		
		1	1	1	1
			1		
		1	1		
					1
		3	13	3	3
		73	205	12	24
		20	53	3	4
		2	8	1	3
		22	69	3	5
			3		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Feeling of body temperature change	6	11
Fever neonatal	1	1
Fibrin D dimer increased	1	5
Fibromyalgia	1	3
Fine motor skill dysfunction		1
Fistula		1
Flank pain		2
Flatulence	3	9
Fluid intake reduced		1
Fluid overload		1
Fluid retention	2	5
Flushing	4	30
Food poisoning	1	1
Foreign body sensation in eyes	2	4
Formication		1
Freezing phenomenon	1	1
Frequent bowel movements	1	3
Frustration tolerance decreased	1	2
Full blood count abnormal		1
Fungal infection		1
Fungal peritonitis	1	1
Gait disturbance	30	80
Gait inability	5	24
Gal bladder disorder		2
Gal bladder oedema	1	1
Gangrene	1	1
Gastric disorder	2	8
Gastric haemorrhage	1	2
Gastric ulcer		1
Gastritis	1	4
Gastroenteritis		1
Gastroenteritis viral	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	9	1	2
				1	1
			2	1	3
		1	2		1
			1		
			1		
			2		
		3	8		1
			1		
					1
		1	1	1	4
		3	26	1	4
		1	1		
		2	4		
			1		
		1	1		
			2	1	1
		1	2		
					1
			1		
		18	57	12	23
		2	12	3	12
			1		1
				1	1
				1	1
		2	8		
				1	2
					1
		1	3		1
					1
		3	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal disorder	2	9
Gastrointestinal haemorrhage		1
Gastrointestinal hypomotility		1
Gastrointestinal inflammation		1
Gastrointestinal motility disorder		1
Gastrointestinal oedema		1
Gastrointestinal pain		3
Gastrointestinal sounds abnormal		1
Gastrointestinal tract irritation	2	2
Gastrooesophageal reflux disease	2	7
Generalised tonic-clonic seizure	1	5
General physical health deterioration	1	2
Genital haemorrhage		1
Gingival bleeding		2
Gingival discolouration		1
Gingival erythema		1
Gingival pain		1
Gingival swelling		4
Gingivitis	1	1
Glare		1
Glassy eyes	1	2
Glaucoma		1
Glossitis		2
Glossodynia	2	5
Glycosylated haemoglobin increased	1	3
Good syndrome		1
Gout	3	11
Grip strength decreased	1	1
Groin pain	3	8
Grunting	1	1
Guillain-Barre syndrome	3	11
Haematemesis	3	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6	1	3
					1
			1		1
			1		
			2		1
			1		
		2	2		
		2	7		
				1	5
				1	2
					1
			1		1
			1		1
			4		
		1	1		
			1		
			1	1	1
					1
			2		
		2	5		
		1	1		2
					1
		2	9	1	2
				1	1
		2	6	1	2
		1	1		
				3	11
				3	6

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematochezia	10	22
Haematocrit decreased		1
Haematology test abnormal		1
Haematoma	2	4
Haematuria		6
Haemoglobin decreased	1	6
Haemolytic anaemia	1	4
Haemoptysis	3	7
Haemorrhage	2	17
Haemorrhage intracranial		1
Haemorrhage subcutaneous		1
Haemorrhage urinary tract	1	4
Haemorrhagic stroke		3
Haemorrhoids		3
Hallucination	3	15
Hallucination, visual		2
Hand deformity		1
Hangover	2	5
Haptoglobin increased	1	1
Headache	258	1,074
Head deformity	1	1
Head discomfort	11	30
Head injury	3	10
Head titubation		2
Hearing disability		1
Heart injury	3	3
Heart rate abnormal	1	7
Heart rate decreased	1	11
Heart rate increased	24	94
Heart rate irregular	7	16
Hemiparesis	1	4
Hemiplegia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	9	21
					1
			1		
		2	4		
			2		4
			2	1	4
				1	4
		2	5	1	2
			2	2	15
					1
					1
				1	4
					3
			3		
				3	15
					2
					1
		2	5		
		1	1		
		231	998	27	76
				1	1
		7	25	4	5
		2	4	1	6
			2		
			1		
				3	3
			5	1	2
		1	7		4
		16	73	8	21
		5	12	2	4
				1	4
					2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Henoch-Schonlein purpura		1
Hepatic enzyme abnormal		1
Hepatic enzyme increased	6	7
Hepatic haemorrhage	1	1
Hepatic pain	1	1
Hepatitis	2	4
Hepatitis acute		1
Hepatitis A virus test positive	1	1
Hepatomegaly	1	2
Hereditary haemorrhagic telangiectasia		1
Hernia		1
Herpes simplex		3
Herpes zoster	18	68
Herpes zoster oticus	1	2
Hiatus hernia		1
Hiccups		6
Hip fracture	2	5
HIV test false positive	1	1
Hordeolum		1
Hot flush	9	21
Hunger	1	3
Hydronephrosis		1
Hyperactive pharyngeal reflex		1
Hyperacusis	1	2
Hyperaesthesia	1	6
Hyperaesthesia teeth		2
Hyperchlorhydria		1
Hyperglycaemia	1	3
Hyperhidrosis	47	158
Hyperpyrexia		1
Hypersensitivity	24	58
Hypersensitivity vasculitis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		4	5	2	2
				1	1
				1	1
				2	4
					1
		1	1		
		1	1		1
			1		
					1
			2		1
		12	56	6	12
				1	2
			1		
			6		
				2	5
		1	1		
			1		
		7	19	2	2
		1	3		
					1
			1		
		1	1		1
		1	6		
			2		
					1
			1	1	2
		34	135	13	23
					1
		17	39	7	19
					3

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypersomnia	4	20
Hypertension	13	55
Hypertensive crisis	1	2
Hypertensive emergency		1
Hypertensive heart disease		1
Hyperthermia		2
Hypertonia		1
Hyperventilation	5	12
Hypervigilance		1
Hypoacusis	9	24
Hypoaesthesia	35	128
Hypoaesthesia eye		1
Hypoaesthesia oral	7	26
Hypoaesthesia teeth		1
Hypogeusia	1	6
Hypoglycaemia		5
Hypokalaemia		1
Hypokinesia	5	8
Hypophagia		2
Hypopnoea	2	4
Hyposmia		2
Hypotension	5	18
Hypothermia		3
Hypoxia	2	6
Illrd nerve paralysis	1	2
Illness	49	103
Immobile		1
Immune system disorder	1	6
Immune thrombocytopenia	3	9
Immunisation		1
Immunodeficiency	1	3
Immunoglobulins decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	18	1	2
		4	33	9	22
				1	2
					1
			2		
					1
		5	10		2
			1		
		7	19	2	5
		26	99	9	29
			1		
		5	21	2	5
			1		
			5	1	1
			3		2
					1
		2	5	3	3
			2		
			1	2	3
			2		
		3	6	2	12
					3
				2	6
				1	2
1	1	43	90	6	13
					1
		1	5		1
				3	9
			1		
				1	3
			1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Impaired driving ability	2	5
Impaired healing		1
Impaired self-care	1	1
Impaired work ability	1	5
Impetigo		1
Inappropriate schedule of product administration	48	209
Incision site haemorrhage		1
Incoherent	3	4
Incomplete course of vaccination	1	4
Incontinence		2
Incorrect dose administered	3	10
Incorrect route of product administration	5	26
Increased appetite		1
Increased bronchial secretion		1
Increased viscosity of bronchial secretion		1
Infantile vomiting		1
Infant irritability		2
Infection	4	10
Infectious mononucleosis	2	2
Inflammation	7	13
Inflammatory bowel disease		1
Influenza	9	22
Influenza like illness	30	127
Inhibitory drug interaction		1
Initial insomnia	1	4
Injection site bruising		3
Injection site discolouration		1
Injection site discomfort		5
Injection site erythema	2	7
Injection site extravasation		2
Injection site haemorrhage		2
Injection site mass		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		1
			1		
			4	1	1
			1		
		47	208	1	1
					1
			1	3	3
		1	4		
					2
		3	10		
		5	25		1
			1		
			1		
			1		
			2		
		2	3	2	7
		1	1	1	1
		6	11	1	2
					1
		7	18	2	4
		27	114	3	13
			1		
		1	4		
			3		
			1		
			5		
		2	7		
			2		
			2		
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site pain	6	43
Injection site pruritus		2
Injection site rash		2
Injection site swelling	1	4
Injection site warmth		2
Injury	3	4
Insomnia	44	112
Inspiratory capacity decreased		1
Insulin resistance	1	1
Insulin resistant diabetes	1	1
International normalised ratio decreased		3
International normalised ratio increased		2
Intervertebral disc protrusion	1	2
Intestinal obstruction		1
Intracardiac thrombus		1
Intracranial mass	1	1
Intraocular pressure increased	1	2
Intrusive thoughts		1
Iridocyclitis		1
Iritis	1	2
Irregular breathing		1
Irritability	6	8
Irritable bowel syndrome	1	4
Ischaemic stroke	1	4
IVth nerve paralysis		1
Jaundice	2	5
Jaw disorder	2	2
Job dissatisfaction	1	1
Joint effusion		1
Joint injury	4	5
Joint lock	1	1
Joint range of motion decreased	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	43		
			2		
			2		
		1	4		
			2		
			1	3	3
		36	97	8	15
			1		
		1	1		
				1	1
			2		1
			2		
		1	2		
					1
					1
		1	2		
			1		
					1
		1	2		
			1		
		6	8		
		1	3		1
				1	4
					1
		1	2	1	3
1	1	2	2		
		1	1		
			1		
		3	4	1	1
		1	1		
		2	12	1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Joint stiffness	4	7
Joint swelling	11	26
Keratic precipitates		2
Keratitis		1
Kidney infection	2	6
Laboratory test abnormal	2	2
Laboratory test normal		1
Lack of spontaneous speech	1	1
Lacrimal disorder		1
Lacrimation increased	2	13
Lacunar infarction		1
Large intestinal haemorrhage		1
Laryngeal oedema		1
Laziness		2
Lethargy	20	65
Leukaemia	1	3
Leukaemia recurrent	1	1
Leukocytosis		3
Ligament sprain	2	3
Limb discomfort	10	38
Limb injury	3	9
Limb mass	1	2
Lip blister	1	1
Lip disorder	1	3
Lip dry		1
Lipids increased		1
Lip injury	1	1
Lipoma	1	1
Lip pain	1	1
Lip pruritus		1
Lip swelling	11	38
Liquid product physical issue		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	7		
		9	20	2	6
					2
			1		
				2	6
		2	2		
			1		
				1	1
			1		
		1	11	1	2
					1
					1
			2		
		15	57	5	8
				1	3
				1	1
			1		2
		2	3		
		10	35		3
		3	8		1
		1	2		
		1	1		
		1	3		
			1		
			1		
		1	1		
				1	1
		1	1		
			1		
		7	29	4	9
			2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver function test abnormal		1
Liver function test increased	1	2
Liver injury	2	3
Localised infection	1	4
Localised oedema		1
Loss of consciousness	49	99
Loss of control of legs		2
Loss of personal independence in daily activities	8	20
Lower gastrointestinal haemorrhage		1
Lower limb fracture	1	1
Lumbar puncture abnormal		1
Lung disorder	4	5
Lung hyperinflation	1	1
Lung infiltration		3
Lung opacity	1	1
Lymphadenitis	1	5
Lymphadenopathy	31	141
Lymphangitis		1
Lymph node pain	6	23
Lymphoedema		2
Lymphoma		1
Macular oedema		1
Macule		1
Maculopathy	1	1
Madarosis		1
Malaise	108	387
Malnutrition		1
Mania	1	1
Mass	1	3
Mast cell degranulation present		1
Mastication disorder		2
Mastitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		
				2	3
		1	4		
					1
		1	1	48	98
					2
		5	14	3	6
					1
				1	1
					1
		4	4		1
		1	1		
			1		2
		1	1		
		1	3		2
1	1	28	129	3	12
					1
		6	22		1
			2		
					1
			1		
				1	1
			1		
		97	355	11	32
			1		
		1	1		
		1	3		
			1		
			2		
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Maternal exposure during pregnancy	1	2
Medication error		1
Melanoma recurrent	2	2
Memory impairment	6	14
Meniere's disease	1	1
Meningitis	1	2
Meningitis aseptic		1
Meningitis noninfective		1
Meningitis viral		3
Mental disorder	2	2
Mental fatigue		2
Mental impairment	7	13
Mental status changes	1	1
Mesenteric artery aneurysm	1	1
Mesenteric panniculitis		1
Mesenteric vein thrombosis	1	1
Metabolic acidosis		1
Metamorphopsia		1
Micturition disorder		1
Micturition urgency	1	2
Middle insomnia	1	6
Migraine	10	39
Migraine with aura	1	2
Miosis	1	1
Mitral valve incompetence		1
Moaning	1	2
Mobility decreased	9	23
Monoclonal gammopathy	1	1
Monocyte count increased		1
Monoplegia	1	2
Mood swings		1
Motion sickness		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		
				2	2
		6	12		2
				1	1
				1	2
					1
					1
					3
		1	1	1	1
			2		
				7	13
		1	1		
				1	1
					1
			1		
					1
		1	2		
		1	6		
		7	32	3	7
			1	1	1
		1	1		
					1
		1	2		
		6	16	3	7
		1	1		
			1		
				1	2
			1		
			2		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Motor dysfunction	1	3
Mouth haemorrhage		1
Mouth injury	1	1
Mouth swelling	1	4
Mouth ulceration		2
Movement disorder	7	18
Mucosal disorder		1
Mucous stools		1
Multi-organ disorder	1	1
Multiple fractures		1
Multiple organ dysfunction syndrome		2
Multiple sclerosis		2
Muscle contractions involuntary		3
Muscle contracture	1	1
Muscle discomfort		2
Muscle disorder	1	4
Muscle fatigue	1	4
Muscle rigidity		1
Muscle spasms	13	47
Muscle strain	1	3
Muscle swelling		1
Muscle tightness	6	15
Muscle twitching	6	13
Muscular weakness	18	71
Musculoskeletal chest pain	1	6
Musculoskeletal discomfort	5	15
Musculoskeletal disorder		5
Musculoskeletal pain	2	8
Musculoskeletal stiffness	18	63
Mutism		1
Myalgia	103	450
Myasthenia gravis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
			1		
		1	1		
		1	4		
			2		
		3	13	4	5
			1		
			1		
		1	1		
					1
					2
					2
			2		1
		1	1		
			2		
		1	2		2
			3	1	1
					1
		8	36	5	11
		1	3		
			1		
		4	11	2	4
		3	9	3	4
		8	42	10	29
		1	5		1
		4	13	1	2
			2		3
		1	4	1	4
		17	57	1	6
			1		
1	1	87	418	16	32
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Myelitis transverse	2	5
Myocardial infarction	18	40
Myocardial necrosis marker increased	1	1
Myocarditis	8	13
Myoclonus		3
Myositis		2
Nail discolouration	1	1
Nasal congestion	16	69
Nasal discomfort		4
Nasal disorder	1	2
Nasal dryness		3
Nasal injury	1	1
Nasal mucosal disorder		1
Nasal oedema		1
Nasal pruritus		1
Nasopharyngitis	26	73
Nausea	95	444
Near death experience	1	4
Neck injury		1
Neck mass	1	2
Neck pain	18	74
Necrosis	1	1
Necrotising retinitis	1	1
Needle issue		6
Neoplasm	5	5
Neoplasm malignant	2	6
Nephrolithiasis	4	9
Nephropathy	1	1
Nerve compression	3	5
Nerve injury	3	4
Nervousness	5	9
Nervous system disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
		1	1	17	39
				1	1
			1	8	13
			1		2
			1		1
		1	1		
		15	66	1	3
			4		
		1	2		
			2		1
		1	1		
			1		
			1		1
		25	72	1	1
1	1	81	408	14	36
				1	4
			1		
		1	2		
		11	60	7	14
				1	1
			5		1
		4	4	1	1
				2	6
				4	9
				1	1
		2	4	1	1
		2	3	1	1
		4	8	1	1
		1	1		1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neuralgia	6	16
Neurological examination normal		1
Neurological symptom	2	4
Neuropathy peripheral	6	19
Neutropenia neonatal		1
Neutrophil count decreased	1	1
Nightmare	1	6
Night sweats	10	36
Nipple infection	1	1
Nipple pain	1	3
Nipple swelling	1	2
No adverse event	3	22
Nocturia	1	2
Nodal rhythm		1
Nodule	2	4
Noninfective encephalitis		2
Noninfective gingivitis		2
Nystagmus		1
Obstructive airways disorder	1	1
Occipital neuralgia		2
Occupational exposure to product	1	1
Occupational exposure to SARS-CoV-2		1
Ocular discomfort	5	12
Ocular hyperaemia	3	13
Ocular vascular disorder	1	1
Oculofacial paralysis	1	1
Odynophagia	2	4
Oedema		2
Oedema peripheral	2	5
Off label use	25	109
Onychalgia		1
Ophthalmic vein thrombosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	12	2	4
			1		
		1	2	1	2
		1	1	5	18
					1
		1	1		
		1	6		
		8	30	2	6
		1	1		
		1	3		
		1	2		
		3	22		
		1	2		
			1		
			2	2	2
					2
			2		
			1		
				1	1
			2		
		1	1		
					1
		5	12		
		2	12	1	1
		1	1		
				1	1
		2	3		1
			2		
		1	3	1	2
		25	109		
			1		
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Optic ischaemic neuropathy	1	1
Optic neuritis		1
Oral blood blister	1	1
Oral discomfort	2	4
Oral disorder		3
Oral fungal infection	1	1
Oral herpes	1	7
Oral mucosal blistering	1	2
Oral mucosal eruption		1
Oral pain	2	6
Oral pruritus	1	2
Orchitis		2
Orchitis noninfective		1
Organ failure	1	1
Organising pneumonia		1
Oropharyngeal discomfort	4	11
Oropharyngeal pain	29	89
Oropharyngeal spasm		1
Oropharyngeal swelling		1
Osteoarthritis		1
Overdose	6	22
Overweight		2
Oxygen consumption decreased		1
Oxygen saturation abnormal	1	2
Oxygen saturation decreased	6	27
Pain	176	723
Painful respiration	2	4
Pain in extremity	206	700
Pain in jaw	6	16
Pain of skin	4	6
Pallor	3	13
Palpable purpura		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	1
		2	4		
			3		
		1	1		
		1	7		
		1	2		
					1
		2	5		1
		1	2		
			1		1
			1		
				1	1
					1
		4	10		1
		24	80	5	9
					1
					1
			1		
		6	22		
			1		1
					1
		1	2		
1	1	155	670	21	53
			1	2	3
1	2	181	645	25	55
1	1	6	15		1
		3	5	1	1
		1	9	2	4
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations	12	56
Pancreatic disorder		1
Pancreatitis		4
Pancreatitis acute	2	4
Pancytopenia		1
Panic attack	5	10
Panic disorder	1	1
Panic reaction	1	2
Paraesthesia	33	127
Paraesthesia oral	4	24
Paralysis	4	12
Paranasal sinus discomfort	2	8
Paranasal sinus hypersecretion		4
Paranoia	1	2
Paraplegia	1	1
Parkinsonism	2	2
Parkinson's disease		2
Parosmia	3	7
Parotid duct obstruction		1
Pelvic fracture		1
Pelvic pain	1	1
Pemphigoid		2
Pemphigus		2
Penile haemorrhage		1
Pericardial disease		1
Pericardial effusion	1	4
Pericarditis	2	10
Periorbital disorder		2
Periorbital oedema		1
Periorbital swelling	1	10
Peripheral artery thrombosis	1	1
Peripheral coldness	5	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	49	3	7
					1
					4
				2	4
					1
		2	7	3	3
		1	1		
		1	2		
		27	100	6	27
		2	22	2	2
				4	12
		2	8		
			4		
			1	1	1
				1	1
		1	1	1	1
					2
		2	6	1	1
					1
					1
		1	1		
					2
					2
					1
					1
				1	4
				2	10
			2		
			1		
		1	8		2
				1	1
		4	10	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral nerve injury		1
Peripheral paralysis	1	1
Peripheral swelling	31	98
Peripheral venous disease	1	1
Peroneal nerve palsy		4
Personality change	1	2
Petechiae	2	6
Phantom limb syndrome		1
Pharyngeal erythema		1
Pharyngeal hypoaesthesia	1	2
Pharyngeal inflammation		3
Pharyngeal mass		1
Pharyngeal oedema	2	2
Pharyngeal paraesthesia		1
Pharyngeal swelling	5	18
Pharyngitis streptococcal	1	2
Photophobia		6
Photopsia		4
Photosensitivity reaction	1	1
Piloerection		1
Plasma cell myeloma		1
Platelet count decreased	7	17
Platelet count increased		1
Platelet disorder	1	1
Pleurisy	1	2
Pleuritic pain		1
Pneumonia	12	44
Pneumonia aspiration	2	2
Pneumonia bacterial		1
Pneumonia viral		2
Pneumonitis	1	2
Pneumothorax	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
1	1	23	86	8	12
				1	1
			1		3
		1	2		
		1	3	1	3
			1		
					1
				1	2
			3		
			1		
		2	2		
					1
		2	8	3	10
			1	1	1
			6		
			2		2
		1	1		
			1		
					1
		2	5	5	12
			1		
				1	1
		1	1		1
					1
				12	44
				2	2
					1
					2
				1	2
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pollakiuria	6	18
Polyarthritis		1
Polycythaemia		1
Polymyalgia rheumatica	2	3
Polyneuropathy		1
Polyuria		4
Poor quality product administered	13	34
Poor quality sleep	1	12
Poor venous access	1	1
Portal vein thrombosis	3	3
Postictal state		1
Post procedural complication		1
Post procedural haemorrhage		1
Post procedural infection		1
Post procedural oedema		1
Postural orthostatic tachycardia syndrome		2
Posture abnormal		1
Posturing		1
Potentiating drug interaction	1	4
Pre-existing condition improved	1	1
Premature baby	2	2
Prescribed overdose		1
Pressure of speech		1
Presyncope	9	20
Proctalgia		1
Product administered at inappropriate site	9	23
Product administered to patient of inappropriate age	5	9
Product administration error	1	3
Product colour issue	1	2
Product complaint	1	1
Product dispensing issue	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	18		
					1
			1		
				2	3
					1
			4		
		13	34		
		1	12		
		1	1		
				3	3
					1
					1
					1
			1		
					2
			1		
					1
		1	4		
		1	1		
				2	2
			1		
					1
		4	14	5	6
			1		
		8	21	1	2
		5	9		
		1	2		1
		1	2		
		1	1		
		1	1		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product dose omission in error	1	2
Product dose omission issue	15	28
Productive cough	6	12
Product leakage		2
Product preparation error	1	17
Product preparation issue	5	11
Product prescribing error		1
Product quality issue	2	7
Product storage error	1	1
Product supply issue	4	6
Product temperature excursion issue	7	10
Product use issue	2	57
Prostate cancer	3	5
Prostate infection		1
Prostatic specific antigen increased		1
Protein total decreased	1	1
Prothrombin level increased		1
Pruritus	50	154
Psoriasis	3	6
Psoriatic arthropathy	1	1
Psychomotor hyperactivity		3
Psychotic disorder		1
Pulmonary arterial pressure abnormal		1
Pulmonary artery thrombosis		1
Pulmonary congestion	1	2
Pulmonary embolism	19	35
Pulmonary fibrosis	1	4
Pulmonary infarction	1	2
Pulmonary oedema	3	6
Pulmonary pain	2	4
Pulmonary thrombosis	11	15
Pulse abnormal	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		15	28		
		5	11	1	1
			2		
		1	17		
		5	11		
			1		
		2	7		
		1	1		
		4	6		
		7	10		
		2	57		
				3	5
					1
			1		
		1	1		
					1
		41	134	9	20
		1	4	2	2
				1	1
			2		1
					1
					1
				1	2
				19	35
				1	4
				1	2
				3	6
			2	2	2
				11	15
			1	1	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulse absent	1	1
Pulse pressure increased		1
Purpura		1
Pustule	1	4
Pyrexia	229	990
Rash	65	199
Rash erythematous	7	21
Rash macular	6	14
Rash maculo-papular		7
Rash morbilliform	1	3
Rash neonatal	1	1
Rash papular	1	9
Rash pruritic	6	35
Rash vesicular	1	7
Raynaud's phenomenon		1
Rectal haemorrhage	1	3
Red blood cell count decreased	1	1
Red blood cell sedimentation rate increased		2
Red blood cells urine positive		1
Renal atrophy	1	2
Renal cyst		1
Renal disorder	1	7
Renal failure	4	10
Renal impairment		2
Renal injury	1	1
Renal pain	2	8
Respiration abnormal	1	4
Respiratory arrest	2	4
Respiratory disorder	1	5
Respiratory disorder neonatal	1	1
Respiratory distress	2	8
Respiratory failure		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
					1
			2	1	2
		191	896	38	94
		56	174	9	25
		7	19		2
		3	11	3	3
			7		
				1	3
		1	1		
			8	1	1
		5	31	1	4
			6	1	1
			1		
				1	3
		1	1		
			1		1
				1	2
					1
			2	1	5
				4	10
					2
				1	1
		2	8		
		1	3		1
				2	4
			4	1	1
				1	1
				2	8
					5

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Respiratory rate decreased	1	2
Respiratory rate increased	1	3
Respiratory symptom		1
Respiratory tract congestion	4	7
Respiratory tract infection	1	5
Respiratory tract inflammation	1	1
Respiratory tract irritation	1	1
Restlessness	5	14
Retching	2	11
Retinal artery occlusion	1	3
Retinal detachment	2	2
Retinal tear	2	2
Retinal vascular thrombosis	2	2
Retinal vein occlusion	2	3
Retinitis pigmentosa		1
Retinopathy hypertensive		1
Rhabdomyolysis	2	2
Rheumatic disorder	1	1
Rheumatoid arthritis	2	5
Rhinalgia		3
Rhinitis		3
Rhinitis allergic	2	4
Rhinorrhoea	25	82
Rib fracture		2
Road traffic accident	1	1
Rotator cuff syndrome		1
Salivary gland disorder	2	2
Salivary hypersecretion	3	5
SARS-CoV-2 ant body test negative	5	23
SARS-CoV-2 ant body test positive		5
SARS-CoV-2 test false positive	1	3
SARS-CoV-2 test negative	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1	1	2
			1		
		3	6	1	1
				1	5
		1	1		
		1	1		
		4	12	1	2
		1	9	1	2
				1	3
				2	2
				2	2
		1	1	1	1
				2	3
					1
					1
				2	2
		1	1		
				2	5
			3		
			2		1
		2	4		
		25	78		4
			1		1
				1	1
			1		
		1	1	1	1
		2	4	1	1
		5	22		1
			4		1
			2	1	1
		1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test positive	14	95
Scab	1	1
Scar	2	3
Schizophrenia	1	1
Sciatica	2	12
Scratch	2	6
Screaming	1	1
Scrotal disorder		1
Scrotal erythema		1
Scrotal infection		1
Scrotal inflammation		1
Scrotal pain	1	2
Seasonal allergy		1
Seborrhoea		1
Secretion discharge	5	7
Sedation		1
Seizure	25	56
Sensation of foreign body		5
Sensitive skin	1	6
Sensory disturbance	1	4
Sensory level abnormal	1	1
Sensory loss	2	6
Sepsis	5	10
Serotonin syndrome		1
Serum ferritin decreased		1
Shock		2
Shoulder injury related to vaccine administration	1	1
Sialoadenitis	1	2
Sinus congestion	1	10
Sinus disorder	4	14
Sinus headache	2	7
Sinusitis	4	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	24	9	71
		1	1		
		1	1	1	2
				1	1
		2	7		5
		2	5		1
		1	1		
			1		
			1		
					1
			1		
		1	2		
			1		
			1		
		4	6	1	1
			1		
				25	56
			4		1
		1	6		
		1	4		
		1	1		
			3	2	3
				5	10
					1
					1
					2
		1	1		
				1	2
			8	1	2
		4	13		1
		2	7		
		2	13	2	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus pain	1	6
Sinus tarsi syndrome		1
Sitophobia		1
Skin abrasion		1
Skin burning sensation	1	7
Skin discolouration	6	18
Skin discomfort		1
Skin disorder	1	7
Skin exfoliation	4	6
Skin fissures	2	2
Skin haemorrhage	4	5
Skin infection	1	1
Skin injury		1
Skin irritation	2	5
Skin laceration	1	2
Skin laxity		1
Skin lesion	3	7
Skin lesion removal		1
Skin mass	4	5
Skin odour abnormal		1
Skin oedema		1
Skin reaction	1	4
Skin swelling	1	4
Skin ulcer		2
Sleep deficit	1	1
Sleep disorder	5	26
Sleep disorder due to a general medical condition		2
Sleep talking		1
Slow response to stimuli		1
Slow speech	1	1
Sluggishness	6	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6		
			1		
			1		
			1		
		1	6		1
		4	16	2	2
			1		
			6	1	1
		2	4	2	2
		2	2		
		4	5		
				1	1
			1		
		2	5		
		1	1		1
			1		
		3	7		
			1		
		4	4		1
			1		
			1		
			3	1	1
		1	3		1
			2		
		1	1		
		4	24	1	2
			2		
			1		
			1		
		1	1		
		5	12	1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Small intestinal haemorrhage		1
Small intestinal obstruction		1
Sneezing	4	20
Snoring		1
Soft tissue injury		1
Soft tissue swelling	1	1
Somatic symptom disorder		1
Somnolence	22	76
Speech disorder	5	20
Spinal cord disorder		1
Spinal disorder		1
Spinal osteoarthritis		1
Spinal pain	1	5
Spinal stenosis		1
Spleen disorder	1	1
Splenic infarction	1	1
Splenomegaly		1
Spondylitis	1	1
Sputum discoloured	2	2
Sputum increased	1	1
Staphylococcal infection	1	3
Staphylococcal skin infection		1
Staring	1	2
Stevens-Johnson syndrome	1	1
Still's disease	1	1
Stoma site haemorrhage		1
Stoma site pruritus		1
Stomatitis	1	3
Strabismus		2
Streptococcus test positive		1
Stress	2	4
Subarachnoid haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		4	19		1
			1		
			1		
		1	1		
			1		
		20	74	2	2
		2	15	3	5
					1
					1
			1		
		1	5		
			1		
				1	1
				1	1
					1
				1	1
		1	1	1	1
		1	1		
				1	3
					1
			1	1	1
				1	1
				1	1
					1
			1		
		1	3		
			1		1
		1	3	1	1
					2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Subdural haematoma	1	1
Subdural haemorrhage		1
Substance abuse		1
Sudden cardiac death		2
Sudden death	2	2
Sudden hearing loss	4	4
Sudden visual loss	1	1
Suffocation feeling		1
Suicidal ideation	2	3
Sunburn		3
Superficial injury of eye		1
Superior sagittal sinus thrombosis	1	1
Supraventricular extrasystoles		1
Supraventricular tachycardia		3
Suspected counterfeit product		1
Suspected COVID-19	12	30
Sweating fever	1	1
Swelling	18	61
Swelling face	17	52
Swelling of eyelid	3	11
Swollen tongue	6	18
Syncope	21	61
Synovial cyst		1
Synovitis		1
Syphilis		1
Syringe issue		2
Systemic inflammatory response syndrome		2
Systolic hypertension		1
Tachycardia	5	36
Tachyphrenia		2
Tachypnoea	1	1
Taste disorder	5	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					2
				2	2
				4	4
				1	1
			1		
				2	3
			2		1
			1		
				1	1
					1
			1		2
			1		
		5	8	7	22
				1	1
		16	55	2	6
		12	40	5	12
		3	10		1
1	1	3	10	3	8
			1	21	60
			1		
			1		
					1
			2		
					2
					1
		3	25	2	11
			2		
		1	1		
		3	15	2	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temperature intolerance		3
Temperature regulation disorder		1
Tenderness	5	15
Tendonitis		3
Tendon pain	1	1
Tenosynovitis		1
Tension		2
Tension headache	1	7
Terminal insomnia		1
Testicular pain	1	4
Testicular swelling	1	3
Tetanus	1	1
Therapeutic product effect delayed	1	1
Therapeutic response unexpected	7	18
Thinking abnormal	3	9
Thirst	3	9
Throat clearing		1
Throat irritation	5	26
Throat tightness	1	9
Thrombocytopenia	8	11
Thrombophlebitis superficial	3	5
Thrombosis	37	58
Thyroiditis subacute		1
Tic		1
Tinea pedis	1	1
Tinnitus	51	90
Tongue coated		1
Tongue discolouration	1	2
Tongue disorder	2	3
Tongue eruption	1	2
Tongue erythema	1	2
Tongue paralysis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
			1		
		5	13		2
			2		1
				1	1
			1		
			2		
		1	6		1
			1		
			3	1	1
		1	2		1
				1	1
		1	1		
		7	18		
		3	9		
		3	8		1
			1		
		5	24		2
		1	6		3
				8	11
				3	5
		1	1	36	57
			1		
					1
		1	1		
		34	63	17	27
			1		
				1	2
		2	3		
		1	1		1
		1	2		
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tongue pruritus		1
Tonic clonic movements		1
Tonsillar inflammation	1	1
Tonsillitis		2
Toothache	5	13
Tooth disorder	1	4
Tooth extraction	1	1
Tooth infection		1
Torsade de pointes		1
Total lung capacity decreased	1	1
Toxicity to various agents		1
Tracheal obstruction	1	1
Transaminases decreased	1	1
Transient global amnesia		1
Transient ischaemic attack	7	15
Transplant failure		1
Tremor	35	89
Trigeminal nerve disorder		2
Trigeminal neuralgia		1
Trigger finger	1	1
Troponin I increased	1	1
Troponin increased	5	6
Tuberculin test positive		1
Tunnel vision	1	5
Type IV hypersensitivity reaction		1
Type V hyperlipidaemia		1
Ulcer		3
Underdose	4	31
Unresponsive to stimuli	3	16
Upper-airway cough syndrome	2	10
Upper airway obstruction		1
Upper gastrointestinal haemorrhage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	1		
			2		
		5	13		
		1	4		
		1	1		
			1		
					1
		1	1		
					1
				1	1
			1		
				7	15
					1
		25	66	10	23
			2		
					1
		1	1		
		1	1		
				5	6
			1		
				1	5
			1		
					1
			2		1
		4	31		
				3	16
		2	10		
					1
				1	1

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Upper limb fracture	1	1
Upper respiratory tract congestion	2	5
Upper respiratory tract infection	2	4
Urethral haemorrhage		1
Urinary assistance device user		1
Urinary incontinence	2	4
Urinary retention	3	4
Urinary tract disorder		1
Urinary tract infection	10	26
Urinary tract infection bacterial		1
Urine abnormality	1	2
Urine odour abnormal		1
Urine output decreased	1	1
Urticaria	27	85
Uveitis		3
Uvulitis		1
Vaccination complication	1	2
Vaccination error		1
Vaccination failure	26	38
Vaccination site bruising	2	11
Vaccination site cellulitis		1
Vaccination site coldness		5
Vaccination site discolouration	1	5
Vaccination site discomfort	2	14
Vaccination site erythema	5	33
Vaccination site extravasation		2
Vaccination site haematoma		2
Vaccination site haemorrhage	3	16
Vaccination site hypoaesthesia		2
Vaccination site induration	1	5
Vaccination site infection		2
Vaccination site inflammation		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	4	1	1
		2	4		
					1
			1		
		1	2	1	2
				3	4
			1		
		7	15	3	11
					1
		1	2		
			1		
		1	1		
		19	69	8	16
					3
			1		
			1	1	1
			1		
1	1			26	38
		2	9		2
					1
			5		
		1	5		
		2	14		
		5	30		3
			2		
			1		1
		3	15		1
			2		
		1	5		
			2		
			3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site irritation		1
Vaccination site joint erythema		1
Vaccination site joint movement impairment		2
Vaccination site joint pain		3
Vaccination site joint swelling		1
Vaccination site lymphadenopathy	1	3
Vaccination site mass	4	16
Vaccination site movement impairment	3	10
Vaccination site oedema	1	2
Vaccination site pain	95	612
Vaccination site paraesthesia	1	5
Vaccination site pruritus	2	17
Vaccination site rash	1	12
Vaccination site reaction	1	7
Vaccination site scab		1
Vaccination site swelling	8	42
Vaccination site ulcer		1
Vaccination site urticaria	1	5
Vaccination site vesicles		1
Vaccination site warmth	2	12
Varicocele	1	1
Varicose vein	1	2
Vascular dementia		1
Vascular pain	1	1
Venous thrombosis limb	1	2
Ventricular arrhythmia		2
Ventricular extrasystoles		4
Ventricular fibrillation		4
Ventricular hypertrophy		1
Ventricular tachycardia		2
Vertigo	15	57
Vertigo positional		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			2		
			2		1
					1
		1	3		
		4	15		1
		3	10		
		1	1		1
		91	599	4	13
		1	5		
		2	14		3
		1	11		1
		1	7		
			1		
		8	41		1
			1		
		1	5		
			1		
		2	12		
		1	1		
			1	1	1
					1
				1	1
				1	2
					2
			2		2
					4
					1
					2
		9	46	6	11
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Viral infection	1	2				1	1	1	
Viral test positive	1	1			1	1			
Vision blurred	22	61			17	46	5	15	
Visual acuity reduced	1	2			1	2			
Visual field defect	1	3			1	2			1
Visual impairment	12	29			6	17	6	12	
Vitamin D decreased		2				2			
Vitamin D deficiency		3				3			
Vlth nerve paralysis	1	4					1	4	
Vitreous detachment	1	1					1	1	
Vitreous floaters	2	3			1	1	1	2	
Vocal cord disorder	1	1					1	1	
Vomiting	39	156	1	1	29	128	10	28	
Vomiting projectile	2	3			2	3			
Walking aid user	1	1			1	1			
Walking disability		1							1
Weight bearing difficulty	1	1			1	1			
Weight decreased	16	38			10	31	6	7	
Weight fluctuation		1				1			
Weight increased	2	4			2	4			
Wheezing	10	18			6	13	4	5	
White blood cell count abnormal	1	1			1	1			
White blood cell count decreased		1				1			
White blood cell count increased	3	12			2	7	1	5	
Wound	1	4				3	1	1	
Wound haemorrhage	2	3			2	3			
Wound infection	1	1					1	1	
Wrong product administered	2	12			2	12			
Wrong technique in product usage process	3	14			3	14			
Yellow skin	1	2				1	1	1	
		1				1			
	6,567	22,089	20	21	4325	16606	2242	5483	

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal pain	2	2	2	2		
Abdominal pain upper	1	3	1	3		
Abnormal faeces		1		1		
Abnormal sensation in eye		1		1		
Accidental exposure to product	2	6	2	6		
Accidental overdose	1	21	1	21		
Acne	1	1	1	1		
Adverse event	2	5	2	5		
Ageusia	1	5	1	4		1
Aggression		2		2		
Allergy to vaccine	1	8		7	1	1
Alopecia	2	2	2	2		
Anaesthesia		1		1		
Anaphylactic reaction	2	24			2	24
Anger		1		1		
Angina pectoris	2	2			2	2
Angioedema	1	2			1	2
Anhedonia	1	1	1	1		
Anosmia	2	4	2	3		1
Anxiety	2	8	2	7		1
Aphasia		2		1		1
Aphthous ulcer		1		1		
Appendicitis	2	2			2	2
Arrhythmia	3	5			3	5
Arthralgia	13	45	13	44		1
Arthritis	1	2	1	2		
Asthenia	8	21	7	20	1	1
Asthenopia		1		1		
Asthma	2	2	1	1	1	1
Asymptomatic COVID-19		6		2		4
Atrial fibrillation	1	3			1	3

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autism spectrum disorder	1	1			1	1
Axillary pain	1	2	1	2		
Back disorder		1		1		
Back pain	4	14	4	14		
Balance disorder	3	4	3	4		
Basedow's disease		1				1
Biopsy	1	1	1	1		
Bladder disorder	1	1	1	1		
Blindness		3				3
Blindness unilateral	1	1			1	1
Blood bilirubin increased		1				1
Blood cholesterol increased		1		1		
Blood glucose decreased		1				1
Blood glucose increased		1		1		
Blood immunoglobulin G decreased		2		2		
Blood immunoglobulin G increased		1		1		
Blood potassium decreased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased	1	4	1	3		1
Blood sodium decreased		1		1		
Blood thyroid stimulating hormone increased		1		1		
Blood urine present	2	2	2	2		
Body temperature abnormal		2		2		
Body temperature decreased		1		1		
Body temperature increased	1	3	1	3		
Bone pain	1	3	1	3		
Breast engorgement		1		1		
Breast induration		1		1		
Breast pain	1	2	1	2		
Burning sensation	3	6	2	5	1	1
Cardiac arrest	2	2			2	2
Cardiac disorder	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac flutter		1				1
Cellulitis	1	1			1	1
Cerebral haemorrhage	1	3			1	3
Cerebral palsy	1	1			1	1
Cerebrovascular accident	3	6			3	6
Cervical radiculopathy		1		1		
Chest discomfort	2	9	1	8	1	1
Chest pain	2	4	2	4		
Chillblains		1		1		
Chills	33	117	33	117		
Circumstance or information capable of leading to device use error		1		1		
Circumstance or information capable of leading to medication error	5	33	5	33		
Clostridium difficile infection		1				1
Coagulopathy	1	1			1	1
Cognitive disorder		1		1		
Cold sweat		2		2		
Condition aggravated	3	8	1	6	2	2
Confusional state	1	3	1	3		
Conjunctivitis		1		1		
Constipation	2	2	2	2		
Contusion	1	2	1	2		
Coordination abnormal		1				1
Cough	6	14	5	12	1	2
COVID-19	77	266	12	48	65	218
Cyanosis		1		1		
Deafness	2	2			2	2
Deafness unilateral	1	1			1	1
Death	10	20			10	20
Decreased appetite	3	7	3	7		
Deep vein thrombosis	2	3			2	3

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration		2		1		1
Dementia	1	1			1	1
Depressed mood		1		1		
Diabetes mellitus		1				1
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea	10	35	10	34		1
Diplopia		1		1		
Discomfort	2	3	2	3		
Disease recurrence	1	1	1	1		
Disturbance in attention		3		3		
Dizziness	14	50	12	48	2	2
Dizziness postural	1	2	1	2		
Drug hypersensitivity	1	2	1	2		
Drug ineffective	60	254			60	254
Drug interaction		1		1		
Dry eye	1	2	1	2		
Dry mouth		1		1		
Dry skin		2		2		
Dry throat	1	4	1	4		
Dysarthria		1		1		
Dysgeusia	1	10	1	10		
Dyskinesia		3		3		
Dyspepsia	1	3	1	3		
Dysphagia	1	3	1	2		1
Dysphonia		1		1		
Dyspnoea	9	21	8	19	1	2
Dysstasia	3	4	2	2	1	2
Dysuria		1		1		
Ear discomfort	1	1	1	1		
Ear infection	2	2	2	2		
Ear pain	2	3	2	3		
Ecchymosis	4	4	4	4		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Emotional disorder		1		1		
Emphysema	1	1	1	1		
Encephalopathy	1	1			1	1
Energy increased		1		1		
Epistaxis	1	4	1	4		
Erythema	6	17	6	16		1
Euphoric mood		1		1		
Excessive cerumen production		1		1		
Expired product administered	11	28	11	28		
Exposure during pregnancy	1	3			1	3
Exposure to SARS-CoV-2	1	6	1	6		
Exposure via breast milk	5	69	4	68	1	1
Exposure via eye contact	1	2	1	2		
Exposure via skin contact	1	5	1	5		
Eye colour change	1	2		1	1	1
Eye disorder	2	3	2	2		1
Eye haemorrhage	1	1			1	1
Eye irritation	1	3	1	3		
Eyelid function disorder	1	1			1	1
Eyelid oedema	1	1	1	1		
Eyelid vascular disorder	1	1	1	1		
Eye pain	1	1	1	1		
Eye pruritus		3		3		
Eye swelling	3	4	2	3	1	1
Face oedema	1	1	1	1		
Facial asymmetry		1		1		
Facial pain	1	3	1	3		
Facial paralysis	8	26			8	26
Faeces discoloured	1	1	1	1		
Fall	5	5	5	5		
Fatigue	43	156	43	153		3
Fear	1	2		1	1	1

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**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	1		
8	24	2	3
2	12		
	1		
3	6		1
	1		
	1		
		1	1
2	2		
1	11	2	3
			1
			1
			1
		1	1
		1	1
1	1		
			1
	1		
1	4		
1	3		
1	1		
2	6		
		1	1
	1		
	1		
	1		
	2		
1	1		1
			1
		1	3

Febrile neutropenia  
Feeding disorder  
Feeling abnormal 10 27  
Feeling cold 2 12  
Feeling drunk 1  
Feeling hot 3 7  
Feeling jittery 1  
Feeling of body temperature change 1  
Fever neonatal 1 1  
Flatulence 2 2  
Flushing 3 14  
Foetal cystic hygroma 1  
Foetal death 1  
Foetal exposure during pregnancy 1  
Foetal heart rate abnormal 1  
Foetal heart rate decreased 1 1  
Foetal hypokinesia 1 1  
Formication 1 1  
Frustration tolerance decreased 1  
Gait disturbance 1 4  
Gait inability 1 3  
Gastric disorder 1 1  
Gastrointestinal disorder 2 6  
Gastrointestinal haemorrhage 1 1  
Gingival bleeding 1  
Gingival pain 1  
Gingival swelling 1  
Glassy eyes 1  
Gout 2  
Groin pain 1 2  
Guillain-Barre syndrome 1  
Haematochezia 1 3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage	2	4			2	4
Hair growth abnormal	1	1	1	1		
Hallucination		1				1
Headache	43	182	41	177	2	5
Head discomfort	1	1			1	1
Head injury	2	2	1	1	1	1
Heart rate decreased		1		1		
Heart rate increased	5	23	4	21	1	2
Heart rate irregular		1		1		
Hemiparesis	1	1			1	1
Hepatic enzyme abnormal	1	1			1	1
Hepatic enzyme increased	1	2	1	1		1
Herpes zoster	2	15	2	15		
Hiccups		1		1		
HIV test false positive	1	1	1	1		
Hyperacusis		1		1		
Hyperaesthesia		2		2		
Hyperhidrosis	5	13	5	13		
Hypersensitivity	3	23	3	20		3
Hypersomnia		2		2		
Hypertension	3	7	2	4	1	3
Hypoacusis		3		3		
Hypoaesthesia	10	21	9	19	1	2
Hypoaesthesia eye		1		1		
Hypoaesthesia oral		4		4		
Hypokinesia		3		3		
Hypotonia		1		1		
Hypoxia	1	1			1	1
Illness	2	27	2	27		
Immune thrombocytopenia	1	3			1	3
Impaired gastric emptying	1	1			1	1
Inappropriate schedule of product administration	14	43	14	43		

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incomplete course of vaccination	1	1	1	1		
Incontinence	1	1	1	1		
Incorrect dosage administered		1		1		
Incorrect dose administered	2	14	2	14		
Incorrect route of product administration	2	16	2	15		1
Induration		1				1
Infantile vomiting		1		1		
Infant irritability	1	1			1	1
Infection	1	3	1	3		
Influenza		4		4		
Influenza like illness	1	17	1	17		
Infrequent bowel movements		1		1		
Injection site discomfort		1		1		
Injection site erythema	1	1	1	1		
Injection site nodule	1	1	1	1		
Injection site pain	2	4	2	4		
Injection site swelling	1	1	1	1		
Injection site warmth	1	1	1	1		
Injury	1	1	1	1		
Insomnia	7	14	7	14		
Intentional product misuse	1	2	1	2		
Intervertebral disc protrusion		1		1		
Irritability	1	2	1	2		
Joint effusion	1	1			1	1
Joint injury	1	1	1	1		
Joint range of motion decreased	2	2	2	2		
Joint swelling	5	5	3	3	2	2
Joint warmth	1	1	1	1		
Lacrimation increased	2	3	1	2	1	1
Lethargy	3	13	3	13		
Leukocytosis		1				1
Limb discomfort	1	6	1	5		1

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Gender

**UNKNOWN**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
			1
	1		1
	1		
	2		1
	3	1	1
1	6		
1	1		
	1		
		5	7
	2	1	1
	1		
		1	1
			1
5	25		
1	4		
13	52	2	3
	1		
	1		
		3	5
1	1		
	1		
1	1		
	1		
1	6	1	1
1	2		
	1		
	5		
	1		
1	1		

Limb injury	1	2
Limb mass		1
Lip oedema		2
Lip pain		1
Lip pruritus		3
Lip swelling	1	4
Liquid product physical issue	1	6
Liver disorder	1	1
Localised infection		1
Loss of consciousness	5	7
Loss of personal independence in daily activities	1	3
Low density lipoprotein increased		1
Lung disorder	1	1
Lung neoplasm malignant		1
Lymphadenitis		1
Lymphadenopathy	5	25
Lymph node pain	1	4
Malaise	15	55
Mass		1
Maternal exposure during breast feeding		1
Maternal exposure during pregnancy	3	5
Maternal exposure timing unspecified	1	1
Medication error		1
Memory impairment	1	1
Mental fatigue	1	1
Middle insomnia		1
Migraine	2	7
Mobility decreased	1	2
Mouth swelling		1
Movement disorder		5
Mucous stools		1
Muscle fatigue	1	1

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	3	10	3	10		
Muscular weakness	2	3	2	3		
Musculoskeletal chest pain		3		3		
Musculoskeletal discomfort		2		2		
Musculoskeletal stiffness	1	4	1	3		1
Myalgia	18	49	18	48		1
Myocardial infarction	4	4			4	4
Nasal congestion	4	13	4	13		
Nasal discomfort		1		1		
Nasal oedema		1		1		
Nasopharyngitis	2	6	2	6		
Nausea	17	59	16	58	1	1
Near death experience	1	1			1	1
Neck mass		2		2		
Neck pain	3	10	3	10		
Needle issue		3		3		
Nephrolithiasis		1				1
Nerve compression		1		1		
Nervousness	2	7	2	6		1
Nervous system disorder		1		1		
Neuralgia		2		2		
Neuritis		1		1		
Neurological symptom	1	1	1	1		
Neuropathy peripheral	1	3			1	3
Neutropenia		1				1
Nightmare		1		1		
Night sweats		4		4		
No adverse event	3	6	3	6		
Occupational exposure to product	2	3	2	3		
Ocular hyperaemia	1	2	1	2		
Off label use	9	45	9	45		
Oral discomfort	1	1	1	1		

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oral disorder		1		1			
Oral dysaesthesia		1					1
Oral herpes		3		3			
Oral mucosal blistering		1		1			
Oropharyngeal pain	2	12	2	12			
Orthostatic hypotension		1		1			
Overdose	94	151	94	151			
Oxygen consumption		1		1			
Oxygen saturation decreased		1		1			
Pain	24	129	24	128			1
Pain in extremity	27	135	27	133			2
Pain in jaw	1	2	1	2			
Palpitations	1	8	1	7			1
Panic attack		1		1			
Panic reaction	1	1	1	1			
Paraesthesia	3	15	3	14			1
Paraesthesia oral	2	4	1	3	1		1
Paralysis	1	1			1		1
Paranasal sinus discomfort		1		1			
Pericarditis		1					1
Peripheral sensory neuropathy		1					1
Peripheral swelling	5	28	5	28			
Peripheral venous disease	1	1	1	1			
Pharyngeal disorder	1	1	1	1			
Pharyngeal hypoaesthesia		1		1			
Pharyngeal paraesthesia		2		2			
Pharyngeal swelling	2	7	1	5	1		2
Photophobia	1	1	1	1			
Photopsia	1	1	1	1			
Piloerection	1	1	1	1			
Plantar erythema		1		1			
Platelet count decreased	2	4	2	3			1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count increased		1		1		
Platelet disorder		1		1		
Pleurisy		1				1
Pneumonia	1	2			1	2
Poisoning	1	1			1	1
Pollakiuria		2		2		
Poor feeding infant		1		1		
Poor quality product administered	45	257	45	257		
Poor quality sleep		2		2		
Postmenopausal haemorrhage		1				1
Pre-existing condition improved	1	1	1	1		
Premature baby	3	5			3	5
Presyncope	1	1	1	1		
Product administered at inappropriate site	1	6	1	6		
Product administered to patient of inappropriate age	1	2	1	2		
Product administration error	1	14	1	14		
Product colour issue	1	1	1	1		
Product complaint	1	2	1	2		
Product container issue		1		1		
Product dose omission issue	1	1	1	1		
Productive cough		1				1
Product leakage		3		3		
Product packaging quantity issue		4		4		
Product preparation error	14	80	14	80		
Product preparation issue	96	160	96	160		
Product quality issue	2	5	2	5		
Product storage error	9	13	9	13		
Product temperature excursion issue	38	166	38	166		
Product use issue		8		8		
Protein total increased		1		1		
Prothrombin time prolonged	1	1	1	1		

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	3	24	2	22	1	2
Psoriatic arthropathy		1				1
Psychomotor hyperactivity	1	1	1	1		
Pulmonary congestion		2				2
Pulmonary embolism	2	4			2	4
Pulmonary thrombosis	2	2			2	2
Pyrexia	37	153	37	151		2
Rash	11	45	9	42	2	3
Rash erythematous		6		6		
Rash morbilliform		1		1		
Rash papular	1	1	1	1		
Rash pruritic	1	2	1	2		
Renal failure	1	1			1	1
Renal pain		1		1		
Respiratory symptom		1		1		
Retching		1		1		
Rheumatoid arthritis	3	3			3	3
Rhinalgia		1		1		
Rhinorrhoea	4	7	3	6	1	1
Salivary hypersecretion	1	1	1	1		
SARS-CoV-2 ant body test negative		7		7		
SARS-CoV-2 ant body test positive	1	6	1	5		1
SARS-CoV-2 test positive	4	46		1	4	45
Sedation		1		1		
Seizure	2	4			2	4
Sensation of foreign body		2		2		
Sepsis	1	1			1	1
Sinus congestion		1		1		
Sinus disorder		2		2		
Sinus headache	1	2	1	2		
Sinusitis		2		2		
Skin burning sensation	1	2	1	2		

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**UNKNOWN**

*Preferred Term*

*Interval Total #  
Spontaneous AE*

*Cumulative Total #  
Spontaneous AE*

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
	1		
1	1		
1	1		
	1		
	1		
	1		
2	4		1
		1	1
1	4		
1	5		
	1		
	1		
			1
	1		
	2	2	5
6	16	1	1
4	6	1	1
1	2		
		3	7
	1		
			1
1	6	1	3
			1
1	3		
	1		
1	2		
5	12		
	1		
1	3		2
	4		
			1

Skin discolouration 2

Skin disorder 1

Skin infection 1

Skin irritation 1

Skin laceration 1

Skin odour abnormal 1

Skin reaction 1

Sleep disorder 2

Small intestinal haemorrhage 1

Sneezing 1

Somnolence 1

Speech disorder 1

Spinal pain 1

Streptobacillus infection 1

Stress 1

Suspected COVID-19 2

Swelling 7

Swelling face 5

Swollen tongue 1

Syncope 3

Syringe issue 1

Systemic lupus erythematosus 1

Tachycardia 2

Tachycardia foetal 1

Taste disorder 1

Temperature intolerance 1

Tenderness 1

Therapeutic response unexpected 5

Thinking abnormal 1

Throat irritation 1

Throat tightness 4

Thrombocytopenia 1

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombosis	7	10			7	10
Tinnitus	4	6	3	5	1	1
Tongue disorder		1		1		
Tongue erythema		1		1		
Tongue paralysis	2	2			2	2
Tongue ulceration		1		1		
Toothache	2	4	2	4		
Tooth infection		1		1		
Transient ischaemic attack		1				1
Tremor	5	15	5	15		
Tunnel vision		1				1
Underdose	15	105	15	105		
Upper respiratory tract congestion		1		1		
Urine output decreased	1	1	1	1		
Urticaria	4	19	2	17	2	2
Vaccination complication		2		2		
Vaccination failure	8	10			8	10
Vaccination site bruising		2		2		
Vaccination site discharge		2		2		
Vaccination site discolouration		2		2		
Vaccination site erythema	3	15	3	15		
Vaccination site extravasation	2	3	2	3		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		4		3		1
Vaccination site inflammation	1	1	1	1		
Vaccination site irritation		1		1		
Vaccination site joint pain	1	1	1	1		
Vaccination site mass	1	4	1	4		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	10	74	9	73	1	1
Vaccination site paraesthesia		2		2		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	2	6	2	6		
Vaccination site rash	1	4	1	4		
Vaccination site reaction	1	4	1	4		
Vaccination site scar		1		1		
Vaccination site swelling	4	15	3	14	1	1
Vaccination site vesicles		1		1		
Vaccination site warmth	2	4	2	4		
Vaginal haemorrhage		1		1		
Vertigo	1	7		6	1	1
Vessel puncture site haemorrhage		1		1		
Vessel puncture site injury		1		1		
Vision blurred	1	3	1	3		
Visual field defect	1	1	1	1		
Visual impairment	1	2	1	2		
Vitreous floaters		1		1		
Vomiting	7	24	6	23	1	1
Von Willebrand's disease		1				1
Weight decreased	1	2	1	2		
Wheezing	3	6	2	5	1	1
White blood cell count decreased	1	1	1	1		
Wrong dose		1		1		
Wrong product administered	1	9	1	9		
Wrong technique in product usage process	4	46	4	46		
Yellow skin		1				1
	1,342	4,715	1040	3828	302	887

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**UNITED STATES MINOR OUTLYING ISLA**

Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
Vaccination site pain		1		1
		2		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**URUGUAY**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inflammation	1	1	1	1
Pain	1	1	1	1
Synovial cyst	1	1	1	1
	3	3	3	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

**APPENDIX 2.5.4: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Patient with Relevant Co-Morbidities by Preferred Term per Country**

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 6,575 (Interval) / 22,320 (Cumulative)

Total Number of Adverse Events (PT): 27,821 (Interval) / 99,261 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**ARGENTINA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error		1		1
SARS-CoV-2 ant body test negative		1		1
		2		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRALIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
Acute pulmonary oedema		1				1
Arthralgia		1		1		
Cardiac arrest		2				2
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Condition aggravated		2				2
Contusion		1				1
Cough		1				1
Death		2				2
Depressed level of consciousness		1				1
Dizziness		1				1
Dysphagia		2				2
Dyspnoea		2				2
Fatigue		2		2		
Feeling abnormal		1		1		
General physical health deterioration		1				1
Headache		1				1
Heart rate increased		1				1
Hypoaesthesia oral		1				1
Hypophagia		1				1
Hyporesponsive to stimuli		1				1
Hypotension		2				2
Hypoxia		2				2
Loss of consciousness		2				2
Malaise		1				1
Multiple organ dysfunction syndrome		1				1
Myalgia		2		1		1
Oedema peripheral		1				1
Oxygen saturation decreased		2				2
Pneumonia		4				4
Pneumonia aspiration		1				1
Pneumonia viral		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation error		1		1		
Pruritus		1		1		
Pyrexia		2		1		1
Rales		1				1
Respiratory failure		1				1
Sepsis		1				1
Septic shock		1				1
Somnolence		3		2		1
Unresponsive to stimuli		1				1
Urinary incontinence		1				1
Urosepsis		1				1
Vaccination site erythema		1				1
Vaccination site pain		1				1
Vaccination site swelling		1				1
Vomiting		3				3
Weight decreased		1				1
Wheezing		1				1
		69		11		58

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acidosis	1	1	1	1		
Acute coronary syndrome		1				1
Acute kidney injury	1	1			1	1
Acute left ventricular failure	1	1			1	1
Acute myocardial infarction		1				1
Agitation		1		1		
Agranulocytosis		1				1
Alanine aminotransferase increased		1		1		
Alopecia		1		1		
Altered visual depth perception	1	1	1	1		
Amnesia	1	1	1	1		
Anaemia	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactic shock		2				2
Anaphylactoid reaction		1				1
Angina pectoris		1				1
Antiphospholipid syndrome		1				1
Aphasia	1	1			1	1
Apnoea	1	1			1	1
Application site pain		1		1		
Arrhythmia	1	3			1	3
Arterial occlusive disease	1	1			1	1
Arthralgia	1	14		6	1	8
Aspartate aminotransferase increased		1		1		
Asthenia	4	12	3	7	1	5
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation	2	5			2	5
Autoimmune thyroiditis		1				1
Back pain	3	4	1	1	2	3
Bacterial sepsis		1				1
Balance disorder		2				2
Basal ganglia stroke	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Basilar migraine	1	1			1	1
Blood creatine phosphokinase increased	1	2		1	1	1
Blood creatine phosphokinase MB increased		1				1
Blood glucose increased	1	1			1	1
Blood pressure decreased		2				2
Blood pressure immeasurable		1				1
Blood pressure increased		2				2
Blood pressure systolic increased		1				1
Body temperature increased		3		2		1
Bradycardia		1				1
Bradykinesia		1		1		
Brain natriuretic peptide increased		1				1
Breath sounds		1		1		
Breath sounds abnormal	1	1			1	1
Bronchial obstruction	1	1			1	1
Bronchitis	1	1			1	1
Bundle branch block left	1	1			1	1
Bundle branch block right		1				1
Burning sensation	1	1	1	1		
Bursitis		1		1		
Cachexia	1	2			1	2
Cardiac arrest	3	3			3	3
Cardiac death		1				1
Cardiac failure	2	6			2	6
Cardiopulmonary failure	1	2			1	2
Cardio-respiratory arrest		2				2
Cardiovascular disorder		3		2		1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebral ischaemia		1				1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident		2				2
Chest discomfort	2	7		2	2	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	7		3	1	4
Chills	4	21	4	12		9
Choking		1				1
Cholestasis		1				1
Chronic obstructive pulmonary disease	1	2	1	1		1
Circulatory collapse	3	8			3	8
Concomitant disease aggravated		1				1
Concomitant disease progression		1				1
Concussion	1	1			1	1
Condition aggravated	2	2	1	1	1	1
Confusional state	3	4	1	1	2	3
Conjunctival haemorrhage	1	1			1	1
Cough		4		3		1
COVID-19	1	12			1	12
COVID-19 pneumonia		2				2
C-reactive protein increased		2		1		1
Death	2	14			2	14
Decreased appetite	1	4		3	1	1
Deep vein thrombosis	2	5			2	5
Dehydration	1	1			1	1
Diarrhoea	1	7	1	6		1
Diarrhoea haemorrhagic	1	1			1	1
Discomfort		1		1		
Disease progression		1				1
Disease recurrence		1				1
Disorientation		3		2		1
Disturbance in attention	1	1	1	1		
Dizziness	2	12		4	2	8
Dizziness postural		1		1		
Drug eruption		1				1
Drug ineffective		8				8
Dry mouth		2		2		
Dry throat		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia	1	3		1	1	2
Dyskinesia	1	1			1	1
Dysphagia	2	3		1	2	2
Dyspnoea	7	15	2	2	5	13
Dyspnoea exertional		2				2
Dysstasia		1				1
Ear discomfort		1		1		
Eczema		2		1		1
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram ST-T change	1	1			1	1
Emphysema		1				1
Endocrine ophthalmopathy	1	1			1	1
Epilepsy	1	2			1	2
Erythema		2		1		1
Escherichia sepsis		1				1
Exercise tolerance decreased		1		1		
External ear pain	1	1			1	1
Extrasystoles	1	2		1	1	1
Eye contusion	1	1			1	1
Eye haemorrhage		1				1
Eyelid contusion	1	1			1	1
Eye pain	1	1			1	1
Eye pruritus		1		1		
Facial asymmetry	1	1			1	1
Facial paresis	2	4			2	4
Faecal calprotectin increased	1	1			1	1
Fall	2	4			2	4
Fatigue	8	31	7	24	1	7
Feeling abnormal	1	2	1	1		1
Feeling cold		1				1
Feeling hot		1				1
Fibrin D dimer increased		1				1
Flushing		3		1		2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Foreign body aspiration		1				1
Formication		1		1		
Gait disturbance	1	4		2	1	2
Gastroenteritis		1		1		
Gastrointestinal disorder		1		1		
Generalised tonic-clonic seizure		2				2
General physical health deterioration	3	10		1	3	9
Haematemesis		1				1
Haematoma	1	1			1	1
Headache	4	33	1	21	3	12
Head banging		1				1
Head injury		1				1
Heart rate decreased		1				1
Heart rate increased		1				1
Hemiparesis	1	2			1	2
Herpes zoster		1				1
Hyperglycaemia		2				2
Hypernatraemia		1				1
Hypersensitivity	2	3			2	3
Hypersomnia		1		1		
Hypertension		2				2
Hypertensive crisis		2				2
Hypertensive emergency		1				1
Hyperventilation	2	3	1	1	1	2
Hypoaesthesia		5		2		3
Hypoaesthesia oral		1		1		
Hypogeusia		1				1
Hypokinesia		1		1		
Hypophagia		1				1
Hypopnoea	1	1			1	1
Hyposmia		1				1
Hypotension		3		2		1
Hypotonia		3		2		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune thrombocytopenia		1				1
Impaired driving ability		1				1
Inappropriate schedule of product administration		1		1		
Incontinence	1	1			1	1
Incorrect route of product administration	1	3	1	3		
Infection	1	1			1	1
Influenza like illness		1				1
Insomnia		1		1		
Interleukin level increased		1				1
Intervertebral disc protrusion	1	1			1	1
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke	1	1			1	1
Joint swelling	2	4	1	2	1	2
Lack of spontaneous speech	1	1			1	1
Language disorder	1	1	1	1		
Left ventricular failure		2				2
Leukocytosis		2				2
Leukoencephalopathy	1	1			1	1
Leukopenia		1				1
Limb discomfort		1				1
Lip pruritus		1				1
Lip swelling		1				1
Locked-in syndrome	1	1			1	1
Loss of consciousness	1	3			1	3
Loss of personal independence in daily activities		1				1
Lung infiltration		1				1
Lymphadenopathy	1	2	1	2		
Lymph node pain		1		1		
Lymph node palpable		1		1		
Lymphocyte count increased		1				1
Lymphocytosis		1				1
Lymphopenia		1		1		
Malaise		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Marasmus		1				1
Meningitis bacterial		1				1
Migraine	1	1	1	1		
Mouth swelling		1				1
Multiple organ dysfunction syndrome	1	3			1	3
Muscle contractions involuntary		1		1		
Muscle disorder	1	1			1	1
Muscle spasms	1	5	1	4		1
Muscular weakness	1	3		1	1	2
Musculoskeletal disorder	1	1			1	1
Myalgia	2	13	2	10		3
Myocardial infarction	1	2			1	2
Myocarditis		2				2
Nausea	5	22	4	16	1	6
Neck pain		1		1		
Neuralgia		1				1
Neuralgic amyotrophy		1				1
Neuropathy peripheral		1				1
Neutropenia		1				1
Obstructive airways disorder		1		1		
Ocular hyperaemia		1		1		
Oedema peripheral		1				1
Off label use	1	7	1	7		
Oral pruritus		1				1
Oropharyngeal pain		1		1		
Oxygen saturation		1				1
Oxygen saturation decreased	2	4		1	2	3
Oxygen saturation immeasurable		1				1
Pain	1	4		2	1	2
Pain in extremity	2	12	2	10		2
Pallor		4		2		2
Palmar erythema		1				1
Palpitations	1	2		1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Panic attack		1					1
Paraesthesia	1	7		3	1		4
Paraesthesia oral		2					2
Paresis		1					1
Pemphigus		1					1
Pericardial effusion	1	1			1		1
Pericarditis		1					1
Peripheral swelling		4		1			3
Peripheral vascular disorder	1	1	1	1			
Personality change		1					1
Petit mal epilepsy		1					1
Pharyngeal swelling		1		1			
Photophobia		2		2			
Pleural effusion	1	3			1		3
Pneumonia	2	7			2		7
Pneumonia aspiration		4					4
Pneumonia bacterial		1					1
Presyncope	2	9		1	2		8
Productive cough		1		1			
Product use issue	1	6	1	6			
Pruritus	1	12		2	1		10
Psoriasis	1	1			1		1
Pulmonary embolism	7	13			7		13
Pulmonary hypertensive crisis	1	1			1		1
Pulmonary infarction		1					1
Pulmonary oedema		2					2
Pupillary reflex impaired		1					1
Pyrexia	8	33	3	16	5		17
Rales		2		1			1
Rash	3	8	1	2	2		6
Rash macular		2					2
Rash morbilliform		1					1
Rash pruritic	2	3	1	2	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure	1	2			1	2
Respiratory depression		1				1
Respiratory failure		1				1
Respiratory rate decreased		1				1
Restlessness		2		2		
Retinal artery occlusion	1	1			1	1
Rhabdomyolysis	1	1			1	1
Rheumatoid arthritis		1				1
Rib fracture	1	1			1	1
Road traffic accident	1	1			1	1
SARS-CoV-2 ant body test negative	1	2			1	2
SARS-CoV-2 test positive	1	2			1	2
Seizure		3				3
Sensation of foreign body		1				1
Sepsis		1				1
Septic shock		1				1
Shock		1				1
Sinus tachycardia	1	1			1	1
Skin exfoliation	1	1	1	1		
Skin lesion		1				1
Somnolence	2	8	1	4	1	4
Speech disorder	1	2		1	1	1
Spinal pain		2		1		1
Splenic vein thrombosis	1	1			1	1
Status epilepticus		1				1
Subdural haemorrhage	1	1			1	1
Supraventricular tachycardia	1	1			1	1
Swelling		3		2		1
Swelling face		1		1		
Syncope		7				7
Systemic inflammatory response syndrome		1				1
Tachycardia		1				1
Tachycardia paroxysmal		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Tachypnoea		1		1			
Thirst	1	1	1	1			
Throat irritation		2		1			1
Thrombocytopenia		1					1
Thrombophlebitis	2	2	1	1	1		1
Thrombosed varicose vein	1	1			1		1
Thrombosis	3	3			3		3
Tinnitus		2		1			1
Tongue discomfort		1					1
Toothache	1	1			1		1
Transient ischaemic attack	1	1			1		1
Tremor		1		1			
Trichoglossia		1		1			
Trigeminal neuralgia	1	1			1		1
Troponin T increased	1	2			1		2
Type I hypersensitivity	1	1			1		1
Unresponsive to stimuli		2					2
Urinary retention		1					1
Urine ketone body present	1	1	1	1			
Urticaria	1	5	1	1			4
Vaccination failure	3	3			3		3
Vaccination site discolouration		1					1
Vaccination site erythema		2		1			1
Vaccination site haemorrhage		1		1			
Vaccination site lymphadenopathy		1		1			
Vaccination site movement impairment		1		1			
Vaccination site pain	3	18	2	13	1		5
Vaccination site rash		1					1
Vaccination site reaction		1		1			
Vaccination site swelling		3		1			2
Vaccination site urticaria	1	2		1	1		1
Vaccination site warmth		1		1			
Vaginal discharge		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular encephalopathy	1	1			1	1
Venous thrombosis limb	1	3		1	1	2
Ventricular extrasystoles		1				1
Vertigo	1	7		3	1	4
Vision blurred	1	2	1	2		
Visual impairment	2	3			2	3
Vomiting	3	9	2	6	1	3
Wound haemorrhage	1	1			1	1
Wrong technique in product usage process		1		1		
	234	881	62	317	172	564

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BAHRAIN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
Pyrexia		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BELGIUM**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain		2					2
Abdominal pain upper	2	3			2		3
Acute kidney injury	1	3			1		3
Acute psychosis	1	1			1		1
Acute respiratory failure		3					3
Agitation		4					4
Altered state of consciousness		2					2
Amnesia		1					1
Anaphylactic reaction	2	10			2		10
Anaphylactic shock		1					1
Angle closure glaucoma		1					1
Anxiety		2					2
Apathy		2		1			1
Aphasia	1	2			1		2
Aphonia		1		1			
Aphthous ulcer		1					1
Arthralgia	8	32	2	6	6		26
Arthritis		1		1			
Asthenia	1	8			1		8
Asthma		1					1
Asthma exercise induced		1					1
Atrioventricular block complete		1					1
Autoimmune disorder	2	3			2		3
Axillary mass		1					1
Back pain		1					1
Balance disorder	1	4			1		4
Blood glucose decreased		1		1			
Blood glucose increased		1		1			
Blood lactic acid increased		1					1
Blood pressure decreased	1	1			1		1
Blood pressure increased		2					2
Blood urine present		1					1
Body temperature increased		3		1			2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bone pain		1					1
Bradycardia		2					2
Brain injury	1	1			1		1
Bronchial disorder		1					1
Bronchospasm		1					1
Burning sensation		1		1			
Cardiac arrest	1	4	1	1			3
Cardiac failure	1	3			1		3
Cardiogenic shock	1	2			1		2
Cardiomegaly	1	1			1		1
Cardio-respiratory arrest		2					2
Cardiovascular disorder	5	17		1	5		16
Cerebral haemorrhage	1	1			1		1
Cerebral ischaemia	1	1			1		1
Cerebrovascular accident	3	5			3		5
Chest discomfort		1		1			
Chest pain	2	5			2		5
Cheyne-Stokes respiration		1					1
Chills	7	50	1	2	6		48
Coagulopathy	3	4			3		4
Cold sweat		2					2
Coma		1					1
Confusional state		2					2
Contusion		1					1
Cough	4	6	1	1	3		5
COVID-19	4	9	1	1	3		8
COVID-19 pneumonia		1					1
C-reactive protein increased		2		1			1
Cyanosis		1					1
Decreased appetite	1	6		1	1		5
Deep vein thrombosis	2	2			2		2
Depressed level of consciousness		5					5
Diabetic complication		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diaphragmalgia	1	1			1	1
Diarrhoea	1	3		1	1	2
Disease recurrence		1				1
Disorientation		1				1
Dizziness	5	14	1	3	4	11
Dizziness postural		1				1
Drug ineffective	2	4			2	4
Dry mouth	1	2			1	2
Dry throat		1				1
Dysphonia		2		1		1
Dyspnoea	3	19		1	3	18
Dyspnoea exertional		1				1
Dyspraxia	1	1			1	1
Dysstasia	1	2			1	2
Dystonia		1				1
Ear discomfort	1	1	1	1		
Endocrine ophthalmopathy	1	1			1	1
Epilepsy		3				3
Epistaxis		1				1
Erythema	2	4	2	2		2
Eschar		1				1
Exercise tolerance decreased		1				1
Extensive swelling of vaccinated limb	2	2			2	2
Eye movement disorder		1				1
Eye pain		3		1		2
Eye swelling		1				1
Face oedema		1				1
Facial paralysis	1	2			1	2
Facial paresis		2				2
Fall	2	5		1	2	4
Fatigue	12	63	3	9	9	54
Feeling abnormal	1	1			1	1
Feeling cold		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling of body temperature change		1				1
Fibrin D dimer increased		1				1
Gait disturbance		2				2
Gastric dilatation	1	1	1	1		
Gastrointestinal disorder		1				1
Gastrointestinal pain		1				1
Generalised tonic-clonic seizure	1	3			1	3
General physical health deterioration		10				10
Glaucoma		1				1
Hallucination	1	1			1	1
Hallucination, visual		1				1
Headache	13	73	3	9	10	64
Heart rate increased	1	3			1	3
Hemiparesis		1				1
Hemiplegia		1				1
Hepatic failure		1				1
Herpes ophthalmic		1				1
Herpes simplex		1				1
Herpes zoster		1				1
Hot flush	1	2	1	2		
Hyperhidrosis		2		1		1
Hypersensitivity	1	1			1	1
Hypersomnia		1				1
Hypertension	2	5			2	5
Hypoaesthesia		2				2
Hypoglycaemia		4				4
Hypokalaemia		1				1
Hyponatraemia		1				1
Hypotension	1	7		1	1	6
Hypovolaemic shock		1				1
Hypoxia		1				1
Illusion		1				1
Immobile		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		1		1		
Inflammation		1				1
Influenza like illness	2	9	2	4		5
Injection site erythema	1	1			1	1
Injection site hypersensitivity		1				1
Insomnia		1		1		
Intestinal ischaemia		1				1
Joint range of motion decreased	1	1			1	1
Joint stiffness		1				1
Ketoacidosis		3				3
Lacrimation increased		1		1		
Lactic acidosis	1	2			1	2
Laryngitis		1				1
Leukocyturia		1		1		
Limb discomfort	1	1			1	1
Livedo reticularis		1				1
Liver function test abnormal		3				3
Loss of consciousness		1				1
Lung infiltration		1				1
Lymphadenopathy		3				3
Lymph node pain		1				1
Malaise	15	46	2	4	13	42
Memory impairment	1	1			1	1
Metabolic acidosis		1				1
Mobility decreased	1	1			1	1
Multiple organ dysfunction syndrome		1				1
Muscle contractions involuntary	1	1			1	1
Muscle spasms		1		1		
Muscle strain		2		1		1
Muscular weakness	1	4		1	1	3
Musculoskeletal chest pain		2		1		1
Musculoskeletal stiffness		5				5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	9	47	1	3	8	44
Myocardial infarction		1				1
Nausea	7	41	1	3	6	38
Neck pain	1	5			1	5
Nervous system disorder	5	14	1	3	4	11
Neuropathy peripheral		1				1
Neutropenia		1				1
Night sweats		1				1
N-terminal prohormone brain natriuretic peptide increased		1				1
Ocular hyperaemia		1		1		
Off label use		2		2		
Oral herpes		3		1		2
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		3				3
Orthostatic hypotension		1		1		
Oxygen saturation decreased	1	10			1	10
Pain		4		1		3
Painful respiration		2				2
Pain in extremity	3	10	1	2	2	8
Pain of skin	1	1			1	1
Pallor		2				2
Palmoplantar pustulosis		1		1		
Palpitations		1				1
Paraesthesia	1	3	1	1		2
Paraesthesia oral		2				2
Parapharyngeal space infection		1				1
Paresis		1				1
Parkinson's disease		1				1
Patient elopement		1				1
Peripheral swelling	1	4	1	1		3
Pharyngeal swelling		1				1
Pleural effusion		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia		1				1
Pneumonitis		2				2
Posture abnormal	1	1	1	1		
Presyncope		3				3
Productive cough		1				1
Product use issue		2		2		
Prohormone brain natriuretic peptide increased	1	1			1	1
Pruritus	1	4		1	1	3
Pulmonary embolism	1	3			1	3
Pulmonary infarction		1				1
Pulmonary oedema	1	2			1	2
Pyrexia	15	52	6	7	9	45
Rales		1				1
Rash macular	1	1			1	1
Red blood cell sedimentation rate increased		1		1		
Renal disorder		2				2
Renal failure		3				3
Respiration abnormal		2				2
Respiratory acidosis	1	1			1	1
Respiratory disorder	5	15	1	2	4	13
Respiratory distress		3				3
Respiratory failure		1				1
Respiratory rate increased		1				1
Restlessness	1	2		1	1	1
Retching		2				2
Rhinitis		1				1
Rhinorrhoea		1				1
Rhythm idioventricular		1				1
SAPHO syndrome		1				1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		1				1
Sedation		2				2
Seizure	1	3			1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sense of oppression		1		1		
Septic shock	1	2			1	2
Sinus headache		1				1
Sinus pain		1				1
Skin disorder	6	10	1	2	5	8
Sleep disorder		1				1
Sneezing		1		1		
Somnolence	1	4			1	4
Speech disorder	1	2	1	2		
Spinal pain		1		1		
Staring		1				1
Sudden death		10				10
Swelling face	1	2	1	1		1
Swollen tongue		1				1
Syncope		2				2
Tachycardia	1	5		1	1	4
Tachypnoea		2				2
Therapeutic response unexpected	1	1	1	1		
Tonsillitis		1				1
Tremor	1	2			1	2
Troponin increased		2				2
Troponin T increased	1	1			1	1
Unresponsive to stimuli		2				2
Urinary tract infection		1		1		
Urticaria	1	3			1	3
Vaccination failure	1	1			1	1
Vaccination site erythema	1	3	1	1		2
Vaccination site haematoma		1		1		
Vaccination site induration		1				1
Vaccination site pain	2	15	1	2	1	13
Vaccination site reaction	10	29	1	2	9	27
Vaccination site swelling		2				2
Vaccination site warmth		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	3	7	1	2	2	5
Visual impairment	1	2			1	2
Vomiting		8				8
Wheezing	1	2			1	2
White blood cell count decreased		1		1		
Wrong product administered	1	1	1	1		
	236	1,053	46	131	190	922

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BERMUDA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Dizziness		1		1		
Sudden visual loss		1				1
		3		2		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BULGARIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1		1		
Antibody test abnormal	1	1	1	1		
Arthralgia		4		4		
Asthenia		2		2		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic decreased		1		1		
Blood pressure increased	1	2		1	1	1
Body temperature increased		4		4		
Chest pain		1		1		
Chills	1	3	1	2		1
Cough		1		1		
COVID-19	1	2			1	2
Diarrhoea		1		1		
Dizziness	1	4	1	3		1
Dizziness postural		1		1		
Drug ineffective	1	2			1	2
Dyspnoea		2		1		1
Epistaxis	1	1	1	1		
Erythema		1		1		
Extrasystoles		1		1		
Fatigue	2	4	2	4		
Gait disturbance		2		2		
Headache	2	5	2	4		1
Head discomfort		1				1
Hyperhidrosis		1				1
Lacrimation increased		1		1		
Lethargy	1	1	1	1		
Limb discomfort	1	2	1	2		
Mastication disorder		1		1		
Myalgia		2		2		
Myelitis transverse		1				1
Nasopharyngitis	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		2		1		1
Neuromyelitis optica spectrum disorder		1				1
Oedema peripheral	1	1	1	1		
Oropharyngeal pain		1		1		
Pain		1		1		
Painful respiration		1		1		
Pallor		1		1		
Paraesthesia		1		1		
Paraesthesia oral		1		1		
Paranasal sinus discomfort	1	1	1	1		
Peripheral coldness		1		1		
Peripheral sensory neuropathy		1		1		
Photophobia		1		1		
Pyrexia		1		1		
Rash		1		1		
Rash erythematous		1		1		
Rash pruritic		1		1		
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Seizure		1				1
Swelling		1		1		
Thirst		1		1		
Trismus		1		1		
Vaccination site erythema		2		2		
Vaccination site extravasation		1		1		
Vaccination site pain	1	5	1	5		
Vaccination site reaction		1		1		
Vaccination site swelling		2		2		
Vertigo		1				1
	19	95	15	77	4	18

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CANADA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain upper	1	2		1	1	1
Acute kidney injury		1				1
Ageusia	1	1	1	1		
Agitation		1		1		
Anaphylactic reaction	3	8			3	8
Anaphylactic shock	1	2			1	2
Angioedema	1	1			1	1
Angiopathy		1		1		
Anosmia	1	1	1	1		
Anxiety	1	1	1	1		
Aphthous ulcer		1		1		
Arrhythmia	1	1			1	1
Arthralgia	3	12	2	10	1	2
Asthenia	4	7	3	5	1	2
Autoimmune disorder	1	1			1	1
Axillary pain		1		1		
Back pain	1	2	1	1		1
Balance disorder	1	1			1	1
Blindness	1	1			1	1
Blood pressure decreased	2	2			2	2
Blood urine present	1	1	1	1		
Body temperature increased		1		1		
Bradycardia		1				1
Bronchitis	1	1	1	1		
Burning sensation	1	1	1	1		
Bursitis	1	1	1	1		
Cardiac disorder	1	1			1	1
Cardiac flutter	2	2			2	2
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cellulitis		1				1
Cerebrovascular accident	2	3			2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	2	5	2	3		2
Chest pain		2		2		
Chills	6	16	5	15	1	1
Chronic obstructive pulmonary disease	1	1			1	1
Circumstance or information capable of leading to medication error		1		1		
Colitis ulcerative	1	1			1	1
Condition aggravated	2	2			2	2
Confusional state	1	1	1	1		
Cough	1	3	1	3		
Deafness		1				1
Death	1	2			1	2
Decreased appetite	2	5	2	4		1
Delirium	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dermatitis	1	1			1	1
Diarrhoea	4	9	2	7	2	2
Diplopia		1				1
Disease recurrence	1	3			1	3
Disseminated varicella zoster virus infection		1				1
Disturbance in attention	1	1	1	1		
Dizziness	8	18	5	13	3	5
Drug interaction	1	1			1	1
Drug level increased	1	1			1	1
Dry eye	1	1	1	1		
Dry mouth	2	2	2	2		
Dysgeusia	4	4	4	4		
Dysphagia	2	3	1	2	1	1
Dyspnoea	6	8	3	5	3	3
Dysuria	2	2	1	1	1	1
Ear discomfort	1	2	1	2		
Erythema	2	3	1	1	1	2
Exposure during pregnancy		3		3		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Face oedema		1				1	
Facial paralysis	1	3			1		3
Faeces soft	1	1	1	1			
Fall	2	3		1	2		2
Fatigue	7	30	5	27	2		3
Feeling abnormal	4	5	4	5			
Feeling cold	1	2	1	2			
Feeling hot		2		2			
Feeling of body temperature change		1		1			
Fibromyalgia		1		1			
Flatulence	1	1	1	1			
Flushing		2		1			1
Gait disturbance	1	1			1		1
Gastric ulcer	2	2			2		2
Gastrointestinal disorder	1	1	1	1			
Gastrointestinal pain	1	1	1	1			
Generalised tonic-clonic seizure		1					1
Gout		1		1			
Haematemesis		1					1
Haemorrhage urinary tract	2	2			2		2
Headache	11	31	9	28	2		3
Heart rate decreased	1	2			1		2
Heart rate increased	3	4	1	1	2		3
Herpes simplex	1	1			1		1
Herpes zoster	3	4	2	3	1		1
Hiatus hernia	1	1	1	1			
Hyperaesthesia	1	1			1		1
Hyperhidrosis		1					1
Hypersensitivity	5	6	3	4	2		2
Hypersomnia	1	1	1	1			
Hypertension	2	4	1	1	1		3
Hypoacusis	1	1	1	1			
Hypoaesthesia	4	5	3	3	1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	1	3	1	1		2
Hypokinesia		1		1		
Hypotension	1	2		1	1	1
Illness		1		1		
Impaired work ability		1		1		
Inappropriate schedule of product administration		2		2		
Incontinence	1	1			1	1
Influenza like illness	1	2	1	2		
Injection site bruising		1		1		
Injection site hypersensitivity		1		1		
Injection site pain		3		3		
Insomnia	3	4	3	4		
Ischaemic stroke	1	1			1	1
IVth nerve paralysis		1				1
Joint noise		1		1		
Joint swelling		1		1		
Lacrimation increased	2	2	2	2		
Lethargy		1		1		
Leukoplakia		1		1		
Limb discomfort		3		3		
Lip disorder	1	1	1	1		
Lipoma		1		1		
Lip pain	1	1	1	1		
Lip swelling	3	3	3	3		
Loss of consciousness	3	4			3	4
Loss of personal independence in daily activities	1	1	1	1		
Lung disorder	1	1			1	1
Lymphadenopathy		3		3		
Lymphoedema		1		1		
Malaise	4	8	3	7	1	1
Maternal exposure during pregnancy		3		3		
Meningitis aseptic		1				1
Migraine	2	3	1	2	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monoparesis	1	1			1	1
Mucosal discoloration	1	1	1	1		
Multiple sclerosis relapse	1	1			1	1
Muscle injury		1		1		
Muscle spasms		1				1
Muscle twitching	1	1	1	1		
Muscular weakness	1	3	1	2		1
Musculoskeletal stiffness	3	4	3	4		
Myalgia	4	13	3	11	1	2
Myocardial infarction	2	2			2	2
Myocarditis	1	1			1	1
Nasopharyngitis		1		1		
Nausea	9	20	6	16	3	4
Neck pain	1	2	1	1		1
Necrosis		1				1
Nervous system disorder	1	1			1	1
Night sweats	2	2	1	1	1	1
Oedema		1		1		
Oedema peripheral		1		1		
Oesophagitis	1	1			1	1
Off label use		17		17		
Oral discomfort	1	1	1	1		
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	2	1	2		
Overdose		1		1		
Oxygen saturation decreased		1				1
Pain	6	15	4	13	2	2
Pain in extremity	4	14	4	12		2
Pain in jaw	1	2		1	1	1
Pallor	1	2	1	2		
Palpitations	2	2	2	2		
Paraesthesia	2	7		1	2	6
Paraesthesia oral		4		1		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis	1	1			1	1
Pericarditis		1				1
Periorbital swelling	1	1	1	1		
Peripheral coldness	1	1	1	1		
Peripheral swelling		2		2		
Petechiae		1		1		
Pharyngeal hypoesthesia		1				1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1				1
Pneumonia	1	2			1	2
Presyncope		1		1		
Productive cough	1	1	1	1		
Product use issue		15		15		
Pruritus	2	6	1	4	1	2
Pulmonary embolism		1				1
Pulmonary oedema	1	1			1	1
Pulse volume decreased		2		1		1
Pyrexia	7	14	5	12	2	2
Rash	6	8	4	5	2	3
Rash macular		1		1		
Rash maculo-papular		1				1
Rash papular	1	1	1	1		
Rash pruritic	1	1	1	1		
Raynaud's phenomenon	1	1			1	1
Respiratory disorder	1	1	1	1		
Rheumatoid arthritis	2	4			2	4
Rhinorrhoea	2	3	2	2		1
Secretion discharge		1		1		
Seizure	1	1			1	1
Sensory disturbance		1				1
Sepsis	1	1			1	1
Sinus pain		1		1		
Skin injury		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder	1	1	1	1		
Sneezing	1	1	1	1		
Somnolence		1		1		
Swelling		1				1
Swelling face	1	1	1	1		
Swollen tongue	2	4	2	2		2
Syncope	3	8			3	8
Systemic lupus erythematosus		1				1
Tachycardia	1	4		1	1	3
Tendon disorder		1		1		
Therapeutic response unexpected	1	3	1	3		
Thirst	2	2	2	2		
Throat irritation	1	2	1	2		
Throat tightness	1	2	1	2		
Tinnitus	2	3	2	3		
Tongue disorder	1	1	1	1		
Toxicity to various agents	1	1			1	1
Transient ischaemic attack	1	2			1	2
Tremor	1	3	1	3		
Underdose		1		1		
Upper-airway cough syndrome		1		1		
Urinary incontinence		1				1
Urticaria	6	11	4	8	2	3
Uveitis		1				1
Vaccination site erythema	2	2	2	2		
Vaccination site pain	5	16	5	14		2
Vaccination site rash	2	2	2	2		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria		1				1
Vaccination site warmth	2	2	2	2		
Varicella		1		1		
Ventricular tachycardia		1				1
Vertebral artery dissection		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	1	1	1	1		
Vital functions abnormal		1				1
Vitreous detachment		1				1
Vitreous floaters		1		1		
Vomiting	6	11	3	8	3	3
Vulval disorder		1				1
Vulvitis		1		1		
Weight decreased		1		1		
Weight increased		1		1		
Wheezing		2		2		
	297	671	183	458	114	213

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CHILE**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain upper		2		1		1	
Anaphylactic reaction		1					1
Angina pectoris	1	1			1		1
Arrhythmia		1					1
Arthralgia	1	2	1	2			
Aversion	1	1	1	1			
Back pain	1	1	1	1			
Blood glucose increased	1	1			1		1
Bone pain	1	1	1	1			
Chest pain		1					1
Chills		1		1			
Choking		1					1
Cough	1	2	1	2			
Decreased appetite		1		1			
Dermatitis allergic	1	1			1		1
Diarrhoea		1		1			
Dizziness		1		1			
Dry skin		1		1			
Dysbiosis		1					1
Dyspnoea		1					1
Fall		1					1
Fatigue		2		2			
Glossitis		1		1			
Headache	2	5	2	5			
Head injury		1					1
Hemiparaesthesia	1	1			1		1
Hypersensitivity		3		3			
Hyperventilation		1					1
Hypoaesthesia		1					1
Hypotension		1					1
Loss of consciousness		1					1
Lymph node pain		1		1			
Malaise	1	2	1	2			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Maternal exposure during pregnancy		1		1		
Muscle spasms		1		1		
Myalgia		2		2		
Nasal congestion	1	2	1	2		
Nausea	1	3	1	2		1
Pain	1	3	1	2		1
Pain in extremity	1	2	1	2		
Pallor		1				1
Pancreatitis		1				1
Panic reaction	1	1	1	1		
Paraesthesia	1	2	1	1		1
Pruritus		1		1		
Pyrexia	1	3	1	3		
Rash		2		1		1
Rash pruritic		1				1
Seizure		1				1
Sensory loss		1		1		
Skin burning sensation	1	1	1	1		
Somnolence	1	1	1	1		
Swollen tongue		1		1		
Synovial cyst		1		1		
Tachycardia		1				1
Urine analysis abnormal		1				1
Urticaria		1				1
Vaccination site pain	1	2	1	2		
Vestibular disorder		1		1		
Wound haemorrhage		1				1
Wrong product administered	1	1	1	1		
	23	84	19	55	4	29

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**COLOMBIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Candida infection		1		1		
Chills	1	2	1	2		
Cough		1		1		
Diarrhoea	1	1	1	1		
Dyspnoea	1	1	1	1		
Erythema	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Feeling hot		1		1		
Gingivitis		1		1		
Headache	1	3	1	3		
Hypersensitivity		1		1		
Hypertension		1		1		
Leukocytosis		1		1		
Malaise	2	2	2	2		
Off label use		1		1		
Oral candidiasis		1		1		
Oropharyngeal pain		1		1		
Product use issue		1		1		
Puncture site pain	1	1	1	1		
Pyrexia	1	2	1	2		
Rash		1		1		
Stomatitis		1		1		
Urticaria		1		1		
Vomiting	1	2	1	2		
	13	33	13	32		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**COSTA RICA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain upper	1	3			1	3
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Arthralgia		2		2		
Asthenia		2				2
Burning sensation		1		1		
Chest discomfort		1				1
Chest pain		1				1
Chills		3		2		1
Condition aggravated		2		1		1
Constipation		1		1		
Contusion	1	1			1	1
COVID-19	1	1			1	1
Death	1	1			1	1
Dermatitis allergic		2		1		1
Diarrhoea	1	1			1	1
Discomfort		1				1
Dizziness	1	2			1	2
Dry mouth		1				1
Dysgeusia		1				1
Dyspepsia	1	2			1	2
Dysphonia		1		1		
Dyspnoea	1	3	1	2		1
Energy increased		1		1		
Epistaxis	1	1			1	1
Erythema		1		1		
Euphoric mood		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye pruritus		2		2		
Faeces soft		1		1		
Fatigue	3	8	2	5	1	3
Feeling abnormal	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Feeling cold		1		1			
Flatulence		1		1			
Gastritis		1					1
Gastrointestinal pain		1		1			
Gastrointestinal sounds abnormal		1		1			
Haemorrhage	1	1			1		1
Headache	2	8	1	4	1		4
Heart rate increased		1					1
Heart rate irregular		1		1			
Hyperhidrosis		1					1
Hypersensitivity		1		1			
Hypertension		1					1
Immune thrombocytopenia	1	1			1		1
Infection		1		1			
Influenza like illness		1					1
Insomnia		1		1			
Limb discomfort	1	2	1	2			
Lymphadenopathy		1		1			
Miosis		1					1
Mobility decreased	1	1	1	1			
Mouth swelling		1		1			
Myalgia	1	3	1	2			1
Myocardial infarction	1	1			1		1
Nasopharyngitis		1		1			
Nausea	1	3		1	1		2
Ocular hyperaemia		2		2			
Oropharyngeal discomfort		1					1
Oxygen saturation decreased		1					1
Pain	1	1	1	1			
Pain in extremity	2	4	2	4			
Paraesthesia		1		1			
Petechiae	1	1			1		1
Platelet count abnormal	1	1			1		1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus		1		1		
Pyrexia	1	4		3	1	1
Rash		1		1		
Red blood cell sedimentation rate increased		1		1		
Respiratory distress		1				1
Sensation of foreign body		1		1		
Skin lesion		1		1		
Sleep disorder		1		1		
Somnolence	1	2	1	2		
Swelling face		1		1		
Syncope	1	1			1	1
Tachycardia		2		2		
Tachypnoea		1		1		
Thirst		2				2
Throat tightness		1				1
Urticaria		1		1		
Vaccination failure	1	1			1	1
Vaccination site discomfort		1		1		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	4	8	4	8		
Vaccination site urticaria		1		1		
Vasculitis		1		1		
Vomiting	1	2		1	1	1
	38	139	16	81	22	58

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CROATIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Anaemia		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema		1				1
Arrhythmia	3	4			3	4
Arthralgia	1	5		4	1	1
Asthenia	1	5		2	1	3
Asthma		1				1
Atrial fibrillation		1				1
Axillary pain	1	1			1	1
Back pain		1				1
Blood creatine phosphokinase increased	1	1	1	1		
Blood glucose increased	3	3	2	2	1	1
Blood pressure increased	3	4	1	2	2	2
Body temperature increased	1	8		6	1	2
Bone pain		4		4		
Breast pain	1	1	1	1		
Breath sounds abnormal		1				1
Bronchitis		1				1
Bronchospasm		2				2
Burning sensation		1				1
Cardiac arrest		1				1
Cardiac failure		1				1
Cardio-respiratory arrest	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort	2	3	1	1	1	2
Chest pain	1	2			1	2
Chills	3	11	1	8	2	3

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma	1	1			1	1
Confusional state		1		1		
Cough		2		1		1
COVID-19	1	3		1	1	2
Cyanosis	1	1			1	1
Deafness bilateral		1				1
Death		1				1
Deep vein thrombosis	1	2			1	2
Defaecation urgency	1	1	1	1		
Dermatitis allergic		1				1
Diabetes mellitus		1				1
Diarrhoea		1				1
Disturbance in attention		1		1		
Dizziness	1	1			1	1
Drug ineffective		1				1
Dysgeusia		2		1		1
Dysphonia		1				1
Dyspnoea	3	10		1	3	9
Erythema	1	4			1	4
Extensive swelling of vaccinated limb		6				6
Extensor plantar response	1	1	1	1		
Eyelid oedema		1		1		
Eyelid pain		1		1		
Eyelid ptosis		1				1
Facial nerve disorder		1		1		
Facial pain		1		1		
Facial paresis	1	2			1	2
Fall		1				1
Fatigue	3	10	1	8	2	2
Fear		1				1
Feeling abnormal	1	1			1	1
Feeling hot		1		1		
Fibromyalgia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
General physical health deterioration		1				1	
Haemorrhage subcutaneous		1				1	
Headache	4	22	3	15	1	7	
Heart rate increased		1				1	
Hemiparesis	1	1			1	1	
Hyperaesthesia		1		1			
Hyperhidrosis	1	1			1	1	
Hypertension	5	7		1	5	6	
Hypertensive crisis	1	1			1	1	
Hypoaesthesia	1	1			1	1	
Hypoaesthesia oral		1				1	
Hypotension		2		1		1	
Lip disorder		1				1	
Lip oedema	1	1			1	1	
Livedo reticularis		1				1	
Loss of consciousness	2	2			2	2	
Lymphadenitis		1				1	
Lymphadenopathy	2	3	1	2	1	1	
Lymph node pain	1	1	1	1			
Malaise	2	6	2	4		2	
Melaena	1	1			1	1	
Multi-organ disorder		1				1	
Muscular weakness	1	3	1	2		1	
Myalgia	1	11		10	1	1	
Nausea	2	4	1	3	1	1	
Neuritis		1		1			
Neurological symptom	1	1	1	1			
Neutrophil count increased	1	1	1	1			
Night sweats		1		1			
Oedema peripheral		1				1	
Organic brain syndrome		1				1	
Pain	1	2	1	2			
Pain in extremity	3	7	1	3	2	4	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pallor		2				2	
Palpitations	3	7	1	2	2	5	
Panic attack		1				1	
Paraesthesia	1	2	1	1		1	
Paraesthesia oral	1	2			1	2	
Peripheral coldness	1	1			1	1	
Pharyngeal paraesthesia		1				1	
Pharyngeal swelling		1		1			
Pneumonia		1				1	
Presyncope	1	2		1	1	1	
Pruritus	1	2			1	2	
Pulmonary embolism	1	1			1	1	
Pulmonary pain		1		1			
Pyrexia	5	18	2	14	3	4	
Rales		1				1	
Rash		1				1	
Rash macular	1	1			1	1	
Rash maculo-papular		1				1	
Respiratory distress	1	1			1	1	
Respiratory failure		1				1	
Respiratory rate decreased	1	1	1	1			
Respiratory tract oedema		1				1	
Skin burning sensation	1	1			1	1	
Skin hypertrophy	1	1			1	1	
Skin oedema		1		1			
Skin reaction		1				1	
Skin tightness	1	1			1	1	
Somnolence		1				1	
Speech disorder	1	1			1	1	
Stridor		2				2	
Suffocation feeling		1				1	
Swelling face		1				1	
Swollen tongue		1				1	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	1	1			1	1
Tachycardia	4	9	1	3	3	6
Tachypnoea		1				1
Throat tightness	1	1			1	1
Thrombocytopenia		1				1
Tinnitus		2		1		1
Tongue oedema		1				1
Tremor		2		1		1
Type I hypersensitivity	1	4			1	4
Unresponsive to stimuli		1				1
Urinary tract infection		1				1
Use of accessory respiratory muscles		1				1
Vaccination failure	1	1			1	1
Vaccination site erythema	2	13		8	2	5
Vaccination site induration		3		2		1
Vaccination site lymphadenopathy	2	2	2	2		
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema	2	4	1	2	1	2
Vaccination site pain	5	26	1	18	4	8
Vaccination site pruritus		1				1
Vaccination site swelling		7		6		1
Vertigo	2	2	1	1	1	1
Vomiting	1	2			1	2
Wheezing		2				2
White blood cell count increased	1	1	1	1		
	119	382	35	169	84	213

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**CYPRUS**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Anaphylactic reaction		1				1
Aortic aneurysm	1	1			1	1
Bacterial sepsis	1	1			1	1
Cervix oedema		1		1		
Chills		3		3		
Condition aggravated		1		1		
COVID-19	1	2			1	2
Death	1	1			1	1
Dehydration	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness		2		2		
Drug ineffective	1	2			1	2
Dyspnoea		2		2		
Face oedema		1		1		
Facial paresis		2				2
Fatigue	1	2	1	2		
Gastrointestinal infection	1	1			1	1
Generalised tonic-clonic seizure		1				1
Headache		2		2		
Hypersensitivity		1		1		
Hypertension		1				1
Hypoacusis		1		1		
Hypotension	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Injection site pain	1	1	1	1		
Insomnia		1		1		
Lymphadenopathy		4		4		
Malaise	1	1	1	1		
Multiple organ dysfunction syndrome	1	1			1	1
Myalgia	1	5	1	5		
Myocardial infarction		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nasal congestion		1		1			
Nausea	1	2	1	2			
Off label use	1	2	1	2			
Overdose		1		1			
Product use issue		1		1			
Pulmonary oedema	1	1			1	1	
Pyrexia	1	2	1	2			
Rash		1		1			
Respiratory distress		1					1
Shock	1	1			1	1	
Syncope		1					1
Tachyarrhythmia		1					1
Tachycardia		2		1			1
Unresponsive to stimuli	1	1			1	1	
Vaccination site oedema	1	2	1	2			
Vaccination site pain		1		1			
Vasculitis	1	2		1	1	1	
Viral sepsis	1	1			1	1	
Vomiting	1	1			1	1	
	27	74	10	45	17	29	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CZECH REPUBLIC**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal discomfort		1					1
Abdominal pain	1	6	1	2			4
Abdominal pain lower	2	2	1	1	1		1
Abdominal pain upper		4		3			1
Abnormal dreams		2		2			
Acne	1	1	1	1			
Acute kidney injury		1					1
Acute respiratory failure		1					1
Ageusia		2		1			1
Airway burns		2					2
Akinesia	1	1			1		1
Allergy to vaccine		2					2
Alopecia		1		1			
Altered state of consciousness	1	2			1		2
Anaemia		3		1			2
Anaesthesia oral		1					1
Anaphylactic reaction	2	6			2		6
Aneurysm	1	1			1		1
Angina pectoris		2					2
Angioedema	1	2			1		2
Anosmia	2	4	1	2	1		2
Anuria		1					1
Anxiety		5		2			3
Aortic arteriosclerosis		1					1
Aortic stenosis	1	1			1		1
Apathy	1	4		1	1		3
Aphasia	2	2	1	1	1		1
Aphthous ulcer		2					2
Apnoea	1	1			1		1
Application site coldness		1					1
Arrhythmia	1	2			1		2
Arteriosclerosis		1					1
Arthralgia	13	43	12	31	1		12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	11	31	8	20	3	11
Asthma		1		1		
Atrial fibrillation	2	4			2	4
Atrial flutter		1				1
Axillary pain		1				1
Back pain	1	7		5	1	2
Bacterial rhinitis		1				1
Bacterial test positive	1	1	1	1		
Basal ganglia haemorrhage		1				1
Blister	1	1			1	1
Blood chloride increased		1		1		
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation		2		1		1
Blood pressure increased	1	6		1	1	5
Blood urine present	1	1	1	1		
Bone pain	1	1			1	1
Bradycardia		2				2
Bradyphrenia		2		1		1
Breast pain	1	3	1	1		2
Bundle branch block right	1	1			1	1
Cardiac arrest	1	2			1	2
Cardiac failure	2	3			2	3
Cardiomyopathy		1				1
Cardio-respiratory arrest		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	2	6			2	6
Chest discomfort	3	8		1	3	7
Chest pain	1	5		2	1	3
Chills	15	45	12	35	3	10
Choking sensation		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse	1	3			1	3
Coagulopathy		1				1
Coma		1				1
Communication disorder		1				1
Concussion		1				1
Condition aggravated		1		1		
Confusional state	1	5	1	2		3
Constipation	1	2		1	1	1
Contusion	1	2			1	2
Cough	5	12	5	10		2
COVID-19	10	16	2	3	8	13
COVID-19 pneumonia		5				5
C-reactive protein increased		2		1		1
Cyanosis		1				1
Cystitis noninfective		1		1		
Deafness		1				1
Deafness neurosensory	1	2			1	2
Death		2				2
Decreased activity		1		1		
Decreased appetite	4	12	4	10		2
Deep vein thrombosis	1	1			1	1
Dehydration		2		1		1
Delirium		2				2
Dementia	1	1			1	1
Depression		1				1
Dermatitis		1				1
Diarrhoea	6	16	4	10	2	6
Diplopia		1				1
Disease recurrence		1				1
Disorganised speech	1	1			1	1
Disorientation		3		1		2
Disturbance in attention	1	3		1	1	2
Dizziness		9		8		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug hypersensitivity	1	1			1	1
Drug ineffective	5	8			5	8
Drug interaction	1	1			1	1
Dry mouth	1	2		1	1	1
Duodenal ulcer		1				1
Dysaesthesia		1				1
Dysarthria		2		1		1
Dyskinesia	1	1			1	1
Dyspepsia		2		1		1
Dysphagia	1	3		2	1	1
Dyspnoea	9	31	2	9	7	22
Dyspnoea at rest		1				1
Dyspnoea exertional	1	2	1	1		1
Dysuria	1	1			1	1
Ear discomfort	1	3	1	2		1
Ear pain	1	2	1	2		
Ear swelling		1				1
Eating disorder		2		1		1
Epistaxis	3	5	1	2	2	3
Erysipelas		1				1
Erythema	5	14	2	8	3	6
Eye haemorrhage	3	3			3	3
Eye irritation		1				1
Eye pain	1	1	1	1		
Eye swelling	1	2	1	2		
Face oedema	1	2			1	2
Facial paralysis	2	4			2	4
Fall		3		2		1
Fatigue	20	74	17	56	3	18
Feeling abnormal		3		2		1
Feeling hot	1	4		3	1	1
Flank pain	1	1	1	1		
Flatulence		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fluid intake reduced		1		1		
Flushing		1				1
Food intolerance		1				1
Formication		1				1
Gait disturbance	1	3		1	1	2
Gait inability		1		1		
Gastrointestinal disorder		1		1		
Gastrointestinal hypermotility		1				1
Gastrointestinal necrosis		1				1
General physical health deterioration	1	4	1	1		3
Glaucoma	1	1			1	1
Glomerular filtration rate decreased		1		1		
Gout		1		1		
Groin pain	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Haematochezia		1				1
Haematoma	1	2	1	1		1
Haemorrhage		1				1
Haemorrhage intracranial	1	1			1	1
Hallucination		1				1
Hallucinations, mixed	1	1			1	1
Headache	12	50	12	42		8
Head discomfort		1				1
Heart rate increased		2				2
Heart rate irregular		1		1		
Hemiparesis	1	1			1	1
Hemiplegia	1	2			1	2
Hepatic function abnormal		1				1
Hepatic infarction		1				1
Hepatitis		1				1
Herpes simplex	1	2			1	2
Herpes zoster	3	7			3	7
Hot flush	3	4			3	4

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemia	2	3			2	3
Hyperhidrosis	2	7	2	6		1
Hyperphagia		1		1		
Hypersensitivity	10	17	1	5	9	12
Hypersomnia		2				2
Hypertension	6	11	1	2	5	9
Hyperventilation		1		1		
Hypoacusis	1	1			1	1
Hypoaesthesia		3		1		2
Hypoaesthesia oral		1				1
Hypoglycaemia	1	2		1	1	1
Hypokalaemia	2	3			2	3
Hypokinesia	1	2	1	2		
Hypophagia		1		1		
Hypotension	1	11		2	1	9
Hypoxia		2				2
Illusion		1		1		
Immune system disorder		1				1
Inappropriate schedule of product administration	2	3	2	3		
Incorrect route of product administration	1	2	1	2		
Infection	1	1	1	1		
Inflammation		1				1
Influenza like illness	15	33	14	23	1	10
Injection site pain		1		1		
Insomnia	2	6	2	4		2
International normalised ratio increased		2		1		1
Intestinal infarction		1				1
Ischaemic stroke		2				2
Jaundice		1		1		
Joint effusion		1				1
Joint range of motion decreased		2		1		1
Joint stiffness		2		1		1
Joint swelling	1	2		1	1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Jugular vein distension		1		1			
Lacrimation increased	1	1	1	1			
Language disorder		1					1
Laryngospasm	1	1			1		1
Lethargy	1	1	1	1			
Leukopenia	1	2			1		2
Limb discomfort	1	1			1		1
Lip swelling	1	3			1		3
Livedo reticularis	1	1	1	1			
Localised oedema		1					1
Loss of consciousness	1	3			1		3
Loss of personal independence in daily activities		1		1			
Lymphadenitis	1	1			1		1
Lymphadenopathy	5	20	3	9	2		11
Lymph node pain		2		1			1
Malaise	2	11	1	8	1		3
Melaena		1					1
Memory impairment		1					1
Mesenteric arterial occlusion		1					1
Mesenteric vascular insufficiency		1					1
Migraine		2		1			1
Migraine with aura		1		1			
Mobility decreased		2		2			
Monoparesis		1					1
Movement disorder	1	1			1		1
Mucosal disorder		1					1
Mucosal dryness		1					1
Multiple organ dysfunction syndrome		2					2
Muscle spasms	1	2	1	2			
Muscular weakness	1	6	1	5			1
Musculoskeletal pain		1		1			
Musculoskeletal stiffness	1	3	1	3			
Myalgia	7	27	7	22			5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	1	1			1	1
Myositis	1	1			1	1
Nasopharyngitis	1	1	1	1		
Nausea	6	32	5	24	1	8
Neck pain	1	3		2	1	1
Nervousness		1		1		
Neuropathy peripheral	1	2			1	2
Neutropenia		1				1
Night sweats	1	2		1	1	1
Nystagmus	1	1	1	1		
Ocular discomfort		1				1
Oedema peripheral	2	5	2	3		2
Off label use		7		7		
Oral pruritus		2		2		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	2	2	2	2		
Overdose	1	3	1	3		
Oxygen saturation decreased		3		2		1
Pain	3	9	3	6		3
Pain in extremity	18	31	14	25	4	6
Palpitations	2	5		1	2	4
Pancreatic infarction		1				1
Paraesthesia	4	18	1	7	3	11
Paraesthesia oral	3	5			3	5
Paralysis	1	1			1	1
Paraparesis		1				1
Paresis		1				1
Patient uncooperative	1	1	1	1		
Peripheral coldness		4		3		1
Peripheral swelling	1	4		1	1	3
Petechiae	2	2			2	2
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling		1				1
Photophobia		1		1		
Pneumonia	2	4			2	4
Pneumonitis	1	1			1	1
Polyarthritits		1				1
Poor quality product administered		1		1		
Posture abnormal	1	1	1	1		
Presyncope		2				2
Productive cough	1	3			1	3
Product preparation error	1	2	1	2		
Product use issue		6		6		
Prolonged expiration		1		1		
Prostate cancer		1				1
Pruritus	5	13	2	6	3	7
Psychomotor hyperactivity	1	1			1	1
Pulmonary embolism		2				2
Pulse abnormal		1		1		
Purpura	1	1			1	1
Pyrexia	25	74	16	43	9	31
Quadripareisis		1				1
Radiculitis brachial		1				1
Rash	2	12		3	2	9
Rash macular	1	1			1	1
Rash maculo-papular	1	3			1	3
Rash pruritic	2	5	1	1	1	4
Red blood cell sedimentation rate increased		1		1		
Renal disorder		1		1		
Renal failure		2				2
Renal impairment	1	1			1	1
Renal pain	2	2	2	2		
Renal transplant failure	1	1			1	1
Respiration abnormal		1				1
Respiratory acidosis		1		1		

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder		1				1
Respiratory failure		3				3
Restlessness		3		3		
Retching	1	3			1	3
Rheumatoid arthritis	1	1			1	1
Rhinalgia	1	1	1	1		
Rhinitis	2	3	2	3		
Rhinorrhoea	1	5	1	4		1
SARS-CoV-2 ant body test negative	1	1			1	1
SARS-CoV-2 test positive		1				1
Scab	1	2	1	2		
Seizure	2	2			2	2
Sensation of foreign body		1				1
Sepsis		2				2
Sinus bradycardia		1		1		
Sinus pain	1	1	1	1		
Sinus tachycardia	1	1			1	1
Skin burning sensation	2	2	1	1	1	1
Skin disorder		1				1
Skin mass		1		1		
Sleep talking		1		1		
Somnolence		6		4		2
Speech disorder		1				1
Spinal disorder		1				1
Spinal pain		3		1		2
Splenic infarction		1				1
Splenic infection		1				1
Sputum purulent	1	1			1	1
Stridor		1		1		
Sudden death		3				3
Suspected COVID-19	1	1			1	1
Swelling	1	2	1	1		1
Swelling face	2	7			2	7

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling of eyelid	1	1			1	1
Swollen tongue		1				1
Syncope	3	6			3	6
Tachycardia	2	10		5	2	5
Tachypnoea	1	3			1	3
Tenderness	1	2	1	1		1
Tension headache	1	3		1	1	2
Throat irritation	1	2			1	2
Throat tightness	1	4		2	1	2
Thrombocytopenia		1				1
Tinnitus	2	3			2	3
Tongue oedema	1	3			1	3
Toothache		1				1
Tooth infection		1				1
Transient ischaemic attack	1	2			1	2
Tremor	3	5	1	3	2	2
Truncus coeliacus thrombosis		1				1
Urinary tract infection	2	3		1	2	2
Urinary tract infection enterococcal		1				1
Urogenital infection bacterial	1	1			1	1
Urosepsis		1				1
Urticaria	2	3			2	3
Vaccination complication		1				1
Vaccination failure	3	5			3	5
Vaccination site bruising		1		1		
Vaccination site erythema	4	14	1	7	3	7
Vaccination site hypersensitivity		1				1
Vaccination site induration		2		1		1
Vaccination site joint movement impairment		1		1		
Vaccination site joint pain		1		1		
Vaccination site mass		1				1
Vaccination site oedema	1	5		3	1	2
Vaccination site pain	6	26	6	23		3

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	2	5	2	4		1
Vaccination site rash		1		1		
Vaccination site reaction		2		1		1
Vaccination site swelling	2	5	1	4	1	1
Vaccination site urticaria	1	2			1	2
Vaccination site warmth		1		1		
Vascular pain		1				1
Vena cava thrombosis		1				1
Ventricular tachycardia		1				1
Vertigo	1	14		11	1	3
Vision blurred	3	9		4	3	5
Visual impairment		1		1		
Vomiting	5	21	4	14	1	7
Wheezing		2		2		
Yellow skin	1	1			1	1
	448	1,442	219	728	229	714

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**DENMARK**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain	2	5		1	2	4
Abdominal pain upper	1	1			1	1
Abortion missed		1				1
Acute kidney injury	1	3			1	3
Acute leukaemia		1				1
Acute myocardial infarction		1				1
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Adrenal insufficiency		1				1
Aggression	1	2			1	2
Alanine aminotransferase increased		1		1		
Altered state of consciousness	1	2			1	2
Amnesia	1	1			1	1
Anaemia		1				1
Anaphylactic reaction	2	7			2	7
Anaphylactic shock	1	2			1	2
Angioedema		4				4
Anti-glomerular basement membrane disease	1	1			1	1
Aphasia	2	2			2	2
Arthralgia	5	13		4	5	9
Arthritis		1		1		
Arthritis reactive		1				1
Aspiration		1				1
Asthenia	3	11	1	2	2	9
Asthma	1	4			1	4
Atrial fibrillation	3	5			3	5
Atrial flutter		2				2
Back pain		3		2		1
Bacteraemia		1				1
Bacterial infection		1				1
Balance disorder	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Basilar artery occlusion	1	1			1	1
Blood albumin decreased		1		1		
Blood chloride increased		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine increased		1				1
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood potassium increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased	1	3			1	3
Blood pressure systolic increased	1	2		1	1	1
Blood sodium decreased		1		1		
Blood uric acid abnormal		1		1		
Body temperature increased		2		2		
Bradycardia	1	2			1	2
Breath sounds abnormal		1				1
Bronchospasm	2	3			2	3
Burning sensation	1	1	1	1		
Bursitis		1				1
Calcium ionised increased		1		1		
Carbon monoxide poisoning	1	1			1	1
Cardiac arrest	4	5			4	5
Cardiac failure	1	1			1	1
Cardiogenic shock		1				1
Cardiovascular disorder	1	1			1	1
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis	2	3			2	3
Cerebrovascular accident	8	10			8	10
Chest discomfort		4		1		3
Chest pain	1	6		2	1	4
Chills	2	14	1	8	1	6
Chorioretinitis		1				1
Chronic obstructive pulmonary disease	3	7			3	7

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse		1				1
Cognitive disorder	1	1			1	1
Colitis	1	1			1	1
Coma		1				1
Condition aggravated	1	9			1	9
Confusional state	2	6		1	2	5
Contusion	1	1			1	1
Coordination abnormal		2				2
Coronary artery thrombosis	1	1			1	1
Cough	3	9		2	3	7
COVID-19	3	8	2	2	1	6
C-reactive protein increased	3	6		1	3	5
Crying		1				1
Death	6	11			6	11
Decreased appetite	1	6		1	1	5
Deep vein thrombosis	6	6			6	6
Dehydration	1	2			1	2
Delirium	3	8			3	8
Delusion		1				1
Dementia	1	1			1	1
Depressed level of consciousness	3	8			3	8
Dermatitis allergic		1				1
Diarrhoea	3	10		5	3	5
Diplopia	1	1			1	1
Discomfort	1	5		1	1	4
Disseminated intravascular coagulation	1	1			1	1
Disturbance in attention		1				1
Dizziness	2	23		8	2	15
Drug ineffective		3				3
Dry eye		1		1		
Dysaesthesia		1				1
Dysarthria		1				1
Dysgeusia	1	2		1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	1	2			1	2
Dysphonia		3		3		
Dyspnoea	16	54		5	16	49
Dyspnoea at rest		1				1
Dyspnoea exertional	1	2			1	2
Dysstasia		1				1
Dysuria	1	1			1	1
Epilepsy	1	1			1	1
Epistaxis		2		1		1
Erysipelas		1				1
Erythema	1	7		3	1	4
Eyelid ptosis		2				2
Eye pain		3		3		
Eye pruritus		2		2		
Face oedema		1				1
Facial paralysis	2	2			2	2
Facial paresis	1	2			1	2
Fall	2	3			2	3
Fatigue	11	48	1	20	10	28
Feeling abnormal		2		2		
Feeling cold		1				1
Feeling hot		3		1		2
Fibrin D dimer increased	2	2			2	2
Flatulence		1		1		
Fluid intake reduced	1	3		1	1	2
Flushing		2				2
Foaming at mouth		2		1		1
Gait disturbance	2	3		1	2	2
Gastric ulcer	1	1			1	1
Gastrointestinal necrosis	1	1			1	1
Gastrooesophageal reflux disease	1	1			1	1
Generalised tonic-clonic seizure		2				2
General physical health deterioration	5	15	1	2	4	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Glomerular filtration rate decreased		1				1	
Guillain-Barre syndrome		1				1	
Haematemesis	1	1			1	1	
Haematochezia	1	1			1	1	
Haematology test abnormal	1	1			1	1	
Haematuria		1				1	
Haemodynamic instability	1	1			1	1	
Haemoglobin decreased		1				1	
Haemolysis		1				1	
Haemorrhage intracranial		1				1	
Haemorrhagic diathesis	1	1			1	1	
Hallucination, visual		1				1	
Headache	12	53	3	22	9	31	
Head discomfort		1				1	
Head injury		1				1	
Heart rate increased	4	7	1	2	3	5	
Hemiparesis	1	3			1	3	
Hemiplegia	2	2			2	2	
Hepatic enzyme increased	1	2	1	2			
Herpes zoster		1		1			
Hot flush		1		1			
Hyperacusis		1				1	
Hyperglycaemia		1				1	
Hyperhidrosis	2	4		1	2	3	
Hypersensitivity	1	5	1	2		3	
Hypersomnia		2		1		1	
Hypertension		5		1		4	
Hypertonia		1				1	
Hypoaesthesia		1				1	
Hypoglycaemia		2		1		1	
Hypophagia		2		2			
Hypotension	2	7		1	2	6	
Hypothermia		2				2	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hypoxia		1				1	
Idiopathic pulmonary fibrosis	1	1			1	1	
Illrd nerve paresis		1				1	
Immune-mediated adverse reaction		1				1	
Immune thrombocytopenia		1				1	
Immunisation reaction		1		1			
Inappropriate schedule of product administration	2	4	2	4			
Incorrect route of product administration		1		1			
Infarction	1	1			1	1	
Infection		1				1	
Influenza		4		2		2	
Influenza like illness	2	3		1	2	2	
Injection site erythema		1		1			
Injection site swelling		1		1			
Intestinal ischaemia	1	1			1	1	
Joint stiffness		2		1		1	
Joint swelling		2				2	
Ketoacidosis		1				1	
Lethargy		1		1			
Limb discomfort	1	2		1	1	1	
Lip pruritus		1				1	
Lip swelling	1	1			1	1	
Livedo reticularis	1	2			1	2	
Loss of consciousness	1	3			1	3	
Lung disorder	2	2			2	2	
Lung infiltration	1	1			1	1	
Lymphadenopathy		5		3		2	
Lymph node pain		1		1			
Lymphopenia		1				1	
Malaise	7	36	1	13	6	23	
Maternal exposure during pregnancy		1				1	
Melaena	1	1			1	1	
Mesenteric artery thrombosis	1	1			1	1	

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metabolic acidosis	1	1			1	1
Metabolic alkalosis		1		1		
Micturition urgency		1				1
Migraine	1	1	1	1		
Mobility decreased	1	2			1	2
Monoparesis	1	2			1	2
Monoplegia		1				1
Multimorbidity	1	1			1	1
Muscle spasms		1		1		
Muscular weakness	1	5		1	1	4
Myalgia	4	23		11	4	12
Myelitis		1				1
Myelosuppression		1				1
Myocardial infarction	1	1			1	1
Nasal congestion		1		1		
Nasal discomfort		1				1
Nasal pruritus		1				1
Nasopharyngitis		1		1		
Nausea	6	32	2	17	4	15
Neck pain		1		1		
Nervous system disorder		1				1
Neuralgia		1				1
Neutrophil count increased		1		1		
Obliterative bronchiolitis		1				1
Obstructive airways disorder	1	3			1	3
Oedema peripheral	3	5		1	3	4
Off label use	2	8	2	8		
Oral discomfort		1				1
Oral mucosal eruption		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		3		1		2
Oxygen saturation decreased	3	8	1	1	2	7
Pain	1	4		2	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Painful respiration		1		1			
Pain in extremity	3	7		3	3		4
Pallor	1	4		1	1		3
Palpitations		6		2			4
Pancytopenia	1	1			1		1
Paraesthesia		5		2			3
Paraesthesia oral	1	3		1	1		2
Paresis		1					1
Parkinson's disease		1					1
Periarthritis		1		1			
Periorbital swelling	1	2		1	1		1
Peripheral coldness	1	2			1		2
Peripheral swelling	2	4			2		4
Pharyngeal paraesthesia		1		1			
Pharyngeal swelling	1	2		1	1		1
Photophobia	1	2			1		2
Photopsia		2					2
Photosensitivity reaction	1	1	1	1			
Pleural effusion		2					2
Pleuritic pain	1	1	1	1			
Pneumonia	5	15			5		15
Pneumonia aspiration		1					1
Pneumonia bacterial		1					1
Pneumonitis		1					1
Presyncope		1					1
Productive cough	1	1			1		1
Product use issue		6		6			
Prolonged expiration		1					1
Pruritus		7		5			2
Pulmonary arterial hypertension		1					1
Pulmonary arterial pressure increased	1	1	1	1			
Pulmonary embolism	12	16			12		16
Pulmonary fibrosis		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary oedema	2	6			2	6
Pulmonary pain		1		1		
Pulse abnormal	1	1			1	1
Pyrexia	8	50	2	16	6	34
Rales		1				1
Rash	2	8	2	6		2
Rash erythematous		3		2		1
Rash pruritic	2	3		1	2	2
Renal failure	1	4			1	4
Respiration abnormal	1	2			1	2
Respiratory acidosis	2	4			2	4
Respiratory arrest	2	3			2	3
Respiratory disorder		1		1		
Respiratory distress	1	1			1	1
Respiratory failure	4	11			4	11
Restlessness	1	3		2	1	1
Rheumatoid arthritis	1	1			1	1
Rheumatoid factor increased	1	1			1	1
Rhinorrhoea	1	1			1	1
Salivary hypersecretion		1				1
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensation of foreign body	2	2			2	2
Sensory disturbance	1	2		1	1	1
Sepsis	1	2			1	2
Sinus tachycardia		1		1		
Sneezing		1		1		
Somnolence	1	4		2	1	2
Speech disorder	1	2			1	2
Splenic infarction	1	1			1	1
Staphylococcal infection		1				1
Stress cardiomyopathy		1				1
Stridor		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sudden cardiac death		1				1	
Sudden death	1	4			1		4
Swelling		2		1			1
Swelling face		4		1			3
Swelling of eyelid		1		1			
Swollen tongue	1	2			1		2
Syncope	2	4			2		4
Systemic immune activation	2	2			2		2
Systemic inflammatory response syndrome		1					1
Tachycardia	1	1			1		1
Tachypnoea		2					2
Tenderness	2	5	1	4	1		1
Therapeutic response unexpected		1		1			
Throat irritation	1	3		1	1		2
Throat tightness		1					1
Thrombocytopenia	2	3			2		3
Thrombosis	4	6			4		6
Toxicity to various agents		1					1
Tracheal stenosis	1	1			1		1
Transient ischaemic attack	1	2			1		2
Transplant failure		1					1
Tremor	3	5			3		5
Troponin I increased		1					1
Troponin increased	1	1			1		1
Type I hypersensitivity		1					1
Unresponsive to stimuli	1	1			1		1
Urinary tract infection	1	2			1		2
Urosepsis	1	1			1		1
Urticaria	4	11	1	5	3		6
Vaccination site erythema	1	7	1	6			1
Vaccination site induration		1		1			
Vaccination site inflammation		1		1			
Vaccination site pain	2	32	2	26			6

\* I=Interval, C=Cumulative  
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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		2		2		
Vaccination site rash		1		1		
Vaccination site swelling	1	7	1	6		1
Vaccination site warmth	1	4	1	4		
Vasculitis	1	1	1	1		
Viral infection		1		1		
Vision blurred		1				1
Vomiting	3	17	1	5	2	12
Wheezing		1				1
Wound		1				1
Wound infection	1	1			1	1
	342	1,181	38	354	304	827

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**ECUADOR**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
Pyrexia	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ESTONIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain upper		1				1	
Acute myocardial infarction	1	1			1	1	
Ageusia	1	2	1	2			
Arthralgia		3		3			
Asthenia	1	6	1	4			2
Blindness unilateral	1	1			1	1	
Bone pain		1					1
Cardiac failure congestive	1	1			1	1	
Cerebral haemorrhage		1					1
Cerebral infarction	1	1			1	1	
Cerebrovascular accident		1					1
Chest discomfort		1		1			
Chest pain	1	2	1	1			1
Chills	2	9	2	8			1
Chronic obstructive pulmonary disease	1	1			1	1	
Cold sweat		1					1
Cough		2		2			
COVID-19	6	6			6	6	
Death	2	2			2	2	
Decreased appetite	1	2	1	2			
Diarrhoea	1	1	1	1			
Disease recurrence	1	2	1	1			1
Dizziness	2	4	2	3			1
Drug ineffective	2	2			2	2	
Dysgeusia		2		1			1
Dysphagia		1		1			
Dyspnoea	3	4	3	4			
Ear disorder	1	1	1	1			
Facial paralysis		1					1
Fatigue	1	6	1	6			
Feeling hot	1	1	1	1			
Flushing		1		1			
Headache		5		4			1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	1	1	1		
Hypersensitivity		1				1
Hypertension		1		1		
Hypertensive heart disease	1	1			1	1
Hypoaesthesia		2		2		
Hypoaesthesia oral		2		2		
Hypoglycaemia	1	1			1	1
Hypotension		1				1
Hypothermia	1	2			1	2
Immunisation anxiety related reaction		1				1
Insomnia	1	2	1	2		
Intranasal paraesthesia		1		1		
Lymphadenopathy		1		1		
Malaise		5		3		2
Migraine with aura		1		1		
Muscular weakness		1		1		
Myalgia	1	3	1	2		1
Nasal congestion		1		1		
Nausea		4		3		1
Off label use		1		1		
Oral herpes		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	1	2	1	2		
Pain in extremity		1		1		
Pallor		1				1
Panic attack		1		1		
Paraesthesia		4		4		
Paraesthesia oral		2		2		
Peripheral sensory neuropathy		1				1
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Photopsia	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Presyncope		1				1	
Product use issue		1		1			
Psoriasis		1				1	
Pulmonary embolism		1				1	
Pulmonary oedema	1	1			1	1	
Pyrexia	2	9	2	8		1	
Respiration abnormal		1				1	
Respiratory failure	2	2			2	2	
Retinal vascular thrombosis	1	1			1	1	
Rhinitis	1	1	1	1			
Seizure		1				1	
Somnolence	1	2	1	2			
Speech disorder		1				1	
Suspected COVID-19	1	1			1	1	
Syncope	1	2			1	2	
Throat tightness		1				1	
Vaccination failure	5	5			5	5	
Vaccination site erythema		2		2			
Vaccination site oedema		1		1			
Vaccination site pain	1	5	1	5			
Vaccine breakthrough infection	1	1			1	1	
Visual impairment		1				1	
Vomiting		1		1			
	56	170	26	105	30	65	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**FINLAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension		2		2		
Abdominal pain		2				2
Abdominal pain upper		1				1
Abdominal symptom		1		1		
Acute myocardial infarction		1				1
Ageusia		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		4				4
Anaphylactic shock		1				1
Ankylosing spondylitis		1				1
Aortitis	1	1			1	1
Aphasia		1				1
Aphonia		1				1
Apnoea		3				3
Areflexia		1				1
Arrhythmia	1	3			1	3
Arthralgia	4	17		1	4	16
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	4	17	1	1	3	16
Asthenopia		1				1
Asthma		1				1
Atrial fibrillation	2	3			2	3
Axillary pain		3		1		2
Back pain		3				3
Bacterial test positive		1				1
Balance disorder		1				1
Blepharitis		1				1
Blood creatinine increased		1				1
Blood glucose increased		1				1
Blood lactic acid decreased		1		1		
Blood pressure decreased		3				3

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood pressure diastolic decreased		1					1
Blood pressure increased	2	6			2		6
Blood uric acid increased		1					1
Body temperature decreased		1					1
Burning sensation	1	3		1	1		2
Cardiac failure	1	3			1		3
Cardiac hypertrophy	1	1			1		1
Cerebral haemorrhage		1					1
Cerebral infarction	4	6			4		6
Cerebrovascular accident		1					1
Cerebrovascular disorder	1	1			1		1
Chest discomfort	1	5			1		5
Chest pain		4		1			3
Chest X-ray abnormal	1	1			1		1
Chills	3	11		1	3		10
Circulatory collapse	1	1			1		1
Cognitive disorder		1					1
Cold sweat		1					1
Coma scale abnormal		2					2
Condition aggravated		2					2
Confusional state	1	3		1	1		2
Congestive cardiomyopathy		1					1
Coronary artery thrombosis	1	1			1		1
Cough	3	10	1	2	2		8
COVID-19	1	1			1		1
C-reactive protein increased		7					7
CREST syndrome		1					1
Crohn's disease		1					1
Cyanosis		1					1
Cystitis	1	1			1		1
Deafness unilateral	2	2			2		2
Death		9					9
Deep vein thrombosis	2	3			2		3

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dementia Alzheimer's type		4				4
Depressed level of consciousness		4				4
Derealisation		1		1		
Diarrhoea	1	6		3	1	3
Disease recurrence	1	2			1	2
Diverticulitis	1	1			1	1
Dizziness	5	19		2	5	17
Dysarthria	6	8			6	8
Dysgeusia		1				1
Dysmetria	1	1			1	1
Dysphagia		5		1		4
Dyspnoea	5	32			5	32
Dyspnoea exertional	1	2			1	2
Dysstasia		1				1
Ear discomfort		2		2		
Ear pain		2		1		1
Eating disorder	1	1	1	1		
Eczema		1				1
Epilepsy		1				1
Epistaxis		2				2
Erysipelas		1				1
Erythema	1	9		2	1	7
Erythema multiforme		1				1
Extensive swelling of vaccinated limb		1		1		
Extrasystoles		1				1
Eye disorder		1				1
Eyelid ptosis		1				1
Eye pain		1				1
Face oedema		2				2
Facial pain		1		1		
Facial paralysis		6				6
Facial paresis		1				1
Fall	3	8		1	3	7

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	9	41		3	9	38
Feeling abnormal	2	6			2	6
Feeling cold		5		1		4
Feeling drunk	1	1			1	1
Feeling hot	1	5		2	1	3
Fibrin D dimer increased	1	1	1	1		
Flatulence		1		1		
Fluid intake reduced		1				1
Flushing		2				2
Foaming at mouth		1				1
Gait disturbance	1	4			1	4
Gastric disorder		1		1		
Gaze palsy		2				2
General physical health deterioration	5	18		1	5	17
Giant cell arteritis	1	1			1	1
Gingival swelling		1		1		
Haematoma	1	1			1	1
Haemodynamic instability	1	1			1	1
Haemoglobin decreased	1	2			1	2
Headache	4	33		5	4	28
Head discomfort		4		1		3
Heart rate decreased		2		1		1
Heart rate increased	1	5			1	5
Heart rate irregular		1				1
Hemianaesthesia	1	3			1	3
Hemiparaesthesia		2				2
Hemiparesis	2	4			2	4
Hemiplegia	2	2			2	2
Herpes zoster	1	2			1	2
Hyperhidrosis		3				3
Hypernatraemia		1				1
Hypersensitivity	1	4			1	4
Hypertension		4		1		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperventilation		1				1
Hypoacusis	2	2	2	2		
Hypoaesthesia	6	11		2	6	9
Hypoaesthesia oral		3				3
Hypokalaemia		4				4
Hyponatraemia	1	1			1	1
Hypophagia		1				1
Hyporeflexia		1				1
Hypotonia		1				1
Immune thrombocytopenia	1	1			1	1
Impaired reasoning		1				1
Impaired work ability	1	5			1	5
Incorrect route of product administration		2		2		
Increased tendency to bruise	1	1			1	1
Increased upper airway secretion		3				3
Infection	1	2			1	2
Inflammatory marker increased		1				1
Influenza	1	1	1	1		
Influenza like illness		1				1
Initial insomnia		1				1
Insomnia		1				1
International normalised ratio decreased	3	3	1	1	2	2
Intervertebral disc disorder		1		1		
Iritis		1				1
Irritability		1				1
Joint effusion		1				1
Joint injury	1	1			1	1
Joint swelling	1	1	1	1		
Limb injury	1	1			1	1
Lip pain		2		2		
Lip swelling		1		1		
Loss of consciousness	1	3			1	3
Loss of control of legs		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of personal independence in daily activities		1				1
Lung disorder	1	2			1	2
Lymphadenopathy		3				3
Lymph node pain		1				1
Malaise	5	17		2	5	15
Memory impairment	1	1			1	1
Mental impairment		1				1
Middle insomnia		2		1		1
Migraine	1	5			1	5
Migraine with aura	1	1			1	1
Mobility decreased		2				2
Mouth haemorrhage	1	1			1	1
Muscle disorder	1	1			1	1
Muscle fatigue		1				1
Muscle spasms		1				1
Muscle spasticity		2				2
Muscle strain		1				1
Muscle tightness		1				1
Muscle twitching		4		1		3
Muscular weakness	3	6			3	6
Musculoskeletal discomfort		1				1
Musculoskeletal disorder		1				1
Musculoskeletal pain		1				1
Musculoskeletal stiffness	3	5	1	1	2	4
Myalgia	4	22		2	4	20
Narcolepsy	1	1			1	1
Nasal congestion		1				1
Nasopharyngitis	1	2			1	2
Nausea	3	21	1	2	2	19
Neck pain	1	3			1	3
Neuralgia	1	3	1	1		2
Neurological symptom	1	2			1	2
Obstruction		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral	2	3	1	1	1	2
Off label use		1		1		
Ophthalmic vein thrombosis	1	1			1	1
Opisthotonus		1				1
Oral discomfort		2		2		
Oral disorder		1				1
Oropharyngeal discomfort		2				2
Oropharyngeal oedema		1				1
Oropharyngeal pain	1	2			1	2
Osteoarthritis		1		1		
Oxygen saturation decreased	1	3			1	3
Pain	3	8			3	8
Painful respiration		1				1
Pain in extremity	4	17	1	2	3	15
Pain of skin		1		1		
Pallor		2				2
Palpitations	1	4			1	4
Papule		1		1		
Paraesthesia	5	13		3	5	10
Paraesthesia oral		7		3		4
Paresis	1	1			1	1
Peak expiratory flow rate decreased		2				2
Pelvic venous thrombosis		1				1
Peripheral embolism	1	1			1	1
Peripheral swelling	1	1	1	1		
Petit mal epilepsy	1	1			1	1
Pharyngeal oedema		2				2
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		4				4
Photopsia	1	2			1	2
Photosensitivity reaction		1				1
Pigmentary glaucoma	1	1			1	1
Pneumonia	2	6			2	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia aspiration		1				1
Polymyalgia rheumatica	1	1			1	1
Porphyria	1	1			1	1
Presyncope	1	3		1	1	2
Productive cough		2				2
Product use issue		1		1		
Pruritus	1	6		3	1	3
Pseudomonal sepsis	1	1			1	1
Pulmonary embolism	5	6			5	6
Pulmonary haemorrhage	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	2			1	2
Pyelonephritis		1				1
Pyrexia	7	42		3	7	39
Rales		1				1
Rash	1	3			1	3
Rash erythematous		3		1		2
Rash macular		2				2
Rectal haemorrhage	1	1			1	1
Reduced facial expression	1	1	1	1		
Respiratory arrest		2				2
Respiratory tract infection		1				1
Retinal tear		1				1
Retinal vascular occlusion	1	1			1	1
Rheumatoid arthritis		1				1
Rhinitis		1				1
Rhinorrhoea		1				1
Rhonchi		1				1
Right ventricular failure	1	1			1	1
SARS-CoV-2 test negative	1	1			1	1
Secretion discharge		1		1		
Seizure		2				2
Sensation of foreign body		3				3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus tachycardia		2				2
Skin sensitisation	1	1			1	1
Skin striae	1	1			1	1
Skin warm	1	2		1	1	1
Skull fractured base		1				1
Slow speech		1				1
Snoring		1				1
Somnolence	1	2			1	2
Speech disorder		2				2
Stiff tongue		1				1
Strabismus		1				1
Stridor		1				1
Stupor		1				1
Subcutaneous abscess		1				1
Sudden death		3				3
Swelling		2		1		1
Swelling face		1				1
Swollen tongue	1	1			1	1
Syncope	2	6			2	6
Synovial fluid white blood cells positive		1				1
Tachycardia		1				1
Throat irritation		1				1
Throat tightness	1	2			1	2
Thrombophlebitis superficial		1				1
Thrombosis	3	4			3	4
Tongue discolouration	1	1			1	1
Tongue discomfort	1	1			1	1
Tongue disorder		1				1
Tongue erythema	1	1			1	1
Tongue oedema		1				1
Toothache		1		1		
Transient aphasia	1	1			1	1
Transient ischaemic attack	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	7			1	7
Ulcerative keratitis		1				1
Unresponsive to stimuli		2				2
Urinary tract infection	2	2	1	1	1	1
Urine porphobilinogen increased	1	1			1	1
Urticaria	2	6		2	2	4
Vaccination failure	1	1			1	1
Vaccination site bruising		1				1
Vaccination site erythema		7		4		3
Vaccination site haematoma		1		1		
Vaccination site hypoaesthesia		1				1
Vaccination site joint movement impairment		1		1		
Vaccination site mass		1				1
Vaccination site movement impairment		2				2
Vaccination site oedema		4		3		1
Vaccination site pain	1	13		2	1	11
Vaccination site pruritus		3		3		
Vaccination site reaction		3		2		1
Vaccination site swelling		1				1
Vaccination site warmth	1	5		2	1	3
Venous thrombosis	1	1			1	1
Vertigo		1				1
Viral infection		2				2
Visual impairment	1	3			1	3
Vomiting	2	12		1	2	11
Weight decreased		1		1		
Wheezing		2				2
White blood cell count increased		2				2
	231	981	17	124	214	857

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Country Where Event Occurred

**FRANCE**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal distension	2	5	2	3		2
Abdominal mass	1	1	1	1		
Abdominal pain	7	35	4	16	3	19
Abdominal pain lower	2	2	1	1	1	1
Abdominal pain upper	8	18		4	8	14
Abnormal behaviour	1	2	1	1		1
Abnormal faeces		1		1		
Abnormal sensation in eye	1	1	1	1		
Abortion spontaneous	3	3			3	3
Acidosis hyperchloraemic		1				1
Acquired haemophilia	1	1			1	1
Activated partial thromboplastin time abnormal	1	1			1	1
Activated partial thromboplastin time shortened	1	1			1	1
Acute abdomen		1				1
Acute coronary syndrome	4	13			4	13
Acute febrile neutrophilic dermatosis		1				1
Acute kidney injury	6	20			6	20
Acute myeloid leukaemia	1	2			1	2
Acute myocardial infarction	2	4			2	4
Acute pulmonary oedema	4	18			4	18
Acute respiratory distress syndrome	4	15			4	15
Acute respiratory failure	1	15			1	15
Acute sinusitis	1	1	1	1		
Adrenal mass	1	1	1	1		
Adrenocortical insufficiency acute		1				1
Adult failure to thrive		1				1
Aerococcus urinae infection		1				1
Ageusia	1	2	1	2		
Aggression	4	5	1	1	3	4
Agitation	6	17	1	6	5	11
Agranulocytosis	1	2			1	2
Air embolism	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		4		3		1
A buminuria		1				1
Altered state of consciousness	1	9			1	9
Amaurosis	1	1			1	1
Amaurosis fugax		1				1
Amenorrhoea	1	1			1	1
Amnesia	1	3			1	3
Anaemia	4	10		1	4	9
Anaemia macrocytic	1	1			1	1
Anaphylactic reaction	6	13			6	13
Anaphylactic shock	2	6			2	6
Anaphylactoid reaction		1				1
Angina pectoris	1	6			1	6
Angina unstable	1	1			1	1
Angioedema	5	21		1	5	20
Ankylosing spondylitis	1	5			1	5
Anticoagulation drug level below therapeutic	2	2	1	1	1	1
Anti-neutrophil cytoplasmic antibody positive vasculitis		1				1
Antinuclear antibody positive		1				1
Antisynthetase syndrome		1				1
Anuria		2				2
Anxiety	3	12		3	3	9
Anxiety disorder		1		1		
Aortic arteriosclerosis		1				1
Aortic stenosis	1	1			1	1
Aortic valve calcification	1	1			1	1
Aortic valve incompetence	2	3			2	3
Apathy	3	4	2	2	1	2
Aphasia	5	14	1	4	4	10
Aphonia		1				1
Aphthous ulcer		2		1		1
Aplasia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aplastic anaemia	1	1			1	1
Appendicitis		2				2
Arrhythmia	9	26			9	26
Arrhythmia supraventricular		3				3
Arterial disorder	1	1			1	1
Arteriosclerosis	1	2			1	2
Arteriovenous fistula thrombosis		1				1
Arthralgia	18	63	5	23	13	40
Arthritis		4		1		3
Arthritis reactive	3	4			3	4
Aspartate aminotransferase increased		4		3		1
Aspiration	2	3			2	3
Asthenia	68	237	17	71	51	166
Asthma	4	11	1	1	3	10
Asthmatic crisis	2	7			2	7
Asymptomatic COVID-19	6	8	1	1	5	7
Ataxia	4	4	2	2	2	2
Atrial fibrillation	24	54			24	54
Atrial flutter	2	4	1	1	1	3
Atrial thrombosis	1	1			1	1
Atrioventricular block	2	5		1	2	4
Atrioventricular block complete		3				3
Autoimmune haemolytic anaemia		1				1
Autoimmune hepatitis	1	1			1	1
Autoimmune thyroiditis		1				1
Axillary pain		4		1		3
Back pain	6	14	3	6	3	8
Bacterial infection		1				1
Bacterial pyelonephritis		1				1
Bacterial sepsis	1	1			1	1
Balance disorder	5	10	2	2	3	8
Bedridden		1		1		
Behaviour disorder	4	8		1	4	7

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign breast neoplasm		1		1		
Benign prostatic hyperplasia	1	1	1	1		
Bilirubin conjugated increased		1		1		
Bipolar disorder		1				1
Bladder dilatation	1	1			1	1
Blastocystis infection		1				1
Blindness transient	1	1			1	1
Blindness unilateral	1	2			1	2
Blister		1				1
Blood albumin decreased	1	1	1	1		
Blood alkaline phosphatase increased	1	3	1	3		
Blood bicarbonate decreased		1				1
Blood bilirubin abnormal	1	1	1	1		
Blood bilirubin increased		1		1		
Blood bilirubin unconjugated increased		1		1		
Blood calcium decreased	1	1	1	1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	1	2	1	2		
Blood culture positive	1	1			1	1
Blood folate decreased	1	1			1	1
Blood glucose fluctuation		1		1		
Blood glucose increased	2	7	2	5		2
Blood lactate dehydrogenase increased	1	1	1	1		
Blood loss anaemia	1	1			1	1
Blood parathyroid hormone increased	1	1	1	1		
Blood potassium increased	1	1	1	1		
Blood pressure abnormal	1	2	1	1		1
Blood pressure decreased		5		2		3
Blood pressure diastolic decreased	1	3		2	1	1
Blood pressure fluctuation		1		1		
Blood pressure increased	1	11	1	3		8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic decreased	1	1	1	1		
Blood pressure systolic increased	2	5	1	1	1	4
Blood sodium decreased	1	1	1	1		
Blood sodium increased	1	3		1	1	2
Blood thyroid stimulating hormone decreased	1	1	1	1		
Blood thyroid stimulating hormone increased	2	3	1	2	1	1
Blood uric acid increased		1		1		
Body temperature decreased		3		1		2
Body temperature increased	2	3	1	1	1	2
Bone abscess		1				1
Bone pain		2				2
Bradycardia	4	19			4	19
Bradyphrenia	1	1			1	1
Brain contusion	1	1			1	1
Brain hypoxia	1	1			1	1
Brain natriuretic peptide increased	3	4	2	2	1	2
Brain stem haemorrhage		1				1
Breast abscess		1				1
Breast pain	1	3	1	1		2
Breast swelling		1		1		
Breath sounds abnormal	1	1			1	1
Bronchial obstruction		1				1
Bronchiolitis		1				1
Bronchitis		5				5
Bronchopneumopathy	1	4	1	1		3
Bronchospasm		6				6
Bundle branch block		1				1
Bundle branch block left		3				3
Bundle branch block right	1	7	1	3		4
Burning sensation		3		1		2
Bursal fluid accumulation		1		1		
Carcinoembryonic antigen increased		1				1
Cardiac arrest	3	11			3	11

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac discomfort	1	1			1	1
Cardiac failure	25	71			25	71
Cardiac failure acute	1	5			1	5
Cardiac failure congestive		1				1
Cardiac fibrillation	1	1			1	1
Cardiac flutter		2				2
Cardiac tamponade	1	1			1	1
Cardiogenic shock	1	5			1	5
Cardiomegaly		1				1
Cardiomyopathy	1	1			1	1
Cardiopulmonary failure	2	3			2	3
Cardio-respiratory arrest	10	27			10	27
Cardio-respiratory distress	1	1			1	1
Cardiovascular disorder	1	3			1	3
Carotid artery occlusion	2	2			2	2
Carotid artery thrombosis	2	2			2	2
Cataract	1	1			1	1
Cell death	2	2			2	2
Central nervous system lesion		1				1
Cerebellar haematoma	1	1			1	1
Cerebellar infarction		1				1
Cerebellar stroke		1				1
Cerebellar syndrome		2				2
Cerebral amyloid angiopathy		1				1
Cerebral arteriosclerosis	1	1			1	1
Cerebral artery stenosis		1				1
Cerebral atrophy	1	2			1	2
Cerebral disorder		1				1
Cerebral haematoma	2	7			2	7
Cerebral haemorrhage	3	7			3	7
Cerebral infarction	4	5			4	5
Cerebral ischaemia		1				1
Cerebral thrombosis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	11	27			11	27
Cervicobrachial syndrome		3		1		2
Chest discomfort	3	21		5	3	16
Chest injury		1				1
Chest pain	19	62	4	8	15	54
Chest X-ray abnormal	1	1			1	1
Chills	22	87	8	32	14	55
Choking	2	3			2	3
Cholestasis	1	4			1	4
Chromaturia		2		1		1
Chronic kidney disease	1	1			1	1
Chronic obstructive pulmonary disease	1	14		2	1	12
Circadian rhythm sleep disorder	1	1	1	1		
Circulatory collapse	2	5			2	5
Citrobacter infection	1	1			1	1
Clumsiness		1				1
Cognitive disorder	1	3		1	1	2
Cold sweat	2	3	2	2		1
Colitis		1				1
Coma	2	9			2	9
Coma scale abnormal	1	1			1	1
Condition aggravated	15	39		7	15	32
Conduction disorder		1				1
Confusional state	20	32	3	3	17	29
Conjunctival haemorrhage	1	4			1	4
Conjunctival hyperaemia	1	1	1	1		
Conjunctivitis		1				1
Conjunctivitis bacterial	1	1			1	1
Constipation	1	5	1	5		
Contusion	1	1	1	1		
Coordination abnormal	1	1			1	1
Coronary artery disease		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronary artery stenosis	2	3			2	3
Coronavirus infection		1				1
Cough	16	42	8	16	8	26
COVID-19	85	152	11	18	74	134
COVID-19 pneumonia	10	18			10	18
C-reactive protein increased	14	35	6	17	8	18
Creatinine renal clearance decreased		1				1
Crepitations	1	3	1	2		1
Culture urine positive	1	1	1	1		
Cutaneous lupus erythematosus	1	1			1	1
Cyanosis	2	9	1	2	1	7
Cystic lymphangioma		1				1
Cystitis	1	1			1	1
Cystitis klebsiella		1				1
Daydreaming	2	2			2	2
Deafness	1	2			1	2
Deafness unilateral		4				4
Death	13	79			13	79
Decreased appetite	16	32	10	17	6	15
Decubitus ulcer	2	3	1	1	1	2
Deep vein thrombosis	15	23			15	23
Defect conduction intraventricular	1	1			1	1
Deformity		1		1		
Dehydration	12	23	4	7	8	16
Delirium	1	5			1	5
Delusion	1	3		1	1	2
Dementia	1	3			1	3
Dependent rubor	1	1			1	1
Depressed level of consciousness	2	12			2	12
Depression		1		1		
Dermabrasion		1		1		
Dermatitis exfoliative generalised		1				1
Dermatomyositis	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermo-hypodermatitis	1	2			1	2
Diabetes mellitus	5	8			5	8
Diabetes mellitus inadequate control	6	11			6	11
Diabetic coma		1				1
Diabetic hyperosmolar coma	1	1			1	1
Diabetic ketoacidosis		3				3
Diabetic ketosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	23	82	5	24	18	58
Diarrhoea haemorrhagic	3	4			3	4
Diarrhoea infectious	1	1			1	1
Diplopia	5	6	1	1	4	5
Discomfort	8	27	3	6	5	21
Disease progression		1				1
Disease recurrence	13	46		1	13	45
Disorientation	9	14	1	2	8	12
Disseminated intravascular coagulation	1	1			1	1
Disturbance in attention	2	6	1	2	1	4
Diverticulitis	1	1			1	1
Dizziness	18	48	6	16	12	32
Dizziness postural		1				1
Drop attacks		1				1
Drug eruption	1	1	1	1		
Drug hypersensitivity	1	2			1	2
Drug ineffective	22	47			22	47
Drug interaction	1	1	1	1		
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry eye		1				1
Dry mouth		3		2		1
Dysaesthesia	1	4		1	1	3
Dysarthria	4	11	1	1	3	10
Dysgeusia	2	11		3	2	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgraphia	1	1			1	1
Dyshidrotic eczema		1		1		
Dyskinesia	1	3	1	2		1
Dyslipidaemia		1		1		
Dysmetria	1	1			1	1
Dyspepsia		2		1		1
Dysphagia	4	12	1	2	3	10
Dysphemia		1				1
Dysphonia	3	6		2	3	4
Dyspnoea	31	109	8	15	23	94
Dyspnoea at rest	2	4			2	4
Dyspnoea exertional	5	10	2	3	3	7
Dysstasia		3				3
Dysuria	1	1	1	1		
Ear haemorrhage	1	1	1	1		
Ear pain	3	5	1	1	2	4
Ear swelling	1	1			1	1
Eating disorder		1				1
Eczema	1	1			1	1
Eczema nummular	1	1			1	1
Ejection fraction decreased		1				1
Electric shock		1				1
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex prolonged	1	1			1	1
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality		2				2
Electrocardiogram T wave inversion		1				1
Embolic stroke	4	4			4	4
Embolism		1				1
Embolism venous		1				1
Encephalitis	1	2			1	2
Enlarged uvula		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enterococcal infection		1				1
Enuresis		1				1
Eosinophil count increased		1		1		
Eosinophilia	2	2			2	2
Epilepsy	7	18			7	18
Epistaxis	5	8	1	3	4	5
Epstein-Barr virus test positive		1		1		
Eructation		2				2
Erysipelas	4	6			4	6
Erythema	10	35	1	12	9	23
Erythema multiforme	1	2			1	2
Erythema nodosum	1	1			1	1
Erythema of eyelid		1				1
Erythrosis		1		1		
Escherichia bacteraemia		1				1
Escherichia test positive	1	1	1	1		
Escherichia urinary tract infection	2	3			2	3
Euphoric mood		1		1		
Exposure to SARS-CoV-2		1				1
Extensive swelling of vaccinated limb	1	3	1	3		
Extensor plantar response		1				1
Extradural haematoma		1				1
Extrapyramidal disorder	3	3	1	1	2	2
Extrasystoles	6	9	1	1	5	8
Extremity necrosis	1	1	1	1		
Eye discharge	1	1			1	1
Eye disorder		1				1
Eye haemorrhage		1				1
Eye irritation		1		1		
Eyelid disorder		1				1
Eyelid haematoma		1		1		
Eyelid oedema		3				3
Eyelid ptosis		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye movement disorder	1	1	1	1		
Eye oedema		1		1		
Eye pain	1	2	1	1		1
Eye swelling	2	2			2	2
Face injury	2	2			2	2
Face oedema	3	18		1	3	17
Facial asymmetry	1	2			1	2
Facial bones fracture	2	2			2	2
Facial paralysis	18	47			18	47
Facial paresis	1	3	1	1		2
Faecaloma	1	1			1	1
Faecal vomiting		2				2
Faeces discoloured		1		1		
Faeces soft		1		1		
Failure to thrive		1				1
Fall	27	58	6	12	21	46
Fatigue	38	117	19	54	19	63
Fat tissue increased		1		1		
Fear	1	2	1	1		1
Feeling abnormal	2	11	1	5	1	6
Feeling cold	2	11	1	6	1	5
Feeling drunk	1	2			1	2
Feeling hot	4	12		3	4	9
Feeling of body temperature change	1	1			1	1
Femur fracture		2				2
Fibrin D dimer increased	2	3			2	3
Flank pain	1	2		1	1	1
Flatulence	2	2	1	1	1	1
Fluid retention		1				1
Flushing	4	9	1	3	3	6
Foaming at mouth		1				1
Focal dyscognitive seizures	1	2			1	2
Food aversion	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Food craving	1	1			1	1
Formication		1				1
Fracture	1	1			1	1
Frostbite		1		1		
Functional gastrointestinal disorder		2				2
Gait disturbance	5	13	4	7	1	6
Gait inability	2	3			2	3
Gamma-glutamyltransferase increased	2	5	2	4		1
Gastric volvulus		1				1
Gastroenteritis		1				1
Gastrointestinal disorder	1	2		1	1	1
Gastrointestinal haemorrhage	1	3			1	3
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain	1	1			1	1
Gastrointestinal sounds abnormal		1		1		
Gastrooesophageal reflux disease		2		1		1
Gaze palsy		1				1
Generalised anxiety disorder		1				1
Generalised oedema		1				1
Generalised tonic-clonic seizure	5	9			5	9
General physical health deterioration	13	36	4	6	9	30
Genital haemorrhage	1	1			1	1
Genital herpes	1	1			1	1
Giant cell arteritis	2	4			2	4
Glomerular filtration rate decreased	1	3	1	1		2
Glossitis		1				1
Glycosylated haemoglobin increased		1		1		
Goitre		1		1		
Gout		3		1		2
Gross motor delay		1				1
Guillain-Barre syndrome	2	3			2	3
Haemarthrosis	1	2			1	2
Haematemesis	2	4			2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Haematochezia		2				2	
Haematoma	6	8	1	1	5	7	
Haematoma muscle	1	1			1	1	
Haematuria	2	4			2	4	
Haemodynamic instability	1	2	1	2			
Haemoglobin decreased	3	6	2	3	1	3	
Haemoglobinuria		1				1	
Haemolytic anaemia	2	2			2	2	
Haemophagocytic lymphohistiocytosis	2	3			2	3	
Haemoptysis	2	3			2	3	
Haemorrhage		1				1	
Haemorrhagic disorder	1	1			1	1	
Haemorrhagic stroke	2	9			2	9	
Haemorrhagic transformation stroke		1				1	
Hallucination	2	8			2	8	
Hallucination, auditory	1	1			1	1	
Hallucination, olfactory		1				1	
Hallucinations, mixed		1				1	
Hallucination, visual	5	7			5	7	
Headache	54	203	18	65	36	138	
Head discomfort		2		1		1	
Head injury	5	9	1	1	4	8	
Heart rate decreased	3	4	1	2	2	2	
Heart rate increased	1	6	1	4		2	
Heart rate irregular		2				2	
Heart sounds abnormal		4		1		3	
Hemianaesthesia		1				1	
Hemianopia homonymous	1	2			1	2	
Hemiapraxia	1	1			1	1	
Hemiparaesthesia		1				1	
Hemiparesis	1	6			1	6	
Hemiplegia	5	14			5	14	
Hepatic cyst	1	1			1	1	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hepatic cyst infection		1					1
Hepatic enzyme increased	1	3	1	1			2
Hepatic function abnormal		1		1			
Hepatic haematoma		1					1
Hepatic infarction	1	1			1		1
Hepatic steatosis	1	1	1	1			
Hepatitis		1					1
Hepatitis B	1	1			1		1
Hepatocellular injury	4	8			4		8
Hepatomegaly	1	2			1		2
Herpes zoster	12	38		11	12		27
Herpes zoster cutaneous disseminated	1	1			1		1
High-pitched crying		1		1			
Hippocampal atrophy		1					1
Hoffmann's sign		1		1			
Horner's syndrome		1					1
Hostility	1	1			1		1
Hot flush	4	15	1	5	3		10
Humerus fracture	1	1			1		1
Hyperacusis	1	1	1	1			
Hyperaesthesia	1	2	1	1			1
Hyperbilirubinaemia	1	3			1		3
Hypercalcaemia	1	1	1	1			
Hypercapnia	1	2			1		2
Hyperchloraemia	1	1			1		1
Hyperglycaemia	5	12	2	5	3		7
Hyperglycinaemia		1					1
Hyperhidrosis	5	23		2	5		21
Hyperkalaemia	3	7			3		7
Hyperlactacidaemia	1	1			1		1
Hyperleukocytosis	5	14			5		14
Hypernatraemia	3	7	1	3	2		4
Hypersensitivity	4	33		7	4		26

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity vasculitis	1	2			1	2
Hypersomnia	2	4	2	2		2
Hypertension	60	178	4	19	56	159
Hypertensive crisis	17	49			17	49
Hyperthermia	9	37	3	11	6	26
Hyperthyroidism		3				3
Hypertonia		1				1
Hypertrophic cardiomyopathy	1	1			1	1
Hyperuricaemia	1	1	1	1		
Hyperventilation		1		1		
Hypoacusis	2	3			2	3
Hypoaesthesia	13	15	8	8	5	7
Hypoaesthesia oral		3				3
Hypocalcaemia		1				1
Hypogammaglobulinaemia	1	1			1	1
Hypoglycaemia	2	8			2	8
Hypokalaemia	2	5			2	5
Hypokinesia	1	1			1	1
Hypotension	17	77	4	15	13	62
Hypothermia	1	6			1	6
Hypotonia	3	7	1	2	2	5
Hypovolaemic shock	1	2			1	2
Hypoxia	3	21			3	21
Illrd nerve paralysis		2				2
Ill-defined disorder		1				1
Illness		1				1
Illusion	1	1			1	1
Immune thrombocytopenia	3	7			3	7
Immunodeficiency	1	1			1	1
Impaired driving ability	1	1			1	1
Impaired work ability	1	3	1	1		2
Inappropriate schedule of product administration	3	5	3	4		1
Incoherent	4	4	2	2	2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect route of product administration	1	5	1	5		
Increased bronchial secretion	1	3			1	3
Induration	1	1			1	1
Infarction	2	4			2	4
Infection	3	4	2	2	1	2
Inflammation	12	19	5	8	7	11
Inflammatory pain	1	2			1	2
Influenza	4	15	1	3	3	12
Influenza like illness	34	117	9	23	25	94
Initial insomnia		1				1
Injected limb mobility decreased	1	6		1	1	5
Injection site erythema		2		2		
Injection site hyperaesthesia		1		1		
Injection site pain		2		2		
Injection site pruritus		1		1		
Injection site rash		1				1
Injection site swelling		2		2		
Insomnia	7	17	3	10	4	7
Insulin-requiring type 2 diabetes mellitus		1				1
International normalised ratio abnormal		1				1
International normalised ratio increased	2	5			2	5
Interstitial lung disease	3	6			3	6
Intervertebral disc compression		1				1
Intervertebral disc protrusion	1	1	1	1		
Intestinal ischaemia	4	4			4	4
Intestinal obstruction		1				1
Intracardiac thrombus	1	2			1	2
Intracranial haematoma		1				1
Intracranial pressure increased		1				1
Iridocyclitis		1				1
Iron deficiency anaemia		1				1
Irritability		1				1
Ischaemic limb pain	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke	19	50			19	50
Jaundice		4				4
Joint dislocation	1	1			1	1
Joint effusion	1	2			1	2
Joint injury		1				1
Joint stiffness	1	2			1	2
Joint swelling	1	3		1	1	2
Jugular vein distension		1				1
Jugular vein thrombosis	1	1			1	1
Klebsiella infection		2				2
Labile blood pressure		1				1
Laboratory test abnormal		1				1
Lacrimation increased	1	3	1	1		2
Lactic acidosis		1				1
Lactobacillus infection		1				1
Lacunar infarction		1				1
Lacunar stroke	1	1			1	1
Language disorder	1	2			1	2
Large intestine infection	1	1			1	1
Laryngeal discomfort	1	2		1	1	1
Laryngeal dyspnoea		2				2
Laryngeal oedema	1	5			1	5
Laryngitis		2				2
Laryngitis allergic		1				1
Left atrial dilatation	1	1			1	1
Left ventricular dilatation	1	1	1	1		
Left ventricular end-diastolic pressure increased		1				1
Left ventricular failure	1	2			1	2
Left ventricular hypertrophy		1				1
Leukocytosis	1	3	1	2		1
Leukocyturia	2	4	2	3		1
Leukoencephalopathy	2	4			2	4
Leukopenia	2	2			2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lichen planus		1					1
Limb discomfort	3	3			3		3
Lipase increased		1		1			
Lip oedema		10		2			8
Lip pain	1	2			1		2
Lip pruritus		1					1
Lip swelling		2					2
Listless		1					1
Lithiasis		1		1			
Livedo reticularis	3	9	2	3	1		6
Liver function test increased	1	1			1		1
Lividity		1					1
Localised oedema		6		2			4
Loss of consciousness	16	45			16		45
Loss of personal independence in daily activities	3	4	2	2	1		2
Lower respiratory tract congestion	2	5			2		5
Lower respiratory tract infection		1					1
Lung abscess		1					1
Lung disorder	9	24	4	6	5		18
Lung opacity		1					1
Lyme disease		1					1
Lymphadenitis	1	4		1	1		3
Lymphadenopathy	5	28	2	12	3		16
Lymph node pain		1					1
Lymphocyte count decreased	1	2	1	1			1
Lymphoedema	2	2	1	1	1		1
Lymphopenia	7	15	4	6	3		9
Macular oedema	1	1			1		1
Macule		1		1			
Madarosis		1					1
Major depression	1	1			1		1
Malaise	30	126	10	29	20		97
Malnutrition	1	3		1	1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mass		1				1
Maternal exposure during pregnancy		2		1		1
Mean cell volume decreased	1	1			1	1
Melaena		1				1
Memory impairment	2	4		1	2	3
Meningitis	1	1			1	1
Meningitis aseptic		1				1
Meningoencephalitis herpetic	2	2			2	2
Meningoradiculitis	1	1			1	1
Meningorrhagia	1	1			1	1
Mental impairment		1				1
Metamorphopsia	1	1			1	1
Metastases to peritoneum		1				1
Middle insomnia	2	2			2	2
Migraine	2	9	2	3		6
Migraine with aura		1		1		
Miosis		1				1
Mitral valve calcification	1	2			1	2
Mitral valve disease		1				1
Mitral valve incompetence	2	3			2	3
Mitral valve stenosis	1	1			1	1
Moaning		1				1
Mobility decreased	4	7	1	2	3	5
Monocytosis	2	2	1	1	1	1
Mononeuropathy multiplex	1	1			1	1
Monoparesis		3				3
Moraxella infection		1				1
Morning sickness		1		1		
Motor dysfunction	5	10		1	5	9
Movement disorder	1	2		1	1	1
Mucosal discolouration	1	1			1	1
Multiple organ dysfunction syndrome	4	6			4	6
Muscle contracture	1	3		1	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscle disorder		1		1			
Muscle fatigue	2	4	1	2	1	2	
Muscle rigidity		1		1			
Muscle spasms	1	6		2	1	4	
Muscle strength abnormal		1				1	
Muscle tightness		1		1			
Muscular weakness	9	15	4	4	5	11	
Musculoskeletal chest pain		3		1		2	
Musculoskeletal pain	2	2	2	2			
Musculoskeletal stiffness	9	27	1	5	8	22	
Mutism	1	2	1	1		1	
Myalgia	16	83	5	31	11	52	
Myasthenia gravis	2	2			2	2	
Myasthenia gravis crisis	2	2			2	2	
Mydriasis	1	5	1	2		3	
Myelocytosis		1				1	
Myelodysplastic syndrome	1	1			1	1	
Myelof brosis		1				1	
Myocardial infarction	5	20			5	20	
Myocardial ischaemia		2				2	
Myocardial necrosis marker increased		1				1	
Myocarditis		2				2	
Myoclonus	1	3			1	3	
Myositis	1	2			1	2	
Nasal congestion		1				1	
Nasopharyngitis	1	2	1	2			
Nausea	26	105	5	30	21	75	
Near death experience		1				1	
Neck pain	3	9	2	4	1	5	
Necrotising colitis	1	1			1	1	
Neoplasm		1				1	
Nephropathy	1	1			1	1	
Nerve compression	1	1	1	1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nerve conduction studies abnormal	1	1	1	1		
Nervousness		1				1
Nervous system disorder	2	3	1	1	1	2
Neuralgia	2	14	1	5	1	9
Neuritis		1		1		
Neurological decompensation	1	2	1	1		1
Neuromuscular pain		1		1		
Neuropathy peripheral	3	3			3	3
Neutropenia	2	4			2	4
Neutrophil count abnormal		1				1
Neutrophil count decreased		2				2
Neutrophil count increased	2	5	2	4		1
Neutrophilia		1		1		
Nightmare	1	1			1	1
Night sweats	1	2	1	1		1
Nitrite urine present	1	1	1	1		
Nocturia	1	1	1	1		
Noninfective gingivitis		2		1		1
Normochromic anaemia	1	1			1	1
Normocytic anaemia		1				1
N-terminal prohormone brain natriuretic peptide increased		2				2
Obstructive airways disorder		1		1		
Ocular discomfort		1		1		
Ocular hyperaemia	1	3			1	3
Ocular myasthenia		1				1
Odynophagia	1	2	1	2		
Oedema	1	4			1	4
Oedema mouth		1				1
Oedema peripheral	10	25	3	6	7	19
Oesophageal spasm		1				1
Off label use	2	12	2	12		
Ophthalmic herpes zoster	4	9			4	9

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Optic ischaemic neuropathy		1				1	
Optic neuritis	1	1			1		1
Oral blood blister	1	1			1		1
Oral pain		2		2			
Oral pruritus		2					2
Orbital haematoma		1					1
Oropharyngeal discomfort	1	3	1	2			1
Oropharyngeal pain	1	4	1	3			1
Orthopnoea	1	2			1		2
Orthostatic hypotension		2					2
Osteoarthritis	2	3	2	2			1
Otitis externa		1					1
Otolithiasis		1					1
Overdose	1	1	1	1			
Oxygen saturation abnormal		1					1
Oxygen saturation decreased	15	82	3	7	12		75
Oxygen saturation increased	1	1			1		1
Pain	16	61	4	23	12		38
Pain in extremity	19	44	6	18	13		26
Pain in jaw	1	4			1		4
Palatal oedema		2					2
Pallor	4	13		2	4		11
Palpitations	5	18	1	5	4		13
Pancreatitis		1					1
Pancreatitis acute	1	3			1		3
Pancytopenia		3					3
Paraesthesia	18	45	1	11	17		34
Paraesthesia oral	1	8		3	1		5
Paralysis	2	4			2		4
Paresis		1					1
Parkinsonism	1	1			1		1
Parkinson's disease	1	1			1		1
Partial seizures	1	2			1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peau d'orange		1		1		
Pelvic fracture		1				1
Pelvic pain		1				1
Pemphigoid	3	4			3	4
Peptic ulcer		1				1
Pericardial effusion	2	4			2	4
Pericardial haemorrhage	1	1			1	1
Pericarditis	6	16			6	16
Periorbital pain		1				1
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness	1	8	1	5		3
Peripheral ischaemia	3	5		1	3	4
Peripheral swelling	2	6	1	3	1	3
Peripheral venous disease	1	1	1	1		
Pernio-like erythema		1		1		
Persecutory delusion	1	2		1	1	1
Petechiae	2	3		1	2	2
Petit mal epilepsy	1	2			1	2
Pharyngeal disorder		1				1
Pharyngeal paraesthesia		2				2
Phlebitis	4	4	1	1	3	3
Phonophobia		1				1
Photophobia	1	3	1	1		2
Platelet count decreased	2	3	1	1	1	2
Platelet count increased		1				1
Pleural effusion	3	4	2	2	1	2
Pneumococcal sepsis		1				1
Pneumonia	11	26			11	26
Pneumonia aspiration	4	21			4	21
Pneumonia bacterial	3	3			3	3
Pneumonitis		3				3
Pneumoperitoneum		1				1
Pneumothorax	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pollakiuria	1	1	1	1		
Polyarthritis	1	2			1	2
Polydipsia		2		1		1
Polymyalgia rheumatica	2	2			2	2
Polyneuropathy		1				1
Polyp	1	1	1	1		
Portal vein thrombosis	1	1			1	1
Posterior revers ble encephalopathy syndrome	1	1			1	1
Prerenal failure	1	2			1	2
Presyncope	2	11		4	2	7
Proctitis	1	1	1	1		
Product administration error		1				1
Productive cough	1	4			1	4
Product preparation error	1	1	1	1		
Product use issue		9		9		
Progressive supranuclear palsy	1	1			1	1
Prostatitis	2	2	2	2		
Proteinuria		2		1		1
Prothrombin level abnormal	1	1			1	1
Prothrombin time shortened	2	2	1	1	1	1
Pruritus	5	25		6	5	19
Psoriasis	2	2			2	2
Psoriatic arthropathy		1				1
Psychomotor retardation		1				1
Psychomotor skills impaired	1	1			1	1
Pulmonary arterial hypertension		1				1
Pulmonary arterial pressure increased	1	1			1	1
Pulmonary artery dilatation	1	1			1	1
Pulmonary congestion		2				2
Pulmonary embolism	41	66			41	66
Pulmonary infarction	1	2			1	2
Pulmonary oedema	4	9			4	9
Pulmonary sepsis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pulpitis dental		1				1	
Pulse abnormal		1		1			
Pulse absent	1	3	1	2		1	
Pupils unequal		1		1			
Purpura	3	5	1	1	2	4	
Pyelonephritis	3	3			3	3	
Pyrexia	52	236	14	65	38	171	
Quadripareisis	1	1			1	1	
Quadriplegia	1	2			1	2	
Radial nerve palsy	1	1			1	1	
Rales	3	9	1	1	2	8	
Rash	4	12		5	4	7	
Rash erythematous	1	3			1	3	
Rash macular		2		1		1	
Rash maculo-papular	3	7		1	3	6	
Rash papular		1				1	
Rash pruritic	2	5	1	2	1	3	
Rash vesicular	1	1			1	1	
Raynaud's phenomenon	1	1			1	1	
Rebound effect		1				1	
Recalled product administered	1	1	1	1			
Rectal haemorrhage	3	6			3	6	
Red blood cell sedimentation rate increased		2		2			
Red blood cells urine positive		1				1	
Renal colic	1	1			1	1	
Renal failure	6	16			6	16	
Renal impairment		3				3	
Renal infarct	1	1			1	1	
Renal pain	1	1			1	1	
Respiration abnormal		1				1	
Respiratory acidosis	1	1			1	1	
Respiratory alkalosis		2				2	
Respiratory arrest	1	2			1	2	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory depression		2				2
Respiratory disorder	1	10		1	1	9
Respiratory distress	8	31			8	31
Respiratory failure	1	11			1	11
Respiratory rate decreased	1	1			1	1
Respiratory rate increased	1	2	1	1		1
Respiratory tract congestion		1				1
Respiratory tract infection		2				2
Respiratory tract infection bacterial	1	1			1	1
Respiratory tract oedema		1				1
Restlessness	2	11	1	5	1	6
Retinal artery occlusion	2	2			2	2
Retinal vein occlusion	2	2			2	2
Retrograde amnesia	1	1			1	1
Rhabdomyolysis	3	4			3	4
Rheumatic disorder	1	2		1	1	1
Rheumatoid arthritis	4	12			4	12
Rheumatoid factor increased	1	1			1	1
Rhinitis	2	4	1	1	1	3
Rhinorrhoea	2	7	1	2	1	5
Rhonchi		2		1		1
Right ventricular dilatation	1	1			1	1
Road traffic accident	1	1			1	1
Salivary hypersecretion		1		1		
SARS-CoV-2 ant body test negative	2	3	2	3		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test false positive	1	1	1	1		
SARS-CoV-2 test positive	7	16		1	7	15
Sciatica	1	1	1	1		
Scleritis		1				1
Sedation	1	1	1	1		
Seizure	4	15			4	15
Sense of oppression	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensorimotor disorder	1	1	1	1		
Sensory disturbance	1	1	1	1		
Sensory loss	3	5	1	2	2	3
Sepsis	3	8			3	8
Septic shock	1	6			1	6
Serum sickness	1	1			1	1
Shock		4				4
Shock haemorrhagic	2	2			2	2
Sinus bradycardia		2				2
Sinus tachycardia	4	8	1	2	3	6
Sjogren's syndrome	2	2			2	2
Skin discolouration	1	3	1	2		1
Skin disorder		1		1		
Skin exfoliation		1		1		
Skin fissures		1				1
Skin lesion	1	2	1	1		1
Skin mass		1				1
Skin plaque		1		1		
Skin reaction	1	2	1	2		
Skin warm		1		1		
SLE arthritis		1				1
Sleep apnoea syndrome	1	1			1	1
Sleep disorder	1	3	1	1		2
Sleep talking		1		1		
Sluggishness		1		1		
Somnolence	10	30	3	12	7	18
Speech disorder		5		1		4
Spinal compression fracture		2				2
Spinal cord infarction	2	2			2	2
Spinal cord ischaemia	1	1			1	1
Spinal osteoarthritis		1		1		
Spinal pain		1				1
Splenic infarction	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spondylitis		1				1
Staphylococcal bacteraemia	2	3			2	3
Staphylococcal sepsis	1	1			1	1
Staring		1				1
Status epilepticus	1	4			1	4
Status migrainosus		1				1
Stertor		1				1
Stress		2		2		
Stress cardiomyopathy	1	2			1	2
Subarachnoid haemorrhage	2	2			2	2
Subdural haematoma	2	2			2	2
Subileus		2				2
Sudden death	12	43			12	43
Sudden hearing loss	2	2			2	2
Sudden onset of sleep	1	1			1	1
Suffocation feeling		2				2
Suicidal ideation		1				1
Superinfection	1	1			1	1
Superinfection bacterial	1	1			1	1
Superior vena cava syndrome		1				1
Supraventricular tachyarrhythmia		1				1
Supraventricular tachycardia	2	4			2	4
Suspected COVID-19	1	3	1	1		2
Swelling		1		1		
Swollen tongue		4		1		3
Syncope	5	15			5	15
Systemic inflammatory response syndrome	1	1			1	1
Systemic lupus erythematosus		1				1
Systolic hypertension		1				1
Tachyarrhythmia	1	3		1	1	2
Tachycardia	24	107	8	22	16	85
Tachypnoea	1	9		1	1	8
Tenderness		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tendonitis		1				1
Tension		3		2		1
Testicular pain	1	1	1	1		
Tetany		1				1
Therapeutic response unexpected	1	2	1	2		
Thermal burns of eye		1				1
Thirst	1	3	1	2		1
Throat irritation	1	2			1	2
Throat tightness	2	3			2	3
Thrombocytopenia	13	22			13	22
Thrombocytopenic purpura		1				1
Thrombophlebitis	5	5			5	5
Thrombophlebitis superficial	4	7	1	2	3	5
Thrombosed varicose vein	1	1			1	1
Thrombosis	5	6			5	6
Thrombosis mesenteric vessel	1	1			1	1
Thyroid disorder		1		1		
Thyroid mass		1		1		
Thyroxine free decreased	1	1	1	1		
Tinnitus	7	12	3	3	4	9
Tongue biting	1	2			1	2
Tongue coated		1				1
Tongue discolouration		1				1
Tongue discomfort		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue movement disturbance		1				1
Tongue oedema	1	5	1	2		3
Tonic clonic movements		6				6
Tonic convulsion	1	2			1	2
Tooth abscess		2		1		1
Toothache		1		1		
Torticollis	1	3	1	1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxicity to various agents	1	2			1	2
Toxic skin eruption	1	1			1	1
Toxocariasis	1	1			1	1
Toxoplasmosis	1	1	1	1		
Transaminases increased		1				1
Transient ischaemic attack	10	20			10	20
Tremor	6	27	1	7	5	20
Trigeminal neuralgia	1	1			1	1
Tri-iodothyronine free decreased	1	1	1	1		
Troponin increased	5	10	2	2	3	8
Tumour perforation		1				1
Type I hypersensitivity	1	3			1	3
Type II hypersensitivity		1				1
Ulnar nerve palsy	1	1			1	1
Underdose		1		1		
Unresponsive to stimuli		2				2
Urinary incontinence	5	6	1	1	4	5
Urinary retention	3	3			3	3
Urinary tract candidiasis		1				1
Urinary tract discomfort	1	1	1	1		
Urinary tract infection	2	8		1	2	7
Urinary tract infection bacterial	2	3			2	3
Urine odour abnormal	2	2	2	2		
Urosepsis		1				1
Urticaria	6	29	2	9	4	20
Urticaria chronic		1				1
Uvulitis		1				1
Vaccination complication		1				1
Vaccination failure	67	75			67	75
Vaccination site abscess		1				1
Vaccination site cellulitis		1				1
Vaccination site dysaesthesia	1	1			1	1
Vaccination site eczema		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	2	19	1	12	1	7
Vaccination site exfoliation		1				1
Vaccination site haematoma	2	6	1	2	1	4
Vaccination site hypersensitivity		3		3		
Vaccination site hypoaesthesia		1				1
Vaccination site induration	2	7		3	2	4
Vaccination site infection	1	1			1	1
Vaccination site inflammation	1	8	1	3		5
Vaccination site joint movement impairment		1				1
Vaccination site joint pain		1				1
Vaccination site movement impairment	2	7		2	2	5
Vaccination site oedema		9		3		6
Vaccination site pain	23	111	10	50	13	61
Vaccination site paraesthesia		2		1		1
Vaccination site plaque		1				1
Vaccination site pruritus		6		2		4
Vaccination site rash		1				1
Vaccination site reaction	1	5		2	1	3
Vaccination site swelling	2	10	1	7	1	3
Vaccination site urticaria		2		2		
Vaccination site warmth		5		1		4
Varicella virus test positive	1	1			1	1
Varicose vein	1	1	1	1		
Vascular encephalopathy		1				1
Vascular purpura	2	4		1	2	3
Vascular stenosis	1	1			1	1
Vasoplegia syndrome	1	1			1	1
Vein rupture	1	1			1	1
Vena cava thrombosis	1	1			1	1
Venous oxygen saturation decreased	1	1			1	1
Venous thrombosis		1				1
Venous thrombosis limb	2	2			2	2
Ventricular arrhythmia	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular extrasystoles	1	2		1	1	1
Ventricular failure	1	1			1	1
Ventricular fibrillation	1	2			1	2
Ventricular hypokinesia	2	2			2	2
Ventricular tachycardia	1	5			1	5
Vertigo	15	35	8	14	7	21
Vertigo positional	1	5			1	5
Vestibular disorder	1	2	1	2		
Vestibular neuronitis		1				1
Vision blurred	3	6		1	3	5
Visual acuity reduced		1				1
Visual brightness		1				1
Visual impairment	1	7	1	1		6
Vitamin D deficiency	1	2	1	1		1
Vlth nerve paralysis		1				1
Vitreous floaters		1				1
Vomiting	28	92	10	27	18	65
Walking disability		1				1
Weight decreased	3	6			3	6
Weight increased	2	3	1	1	1	2
Wheezing	2	4	1	1	1	3
White blood cell count decreased	2	3	1	1	1	2
White blood cell count increased	1	2		1	1	1
White matter lesion		1				1
Wound	1	1			1	1
Wrong patient received product		1		1		
	2,520	7,289	528	1573	1992	5716

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**FRENCH POLYNESIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Asthenia		1		1
Cardiopulmonary failure		1		1
Dermatitis bullous		1		1
Dermatosis		1		1
Dyspnoea		1		1
Haemoptysis		1		1
Pulmonary embolism		1		1
Staphylococcal sepsis		1		1
Toxic epidermal necrolysis		1		1
		10		10

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Country Where Event Occurred  
**GEORGIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Sepsis	1	1	1	1
	1	1	1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**GERMANY**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal discomfort		1		1			
Abdominal pain	3	7	2	3	1	4	
Abdominal pain lower		2		2			
Abdominal pain upper		5		4		1	
Abnormal faeces		5		5			
Abortion missed		1				1	
Abscess limb	1	1			1	1	
Abscess neck	1	1			1	1	
Accidental overdose		1		1			
Acute abdomen	1	3			1	3	
Acute coronary syndrome	1	1			1	1	
Acute kidney injury	1	10			1	10	
Acute myeloid leukaemia	1	1			1	1	
Acute myocardial infarction	3	8			3	8	
Acute respiratory distress syndrome		1				1	
Acute respiratory failure	1	2			1	2	
Acute right ventricular failure	1	1			1	1	
Ageusia	1	2	1	2			
Aggression	1	2			1	2	
Agitation		2				2	
Alanine aminotransferase increased	1	1			1	1	
Allergy to vaccine		2				2	
Allodynia	1	1	1	1			
Altered state of consciousness		2				2	
Amnesia		4				4	
Anaphylactic reaction		11				11	
Anaphylactic shock	2	6			2	6	
Angina pectoris	2	6			2	6	
Angioedema	1	7			1	7	
Anosmia	1	1	1	1			
Anxiety	1	2	1	1		1	
Aortic aneurysm		1				1	
Apathy	1	4	1	3		1	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	2	4		1	2	3
Aphthous ulcer		1				1
Arrhythmia	2	13			2	13
Arterial occlusive disease		1				1
Arterial thrombosis		1				1
Arteriosclerosis		1				1
Arthralgia	4	18	4	15		3
Ascites		1				1
Aspartate aminotransferase increased	1	1	1	1		
Aspiration		3				3
Asthenia	14	41	13	30	1	11
Asthma	2	7	1	4	1	3
Ataxia		2				2
Atrial f brillation		8				8
Atrioventricular block complete	1	2			1	2
Atrioventricular block first degree		1		1		
Autoimmune thyroiditis	1	1			1	1
Axillary pain		1				1
Back pain	1	5	1	5		
Bedridden		2		1		1
Blindness unilateral	1	1			1	1
Blister	1	2	1	2		
Blood calcium decreased		2		2		
Blood count abnormal	1	1			1	1
Blood creatine phosphokinase increased		1		1		
Blood creatine phosphokinase MB increased		1		1		
Blood glucose decreased	1	2		1	1	1
Blood glucose fluctuation	1	3	1	3		
Blood glucose increased		2		2		
Blood methaemoglobin present		1		1		
Blood potassium decreased		2		1		1
Blood pressure decreased	4	6	2	3	2	3
Blood pressure fluctuation		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood pressure immeasurable		1					1
Blood pressure increased	3	10	1	2	2		8
Blood pressure systolic increased	1	1			1		1
Blood sodium decreased		1		1			
Blood thyroid stimulating hormone increased		1		1			
Blood urine present	1	2			1		2
Bloody discharge	1	1	1	1			
Body temperature increased	2	11	2	6			5
Bone pain	1	7	1	6			1
Bowel movement irregularity		1		1			
Bradyarrhythmia	1	1			1		1
Bradycardia		1					1
Brain injury		1					1
Brain oedema		1					1
Bronchial obstruction	1	1			1		1
Bronchitis		2		1			1
Bronchospasm		1					1
Burning sensation	1	2	1	2			
Bursitis	1	1			1		1
Capillary nail refill test abnormal		2		1			1
Cardiac aneurysm		1					1
Cardiac arrest	2	11			2		11
Cardiac discomfort	1	2	1	1			1
Cardiac failure	3	17			3		17
Cardiac failure congestive		1					1
Cardiac fibrillation		1					1
Cardiogenic shock		2					2
Cardiopulmonary failure		1					1
Cardio-respiratory arrest		1					1
Cardiovascular disorder		6		1			5
Carotid artery occlusion	1	1			1		1
Cerebellar syndrome		1					1
Cerebral haemorrhage	1	3			1		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral infarction	3	3			3	3
Cerebral ischaemia	2	3			2	3
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	4	11			4	11
Chest discomfort	1	4	1	1		3
Chest pain	1	8	1	7		1
Chest X-ray abnormal		1				1
Chills	14	41	14	34		7
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Chronic kidney disease		2				2
Chronic obstructive pulmonary disease	1	4			1	4
Circulatory collapse	3	19			3	19
Cognitive disorder		1				1
Colitis ulcerative		4				4
Coma		2				2
Condition aggravated	1	6		3	1	3
Confusional state	1	4			1	4
Conjunctival hyperaemia	1	1			1	1
Conjunctivitis		2		1		1
Contusion		3				3
Coronary artery disease	1	1			1	1
Coronavirus test positive		1				1
Cough	2	21	1	12	1	9
COVID-19	6	43	1	6	5	37
COVID-19 pneumonia		11				11
Cranial nerve disorder		1		1		
C-reactive protein increased	3	4	2	2	1	2
Crepitations		1				1
Cyanosis		3				3
Dark circles under eyes	1	1	1	1		
Death	16	74			16	74
Decreased appetite	4	11	2	5	2	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	4	5			4	5
Dehydration		4				4
Delirium		1				1
Delusion		1				1
Dementia	1	4			1	4
Dementia of the Alzheimer's type, with delirium		1				1
Depressed level of consciousness		4				4
Depressed mood		1				1
Depression	1	2	1	2		
Dermatitis allergic	1	2	1	2		
Diabetes mellitus		1				1
Diabetes mellitus inadequate control		1				1
Diaphragmalgia		1		1		
Diarrhoea	6	26	3	16	3	10
Diet refusal		4				4
Diplopia	1	1			1	1
Disease recurrence	2	4	1	1	1	3
Disorientation	1	3	1	2		1
Disturbance in attention	2	15	2	8		7
Diverticulitis		1				1
Dizziness	11	54	9	34	2	20
Dizziness postural		1				1
Drug eruption	1	1	1	1		
Drug ineffective	4	27			4	27
Drug interaction	2	3		1	2	2
Dry mouth		2		1		1
Dry skin		1		1		
Dysaesthesia		3		1		2
Dysarthria		1				1
Dysgeusia	2	4	2	3		1
Dyskinesia		1				1
Dyspepsia		1		1		
Dysphagia		3		2		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia	1	8	1	6		2
Dyspnoea	11	54	7	23	4	31
Dyspnoea at rest		1				1
Dyspnoea exertional	2	4	1	2	1	2
Ear discomfort		1				1
Ear pain	1	1	1	1		
Eczema		1				1
Effusion	1	1			1	1
Electrocardiogram ST segment depression		1				1
Embolic cerebral infarction	1	1			1	1
Embolism	1	1			1	1
Emphysema	1	1			1	1
Enteritis		2				2
Eosinophilia	1	1			1	1
Epilepsy	1	9			1	9
Epistaxis	1	1	1	1		
Erythema	5	13	4	11	1	2
Essential tremor		1				1
Evans syndrome		1				1
Extrasystoles	1	1			1	1
Eye haemorrhage		2				2
Eye irritation		2		1		1
Eyelid oedema	1	1	1	1		
Eye pain		1		1		
Eye pruritus		4		1		3
Eye swelling		2		1		1
Facial paralysis		3				3
Facial paresis	3	5	2	3	1	2
Faeces discoloured		1		1		
Fall	1	8		1	1	7
Fatigue	21	65	18	55	3	10
Fear		1				1
Feeling abnormal	2	4	2	4		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold	4	7	3	4	1	3
Feeling hot	3	8	1	4	2	4
Feeling of body temperature change	1	1	1	1		
Femoral neck fracture		1				1
Femur fracture		1				1
Flatulence	1	1	1	1		
Flushing		4		2		2
Food refusal		2				2
Fracture		1				1
Frequent bowel movements		1		1		
Functional gastrointestinal disorder		1		1		
Gait disturbance		2		1		1
Gait inability		1		1		
Gamma-glutamyltransferase increased	1	1			1	1
Gastrointestinal motility disorder		1		1		
Gastrointestinal necrosis		1				1
Gastrointestinal pain		1				1
Generalised tonic-clonic seizure		1				1
General physical condition abnormal		5				5
General physical health deterioration	4	31	2	6	2	25
Gingival swelling		1				1
Glomerular filtration rate decreased		1		1		
Glomerulonephritis minimal lesion		1				1
Gout		1		1		
Haematemesis		2				2
Haematocrit decreased		2		2		
Haematoma	1	5		2	1	3
Haemoglobin decreased		2		2		
Haemorrhage	1	2			1	2
Hallucination		1				1
Headache	16	68	15	54	1	14
Head discomfort	1	1	1	1		
Heart rate decreased	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	2	6	1	4	1	2
Hemiparaesthesia		1				1
Hemiparesis	3	7			3	7
Hemiplegia	1	2			1	2
Hepatic cirrhosis	1	1			1	1
Hepatic failure		2				2
Hepatitis cholestatic		2				2
Herpes simplex		1				1
Herpes simplex encephalitis		1				1
Herpes zoster		5		5		
Herpes zoster meningitis		1				1
Hot flush	1	3	1	3		
Hypercalcaemia		1				1
Hyperglycaemia		2				2
Hyperhidrosis	1	3	1	3		
Hypersensitivity	3	16	3	6		10
Hypersensitivity vasculitis	1	2			1	2
Hypersomnia		2				2
Hypertension	1	14		2	1	12
Hypertensive crisis		8				8
Hyperthyroidism		1				1
Hypoacusis		1				1
Hypoaesthesia	1	5	1	3		2
Hypoaesthesia oral		3		2		1
Hyponatraemia		1				1
Hypophagia	1	1			1	1
Hyporesponsive to stimuli		1				1
Hypotension		6		1		5
Hypotonia	3	5	1	2	2	3
Hypoxia		1				1
Ileectomy	1	1			1	1
Immune thrombocytopenia	2	5			2	5
Inappropriate schedule of product administration	3	4	3	4		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incontinence		1				1
Incorrect route of product administration	5	29	5	29		
Infarction		1				1
Infection		2		1		1
Infective exacerbation of chronic obstructive airways disease		1				1
Influenza	2	3	1	1	1	2
Influenza like illness	3	19	3	16		3
Injection site pain	2	2	2	2		
Insomnia	3	3	3	3		
Intentional product misuse	1	2	1	2		
International normalised ratio decreased		1		1		
International normalised ratio increased		1		1		
Intestinal ischaemia	1	2			1	2
Intracranial aneurysm		1				1
Irregular breathing		1				1
Ischaemia		1				1
Ischaemic cerebral infarction		2				2
Ischaemic stroke	2	2			2	2
Jaundice		2		1		1
Jaw clicking		1				1
Joint range of motion decreased		3		2		1
Lacrimation increased		4		2		2
Language disorder		1				1
Laryngeal oedema	1	4			1	4
Leukaemia	1	1			1	1
Leukocytosis		1				1
Lhermitte's sign	1	1	1	1		
Limb discomfort	1	3	1	2		1
Lipase increased		1				1
Lip oedema		1				1
Lip swelling		3				3
Listless		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Livedo reticularis		1		1			
Liver function test increased		1					1
Local reaction	3	4	3	4			
Loss of consciousness	3	10			3		10
Lower respiratory tract congestion		1		1			
Lung disorder		1		1			
Lymphadenopathy	7	16	7	15			1
Lymph node pain	1	5	1	5			
Lymphocytic infiltration		1					1
Lymphopenia		1					1
Malaise	8	21	6	12	2		9
Malignant pleural effusion	1	1			1		1
Marasmus		1					1
Maternal exposure during pregnancy		1					1
Memory impairment		3		2			1
Meningism	1	1	1	1			
Mental disorder	1	2			1		2
Mental impairment		1					1
Mesenteric vein thrombosis	1	3			1		3
Metabolic acidosis		1					1
Metabolic disorder		1					1
Microscopic polyangiitis	1	1			1		1
Micturition disorder	1	1	1	1			
Micturition urgency	1	1	1	1			
Migraine	1	4	1	4			
Mobility decreased		3		2			1
Monoparesis	2	2	1	1	1		1
Mouth haemorrhage	1	1	1	1			
Movement disorder	1	1			1		1
Multiple organ dysfunction syndrome	1	6			1		6
Multiple sclerosis		1					1
Multiple sclerosis relapse	1	3			1		3
Muscle discomfort		1		1			

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\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	4	7	2	3	2	4
Muscle spasticity		1				1
Muscle swelling		1		1		
Muscle tightness	1	1	1	1		
Muscle twitching	2	2	2	2		
Muscular weakness	1	3		1	1	2
Myalgia	10	29	10	25		4
Myasthenia gravis		1				1
Myelitis	1	1			1	1
Myocardial infarction	1	2			1	2
Myocarditis		3				3
Myocarditis infectious		1				1
Myocarditis septic		1				1
Nasal congestion		1		1		
Nasopharyngitis	2	6	2	6		
Nausea	10	38	9	25	1	13
Neck pain		3		2		1
Nephrotic syndrome		1				1
Nervous system disorder		1				1
Neuralgia	2	4	2	4		
Neuritis		1		1		
Occipital neuralgia		1		1		
Ocular hyperaemia		2		1		1
Oedema		1				1
Oedema peripheral		2		1		1
Off label use	2	9	2	9		
Oliguria		1				1
Ophthalmic herpes zoster		1				1
Optic ischaemic neuropathy	1	1			1	1
Optic neuritis		1				1
Oral fungal infection		1				1
Organ failure		1				1
Oropharyngeal pain		5		3		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Orthopnoea		1				1
Osteoporosis	1	1	1	1		
Otitis media		1		1		
Overdose		1				1
Oxygen saturation decreased		8		1		7
Pain	4	10	4	5		5
Painful respiration	1	1	1	1		
Pain in extremity	9	34	9	29		5
Palpitations	3	11	2	7	1	4
Pancreatitis acute		1				1
Paraesthesia	2	16	2	9		7
Paraesthesia oral	1	4	1	2		2
Paresis	1	2			1	2
Parkinson's disease		1				1
Partial seizures		1				1
Pathogen resistance		1				1
Pelvic fracture	1	1			1	1
Pelvic pain		1		1		
Perioral dermatitis		1		1		
Peripheral circulatory failure	2	2	1	1	1	1
Peripheral swelling	1	3	1	2		1
Peripheral vascular disorder		7		2		5
Peroneal nerve injury		1				1
Personality change		6				6
Petechiae	1	4	1	2		2
Pharyngeal hypoaesthesia		1		1		
Pharyngeal inflammation		1		1		
Pharyngeal swelling	1	4			1	4
Pleocytosis		1				1
Pleural effusion		2				2
Pleurisy		1				1
Pneumonia	4	18			4	18
Pneumonia bacterial		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia viral	1	1			1	1
PO2 decreased	1	1			1	1
Polydipsia	1	1			1	1
Polymyalgia rheumatica		1				1
Polyuria	1	1			1	1
Poor quality product administered		5		4		1
Poor quality sleep		1				1
Postictal state		1				1
Presbycusis		1				1
Presyncope	1	3	1	1		2
Product preparation issue		2		2		
Product storage error	1	1	1	1		
Product temperature excursion issue		5		4		1
Product use issue		6		6		
Proteinuria		1				1
Pruritus	5	17	4	11	1	6
Pruritus allergic		1				1
Pseudoallergic reaction	1	1			1	1
Psoriasis		1		1		
Pulmonary artery thrombosis		1				1
Pulmonary embolism	13	17			13	17
Pulmonary fibrosis		1				1
Pulmonary haemorrhage	1	1			1	1
Pulmonary infarction	1	1			1	1
Pulmonary oedema		2				2
Pulmonary sepsis		1				1
Pulmonary vasculitis		1				1
Pulse waveform abnormal		1		1		
Purpura		1				1
Pustule	1	1	1	1		
Pyrexia	10	80	8	42	2	38
Quadripareisis		2				2
Rash	2	12	1	4	1	8

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash macular	1	3	1	3		
Rash maculo-papular		2		2		
Rash pruritic		1				1
Raynaud's phenomenon		1		1		
Red blood cell count decreased		2		2		
Red blood cell sedimentation rate increased	1	1	1	1		
Renal failure	1	7			1	7
Renal pain		1				1
Respiration abnormal		1		1		
Respiratory distress	5	31			5	31
Respiratory failure		13				13
Respiratory fume inhalation disorder	1	1			1	1
Respiratory tract infection		2				2
Respiratory tract infection viral	1	1	1	1		
Respiratory tract inflammation		1				1
Restlessness	1	4		2	1	2
Resuscitation		1				1
Retching	1	2	1	2		
Retinal tear		1				1
Retrograde amnesia		1				1
Rheumatic disorder	1	1	1	1		
Rheumatoid arthritis		2				2
Rhinalgia		1		1		
Rhinitis allergic		1		1		
Rhinorrhoea		4		3		1
Rhonchi		1				1
Rosacea		1				1
Salivary gland enlargement		1		1		
SARS-CoV-2 ant body test negative	2	6	2	5		1
SARS-CoV-2 ant body test positive		4		4		
SARS-CoV-2 sepsis		1				1
SARS-CoV-2 test positive		4		3		1
Seizure	1	12			1	12

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		2				2
Sensory disturbance	1	4	1	2		2
Sensory level abnormal		1		1		
Septic arthritis staphylococcal	1	1			1	1
Septic shock		2				2
Shock		1				1
Sinusitis		1		1		
Sinus tachycardia		1				1
Skin exfoliation	1	1	1	1		
Skin warm	1	1	1	1		
Sleep disorder		2		2		
Sneezing		1		1		
Somnolence	3	12	1	6	2	6
Sopor		1				1
Spinal pain		1				1
Staphylococcal sepsis		1				1
Status epilepticus		3				3
Stress		1				1
Stridor		2				2
Stupor		1				1
Subcutaneous abscess	1	1			1	1
Subileus	1	1	1	1		
Sudden cardiac death	1	1			1	1
Sudden death	1	18			1	18
Superinfection bacterial		1				1
Swelling	1	2	1	2		
Swelling face	1	6	1	4		2
Swelling of eyelid		1		1		
Swollen tongue	1	4	1	1		3
Syncope	5	13			5	13
Systemic inflammatory response syndrome		1				1
Systemic lupus erythematosus	1	1			1	1
Tachyarrhythmia		2				2

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	3	25	3	12		13
Tachycardia induced cardiomyopathy		1				1
Tachypnoea		2		1		1
Taste disorder	1	2	1	1		1
Tendonitis	1	1			1	1
Tendon rupture	1	1			1	1
Therapeutic response unexpected	3	5	3	5		
Throat irritation	1	7	1	6		1
Throat tightness	1	6	1	2		4
Thrombectomy	1	1			1	1
Thrombocytopenia	1	4			1	4
Thrombosis	3	3			3	3
Thyroiditis acute		1				1
Toothache		1		1		
Toxicity to various agents		1				1
Transaminases increased		1		1		
Transient aphasia	1	1			1	1
Transient ischaemic attack	2	3			2	3
Tremor	2	8		3	2	5
Trypsinase increased		1				1
Type 1 diabetes mellitus	1	2			1	2
Unresponsive to stimuli		7				7
Upper gastrointestinal haemorrhage		2				2
Upper respiratory tract infection		2				2
Urinary tract infection		1				1
Urine odour abnormal	1	1	1	1		
Urticaria	4	11	2	6	2	5
Vaccination complication		1				1
Vaccination failure		5				5
Vaccination site dermatitis		1		1		
Vaccination site erythema	3	8	2	6	1	2
Vaccination site haematoma		3		2		1
Vaccination site haemorrhage		1		1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	1	2	1	2		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site pain	13	49	13	46		3
Vaccination site paraesthesia		2		2		
Vaccination site pruritus		2		1		1
Vaccination site rash		2		1		1
Vaccination site reaction		4		3		1
Vaccination site swelling	6	14	5	10	1	4
Vaccination site urticaria		1		1		
Vaccination site warmth		6		5		1
Vasculitis		1				1
Venous thrombosis		1				1
Venous thrombosis limb	1	1			1	1
Ventricular extrasystoles	1	1			1	1
Ventricular fibrillation		2				2
Ventricular tachycardia	1	1			1	1
Vertigo		2		1		1
Vision blurred		1				1
Visual impairment	3	8	1	2	2	6
Vitreous disorder		1				1
Vomiting	8	30	4	13	4	17
Weight decreased	2	2			2	2
Wheezing		1		1		
White blood cell count decreased		1		1		
White blood cell count increased		2				2
	575	2,423	318	1054	257	1369

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**GREECE**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain upper		1		1			
Acute myocardial infarction	1	2			1		2
Acute respiratory distress syndrome		1					1
Acute respiratory failure		1					1
Aggression		1					1
Agitation		1					1
Alanine aminotransferase increased		1		1			
Allergy to vaccine		1					1
Anaemia	1	1	1	1			
Anaphylactic reaction	1	1			1		1
Anaphylactic shock		2					2
Angina pectoris	1	1			1		1
Angioedema	2	2			2		2
Ankylosing spondylitis	1	1			1		1
Aphasia	1	1			1		1
Arrhythmia	2	2	1	1	1		1
Arteriosclerosis		1					1
Arteriovenous graft thrombosis	1	1			1		1
Arthralgia		7		5			2
Arthritis enteropathic		1					1
Aspiration	1	1			1		1
Asthenia	1	5		3	1		2
Asthmatic crisis		1					1
Asymptomatic COVID-19		1					1
Atrial fibrillation	2	3			2		3
Auscultation		1		1			
Autonomic nervous system imbalance	1	1	1	1			
Back injury	1	1			1		1
Back pain	1	2	1	1			1
Blood calcium decreased		1		1			
Blood gases abnormal	1	1			1		1
Blood glucose abnormal		3		2			1
Blood glucose increased		1		1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood iron decreased		1		1			
Blood potassium decreased		1		1			
Blood pressure fluctuation		1		1			
Blood pressure inadequately controlled		1		1			
Blood pressure increased	3	8		4	3		4
Blood pressure systolic increased		1					1
Blood triglycerides increased	1	1			1		1
Blood urea increased		1		1			
Bone pain	1	2		1	1		1
Brain death		1					1
Bronchospasm		2					2
Burning sensation	1	1			1		1
Cardiac arrest		3					3
Cardiac valve disease		1					1
Cerebral haemorrhage		1					1
Cerebrovascular accident	1	2			1		2
Chest discomfort	1	1			1		1
Chest pain		3		2			1
Chills	4	9	2	5	2		4
Cholinergic syndrome	1	1			1		1
Coma	1	1			1		1
Communication disorder	1	1	1	1			
Complex regional pain syndrome	1	2			1		2
Condition aggravated	1	4			1		4
Confusional state	1	2		1	1		1
Contusion	1	1			1		1
Coronary artery stenosis		1					1
Cough		2		1			1
COVID-19		2					2
Deafness unilateral		1					1
Death	1	3			1		3
Decreased appetite		1		1			
Deep vein thrombosis	2	3			2		3

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration	1	1			1	1
Dermatitis allergic		1				1
Dermatomyositis	1	1			1	1
Diabetes mellitus inadequate control	2	4			2	4
Diarrhoea		3		2		1
Diastolic hypertension		1				1
Diplegia	1	2			1	2
Diplopia		1				1
Discomfort		1				1
Disease recurrence	2	2			2	2
Disorientation	1	2	1	1		1
Dizziness	3	13		6	3	7
Drug ineffective		1				1
Drug interaction		1				1
Dry eye	1	1	1	1		
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dysarthria	1	1			1	1
Dyspepsia	1	1			1	1
Dysphagia	3	8		3	3	5
Dysphonia	1	2			1	2
Dyspnoea	2	10	1	4	1	6
Dysstasia	1	2		1	1	1
Ear pain		1		1		
Eating disorder	1	1	1	1		
Eating disorder symptom	1	1	1	1		
Electrocardiogram repolarisation abnormality	1	1			1	1
Epilepsy	1	1			1	1
Erythema		5		4		1
Eye disorder	1	1	1	1		
Eye haemorrhage	1	1			1	1
Eye pruritus		1		1		
Facial paralysis	2	3			2	3

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paresis	3	5	1	1	2	4
Fall	1	4		1	1	3
Fatigue	6	15	4	11	2	4
Feeding disorder	1	1	1	1		
Feeling cold	1	2	1	2		
Feeling hot		1		1		
Femur fracture	1	1			1	1
Flushing	1	2			1	2
Gait disturbance	2	4		2	2	2
Gait inability	1	1			1	1
Gastrointestinal disorder	1	2		1	1	1
Glycosylated haemoglobin decreased		1		1		
Goitre	1	1			1	1
Guillain-Barre syndrome	2	3			2	3
Haematoma		1				1
Haematuria		1				1
Haemoglobin decreased		1		1		
Haemoptysis	2	2			2	2
Headache	4	17	2	12	2	5
Head discomfort	1	2		1	1	1
Heart rate decreased	1	1			1	1
Heart rate increased		1				1
Hemiparesis	1	2			1	2
Herpes zoster		1				1
Hyperhidrosis	1	1			1	1
Hypersensitivity	1	3		1	1	2
Hypertension	2	8		3	2	5
Hypertrophic cardiomyopathy		1				1
Hypoesthesia	4	15	1	8	3	7
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	4		3	1	1
Hypokalaemia	2	2			2	2
Hyponatraemia	2	3		1	2	2

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyporeflexia	1	1			1	1
Illness		1				1
Immunoglobulins increased	1	1			1	1
Impaired gastric emptying	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Insomnia		1		1		
Insulin resistance		1				1
Iridocyclitis	1	1			1	1
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke		1				1
Laryngospasm	1	1			1	1
Left ventricular hypertrophy		1				1
Lethargy	1	2		1	1	1
Leukocytosis		1				1
Lip oedema		1				1
Loss of consciousness	1	4			1	4
Loss of personal independence in daily activities		1		1		
Lower respiratory tract infection	1	1			1	1
Lymphadenitis	1	3		1	1	2
Lymphadenopathy		2				2
Lymphoedema		1				1
Malaise	1	7	1	5		2
Memory impairment	1	2			1	2
Migraine		3		2		1
Mouth injury	1	1	1	1		
Movement disorder	1	1	1	1		
Muscle spasms	1	1			1	1
Muscular weakness	1	3			1	3
Musculoskeletal stiffness	1	1	1	1		
Myalgia	1	14		8	1	6
Myocardial infarction		1				1
Nasal pruritus		1		1		
Nausea	1	3		2	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	1	1			1	1
Neuropathy peripheral	1	1			1	1
Ocular hyperaemia	1	1			1	1
Oedema peripheral	1	2		1	1	1
Off label use		3		3		
Ophthalmic artery thrombosis	1	1			1	1
Oral herpes		1				1
Oral mucosal erythema		1		1		
Oropharyngeal pain	1	1			1	1
Oxygen saturation decreased	2	3			2	3
Pain		3		2		1
Pain in extremity	2	3			2	3
Palpitations	1	1			1	1
Paraesthesia	1	1			1	1
Paralysis		1				1
Paraparesis	1	1			1	1
Paratracheal lymphadenopathy	1	1			1	1
Paresis	1	1			1	1
Parotid gland enlargement	1	1			1	1
Peripheral coldness	2	2	1	1	1	1
Peripheral venous disease	1	1			1	1
Petit mal epilepsy		1				1
Photophobia	1	1			1	1
Platelet count increased		1		1		
Pneumonia		1				1
Polydipsia		1		1		
Polyuria		1		1		
Post herpetic neuralgia		1				1
Presyncope		2		1		1
Product use issue		3		3		
Protein total decreased		1		1		
Prothrombin time prolonged		1		1		
Pruritus	1	4		2	1	2

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	1	1			1	1
Pulmonary mass	1	1			1	1
Pulmonary oedema		1				1
Pulse absent		1				1
Pyrexia	5	14	3	8	2	6
Rash		4		2		2
Rash erythematous		1		1		
Rash maculo-papular	1	1			1	1
Raynaud's phenomenon	1	1			1	1
Reflexes abnormal	1	1			1	1
Renal failure	1	1			1	1
Renal impairment	1	1			1	1
Respiratory tract infection		2				2
Rheumatoid arthritis		1				1
Salivary gland enlargement	1	1			1	1
Sarcoidosis	1	1			1	1
Scleritis	1	1			1	1
Seizure		1				1
Sjogren's syndrome	1	1			1	1
Soft tissue swelling		1		1		
Somnolence	1	2	1	2		
Speech disorder	3	5	1	3	2	2
Spinal pain	2	2			2	2
Sputum increased	1	1			1	1
Sudden death		2				2
Suspected COVID-19		1		1		
Swelling	1	1			1	1
Syncope		4				4
Tachycardia	4	8	1	3	3	5
Tension		1		1		
Therapeutic response unexpected		2		2		
Thirst	1	1	1	1		
Throat irritation		3		3		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor		2		1		1
Trigeminal neuralgia		1				1
Urinary incontinence	1	2	1	1		1
Urinary tract infection	1	2			1	2
Uveitis	1	1			1	1
Vaccination failure		1				1
Vaccination site discomfort	1	1	1	1		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site movement impairment		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		4		4		
Vascular pain	1	1			1	1
Vasculitis	1	1			1	1
Vertigo		2		2		
Vomiting	2	5		2	2	3
Walking disability	1	1			1	1
White blood cell count decreased		1		1		
	195	518	40	208	155	310

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**GUINEA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Headache	1	1	1	1
Hypertension	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**HONG KONG**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Blood pressure increased		1		1		
Chest discomfort		1		1		
Coronary artery disease		1				1
Dizziness		1				1
Dyspnoea		1		1		
Fatigue		1		1		
Malaise		1		1		
Myocardial ischaemia		1				1
Neuralgia		1		1		
Syncope		1				1
		11		7		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**HUNGARY**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		3		3		
Abdominal pain		3		3		
Acute respiratory failure	1	1			1	1
Ageusia		2		2		
Aggression	1	1			1	1
Anaemia	1	1			1	1
Anal incontinence		1				1
Anaphylactic reaction		2				2
Angina pectoris	2	2			2	2
Angioedema		1				1
Anosmia		1		1		
Antibody test normal	1	1	1	1		
Anuria	1	1			1	1
Aphthous ulcer		1		1		
Arteriosclerosis		1				1
Arthralgia	1	5		3	1	2
Asphyxia		1				1
Asthenia	5	23	2	12	3	11
Asthenopia	1	1	1	1		
Atrial f brillation	2	3			2	3
Axillary mass		1		1		
Axillary pain		1		1		
Back pain	1	3	1	3		
Bezold-Jarisch reflex		1		1		
Blepharospasm	1	1	1	1		
Blindness		1				1
Blood glucose decreased	1	1	1	1		
Blood glucose increased		4		3		1
Blood pressure decreased		1		1		
Blood pressure fluctuation	1	3	1	2		1
Blood pressure increased	1	5	1	3		2
Blood pressure systolic increased		1				1
Bone pain	1	1	1	1		

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia		1				1
Bradyphrenia		1		1		
Bronchitis	2	2	1	1	1	1
Burning sensation	1	1	1	1		
Cardiac disorder	1	1			1	1
Cardiac failure	1	4			1	4
Cardiomegaly	2	2	1	1	1	1
Cardiopulmonary failure	1	1			1	1
Chest discomfort		2		2		
Chest pain	3	5	1	3	2	2
Chills	4	11	4	11		
Choking	1	1			1	1
Chronic obstructive pulmonary disease		1		1		
Circulatory collapse	1	1			1	1
Cold sweat		1		1		
Condition aggravated	1	3		1	1	2
Confusional state	2	3	1	1	1	2
Cough	1	5	1	5		
COVID-19	5	9			5	9
Craniofacial fracture		1				1
Death	1	3			1	3
Decreased appetite	1	3	1	2		1
Decubitus ulcer		1				1
Defaecation urgency		1		1		
Depressed mood		1		1		
Diarrhoea	2	8	1	7	1	1
Disturbance in attention	1	1			1	1
Dizziness	3	16	2	13	1	3
Drug hypersensitivity		1		1		
Drug ineffective	5	9			5	9
Dry eye		2		2		
Dry mouth	1	3	1	2		1
Dysgeusia	1	2	1	1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia		4		1		3
Dysphemia	1	1			1	1
Dysphonia	1	2		1	1	1
Dyspnoea	2	8	1	3	1	5
Dyspnoea exertional	1	1			1	1
Ear pain		2		2		
Emphysema		1				1
Erythema		1		1		
Extrasystoles		1				1
Eye haemorrhage		1				1
Eye inflammation	1	2		1	1	1
Eye irritation		1		1		
Eye pain	1	1	1	1		
Facial pain		1		1		
Facial paralysis		2				2
Facial paresis		1		1		
Fall	1	3			1	3
Fatigue	3	11	3	10		1
Fear of death		1		1		
Feeding disorder		2				2
Feeling abnormal		1				1
Feeling hot		2		1		1
Feeling of body temperature change		1		1		
Femoral neck fracture		1				1
Fibrin D dimer increased	1	1			1	1
Flushing		2		1		1
Foaming at mouth		1				1
Functional gastrointestinal disorder		1		1		
Gastritis erosive	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
General physical health deterioration	1	1	1	1		
Glomerular filtration rate decreased	1	1	1	1		
Glossodynia		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematoma	2	2			2	2
Haemoptysis	1	1			1	1
Haemorrhage		1				1
Headache	4	20	3	18	1	2
Heart rate decreased		1		1		
Heart rate increased		3		3		
Heart rate irregular	1	1	1	1		
Herpes zoster		1		1		
Hyperaesthesia		1		1		
Hyperhidrosis	1	4	1	3		1
Hypersensitivity	1	1	1	1		
Hypertension		1				1
Hypoaesthesia	2	5	1	4	1	1
Hypoaesthesia oral	2	2	1	1	1	1
Hyporeflexia		2		2		
Hypotension		4		1		3
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		1		1		
Inflammation	1	1	1	1		
Influenza like illness		1		1		
Insomnia		2		2		
Ischaemic stroke		1				1
Joint range of motion decreased		1		1		
Lacrimation increased		1		1		
Left ventricular failure		1				1
Lethargy		2		2		
Listless		1				1
Localised oedema		1		1		
Loss of consciousness		2				2
Lymphadenopathy	1	6	1	6		
Lymph node pain		3		3		
Macular oedema		1				1
Malaise	4	11	4	11		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Megacolon		1				1
Melaena	1	1			1	1
Memory impairment	1	1			1	1
Micturition urgency		1		1		
Migraine		1		1		
Monoplegia		1				1
Mucosal inflammation	1	1			1	1
Muscle spasms	1	1	1	1		
Muscular weakness		1		1		
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness		2		1		1
Myalgia	2	9	2	9		
Nasal congestion		1		1		
Nasopharyngitis		1		1		
Nausea	1	8	1	7		1
Neck pain	1	2	1	2		
Neoplasm progression		1				1
Neuralgia		1				1
Odynophagia		1		1		
Oedema peripheral		1		1		
Off label use	1	2	1	2		
Oral herpes		1		1		
Oropharyngeal pain	2	6	1	5	1	1
Oxygen consumption increased		1		1		
Oxygen saturation decreased		2		1		1
Pain	1	2	1	2		
Pain in extremity	2	10	2	9		1
Pain of skin	1	1	1	1		
Pallor	1	4	1	3		1
Palpitations	1	2	1	1		1
Paraesthesia		1				1
Paralysis		1				1
Pericarditis	1	1			1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Peripheral coldness		1		1			
Peripheral swelling	1	3		2	1		1
Pharyngeal swelling		1		1			
Photopsia		1		1			
Pneumonia	1	1			1		1
Polyarthrits		1					1
Poor quality product administered	1	1	1	1			
Potentiating drug interaction	1	1	1	1			
Product administered at inappropriate site		1		1			
Product complaint	1	1	1	1			
Productive cough	1	2	1	2			
Product use issue		1		1			
Pruritus		2		2			
Psychiatric symptom		1					1
Pulmonary arterial pressure increased	1	1			1		1
Pulmonary embolism	1	1			1		1
Pulpitis dental		1		1			
Pyrexia	7	23	6	18	1		5
Radiculopathy		1		1			
Rash	1	3	1	2			1
Rash erythematous	1	2	1	2			
Rash macular	1	1	1	1			
Rash pruritic	1	2	1	2			
Renal impairment	1	1			1		1
Respiratory disorder	1	1	1	1			
Respiratory distress		2		1			1
Restlessness		1		1			
Rhinorrhoea		1		1			
SARS-CoV-2 test positive	1	2			1		2
Sciatica		1					1
Sensation of foreign body		1					1
Sensory loss		1		1			
Skin burning sensation		1		1			

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin discolouration	1	1	1	1		
Skin ulcer	1	1			1	1
Skin warm		1		1		
Sleep disorder	1	2	1	2		
Somnolence	3	4	2	3	1	1
Spinal osteoarthritis		1		1		
Swelling of eyelid		1		1		
Syncope	2	5			2	5
Tachycardia		3		1		2
Tension	1	1	1	1		
Thirst		2		1		1
Throat tightness		1				1
Thrombophlebitis	1	1	1	1		
Thrombotic stroke		1				1
Toothache	1	1	1	1		
Tooth disorder		1				1
Tremor	1	4	1	3		1
Tricuspid valve incompetence	1	1			1	1
Urinary incontinence	1	1	1	1		
Urticaria		1		1		
Uveitis		1				1
Vaccination site erythema		3		3		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site induration		1		1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site nodule		3		3		
Vaccination site pain	1	13	1	13		
Vaccination site paraesthesia		1		1		
Vaccination site swelling	1	4	1	4		
Vaccination site warmth		3		3		
Varicose vein		2		2		
Vasoconstriction	1	1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred		1		1		
Visual impairment		1		1		
Vomiting		2		1		1
Weight decreased	1	1			1	1
Wound		1		1		
	159	547	88	361	71	186

\* I=Interval, C=Cumulative  
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Country Where Event Occurred  
**ICELAND**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Anal incontinence		1		1		
Aortic aneurysm		1				1
Aphasia		2		1		1
Arthralgia		1		1		
Asthenia		3		3		
Asthma		1				1
Back pain	1	2	1	2		
Balance disorder	1	1			1	1
Blood pressure decreased		1				1
Cardiac failure		2				2
Chills		1		1		
Chronic obstructive pulmonary disease		1				1
Confusional state	1	1			1	1
Cough		3		2		1
Death		3				3
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Disease progression		1				1
Dizziness		1		1		
Dyspnoea		1				1
Fatigue	1	2		1	1	1
Feeling abnormal		1		1		
Headache		3		3		
Hyperhidrosis		1				1
Hypertension		1		1		
Hypoxia		1				1
Joint stiffness		1		1		
Malaise		4		2		2
Migraine		1		1		
Motor dysfunction	1	1			1	1
Myocardial infarction		1				1
Nasopharyngitis		3		3		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		1		1		
Off label use		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		2				2
Peripheral artery thrombosis		1				1
Pneumonia		3				3
Pneumonia aspiration		1				1
Productive cough		1		1		
Product use in unapproved indication		1		1		
Pyrexia		9		6		3
Respiratory failure		1				1
Rhinorrhoea		1		1		
Sepsis		1				1
Sudden death		1				1
Syncope	1	1			1	1
Transient ischaemic attack		1				1
Urinary incontinence		1		1		
Vaccination site erythema		1		1		
Vaccination site pain		1		1		
Ventricular tachycardia	1	1			1	1
	8	81	1	41	7	40

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Country Where Event Occurred

**IRAQ**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Headache	1	1	1	1
Myalgia	1	1	1	1
Nausea	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	6	6	6	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**IRELAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	1	3		1	1	2
Abdominal pain upper		1				1
Acute cardiac event		1				1
Agitation		1				1
Alanine aminotransferase increased		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		6				6
Angioedema		1				1
Anosmia		1				1
Anxiety		1				1
Aortic aneurysm	1	1			1	1
Aphasia	1	1			1	1
Arthralgia	4	7	2	3	2	4
Aspiration		1				1
Asthenia	4	10	2	3	2	7
Asthma		2				2
Atrial fibrillation	1	1			1	1
Back pain	2	4			2	4
Blood bilirubin increased		1				1
Blood glucose fluctuation		1				1
Blood pH decreased	1	1			1	1
Blood pressure increased	2	4			2	4
Body temperature decreased		1				1
Body temperature increased	1	1	1	1		
Bone pain	1	3			1	3
Breast swelling		1				1
Carbon dioxide increased	1	1			1	1
Cardiac arrest	3	3			3	3
Cardiac failure	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort	2	5	1	1	1	4
Chest pain	2	4			2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	4	14			4	14
Chromaturia		1				1
Cold sweat		2				2
Condition aggravated		1				1
Confusional state	1	3			1	3
Cough	2	3			2	3
COVID-19	3	4			3	4
C-reactive protein increased		1				1
Cyanosis		3		1		2
Deafness	1	1			1	1
Death	4	9			4	9
Decreased activity		1				1
Decreased appetite	1	4			1	4
Deep vein thrombosis	3	4			3	4
Depressed level of consciousness		2				2
Depressed mood	1	1			1	1
Diarrhoea	1	5			1	5
Discomfort		2				2
Disease recurrence		3				3
Disturbance in attention		2		1		1
Dizziness	3	16	1	3	2	13
Dry throat		1				1
Dysgeusia	1	1	1	1		
Dysphonia		1				1
Dyspnoea	1	10			1	10
Dyspnoea at rest		1				1
Dysstasia		1				1
Ear discomfort		1				1
Emotional distress		1				1
Erythema	1	2	1	1		1
Exposure during pregnancy		1		1		
Eye pain		2				2
Facial pain		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Faeces discoloured		1				1
Faeces pale		1				1
Fall	1	1			1	1
Fatigue	9	29	5	8	4	21
Feeling cold		2				2
Feeling hot	1	4			1	4
Feeling of body temperature change		2				2
Flushing		1				1
Gait inability		1				1
General physical condition abnormal	1	1			1	1
General physical health deterioration	3	4			3	4
Haematemesis		1				1
Haemoglobin decreased		1				1
Headache	7	34	3	7	4	27
Heart rate increased	2	3			2	3
Heart rate irregular		1				1
Hemiparesis		1				1
Herpes zoster		1				1
Hyperhidrosis		6				6
Hypersensitivity	1	3	1	1		2
Hypertension		5				5
Hypoaesthesia	3	6	3	4		2
Hypoaesthesia oral		3				3
Hypoglycaemia		1				1
Hypopnoea		1				1
Hypotension		3				3
Hypotonia		1				1
Hypoxia		1				1
Impaired work ability	1	4	1	1		3
Inappropriate schedule of product administration	1	1	1	1		
Influenza like illness	2	2	1	1	1	1
Injection site pain		1				1
Injury		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	2	4			2	4
Irritability	1	1			1	1
Jaundice		1				1
Joint stiffness		1				1
Lethargy		4		1		3
Limb discomfort	1	1			1	1
Lip swelling	1	7			1	7
Liver function test increased		1				1
Loss of consciousness	2	5			2	5
Lower respiratory tract infection		1				1
Lymphadenopathy		5				5
Lymph node pain		3				3
Malaise	4	16		1	4	15
Melaena		1				1
Memory impairment	1	1			1	1
Metabolic acidosis		1				1
Migraine		2		1		1
Mobility decreased		1				1
Mood swings	1	1			1	1
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	2	3	2	2		1
Myalgia	2	7		1	2	6
Myelitis transverse		1				1
Myocardial infarction		2				2
Myocardial ischaemia	1	1			1	1
Myocarditis	1	1			1	1
Nasal congestion		1				1
Nausea	4	23	1	4	3	19
Neck pain	1	1			1	1
Negative thoughts	1	1			1	1
Nervous system disorder	1	1			1	1
Neuropathy peripheral		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	1	1	1		
Oral herpes	2	2	1	1	1	1
Oral pruritus	1	1	1	1		
Oropharyngeal pain		5		1		4
Orthostatic hypotension	1	1			1	1
Oxygen saturation decreased	1	6			1	6
Pain	4	15	2	2	2	13
Pain in extremity	3	10	2	4	1	6
Pallor		4		1		3
Palpitations	1	5	1	1		4
Pancreatitis relapsing		1				1
Panic attack	1	1			1	1
Paraesthesia		6		1		5
Paraesthesia oral	1	3	1	1		2
Periorbital oedema		1		1		
Peripheral swelling		3				3
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		2				2
Photophobia		1				1
Platelet count decreased		1				1
Pneumonia		2				2
Pneumonitis		1				1
Poor quality sleep		1		1		
Presyncope	1	4	1	1		3
Pruritus	1	5	1	1		4
Pulmonary sepsis		1				1
Pulse abnormal		1				1
Pyrexia	5	22	2	3	3	19
Rales		1				1
Rash		6				6
Rash erythematous		3				3
Rash macular		1				1
Rash pruritic		1				1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Respiratory rate decreased	1	3			1	3
Respiratory rate increased		2				2
Respiratory tract infection	2	3			2	3
Retching		1				1
Rhinitis	1	1			1	1
Seizure	1	2			1	2
Sensory loss		1				1
Sinusitis		1				1
Skin burning sensation		1				1
Skin discolouration		1		1		
Somnolence		2				2
Stridor		3				3
Sudden death	1	2			1	2
Supraventricular tachycardia	1	1			1	1
Swelling	1	2	1	1		1
Swelling face	1	3		1	1	2
Swollen tongue		5				5
Syncope	1	2			1	2
Tachycardia	1	8	1	1		7
Throat tightness		1				1
Tidal volume decreased	1	1			1	1
Tinnitus	1	2	1	1		1
Tonic clonic movements		1				1
Transient ischaemic attack	1	1			1	1
Tremor		2				2
Troponin increased		1				1
Unresponsive to stimuli		1				1
Upper gastrointestinal haemorrhage		1				1
Urine odour abnormal	1	1	1	1		
Urticaria		4				4
Vaccination site pain	3	6	3	3		3

\* I=Interval, C=Cumulative  
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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site paraesthesia		1				1
Vaccination site pruritus		1				1
Vaccination site urticaria	1	1	1	1		
Vertigo	1	3		2	1	1
Vision blurred		1				1
Vomiting	1	11		1	1	10
Wheezing		6				6
	162	619	48	86	114	533

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ISRAEL**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		2		1
Abdominal pain upper	1	1	1	1		
Activated partial thromboplastin time shortened	1	1			1	1
Acute myocardial infarction		1				1
Adverse event		1		1		
Allergy to vaccine		2				2
Anaemia	1	1			1	1
Anaphylactic reaction		1				1
Angina pectoris		2				2
Anorectal discomfort		1		1		
Anxiety	1	1			1	1
Arthralgia		4		3		1
Arthritis	1	1	1	1		
Aspiration		1				1
Asthenia	5	25	5	21		4
Asthma		2		1		1
Atelectasis		1				1
Atrial fibrillation	3	5			3	5
Back pain		2		2		
Balance disorder		1		1		
Blindness transient	1	1			1	1
Blood chloride increased		2		1		1
Blood glucose increased		2		1		1
Blood pressure decreased		1				1
Blood pressure increased		3		2		1
Bone pain		1		1		
Brain death		1				1
Brain injury		1				1
Brain oedema		1				1
Breast inflammation		1		1		
Burning sensation		1				1
Cardiac arrest		8				8
Cardiac death		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure	3	5			3	5
Cardiac failure chronic	1	1			1	1
Cardiac flutter		1				1
Cardiac tamponade	1	1			1	1
Cerebrovascular accident	2	3			2	3
Chest discomfort		1		1		
Chest pain	5	6	2	3	3	3
Chills	3	7	3	7		
Choking		1				1
Cholelithiasis		1		1		
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Chronic lymphocytic leukaemia		1				1
Chronic obstructive pulmonary disease	1	2			1	2
Circulatory collapse		1				1
Condition aggravated		1				1
Confusional state	1	1			1	1
Contusion		1				1
Coronavirus infection	2	3			2	3
Cough	2	4	1	3	1	1
COVID-19	8	17		2	8	15
C-reactive protein increased	1	2		1	1	1
Crying		1		1		
Deafness	1	1			1	1
Deafness neurosensory	1	1			1	1
Deafness unilateral	1	1			1	1
Death		19				19
Deep vein thrombosis	2	2			2	2
Diabetic ketoacidosis		1				1
Diarrhoea	2	3	2	2		1
Discomfort		1		1		
Disease recurrence		3		2		1
Dizziness	1	11	1	9		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Drug hypersensitivity		2		1		1	
Drug ineffective	7	14			7	14	
Dysgeusia		1		1			
Dysphagia		3		1		2	
Dyspnoea	5	24	1	7	4	17	
Dyspnoea exertional		1		1			
Dysstasia		1		1			
Ear discomfort		1		1			
Ear pain		1		1			
Eosinophilic oesophagitis		1		1			
Erythema	2	6	2	6			
Eye irritation		2		1		1	
Face injury		1				1	
Facial paralysis	3	7			3	7	
Fall		2				2	
Fatigue	1	10	1	10			
Feeling abnormal	1	4		1	1	3	
Feeling cold	1	1	1	1			
Feeling hot		3		3			
Gait disturbance	2	2			2	2	
Gastric haemorrhage		1				1	
Gastrointestinal necrosis		1				1	
General physical health deterioration	2	3			2	3	
Glomerular filtration rate decreased		1				1	
Guillain-Barre syndrome	1	1			1	1	
Haematemesis		1				1	
Haemolytic anaemia		1				1	
Haemorrhage		1				1	
Headache	2	21	2	20		1	
Heart rate increased		2		2			
Herpes virus infection	1	1	1	1			
Herpes zoster	6	11	6	11			
Hormone level abnormal		1		1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	2	1	2		
Hypersensitivity	3	3	1	1	2	2
Hypoaesthesia	2	4	1	3	1	1
Hypoaesthesia oral		3		1		2
Hyponatraemia	1	1			1	1
Hypotension	2	4	1	2	1	2
Hypothermia		1				1
Hypoventilation		1				1
Illrd nerve paralysis	1	1			1	1
Illness		1		1		
Incorrect dose administered	1	1	1	1		
Inflammation of wound	1	1	1	1		
Inflammatory marker increased		1				1
Influenza like illness		2		2		
Injection site pain		1		1		
Insomnia		2		2		
Intentional dose omission		1		1		
International normalised ratio decreased	1	1			1	1
Jaundice		1		1		
Lacrimation increased		2		1		1
Laryngeal inflammation		1		1		
Laryngitis bacterial		1				1
Leukocytosis	3	6			3	6
Lip swelling		1		1		
Loss of consciousness	3	6			3	6
Loss of libido		1		1		
Lung disorder	1	1			1	1
Lung infiltration	1	1			1	1
Lymphocyte count increased		1		1		
Lymphocytosis		1		1		
Lymphopenia		1				1
Malaise		4		3		1
Maternal exposure during pregnancy		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Mean cell haemoglobin concentration decreased		1		1			
Mean cell haemoglobin decreased		2		1			1
Mean cell volume decreased		1		1			
Mobility decreased		1		1			
Multiple sclerosis	1	1			1		1
Multiple sclerosis relapse	1	4			1		4
Muscular weakness	1	3		2	1		1
Musculoskeletal chest pain	1	1	1	1			
Myalgia	1	8	1	8			
Myasthenia gravis		2					2
Myocardial infarction	2	4			2		4
Myocarditis	9	10			9		10
Nasopharyngitis		1		1			
Nausea	1	6		5	1		1
Nephrolithiasis	1	1			1		1
Nervous system disorder	1	1	1	1			
Neutrophil count increased		1					1
Oedema mouth		1					1
Oedema peripheral		1					1
Off label use		3		3			
Ophthalmic herpes zoster	1	2			1		2
Oropharyngeal discomfort		1		1			
Oropharyngeal pain		2		2			
Oxygen saturation decreased		1					1
Pain	3	9	2	8	1		1
Pain in extremity	1	6		5	1		1
Pallor		1		1			
Palpitations	1	4		3	1		1
Paraesthesia	2	7	1	4	1		3
Paraesthesia oral		3		3			
Pericardial effusion	1	1			1		1
Pericarditis	3	4			3		4
Peripheral artery occlusion	1	1			1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral ischaemia	1	1			1	1
Personality change		1		1		
Pharyngeal swelling		1		1		
Pleural effusion	1	2			1	2
Pleuritic pain		1				1
Pneumonia		2				2
Pneumonia aspiration	1	2			1	2
Premenstrual syndrome		1		1		
Presyncope		1		1		
Product use issue		3		3		
Pruritus	1	4	1	1		3
Psoriatic arthropathy	1	1			1	1
Pulmonary embolism	3	3			3	3
Pulmonary oedema		2				2
Pulse abnormal		1				1
Pyrexia	4	20	1	14	3	6
Rash	2	3	1	1	1	2
Rash maculo-papular	1	1	1	1		
Recall phenomenon	2	2	2	2		
Red blood cell count increased		1		1		
Respiratory arrest		1				1
Respiratory disorder	2	4	1	1	1	3
Respiratory distress		1				1
SARS-CoV-2 ant body test negative	1	2	1	2		
Seizure	5	6			5	6
Sepsis		1				1
Septic shock		1				1
Skin burning sensation	1	1	1	1		
Skin exfoliation	1	1	1	1		
Skin reaction	1	1	1	1		
Slow speech		1				1
Speech disorder	1	1			1	1
Streptococcal infection		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death		1				1
Sudden hearing loss	2	2			2	2
Suffocation feeling		1				1
Swollen tongue		2				2
Syncope	3	3			3	3
Systemic inflammatory response syndrome	1	2			1	2
Tachycardia		2		1		1
Therapeutic response unexpected		3		3		
Throat tightness		1				1
Thrombocytopenia	1	1			1	1
Tic		1		1		
Tinnitus	2	4	1	2	1	2
Tongue oedema		1				1
Tonic convulsion	1	1			1	1
Transient ischaemic attack	5	5			5	5
Tremor		1		1		
Unresponsive to stimuli	1	1			1	1
Urticaria	1	2			1	2
Vaccination failure	3	4			3	4
Vaccination site movement impairment		1		1		
Vaccination site pain	2	14	2	14		
Vaccination site swelling		1		1		
Vaginal haemorrhage		1		1		
Ventricular fibrillation		2				2
Vertigo	3	4	1	2	2	2
Vision blurred		1		1		
Vlth nerve paralysis	1	1			1	1
Vomiting	2	4	1	3	1	1
Wheezing	1	2		1	1	1
	197	618	58	291	139	327

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Country Where Event Occurred

**ITALY**

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal discomfort		1				1			
Abdominal distension	1	3				1	1		2
Abdominal pain	7	30			3	22	4		8
Abdominal pain lower	1	1					1		1
Abdominal pain upper	4	13			3	9	1		4
Abnormal behaviour		1				1			
Abortion spontaneous		1							1
Acute abdomen	1	1					1		1
Acute coronary syndrome	2	5					2		5
Acute kidney injury	1	3		1			1		3
Acute motor axonal neuropathy	1	1					1		1
Acute myocardial infarction	1	4					1		4
Acute polyneuropathy		1							1
Acute pulmonary oedema		1							1
Acute respiratory distress syndrome	1	1					1		1
Acute respiratory failure	1	6					1		6
Administration site pain	1	3			1	3			
Adrenomegaly	1	1			1	1			
Age-related macular degeneration	1	1					1		1
Ageusia	1	3			1	2			1
Agitation		7				6			1
Akinesia	1	1					1		1
Allergic respiratory symptom		1							1
Allergy to vaccine		3				1			2
Alopecia		1							1
Alpha globulin increased		1				1			
Altered state of consciousness	1	2					1		2
Amaurosis fugax	1	1					1		1
Amnesia	1	1			1	1			
Anaemia	1	1					1		1
Anaemia macrocytic	1	1					1		1
Anaesthesia oral		1				1			
Anal incontinence		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaphylactic reaction	1	8		2			1	8
Anaphylactic shock		1		1				1
Angina pectoris		1						1
Angioedema	2	5					2	5
Anosmia		2						2
Antibody test abnormal		2				2		
Anti-thyroid antibody positive		1				1		
Anuria		1						1
Anxiety	1	3				1	1	2
Aphasia	5	5					5	5
Aphonia	1	1					1	1
Aphthous ulcer		1				1		
Arrhythmia	3	5					3	5
Arteriosclerosis		1						1
Arteriosclerotic retinopathy	1	1					1	1
Arthralgia	10	97		1	6	72	4	25
Arthritis		1				1		
Asphyxia		1						1
Asthenia	21	98	1	2	10	65	11	33
Asthenopia		1				1		
Asthma	1	12				4	1	8
Asthmatic crisis		3						3
Asymptomatic COVID-19	1	5					1	5
Atrial fibrillation	5	7					5	7
Atrial flutter		2						2
Atrioventricular block complete		1						1
Atrioventricular block first degree	1	1			1	1		
Auditory disorder		1						1
Autoimmune thyroiditis		2						2
Axillary pain		3				3		
Back pain	3	15		1		8	3	7
Balance disorder		5	1	1		2		3
Basedow's disease		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Blepharitis		1				1			
Blepharospasm		1							1
Blindness	1	2					1		2
Blister	1	3			1	3			
Blood glucose abnormal	1	1					1		1
Blood glucose increased		1				1			
Blood pressure decreased		2				2			
Blood pressure increased	1	13			1	7			6
Blood pressure systolic increased		2				2			
Blood thyroid stimulating hormone increased	1	1			1	1			
Bloody discharge	1	1					1		1
Body temperature abnormal	1	1			1	1			
Body temperature decreased	1	1					1		1
Body temperature increased		3				3			
Bone pain	1	12			1	7			5
Bradycardia		4							4
Bradykinesia		1							1
Brain compression	1	1					1		1
Brain stem haemorrhage		1							1
Breath sounds abnormal		1							1
Bronchitis		1							1
Bronchospasm		12				4			8
Brow ptosis		1				1			
Burning sensation	2	7			1	2	1		5
Capillary fragility		1							1
Cardiac arrest	8	12					8		12
Cardiac failure	1	5					1		5
Cardiac failure congestive	1	2					1		2
Cardiac fibrillation	1	1					1		1
Cardiopulmonary failure	1	1					1		1
Cardio-respiratory arrest	3	4					3		4
Catarrh		2							2
Cerebellar haemorrhage		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cerebral haematoma		1						1
Cerebral haemorrhage	4	5					4	5
Cerebral ischaemia	2	2					2	2
Cerebral venous sinus thrombosis		1						1
Cerebral ventricle collapse	1	1					1	1
Cerebrovascular accident	4	6					4	6
Chest discomfort	1	11		1		4	1	7
Chest pain	2	13		1		4	2	9
Chills	12	79		1	6	55	6	24
Choking		1						1
Choking sensation		1						1
Cholangitis		1						1
Chronic obstructive pulmonary disease	1	1					1	1
Circulatory collapse		1						1
Circumoral oedema	1	3			1	3		
Circumoral swelling		2						2
Coagulopathy		1						1
Cold sweat		1						1
Coma		2						2
Coma scale abnormal		1						1
Condition aggravated	4	12				1	4	11
Confusional state	4	9	1	2	1	2	3	7
Conjunctival haemorrhage		1						1
Conjunctivitis		6				4		2
Contusion	1	1			1	1		
Coronary artery disease		1						1
Coronary artery dissection	1	1					1	1
Coronary artery stenosis	1	1					1	1
Cough	5	37			1	17	4	20
COVID-19	9	27		1	2	5	7	22
COVID-19 pneumonia	1	1		1			1	1
C-reactive protein increased	2	4			1	2	1	2
Cyanosis		2				1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cystitis		1						1
Deafness		1						1
Deafness neurosensory		2						2
Death	4	6					4	6
Decreased appetite	1	12				8	1	4
Deep vein thrombosis	4	9	1	1			4	9
Dehydration		2						2
Delusion	1	1					1	1
Depressed level of consciousness				1				
Depressed mood		1				1		
Dermal cyst	1	1			1	1		
Dermatitis		1				1		
Dermatitis allergic		2				1		1
Dermatitis atopic		1				1		
Dermatitis bullous	1	2					1	2
Dermatitis exfoliative generalised		1						1
Dermatitis herpetiformis		1						1
Diarrhoea	8	35	1	1	3	18	5	17
Diplopia	1	2			1	1		1
Discomfort	1	4			1	4		
Disease recurrence	2	12				1	2	11
Disorientation	2	6		2			2	6
Disturbance in attention	2	3			1	2	1	1
Diverticulitis		1						1
Dizziness	9	42		1	2	24	7	18
Drooling		1				1		
Drug abuse	1	1					1	1
Drug hypersensitivity		2						2
Drug ineffective	2	12				1	2	11
Dry mouth		9				7		2
Dry skin		1				1		
Dry throat	1	1			1	1		
Dysaesthesia	1	2			1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Dysaesthesia pharynx		1				1			
Dysarthria	4	6					4		6
Dyschezia	1	1					1		1
Dysentery	4	18					4		18
Dysgeusia		11				6			5
Dysmetria	1	2					1		2
Dyspepsia		2				2			
Dysphagia	5	14			1	4	4		10
Dysphonia	1	7					1		7
Dyspnoea	16	64	1	3		11	16		53
Dyspnoea at rest	1	1					1		1
Dyspnoea exertional	1	3					1		3
Dysuria	1	3				1	1		2
Ear discomfort		2				1			1
Ear haemorrhage	1	1			1	1			
Ear pain		3				3			
Ecchymosis	3	3			1	1	2		2
Electrocardiogram T wave inversion				1					
Embolism		1							1
Embolism venous		1							1
Emotional disorder	1	1			1	1			
Emphysema		1							1
Enthesopathy	1	1					1		1
Eosinophil count increased		1							1
Epilepsy	1	2					1		2
Epistaxis		5				3			2
Erysipelas	1	1					1		1
Erythema	7	43	1	2	1	22	6		21
Erythema nodosum	1	2					1		2
Euphoric mood		1				1			
Exposure during pregnancy		2				2			
Exposure to SARS-CoV-2		1				1			
Extensive swelling of vaccinated limb		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Extremity contracture		1				1			
Eye allergy		1				1			
Eye disorder		1				1			
Eye haemorrhage	1	1					1		1
Eye irritation	1	4			1	2			2
Eyelid oedema		2				1			1
Eyelid ptosis	1	3			1	2			1
Eye oedema		1							1
Eye pain	2	7			1	3	1		4
Eye pruritus	1	2					1		2
Eye swelling	1	2			1	1			1
Face oedema	2	5				1	2		4
Facial asymmetry	1	1					1		1
Facial nerve disorder		1							1
Facial pain	1	1			1	1			
Facial paralysis	1	11					1		11
Facial paresis		2				1			1
Facial spasm		1							1
Fall	1	3					1		3
Fatigue	9	75			7	55	2		20
Feeling abnormal	1	2				1	1		1
Feeling cold		8				6			2
Feeling hot	3	16			2	7	1		9
Feeling jittery	1	1					1		1
Feeling of body temperature change		2							2
Female sexual dysfunction	1	1			1	1			
Fibrin D dimer increased	2	3			1	2	1		1
Fluid retention		2							2
Flushing		12				9			3
Focal discognitive seizures	1	1					1		1
Gait disturbance	4	6				2	4		4
Gait inability	1	4					1		4
Gastrointestinal disorder		1				1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Gastroesophageal reflux disease		1				1			
Generalised tonic-clonic seizure		1							1
General physical health deterioration		2				1			1
Gingival bleeding		1				1			
Gingival pain		1				1			
Glomerulonephritis		1							1
Glossitis	1	1					1		1
Glossodynia		1				1			
Guillain-Barre syndrome		1							1
Guttate psoriasis		1							1
Haematochezia		1							1
Haematoma	3	5			1	2	2		3
Haematuria		1				1			
Haemoglobin decreased		1							1
Haemorrhage subcutaneous		1							1
Haemorrhagic cerebral infarction		1							1
Haemorrhagic stroke	1	1					1		1
Hallucination	1	4					1		4
Hallucination, auditory	1	1					1		1
Hallucination, olfactory		1							1
Hallucinations, mixed		1							1
Hallucination, visual	1	1					1		1
Hand dermatitis		1				1			
Headache	21	156	1	3	11	103	10		53
Heart rate increased	1	3			1	1			2
Heart rate irregular		1							1
Hemianaesthesia		1							1
Hemiparaesthesia		3							3
Hemiparesis	2	7					2		7
Hemiplegia	2	3					2		3
Hepatic enzyme increased				1					
Hepatitis acute		1							1
Herpes ophthalmic		2							2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Herpes zoster	1	4				2	1	2
Hot flush	1	6			1	4		2
Hydrocephalus	1	1					1	1
Hyperaemia		1						1
Hypercapnia		1						1
Hypercreatininaemia	1	1					1	1
Hyperglycaemia	2	3					2	3
Hyperhidrosis	2	13				6	2	7
Hyperpyrexia	5	17		1	1	1	4	16
Hypersensitivity	2	13				3	2	10
Hypersomnia		1				1		
Hypertension	7	17				3	7	14
Hypertensive crisis	5	11					5	11
Hypertensive heart disease	2	2					2	2
Hyperthermia		3				1		2
Hypertonia		1				1		
Hypertransaminasaemia		1						1
Hyperventilation		1						1
Hypoacusis	1	2					1	2
Hypoaesthesia	3	11			2	6	1	5
Hypoaesthesia oral		4				1		3
Hypokalaemia	1	1					1	1
Hypokinesia		1				1		
Hyporeflexia	1	1					1	1
Hyporesponsive to stimuli		1						1
Hypotension	4	15		1		3	4	12
Hypotensive crisis	2	3					2	3
Hypothermia	1	2					1	2
Hypotonia		1						1
Hypovolaemia		1						1
Hypoxia	1	5					1	5
Illrd nerve paralysis	1	1					1	1
Immune thrombocytopenia			1	1				

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Impaired quality of life	1	1			1	1		
Impaired work ability		1						1
Inappropriate schedule of product administration	2	2			1	1	1	1
Incorrect route of product administration	1	3			1	3		
Increased viscosity of bronchial secretion		1						1
Infected cyst		1						1
Infection	1	1			1	1		
Inflammation	1	1					1	1
Influenza		1				1		
Influenza like illness	1	11			1	9		2
Injected limb mobility decreased	1	2			1	1		1
Injection site erythema		2				2		
Injection site oedema		1				1		
Injection site pain		20				20		
Injection site reaction		1				1		
Injection site urticaria		1				1		
Insomnia	2	9			1	6	1	3
International normalised ratio increased		1				1		
Interstitial lung disease		3						3
Intestinal ischaemia	1	1					1	1
Intestinal obstruction		1						1
Intranasal paraesthesia		1				1		
Intraventricular haemorrhage	1	1					1	1
Ischaemia		1						1
Ischaemic stroke		4						4
Jaundice		2						2
Jaundice cholestatic		1						1
Joint effusion		1				1		
Joint range of motion decreased	1	2			1	1		1
Joint swelling	1	2				1	1	1
Labyrinthitis		2						2
Lacrimation increased	2	4			1	2	1	2
Lagophthalmos		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Laryngeal oedema	2	18					2	18
Laryngospasm	1	3					1	3
Lateropulsion	1	1					1	1
Lethargy		1				1		
Leukaemia	1	1					1	1
Leukocytosis		1		1		1		
Leukopenia		1						1
Limb discomfort	1	4			1	4		
Lipase increased		1				1		
Lip oedema	1	7				3	1	4
Lip pruritus		2				1		1
Lip swelling	1	2		1			1	2
Livedo reticularis		1		1		1		
Localised oedema		2		1		1		1
Logorrhoea	1	1					1	1
Loss of consciousness	5	11					5	11
Loss of control of legs		1						1
Lung disorder		1						1
Lung neoplasm malignant		1						1
Lymphadenitis		1				1		
Lymphadenopathy	9	51			4	38	5	13
Lymph node pain	1	5			1	3		2
Lymphocyte count decreased		1				1		
Lymphocytosis		1				1		
Lymphoma	1	1					1	1
Maculopathy	1	1					1	1
Malaise	12	52		1	4	30	8	22
Maternal exposure during pregnancy	2	4			2	4		
Mean cell volume increased		1				1		
Mechanical urticaria		2				1		1
Menorrhagia		1				1		
Metabolic acidosis		1						1
Metrorrhagia		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Migraine	2	12			1	10	1	2
Monocyte count increased		1				1		
Monoparesis		1				1		
Monoplegia		1						1
Mood altered		1				1		
Motor dysfunction	3	4					3	4
Movement disorder	1	3			1	1		2
Mucous stools		1				1		
Multiple organ dysfunction syndrome	1	3		1			1	3
Muscle contractions involuntary		1						1
Muscle contracture		2				1		1
Muscle rigidity		4				3		1
Muscle spasms		7				5		2
Muscle swelling		1						1
Muscle tightness		1				1		
Muscle twitching		1				1		
Muscular weakness	4	8			1	3	3	5
Musculoskeletal pain	1	18			1	14		4
Musculoskeletal stiffness	2	6			1	2	1	4
Myalgia	10	90	1	2	3	61	7	29
Myasthenia gravis crisis	1	2					1	2
Myocardial infarction	2	3					2	3
Myocardial ischaemia	1	2					1	2
Myringitis	1	1					1	1
Nasal discomfort		1				1		
Nasopharyngitis	1	3			1	2		1
Nausea	13	79		1	5	47	8	32
Neck pain	2	11			1	9	1	2
Nervous system disorder	1	2					1	2
Neuralgia	1	5			1	2		3
Neurological symptom				1				
Neuropathy peripheral		3						3
Neutropenia		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Neutrophilia	1	1					1	1
Nightmare		1				1		
Night sweats		2				2		
Non-cardiac chest pain	1	1					1	1
Nuchal rigidity	1	3			1	2		1
Nystagmus		1						1
Obstructive airways disorder		1				1		
Occipital neuralgia		1						1
Ocular discomfort	1	2			1	2		
Ocular hyperaemia	2	4			1	2	1	2
Oedema		1				1		
Oedema mouth	1	2					1	2
Oedema peripheral	3	9	2	2	2	6	1	3
Oesophageal spasm		1						1
Off label use	3	13			2	11	1	2
Oliguria		2						2
Optic neuritis		3						3
Oral discomfort	1	1			1	1		
Oral herpes		3				2		1
Oral pain		3				2		1
Oral pruritus		2						2
Oropharyngeal discomfort		2				1		1
Oropharyngeal pain		11		1		5		6
Oropharyngeal spasm		1						1
Oropharyngeal swelling		1				1		
Orthopnoea		1						1
Orthostatic hypotension		1						1
Overdose	3	6			2	4	1	2
Oxygen saturation abnormal			1	1				
Oxygen saturation decreased	6	19		1		3	6	16
Pain	10	40			4	24	6	16
Pain in extremity	15	67			5	43	10	24
Pain in jaw	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pain of skin	1	1					1	1
Palatal oedema		4				2		2
Palatal swelling		1				1		
Pallor		4				2		2
Palpable purpura		1				1		
Palpitations	1	2				1	1	1
Pancreatitis acute	1	1					1	1
Panniculitis		1						1
Papilloedema		1						1
Paraesthesia	8	45			3	23	5	22
Paraesthesia oral	2	33			1	20	1	13
Paraparesis	1	1					1	1
Partial seizures	1	1					1	1
Pemphigoid		1						1
Pericardial effusion		1						1
Perioral dermatitis		1				1		
Peripheral coldness	2	3			1	2	1	1
Peripheral sensorimotor neuropathy		1						1
Peripheral swelling	4	11				3	4	8
Petechiae	1	1			1	1		
Pharyngeal disorder		1				1		
Pharyngeal erythema		2						2
Pharyngeal oedema	1	3		1			1	3
Pharyngeal paraesthesia		4				1		3
Pharyngeal swelling		1						1
Pharyngitis		2						2
Phlebitis	1	2			1	1		1
Phlebitis superficial	1	1					1	1
Photophobia	1	4				1	1	3
Photopsia		1						1
Photosensitivity reaction		1						1
Pityriasis rosea	1	1					1	1
Platelet count decreased	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pneumonia	1	2					1	2
Pneumonia bacterial	1	2					1	2
Pneumonitis		1						1
Polyuria		1						1
Presyncope	5	11			1	4	4	7
Procalcitonin increased	1	1			1	1		
Productive cough	1	4					1	4
Product use issue	1	11			1	10		1
Proteinuria		1				1		
Pruritus	4	43			1	24	3	19
Psoriasis	1	1			1	1		
Psoriatic arthropathy	2	2					2	2
Psychomotor hyperactivity	1	2				1	1	1
Pulmonary embolism	4	11	2	2			4	11
Pulmonary hypertension	1	1					1	1
Pulmonary hypoperfusion		1						1
Pulmonary microemboli	1	1					1	1
Pulmonary oedema	1	2					1	2
Purpura		1						1
Pustular psoriasis	1	1					1	1
Pyrexia	33	222	3	6	7	132	26	90
Q fever	1	2					1	2
Quality of life decreased	1	1					1	1
Rales		2						2
Rash	5	36				17	5	19
Rash erythematous	1	1					1	1
Rash macular	1	1			1	1		
Rash maculo-papular		1				1		
Rash papular		1				1		
Rash pruritic	2	6			1	5	1	1
Rectal haemorrhage		1						1
Red blood cell count decreased		1						1
Red blood cell sedimentation rate increased	1	2				1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Red cell distribution width increased		1				1			
Reduced facial expression		1							1
Regurgitation		1							1
Renal failure	1	3					1		3
Renal impairment		1							1
Renal pain		1				1			
Respiratory arrest		2							2
Respiratory disorder	1	3				1	1		2
Respiratory distress		6		1					6
Respiratory failure	5	10					5		10
Respiratory fatigue		1							1
Respiratory tract oedema		1							1
Restless legs syndrome		1							1
Restlessness		3				1			2
Retching	1	3					1		3
Retinal artery occlusion	1	1					1		1
Retinal degeneration		1							1
Retinal detachment		1							1
Retinal disorder		1							1
Retinal drusen	1	1					1		1
Retinal oedema	1	1					1		1
Retinal vein occlusion	1	1					1		1
Rheumatoid arthritis	1	3					1		3
Rhinitis	1	2			1	2			
Rhinorrhoea	1	2				1	1		1
Salivary hypersecretion		1				1			
Sarcoidosis		1							1
SARS-CoV-2 ant body test negative		1				1			
SARS-CoV-2 test positive	2	5					2		5
Sciatica		1				1			
Scleral discolouration		1							1
Secretion discharge	1	1					1		1
Seizure	1	4					1		4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Sensation of foreign body		3				1			2
Sense of oppression	1	2			1	1			1
Sensorimotor disorder		1							1
Sensory loss		1							1
Sepsis	1	2					1		2
Septic shock	1	2					1		2
Serratia test positive		1							1
Severe acute respiratory syndrome		1							1
Shock	1	2					1		2
Sinus headache		1				1			
Sinus tachycardia		2	1	1		1			1
Skin burning sensation		1				1			
Skin laceration	1	1					1		1
Skin lesion	1	3				1	1		2
Skin reaction		2				2			
Skin tightness		1							1
Sleep disorder		1				1			
Sneezing		1				1			
Soliloquy		1				1			
Somnolence	3	13	1	2	2	7	1		6
Sopor	3	5	1	2			3		5
Speech disorder	2	3				1	2		2
Spinal pain		2				2			
Stenotrophomonas test positive		1							1
Stertor		1							1
Stupor	1	3					1		3
Subarachnoid haemorrhage	2	2					2		2
Subdural haematoma	1	1					1		1
Sudden death	7	11					7		11
Suffocation feeling		2				1			1
Superinfection bacterial	1	2					1		2
Swelling		4				3			1
Swelling face	1	5			1	3			2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Swollen tongue	1	7				3	1	4
Syncope	2	10		1			2	10
Systemic lupus erythematosus	1	2					1	2
Systolic hypertension		1						1
Tachyarrhythmia	1	1			1	1		
Tachycardia	7	40	1	1	2	19	5	21
Tachypnoea		4				3		1
Taste disorder		1				1		
Tenosynovitis	1	1					1	1
Tension headache		2				2		
Tetany	1	1					1	1
Throat irritation	2	10			1	6	1	4
Throat tightness	1	15				4	1	11
Thromboangiitis obliterans	1	1					1	1
Thrombocytopenia	5	9					5	9
Thrombophlebitis	2	2			2	2		
Thrombophlebitis superficial	1	1					1	1
Thrombosis	3	3					3	3
Thyroid disorder		1				1		
Tinnitus	1	5				2	1	3
Tongue coated		1				1		
Tongue discomfort		3				2		1
Tongue dry		1				1		
Tongue oedema	2	6				1	2	5
Tongue ulceration		1				1		
Transaminases increased		1						1
Transient ischaemic attack	2	2					2	2
Tremor	4	13				5	4	8
Trigeminal nerve disorder		2				2		
Trigeminal neuralgia		1				1		
Trismus		1				1		
Troponin I increased	1	1					1	1
Troponin increased	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Underdose		1				1			
Unresponsive to stimuli	1	2					1		2
Urinary incontinence	1	2					1		2
Urinary retention	1	2					1		2
Urine flow decreased		1				1			
Urine output decreased	1	1					1		1
Urosepsis	1	1					1		1
Urticaria	3	33			2	23	1		10
Use of accessory respiratory muscles		2				1			1
Vaccination complication		5				2			3
Vaccination failure	7	15		1			7		15
Vaccination site anaesthesia		1							1
Vaccination site bruising		1							1
Vaccination site eczema		1				1			
Vaccination site erythema		7				6			1
Vaccination site induration		2				2			
Vaccination site inflammation		3				3			
Vaccination site joint pain		1				1			
Vaccination site lymphadenopathy	1	2			1	2			
Vaccination site movement impairment		3				2			1
Vaccination site oedema		10	1	1		9			1
Vaccination site pain	6	74	1	2	4	59	2		15
Vaccination site pallor		1				1			
Vaccination site paraesthesia	1	5				3	1		2
Vaccination site pruritus		1							1
Vaccination site reaction		2				1			1
Vaccination site swelling	1	9	1	1	1	6			3
Vaccination site warmth		4	1	1		4			
Vascular purpura		1							1
Vasculitis	2	2			1	1	1		1
Vasoconstriction		1							1
Vasodilatation	1	1					1		1
Ventricular extrasystoles		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ventricular fibrillation	1	1					1	1
Vertigo	4	23	1	1		14	4	9
Vertigo positional		1		1				1
Vision blurred	3	6				1	3	5
Visual acuity reduced				1				
Visual impairment	4	7				1	4	6
Vitreous detachment		1						1
Vitreous floaters		1						1
Vitreous haemorrhage	1	1					1	1
Vomiting	7	38		1	1	20	6	18
Weight decreased		1						1
Wheezing		5				3		2
White blood cell count increased		1						1
Withdrawal hypertension		1				1		
Xerosis		1						1
	761	3,519	27	77	195	1687	566	1832

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Country Where Event Occurred

**JAPAN**

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\* AE=Adverse Event

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	5	1	1	3	4
Abdominal pain	7	8	4	4	3	4
Abdominal pain lower	1	1			1	1
Abdominal pain upper	3	4			3	4
Abnormal sensation in eye		1				1
Acute lymphocytic leukaemia	1	1			1	1
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome	2	2			2	2
Affective disorder		1		1		
Altered state of consciousness		1				1
Amnesia	1	1			1	1
Anaemia		1				1
Anaphylactic reaction	116	191	1	1	115	190
Anaphylactic shock	3	5			3	5
Anaphylactoid reaction	2	5			2	5
Angina pectoris		1				1
Anxiety		1		1		
Aphonia	1	1	1	1		
Apraxia		1				1
Arrhythmia	1	1			1	1
Arthralgia	10	10	5	5	5	5
Arthritis	1	1			1	1
Arthritis reactive	1	1			1	1
Ascites	1	1			1	1
Asthenia	6	9	3	4	3	5
Asthenopia	2	2			2	2
Asthma	25	46	3	12	22	34
Autonomic neuropathy	1	1			1	1
Axillary pain	2	2	1	1	1	1
Back pain	2	2	1	1	1	1
Blood glucose decreased		1				1
Blood pressure abnormal		2				2
Blood pressure decreased	5	5	2	2	3	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure diastolic increased	2	2	1	1	1	1
Blood pressure increased	16	24	10	14	6	10
Blood pressure systolic abnormal	1	1			1	1
Blood pressure systolic increased	1	2		1	1	1
Body temperature increased	1	3	1	3		
Bradycardia	2	2			2	2
Brain stem haemorrhage	1	1			1	1
Brain stem infarction	1	1			1	1
Breath sounds abnormal		1				1
Bronchial obstruction		1				1
Bronchiectasis	1	1			1	1
Bronchospasm		1				1
Bronchostenosis	1	1			1	1
Burning sensation		1		1		
Cardiac death	1	1			1	1
Cardiac failure	2	3			2	3
Cardio-respiratory arrest	1	1			1	1
Cellulitis	2	2			2	2
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Chest discomfort	4	5	3	3	1	2
Chest pain	1	1	1	1		
Chills	10	20	5	11	5	9
Cholinergic syndrome	1	1			1	1
Circulatory collapse	1	1			1	1
Cold sweat	9	10	3	3	6	7
Colitis	1	1			1	1
Colitis ulcerative	1	1			1	1
Condition aggravated	3	3	1	1	2	2
Conjunctival hyperaemia		3		1		2
Cough	50	83	16	27	34	56
Cutaneous symptom		1				1
Daydreaming	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	3	1	1	1	2
Dehydration		1				1
Depressed level of consciousness		2				2
Dermatitis allergic	1	3	1	1		2
Dermatitis atopic	2	3	2	2		1
Diarrhoea	7	9	3	5	4	4
Diplopia	1	1	1	1		
Discomfort	2	3	1	2	1	1
Disease recurrence	1	2		1	1	1
Diverticulitis	2	2			2	2
Diverticulum	1	1			1	1
Dizziness	17	25	10	13	7	12
Dizziness postural	2	4	1	3	1	1
Drowning	1	1			1	1
Drug hypersensitivity		1				1
Dry mouth	1	1			1	1
Dysaesthesia	1	1			1	1
Dysgeusia	1	2	1	1		1
Dysphagia	1	1			1	1
Dysphonia	6	12	3	4	3	8
Dysphoria	1	1	1	1		
Dyspnoea	32	58	15	20	17	38
Ear discomfort	2	3	1	1	1	2
Eczema	1	1	1	1		
Enterocolitis	1	1			1	1
Epigastric discomfort	1	1			1	1
Erythema	25	43	15	23	10	20
Erythema of eyelid	1	1	1	1		
Excessive eye blinking		1				1
Eye disorder	2	4	1	2	1	2
Eyelid function disorder	1	1			1	1
Eyelid irritation	1	1			1	1
Eyelid oedema	1	5	1	2		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis	1	1			1	1
Eye oedema		1		1		
Eye pruritus	1	1			1	1
Face oedema	1	2	1	1		1
Facial pain	1	1			1	1
Facial paralysis	4	4			4	4
Fatigue	2	3	2	2		1
Feeling abnormal	15	27	6	7	9	20
Feeling cold	3	5	1	1	2	4
Feeling hot	9	12	4	5	5	7
Feeling jittery	1	1			1	1
Flushing	4	8	2	3	2	5
Foreign body in throat		1				1
Gait disturbance	2	2			2	2
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal hypermotility		1				1
Gastrointestinal motility disorder	1	1	1	1		
Gaze palsy	1	1			1	1
Generalised oedema	1	1	1	1		
General physical health deterioration	1	1			1	1
Guillain-Barre syndrome	2	2			2	2
Haematochezia	2	2			2	2
Haemorrhage	1	1			1	1
Haemorrhage subcutaneous	2	2			2	2
Headache	38	59	21	29	17	30
Head discomfort	3	7	3	5		2
Heart rate decreased	1	1	1	1		
Heart rate increased	2	5	1	3	1	2
Hepatic function abnormal	2	2			2	2
Hot flush	6	11	4	5	2	6
Hyperhidrosis	4	7	3	3	1	4
Hyperreflexia		1		1		
Hypersensitivity	7	11	5	5	2	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	3	5			3	5
Hypertensive emergency	2	2			2	2
Hyperthermia	1	1	1	1		
Hyperventilation	3	5	1	2	2	3
Hypoacusis		1				1
Hypoaesthesia	15	19	6	9	9	10
Hypoaesthesia oral	2	6	1	3	1	3
Hypokalaemia		1				1
Hypophagia	2	2	1	1	1	1
Hypothyroidism	1	1			1	1
Hypotonia	1	1			1	1
Hypoventilation		1				1
Infective spondylitis	1	1			1	1
Injected limb mobility decreased		1		1		
Injection site pain	1	1	1	1		
Injection site pruritus	1	1	1	1		
Injection site rash	1	1	1	1		
Internal haemorrhage	1	1			1	1
Joint swelling	1	1	1	1		
Laryngeal discomfort	1	1			1	1
Laryngeal obstruction		1				1
Laryngeal oedema		1				1
Laryngeal pain	1	1	1	1		
Larynx irritation	1	2			1	2
Lethargy	1	1			1	1
Leukopenia	1	1			1	1
Limb discomfort	3	4	3	4		
Lip erythema	1	1			1	1
Lip pruritus		2				2
Lip swelling	2	6	1	2	1	4
Loss of consciousness	4	5			4	5
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymph node pain	2	2	1	1	1	1
Lymphoedema	1	1			1	1
Malaise	24	33	17	22	7	11
Melaena	1	1			1	1
Meningitis aseptic		1				1
Mobility decreased	1	2		1	1	1
Mouth swelling	2	3	1	2	1	1
Movement disorder	2	2			2	2
Mucosal disorder		1		1		
Muscle spasms	4	5	3	4	1	1
Muscular weakness	6	9	2	4	4	5
Musculoskeletal stiffness	1	1	1	1		
Myalgia	7	7	5	5	2	2
Myocardial infarction	1	1			1	1
Nasal congestion		1				1
Nausea	34	51	16	21	18	30
Neck pain	2	2	1	1	1	1
Nephrotic syndrome	1	1			1	1
Neuropathy peripheral	3	4			3	4
Obstructive airways disorder	1	1			1	1
Ocular hyperaemia	2	2	2	2		
Oculomucocutaneous syndrome	1	1			1	1
Odynophagia		1				1
Oedema	2	2			2	2
Oedema peripheral		1				1
Oral discomfort	2	3	1	1	1	2
Oral mucosa erosion	1	1	1	1		
Oral mucosal blistering	1	1	1	1		
Oral pain	1	1	1	1		
Oral pruritus	3	3	1	1	2	2
Organising pneumonia		1				1
Oropharyngeal discomfort	28	52	16	25	12	27
Oropharyngeal pain	3	9	3	5		4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	7	10	3	4	4	6
Pain	2	2	1	1	1	1
Pain in extremity	6	7	4	5	2	2
Pallor	3	4			3	4
Palpitations	15	25	12	14	3	11
Paraesthesia	4	7	2	5	2	2
Paraesthesia oral	2	4	2	3		1
Parotitis	1	1	1	1		
Peripheral coldness	5	6	3	3	2	3
Peripheral swelling	1	1	1	1		
Pharyngeal swelling		1		1		
Photopsia	1	1	1	1		
Physical deconditioning	2	4		2	2	2
Pneumonia	1	1			1	1
Postural tremor		1		1		
Presyncope	5	6	2	3	3	3
Productive cough	2	3	2	2		1
Protein urine present	1	1	1	1		
Pruritus	34	56	19	27	15	29
Pyrexia	31	41	21	27	10	14
Radial pulse abnormal	1	1			1	1
Rash	14	16	13	14	1	2
Reaction to excipient		1				1
Respiratory disorder	5	5	1	1	4	4
Respiratory distress		2				2
Respiratory symptom	1	4	1	1		3
Rhinorrhoea	1	2		1	1	1
Salivary hypersecretion	1	1			1	1
Seizure	4	4			4	4
Sensation of foreign body	1	1			1	1
Sensory disturbance	2	3	1	2	1	1
Sepsis	1	1			1	1
Shock		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sitting disability	1	1	1	1		
Sneezing	2	3		1	2	2
Somnolence	3	4	1	1	2	3
Speech disorder	1	1			1	1
Sputum discoloured	1	1	1	1		
Stridor	2	4		1	2	3
Sudden hearing loss		1				1
Sunburn	1	1	1	1		
Swelling	3	3	1	1	2	2
Swelling face	1	3	1	1		2
Swelling of eyelid	2	4	1	2	1	2
Syncope	1	3			1	3
Tachycardia	4	8	1	1	3	7
Tachypnoea		1		1		
Thirst	1	2			1	2
Throat irritation	8	15	7	11	1	4
Throat tightness	4	9		1	4	8
Tinnitus		1				1
Tracheal obstruction		1				1
Tremor	4	7	3	4	1	3
Trigeminal nerve disorder	1	2			1	2
Type I hypersensitivity	2	3			2	3
Upper airway obstruction	1	1			1	1
Urinary retention		1				1
Urticaria	22	32	13	15	9	17
Vaccination site erythema	3	7	2	4	1	3
Vaccination site haemorrhage	1	1			1	1
Vaccination site pain	10	13	9	11	1	2
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	3	5	1	3	2	2
Vaccination site swelling	3	3	3	3		
Vaccination site urticaria		2		1		1
Ventricular hypokinesia	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	2	4	1	1	1	3
Visual impairment	1	2			1	2
Vocal cord disorder	1	1			1	1
Vomiting	16	23	6	8	10	15
Wheezing	11	18	1	1	10	17
White blood cell count increased	1	1	1	1		
Yawning	2	2			2	2
	1,019	1,591	421	589	598	1002

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**JORDAN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Condition aggravated		1				1
COVID-19		1				1
COVID-19 pneumonia		1				1
Hypoxia		1				1
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1				1
Lung disorder		1				1
Respiratory failure		1				1
Sputum retention		1				1
Swelling face		1		1		
Tachypnoea		1				1
Vaccination failure		1				1
		13		1		12

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LATVIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		2				2
Anaphylactic reaction		1				1
Anxiety		1				1
Arthralgia		4		3		1
Asthenia		3		3		
Asthma		2		1		1
Body temperature increased		2		2		
Bradycardia		1				1
Chest pain		1		1		
Chills		1		1		
Condition aggravated		1		1		
Cough		1		1		
Decreased appetite		1		1		
Depressed mood		1		1		
Diplopia		1				1
Disturbance in attention		3		3		
Dizziness		5		2		3
Dysphonia		1		1		
Dyspnoea		1		1		
Ear discomfort		1				1
Erythema		1		1		
Extrasystoles		1				1
Eye pain		1		1		
Facial paresis		1				1
Fatigue		7		5		2
Generalised tonic-clonic seizure		1				1
Headache		5		3		2
Heart rate increased		1				1
Hot flush		2		1		1
Hyperaesthesia		2				2
Hypertension		1				1
Initial insomnia		1		1		
Insomnia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased		1				1
Loss of proprioception		1				1
Muscle spasms		1				1
Muscular weakness		1				1
Myalgia		1		1		
Nausea		2		2		
Neuralgia		1				1
Off label use		1		1		
Pain in extremity		2		1		1
Palpitations		1				1
Paraesthesia		3				3
Photophobia		1		1		
Product use issue		1		1		
Pulse volume decreased		1		1		
Pyrexia		6		3		3
Respiratory distress		1				1
Skin burning sensation		1				1
Somatic dysfunction		1				1
Somnolence		2				2
Tachycardia		4		1		3
Thirst		1				1
Throat irritation		1		1		
Vaccination site erythema		4		3		1
Vaccination site mass		1				1
Vaccination site oedema		1		1		
Vaccination site pain		8		7		1
Vaccination site rash		1				1
Vaccination site warmth		1		1		
		110		59		51

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LEBANON**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain		1		1		
Death		1				1
Headache		1		1		
Influenza		1		1		
Limb discomfort		1		1		
Muscle twitching		1		1		
Myalgia		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Paraesthesia		2		2		
		11		10		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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Country Where Event Occurred  
**LITHUANIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Arthralgia	1	2	1	2		
Asthenia	1	1	1	1		
Cardiogenic shock		1				1
Chest pain		1		1		
Condition aggravated		1				1
Cough	1	1	1	1		
COVID-19 pneumonia		1				1
Death		2				2
Dry eye	1	1	1	1		
Dysgeusia		1		1		
Dyspnoea		1				1
Ear pain	1	1	1	1		
Eye pain	1	1	1	1		
Feeling of body temperature change	1	1	1	1		
Headache	1	1	1	1		
Heart rate increased		1		1		
Irritability		1				1
Lacrimation increased	1	1	1	1		
Loss of consciousness		1				1
Lymphadenopathy		1		1		
Malaise		2				2
Mucosal disorder	1	1	1	1		
Myalgia	1	1	1	1		
Off label use		1		1		
Pain		1				1
Peritonsillar abscess	1	1			1	1
Product use issue		1		1		
Pyrexia	1	1	1	1		
Slow response to stimuli	1	1	1	1		
Tonsillar hypertrophy	1	1	1	1		
Vaccination failure		1				1
Vaccination site pain	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	16	36	15	22	1	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**LUXEMBOURG**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper		1				1
Acute coronary syndrome	1	1			1	1
Acute kidney injury		1				1
Altered state of consciousness		1				1
Arthralgia	1	1	1	1		
Asthmatic crisis		1				1
Chest discomfort	1	2			1	2
Chest pain		1				1
Chills	1	3	1	1		2
COVID-19	1	1			1	1
Decreased appetite		1				1
Diarrhoea	1	1	1	1		
Dizziness	1	1			1	1
Dry mouth		1				1
Dry skin		1				1
Dysgeusia		1				1
Dyspnoea		3				3
Fatigue	2	6	1	2	1	4
Haematoma	1	1	1	1		
Headache	1	3	1	1		2
Herpes zoster		1		1		
Hypernatraemia		1				1
Hypersensitivity		1				1
Hypertension	2	3	1	1	1	2
Hyperthermia	1	2	1	1		1
Hypoaesthesia	1	1			1	1
Hypoxia		1				1
Lung disorder		1				1
Malaise	2	4	1	1	1	3
Musculoskeletal stiffness		1				1
Myalgia		2				2
Nausea	1	2			1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Oral herpes		1		1			
Oxygen saturation decreased		1					1
Pain in extremity	2	2	1	1	1		1
Paraesthesia		1					1
Paresis	1	1			1		1
Peripheral coldness	1	1			1		1
Peripheral swelling		1		1			
Pruritus		1					1
Pulmonary pain		1					1
Pyrexia		1					1
Rash		1					1
Sepsis		1					1
Skin haemorrhage		1					1
Somnolence		1					1
Swelling face		1		1			
Tetany	1	1	1	1			
Therapeutic response unexpected	1	1	1	1			
Tremor	1	2	1	1			1
Urinary tract infection	1	1	1	1			
Vaccination complication		1					1
Vaccination site pain		1					1
Vlth nerve paralysis	1	1			1		1
Wheezing		2					2
	27	79	14	19	13		60

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MALTA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain		1		1			
Activated partial thromboplastin time prolonged		1		1			
Activated partial thromboplastin time ratio increased		1		1			
Acute kidney injury		1					1
Alanine aminotransferase increased		1		1			
Altered state of consciousness		1					1
Anaphylactic reaction	1	5			1		5
Arthralgia	1	2	1	2			
Asthma		2					2
Atrial f brillation		1					1
Basophil count increased		1		1			
Blood alkaline phosphatase increased		1		1			
Blood creatinine increased		1		1			
Blood glucose increased		1		1			
Blood magnesium decreased		1		1			
Blood osmolarity increased		1		1			
Blood phosphorus decreased		1		1			
Blood urea increased		2		2			
Bronchospasm		1					1
Cerebellar atrophy		1					1
Cerebral atrophy		2					2
Cerebrovascular accident	1	1			1		1
Chest discomfort	1	1			1		1
Chest pain	1	1	1	1			
Chills	1	1	1	1			
Cough		1					1
COVID-19		3					3
COVID-19 pneumonia		2					2
C-reactive protein increased		2		2			
Dehydration		1		1			
Diarrhoea		2		1			1
Drug ineffective		2					2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia		1		1		
Dysphagia		1				1
Dysphonia	1	2			1	2
Dyspnoea	1	4			1	4
Eosinophil count decreased		1		1		
Erythema	2	4	1	2	1	2
Eye swelling	1	1			1	1
Facial paralysis		2				2
Fatigue	1	3	1	3		
Goitre		1		1		
Haematocrit decreased		2		2		
Haemoglobin decreased		2		2		
Hypersensitivity	1	1			1	1
Hypertension		1				1
Hypoaesthesia		2		2		
Hypothermia		1				1
Hypoxia		2				2
Immature granulocyte count increased		1		1		
Injection		1		1		
Lethargy	1	1	1	1		
Lip swelling	1	1			1	1
Lymphocyte count decreased		2		2		
Malaise		2		2		
Mean cell haemoglobin concentration increased		1		1		
Monocyte count decreased		1		1		
Monocyte count increased		1		1		
Musculoskeletal stiffness		1		1		
Myalgia		1		1		
Nausea		2		1		1
Neck pain	1	2	1	2		
Neutrophil count increased		2		2		
Normochromic normocytic anaemia		1		1		
Nucleated red cells		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	2	1	2		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain		1		1		
Pain in extremity		1		1		
Palpitations	1	1			1	1
Panic reaction		1		1		
Paraesthesia		3		3		
Peripheral coldness		1		1		
Platelet count decreased		1		1		
Platelet count increased		1		1		
Poor peripheral circulation		1		1		
Product use issue		1		1		
Pruritus	1	2			1	2
Pulmonary embolism	1	1			1	1
Pyrexia	2	2	2	2		
Rash		1				1
Rash pruritic	1	2			1	2
Red blood cell count decreased		2		2		
Red cell distribution width increased		1		1		
Respiratory depression		1				1
Respiratory distress		1				1
Reticulocyte count increased		1		1		
Sepsis		1				1
Septic shock		1				1
Somnolence		1		1		
Swelling face	1	2		1	1	1
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachycardia		1				1
Tachypnoea		2				2
Throat tightness		1				1
Thrombocytopenia		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Urticaria		1				1	
Vaccination failure		1				1	
Vaccination site discomfort		1		1			
Vaccination site erythema	1	1	1	1			
Vaccination site induration		1		1			
Vaccination site pain		3		3			
Vaccination site pruritus	1	1	1	1			
Vaccination site rash	1	1	1	1			
Vaccination site urticaria		1					1
Vision blurred	1	1			1	1	
Vomiting		1					1
Wheezing		2					2
White blood cell count increased		1		1			
	30	156	13	86	17	70	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MEXICO**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal distension		1		1			
Abdominal pain	1	8	1	7			1
Abdominal pain lower	1	1	1	1			
Abdominal pain upper		1		1			
Abscess	1	1	1	1			
Acute myocardial infarction		1					1
Ageusia		1		1			
Anaphylactic reaction		2					2
Anaphylactic shock	1	4			1		4
Angioedema		3					3
Anxiety	1	5		3	1		2
Aphasia		1		1			
Arrhythmia	1	1			1		1
Arthralgia	2	15	2	14			1
Asthenia	7	27	7	25			2
Asthma		1		1			
Asthmatic crisis		1					1
Back pain		1		1			
Balance disorder	1	1	1	1			
Blood glucose increased	1	1	1	1			
Blood pressure decreased	1	1			1		1
Blood pressure increased	1	2			1		2
Body temperature increased	1	5	1	5			
Bronchospasm	2	9	1	5	1		4
Cellulitis	1	2			1		2
Cerebral haematoma		1					1
Cerebrovascular accident	1	1			1		1
Chest pain	1	3		2	1		1
Chills	1	16	1	14			2
Colitis	1	1	1	1			
Condition aggravated	1	3		1	1		2
Contusion		1		1			
Cough	2	6	2	5			1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		2				2
COVID-19 pneumonia		1				1
Cyanosis		1		1		
Death		1				1
Decreased appetite	1	5	1	4		1
Dehydration		2		2		
Demyelinating polyneuropathy	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea	3	9	3	9		
Diplopia	1	1	1	1		
Discomfort		1		1		
Disease recurrence		1				1
Disseminated Bacillus Calmette-Guerin infection	1	1			1	1
Dizziness	3	23	2	20	1	3
Drug ineffective		2				2
Dysaesthesia		1		1		
Dysarthria	1	1	1	1		
Dyslalia	1	1			1	1
Dyspepsia		1		1		
Dysphagia		1		1		
Dysphonia		1		1		
Dyspnoea	5	20	3	14	2	6
Dysstasia		1		1		
Ear discomfort		1		1		
Ear pain		1				1
Embolism	1	1			1	1
Encephalitis post immunisation		1				1
Erythema	1	7	1	7		
Eye discharge	1	1	1	1		
Eye injury		1		1		
Eye irritation	1	2	1	2		
Eyelid ptosis	1	1	1	1		
Eye pruritus		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye swelling		1		1		
Face oedema		1		1		
Facial paralysis	1	2			1	2
Fall	1	1	1	1		
Fatigue	7	28	7	25		3
Feeling abnormal		1		1		
Feeling cold	1	2		1	1	1
Flank pain		1		1		
Flushing		2		2		
Gastroenteritis		1		1		
Gastrointestinal hypermotility	1	1	1	1		
Gastrointestinal motility disorder	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Haematochezia		1				1
Haemorrhage	1	1			1	1
Haemorrhagic disorder	1	1			1	1
Hallucination, visual		1				1
Headache	6	31	6	28		3
Hyperaemia		1		1		
Hyperglycaemia	3	3	2	2	1	1
Hyperhidrosis		3		3		
Hypersensitivity	1	3	1	2		1
Hypersomnia	1	1	1	1		
Hypertension	1	4	1	2		2
Hypertensive crisis		1				1
Hypertensive emergency	1	1			1	1
Hyperthermia		2		2		
Hypoaesthesia	2	3	1	1	1	2
Hypoaesthesia oral		1				1
Hypotension		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Induration	2	5	2	5		
Inflammation	3	7	3	7		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	1	1			1	1
Intussusception	1	1			1	1
Irritability	1	3	1	2		1
Joint swelling		1		1		
Laryngeal oedema		1				1
Leukopenia		1				1
Local reaction	1	2	1	2		
Loss of consciousness	1	3			1	3
Lymphadenopathy	2	4	2	4		
Malaise	3	5	3	5		
Masticatory pain		1		1		
Maternal exposure during pregnancy	1	2	1	2		
Measles	1	1			1	1
Mobility decreased		2		2		
Muscle atrophy		1		1		
Muscle spasms		2		1		1
Muscle tightness	1	1	1	1		
Muscular weakness		1		1		
Myalgia	3	18	3	17		1
Myalgia intercostal	1	1	1	1		
Myelitis transverse		1				1
Myocardial infarction	1	2			1	2
Nasal congestion	1	2	1	2		
Nausea	3	21	2	17	1	4
Neck pain	1	2	1	2		
Nervousness		1		1		
Neuritis	1	1	1	1		
Neuropathy peripheral		2				2
Neutrophil count increased	2	2	2	2		
Nodule	3	6	3	6		
Ocular hyperaemia	1	1	1	1		
Odynophagia		1		1		
Oedema	1	10	1	9		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	1	1	1		
Oropharyngeal discomfort		2		2		
Oropharyngeal pain	2	7	2	7		
Oxygen saturation decreased		1				1
Pain	3	15	3	15		
Pain in extremity	2	4	2	4		
Pallor		1		1		
Paraesthesia	2	5	2	4		1
Paraesthesia oral		2		1		1
Paralysis		1				1
Parotid gland enlargement		1		1		
Parotitis		1		1		
Periorbital oedema		1		1		
Peripheral swelling	1	1	1	1		
Peripheral vascular disorder	1	1			1	1
Petit mal epilepsy		1				1
Pharyngeal erythema	1	1	1	1		
Pharyngeal paraesthesia		1				1
Photophobia		1		1		
Platelet count increased	2	2	2	2		
Prurigo		1		1		
Pruritus	3	11	3	10		1
Pyrexia	2	14	2	14		
Rash	4	11	4	9		2
Rash macular	1	1	1	1		
Respiratory distress	5	21			5	21
Respiratory failure	1	2			1	2
Rhinalgia		1		1		
Rhinorrhoea	1	8	1	8		
Seizure		3				3
Sensitive skin	4	11	4	11		
Skin burning sensation		1		1		
Skin discolouration	1	1	1	1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sneezing		1		1		
Somnolence		2		2		
Speech disorder		1		1		
Swollen tongue	1	1	1	1		
Syncope	1	1			1	1
Tachycardia	5	16	4	13	1	3
Tachypnoea	1	2			1	2
Throat irritation	1	2	1	2		
Thrombosis	2	2			2	2
Tinnitus		1		1		
Tongue oedema		1				1
Transaminases increased		1				1
Tremor		1		1		
Urticaria		1		1		
Vaccination site cellulitis		1		1		
Vaccination site discomfort	1	2	1	2		
Vaccination site erythema	2	3	2	3		
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypersensitivity	1	2	1	2		
Vaccination site induration	1	3	1	3		
Vaccination site inflammation		1		1		
Vaccination site nodule		2		2		
Vaccination site oedema	1	2	1	2		
Vaccination site pain	3	12	3	12		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
Vascular test abnormal		1		1		
Vision blurred		1				1
Vomiting	4	13	3	9	1	4
Wheezing	1	3		1	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong technique in product usage process	1	1	1	1		
	186	665	141	509	45	156

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**NETHERLANDS**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	4	2	3		1
Abdominal pain	1	1			1	1
Abdominal pain upper		1		1		
Abnormal behaviour	1	1			1	1
Abnormal faeces		1				1
Acute abdomen		1				1
Acute cardiac event	1	1			1	1
Acute coronary syndrome		1				1
Acute myocardial infarction	3	5			3	5
Acute respiratory failure		1				1
Ageusia	1	2	1	2		
Altered state of consciousness		1				1
Amnesia	1	1			1	1
Amylase increased	1	1	1	1		
Anaphylactic reaction	1	3			1	3
Anaphylactic shock		1				1
Aneurysm		1				1
Angina pectoris	1	2			1	2
Angina unstable		1				1
Angioedema		4				4
Anosmia		1		1		
Anxiety		1		1		
Aortic dissection	1	1			1	1
Aortic valve stenosis		2				2
Apallic syndrome	1	2			1	2
Apathy		1				1
Aphasia		2				2
Aphonia		1				1
Arrhythmia	3	5			3	5
Arterial thrombosis		1				1
Arthralgia	9	24	7	19	2	5
Aspartate aminotransferase increased	1	1	1	1		
Aspiration		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	6	2	3	1	3
Asthma		3				3
Atrial fibrillation		6				6
Atrial flutter	1	1			1	1
Atrioventricular block complete	1	1			1	1
Azotaemia		2				2
Back pain		2		2		
Balance disorder	1	2	1	2		
Basilar artery thrombosis	1	1			1	1
Basophil count decreased	1	1	1	1		
Bedridden		1		1		
Blindness		3				3
Blood alcohol decreased	1	1	1	1		
Blood alkaline phosphatase increased	1	1	1	1		
Blood bicarbonate decreased	1	1	1	1		
Blood bilirubin increased	1	2	1	2		
Blood calcium decreased	1	1	1	1		
Blood creatinine increased	1	2	1	2		
Blood glucose decreased	1	1	1	1		
Blood glucose fluctuation		1		1		
Blood glucose increased	2	5	2	4		1
Blood lactate dehydrogenase increased	1	1	1	1		
Blood potassium decreased	1	1	1	1		
Blood pressure decreased	1	3			1	3
Blood pressure increased	2	5	1	2	1	3
Blood sodium decreased	1	1	1	1		
Blood urea increased	1	2	1	2		
Blood uric acid increased		1		1		
Body temperature decreased		2				2
Body temperature increased	1	5		4	1	1
Bradycardia		1				1
Bradykinesia	1	1	1	1		
Bradyphrenia	2	3	2	2		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		1				1
Burning sensation		1		1		
Cachexia	1	3			1	3
Candida infection		1				1
Cardiac arrest	2	9			2	9
Cardiac asthma	2	3			2	3
Cardiac death	1	3			1	3
Cardiac disorder	1	3			1	3
Cardiac failure	6	23			6	23
Cardiac failure acute		2				2
Cardiac failure congestive		1				1
Cardiogenic shock	1	3			1	3
Carotid artery thrombosis	1	1			1	1
Cerebral amyloid angiopathy	1	1			1	1
Cerebral haemorrhage	3	5			3	5
Cerebral infarction	4	6			4	6
Cerebral ischaemia	1	2			1	2
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	2	13			2	13
Cerebrovascular disorder		1				1
Chest injury	1	1			1	1
Chest pain	4	7	2	3	2	4
Chills	12	47	9	34	3	13
Choking		1				1
Choking sensation		1				1
Chorea		1				1
Chronic obstructive pulmonary disease	1	4	1	1		3
Circulatory collapse		3				3
Coagulopathy	1	1	1	1		
Cognitive disorder		1				1
Cold sweat	1	2			1	2
Coma hepatic		1				1
Condition aggravated	1	7		2	1	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	5	9	1	4	4	5
Consciousness fluctuating		1				1
Constipation		1				1
Coordination abnormal		2		1		1
Coronary artery disease	1	1			1	1
Cough		4		3		1
COVID-19	3	11		1	3	10
COVID-19 pneumonia		1				1
C-reactive protein increased	4	4	3	3	1	1
Cyanosis		2				2
Cystitis	2	4		2	2	2
Cystitis noninfective	1	1			1	1
Deafness unilateral	1	1			1	1
Death	3	23			3	23
Decreased appetite	1	10	1	7		3
Deep vein thrombosis	9	13			9	13
Dehydration	1	4		1	1	3
Delirium	7	13			7	13
Delusion		1		1		
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	2	8			2	8
Depressed mood	2	2	2	2		
Diabetes mellitus inadequate control		1				1
Diarrhoea	3	8	2	6	1	2
Diplopia	2	3	2	3		
Disease recurrence	4	5			4	5
Disorientation	1	1			1	1
Dissociation		1		1		
Disturbance in attention		2		2		
Dizziness	5	13	3	11	2	2
Drug ineffective	2	3			2	3
Dry mouth		2		2		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dysarthria		3		2		1	
Dysphagia	2	8		1	2	7	
Dysphonia		1				1	
Dyspnoea	10	38	2	11	8	27	
Dyspnoea exertional	2	2			2	2	
Dysstasia	1	2		1	1	1	
Ear pain		1		1			
Ecchymosis	1	2			1	2	
Electrolyte imbalance		1				1	
Encephalitis enteroviral		1				1	
Endocarditis		1				1	
Endocrine ophthalmopathy	1	1			1	1	
Eosinophil count decreased	1	1	1	1			
Epilepsy	5	11			5	11	
Epistaxis	1	2			1	2	
Erythema		2		2			
Extensive swelling of vaccinated limb	1	12	1	12			
Eye disorder		1		1			
Eye symptom	1	1	1	1			
Facial bones fracture	1	1			1	1	
Facial paralysis	3	4			3	4	
Fall	6	12	2	4	4	8	
Fatigue	32	94	21	62	11	32	
Febrile convulsion	1	1	1	1			
Feeding disorder	2	3	1	2	1	1	
Feeling abnormal	1	3	1	3			
Feeling cold		2		2			
Feeling hot		3		2		1	
Feeling jittery		1		1			
Fibrin D dimer increased	2	2	1	1	1	1	
Fluid intake reduced	1	3		1	1	2	
Fluid retention		1		1			
Flushing		1		1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Fracture		1				1	
Gait disturbance	1	1			1	1	
Gait inability	1	1			1	1	
Gamma-glutamyltransferase increased	1	2	1	2			
Gastrointestinal haemorrhage	1	3			1	3	
Gastrointestinal obstruction		1				1	
Gaze palsy		1				1	
Generalised tonic-clonic seizure		2				2	
General physical health deterioration	5	11		3	5	8	
Glomerular filtration rate decreased	1	3	1	3			
Glomerulonephritis minimal lesion		1				1	
Glucose tolerance impaired		1		1			
Haematemesis		1				1	
Haematocrit decreased	2	2	2	2			
Haematoma	1	1			1	1	
Haemoglobin decreased	4	4	2	2	2	2	
Haemophagocytic lymphohistiocytosis	1	1			1	1	
Haemophilia		1				1	
Haemorrhoids		1		1			
Hallucination		1				1	
Hand deformity		1				1	
Hand fracture		1				1	
Headache	17	46	15	42	2	4	
Heart rate decreased		1		1			
Heart rate increased		4				4	
Hemianaesthesia		1				1	
Hemiparesis	3	6			3	6	
Hemiplegia		1				1	
Hepatitis C		1				1	
Hernia pain		1		1			
Herpes zoster		1		1			
Herpes zoster reactivation		1				1	
Hip fracture	1	2			1	2	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperaesthesia teeth		1		1			
Hyperglycaemia		1					1
Hyperhidrosis	1	6	1	4			2
Hypernatraemia		2					2
Hyperpyrexia	2	5			2		5
Hypersensitivity	1	1	1	1			
Hypersensitivity vasculitis	2	2			2		2
Hypersomnia		2		2			
Hypertension	2	7	2	2			5
Hypertensive urgency	1	1			1		1
Hypertriglyceridaemia	1	1			1		1
Hyperventilation	1	1			1		1
Hypoglycaemia		2					2
Hypokalaemia		1					1
Hypokinesia	1	1	1	1			
Hypophagia		5		1			4
Hypotension	4	7	1	1	3		6
Hypothermia		1					1
Hypoxia	2	7			2		7
Illness		1					1
Immune thrombocytopenia		1					1
Inappropriate schedule of product administration		1		1			
Incontinence	1	2			1		2
Increased tendency to bruise		1		1			
Infection	1	4			1		4
Inflammation	1	1			1		1
Inflammatory marker increased		1					1
Influenza like illness		2		1			1
Injection site pruritus	1	1	1	1			
International normalised ratio increased	1	1			1		1
Interstitial lung disease		1					1
Intestinal haemorrhage		1					1
Intestinal ischaemia		1					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intestinal obstruction	1	1			1	1
Ischaemic cerebral infarction	4	9			4	9
Ischaemic stroke	1	1			1	1
IVth nerve paralysis	1	1			1	1
Jaundice		1				1
Kidney infection	1	1			1	1
Lacrimation increased	1	1	1	1		
Lacunar infarction	1	1			1	1
Left ventricular dysfunction		1				1
Left ventricular failure	1	1			1	1
Left ventricular hypertrophy	1	1			1	1
Listless	2	3	2	3		
Livedo reticularis		1				1
Loss of consciousness	4	6			4	6
Loss of personal independence in daily activities		3		2		1
Lung disorder		3		1		2
Lymphadenopathy	2	3	2	3		
Lymph node pain		1		1		
Lymphocyte count decreased	2	2	1	1	1	1
Malaise	42	106	22	53	20	53
Melaena		1				1
Memory impairment		1		1		
Mental impairment	2	3			2	3
Mesenteric artery thrombosis		1				1
Migraine	1	1	1	1		
Mobility decreased	1	3	1	2		1
Monoplegia	1	1			1	1
Movement disorder	1	1			1	1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis		1				1
Muscle contractions involuntary	1	1	1	1		
Muscle spasms	1	2		1	1	1
Muscle twitching		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness	3	5	2	4	1	1
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal disorder	1	1			1	1
Musculoskeletal stiffness	1	2	1	2		
Myalgia	23	55	20	46	3	9
Myelodysplastic syndrome		1				1
Myocardial infarction	6	10			6	10
Nasal congestion	2	2	1	1	1	1
Nasopharyngitis		3		2		1
Nausea	16	49	12	32	4	17
Neck pain	1	1	1	1		
Nephrotic syndrome		1				1
Neuritis		1				1
Neurologic neglect syndrome	1	1			1	1
Neuropathy peripheral	4	4			4	4
Neutrophil count decreased	1	1			1	1
Neutrophil count increased	1	1	1	1		
Nystagmus		1		1		
Ocular discomfort		1		1		
Oedema		1		1		
Oedema peripheral	4	4	1	1	3	3
Oliguria		1		1		
Optic neuritis		1				1
Oropharyngeal pain		3		3		
Oxygen saturation abnormal	1	2			1	2
Oxygen saturation decreased	3	14			3	14
Pain	2	5	1	2	1	3
Pain in extremity	2	3	1	2	1	1
Pallor	1	4		2	1	2
Palpitations	2	4	2	4		
Pancytopenia	1	1			1	1
Paraesthesia	1	1	1	1		
Paraesthesia oral		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis	1	1			1	1
Parkinson's disease	2	2			2	2
Pemphigoid		1				1
Peripheral coldness		3		2		1
Peripheral swelling		1		1		
Peroneal nerve palsy		2		1		1
Petechiae	2	2	2	2		
Pharyngeal oedema		1				1
Pharyngeal swelling	1	1			1	1
Platelet count decreased	4	5	3	4	1	1
Pleural effusion	2	2			2	2
Pneumonia	9	17			9	17
Pneumonia aspiration	1	5			1	5
Pneumonia bacterial	1	1			1	1
Polyuria		1		1		
Presyncope		2				2
Productive cough	1	2		1	1	1
Prolapse		1		1		
Prothrombin time ratio increased	1	1	1	1		
Pulmonary embolism	10	13			10	13
Pulmonary haemorrhage		1				1
Pulmonary hypertension	1	1			1	1
Pulmonary oedema	1	1			1	1
Pupillary disorder		1		1		
Pyelonephritis	1	1			1	1
Pyrexia	20	62	12	26	8	36
Rash	1	1	1	1		
Rash erythematous		1		1		
Rash pruritic		1		1		
Raynaud's phenomenon		1		1		
Rectal prolapse		1				1
Red blood cell count decreased	2	2	2	2		
Renal disorder	1	2	1	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure	1	2			1	2
Renal impairment		2				2
Respiration abnormal		1				1
Respiratory disorder		1				1
Respiratory failure	2	7			2	7
Respiratory rate increased	1	3		1	1	2
Respiratory tract infection		1				1
Restlessness	1	4		3	1	1
Retching		1				1
Rheumatoid arthritis		1				1
Rhinitis		1		1		
SARS-CoV-2 test positive		1				1
Seizure	2	3			2	3
Sepsis		1				1
Serum ferritin abnormal	1	1			1	1
Shock		2				2
Sinus bradycardia	1	1			1	1
Sinus tachycardia		1		1		
Skin burning sensation		1		1		
Skin discolouration	1	1			1	1
Sleep disorder	1	1	1	1		
Slow speech	1	1	1	1		
Small intestinal obstruction		1				1
Soft tissue infection		1				1
Somnolence	1	9		4	1	5
Speech disorder	2	2			2	2
Sputum increased		1		1		
Status epilepticus		1				1
Stridor	1	1			1	1
Subdural haematoma	1	1			1	1
Sudden cardiac death	1	3			1	3
Sudden death	3	11			3	11
Sudden hearing loss	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19		2		1		1
Suspiciousness		1		1		
Swelling face		1		1		
Swelling of eyelid	1	1	1	1		
Swollen tongue		1				1
Syncope	8	11			8	11
Tachycardia		3		1		2
Tachypnoea		1		1		
Thirst decreased		1				1
Throat tightness		1		1		
Thrombocytopenia	1	1			1	1
Thrombophlebitis	1	2	1	1		1
Thrombosis	6	8			6	8
Thrombosis mesenteric vessel		1				1
Thunderclap headache		1				1
Tinnitus		1		1		
Tongue oedema		1				1
Torticollis		1		1		
Transient aphasia	1	1			1	1
Transient ischaemic attack	9	9			9	9
Tremor	1	3		2	1	1
Troponin increased	1	1			1	1
Unresponsive to stimuli	1	3			1	3
Upper limb fracture		1				1
Urinary incontinence	2	2	1	1	1	1
Urinary retention	1	2			1	2
Urinary tract infection	2	3	1	1	1	2
Urosepsis	1	4			1	4
Urticaria	1	3	1	3		
Vaccination site bruising	4	7	4	7		
Vaccination site erythema	1	14	1	14		
Vaccination site haematoma	3	9	3	9		
Vaccination site inflammation	5	15	5	15		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	9	37	9	35		2
Vaccination site papule		1		1		
Vaccination site pruritus		6		6		
Vaccination site rash		1		1		
Vaccination site swelling	5	22	5	22		
Vaccination site warmth	3	18	3	18		
Vasculitis	1	1	1	1		
Ventricular fibrillation		1				1
Vertigo		1		1		
Viral infection	1	2			1	2
Vision blurred	2	2	2	2		
Vomiting	4	20	2	5	2	15
Weight decreased		4		2		2
Weight increased		1		1		
White blood cell count decreased	1	1	1	1		
White blood cell count increased	1	1	1	1		
Wound		1		1		
Wrist fracture		1				1
	611	1,664	261	752	350	912

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Country Where Event Occurred  
**NEW ZEALAND**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia	1	3	1	3
Nausea	1	1	1	1
	2	4	2	4

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Country Where Event Occurred

**NORWAY**

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\* AE=Adverse Event

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	4		1	1	3
Abdominal pain upper		4				4
Abnormal behaviour		1				1
Acute kidney injury	1	2			1	2
Acute myocardial infarction		4				4
Aggression	1	1	1	1		
Agitation		1				1
Allergy to vaccine		2				2
Altered state of consciousness		6				6
Amnesia		1				1
Anal incontinence		1				1
Anaphylactic reaction		3				3
Angioedema		1				1
Anxiety		2		1		1
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Apathy		2				2
Aphasia		2				2
Apnoea		2				2
Apnoeic attack		1				1
Arrhythmia	1	1			1	1
Arterial haemorrhage		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	2	6	2	4		2
Arthritis		1		1		
Asthenia	2	9	1	4	1	5
Atelectasis		1				1
Atrial flutter		1				1
Atrioventricular block first degree		1				1
Axillary mass		1				1
Axillary pain		1				1
Back pain	1	8		4	1	4
Bacterial sepsis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		2				2
Bedridden		4				4
Blindness	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose fluctuation		3		3		
Blood glucose increased		1		1		
Blood pressure decreased		4				4
Blood pressure diastolic decreased		1		1		
Body temperature decreased		1		1		
Bone pain	1	2	1	1		1
Bradycardia		3				3
Breast enlargement		1		1		
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchitis		1		1		
Cardiac arrest	1	2			1	2
Cardiac failure		4				4
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1				1
Carotid arteriosclerosis		1		1		
Cerebral artery embolism	1	1			1	1
Cerebral haemorrhage	2	5			2	5
Cerebral infarction	3	6			3	6
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	12			1	12
Cerebrovascular disorder		1				1
Chest pain	3	9	2	2	1	7
Chills	1	9	1	6		3
Cholecystitis		1				1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease	1	6			1	6
Circulatory collapse	2	3			2	3
Cognitive disorder		2		1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		4				4
Coma		1				1
Communication disorder		1		1		
Concomitant disease aggravated		1				1
Concussion	1	1			1	1
Condition aggravated		4		1		3
Confusional state		20		5		15
Conjunctivitis		1		1		
Constipation		1		1		
Coordination abnormal		1				1
Coronary artery occlusion		1				1
Cough	1	8		3	1	5
COVID-19	1	1			1	1
C-reactive protein increased	4	14	1	3	3	11
Cyanosis		2				2
Cystic lung disease		1		1		
Death	2	24			2	24
Decreased appetite		8		2		6
Decubitus ulcer		1		1		
Deep vein thrombosis	2	2			2	2
Defaecation disorder		1				1
Dehydration		1		1		
Delirium		3				3
Dementia		2				2
Dementia Alzheimer's type		1				1
Demyelinating polyneuropathy	1	1			1	1
Depressed level of consciousness	1	5			1	5
Depressed mood		1		1		
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea	2	9	1	2	1	7
Disease recurrence	1	3			1	3
Diverticulitis		1				1
Dizziness	4	11	1	5	3	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drooling		1		1		
Drug interaction		1				1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry mouth		1				1
Dry skin		1		1		
Dysarthria	1	4	1	1		3
Dysgeusia		1		1		
Dysphagia	1	5	1	1		4
Dysphonia		2		2		
Dyspnoea	5	31	2	5	3	26
Dyspnoea at rest		1				1
Ear discomfort	1	1	1	1		
Ear pain		1		1		
Ear swelling		1		1		
Eczema		1				1
Emphysema		1		1		
Epilepsy		3				3
Erysipelas	1	1			1	1
Erythema		2		1		1
Extrasystoles	1	1			1	1
Facial paralysis		1				1
Facial paresis		2				2
Faeces discoloured		1				1
Fall	3	11	1	3	2	8
Fatigue	1	31	1	15		16
Feeling abnormal		2		1		1
Feeling cold		1		1		
Feeling hot		2		1		1
Femur fracture		1				1
Flatulence		1		1		
Foaming at mouth		1		1		
Food refusal		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Fracture		1				1	
Gait disturbance	1	2	1	1			1
Gastric haemorrhage	1	1			1		1
Gastrointestinal haemorrhage		2					2
General physical health deterioration	8	44	3	10	5		34
General symptom		1					1
Giant cell arteritis	1	1			1		1
Glomerulonephritis chronic		1					1
Glomerulonephritis minimal lesion		1					1
Guillain-Barre syndrome	1	1			1		1
Haematemesis	1	2			1		2
Haematoma		2					2
Haemoglobin decreased	1	3			1		3
Haemorrhage		1					1
Haemothorax		1					1
Hallucination		4					4
Headache	2	13		8	2		5
Heart rate increased	1	7		2	1		5
Heart rate irregular		1					1
Hemianopia	1	1			1		1
Hemiparesis		2					2
Hemiplegia	1	2			1		2
Hyperaesthesia		1					1
Hypercapnia	1	1			1		1
Hyperglycaemia	1	2	1	1			1
Hyperhidrosis		2		2			
Hyperkalaemia		1					1
Hypertension		3		3			
Hyperventilation		3		3			
Hypokinesia		2		1			1
Hypophagia		1					1
Hypotension	1	11	1	1			10
Hypoxia		3					3

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\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness	1	1	1	1		
Immune-mediated adverse reaction	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1		1		
Increased bronchial secretion		1				1
Infection		7		1		6
Infective exacerbation of chronic obstructive airways disease		1				1
Inflammation		1				1
Influenza like illness	1	3	1	1		2
International normalised ratio increased		1				1
Interstitial lung disease		1				1
Irritability postvaccinal		1				1
Ischaemic stroke		1				1
Joint swelling		1		1		
Kidney fibrosis		1				1
Left ventricular failure		1				1
Lethargy		1		1		
Leukocytosis		2		1		1
Local reaction		1				1
Loss of consciousness	1	7			1	7
Lung consolidation	1	1			1	1
Lung opacity	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy		1		1		
Malaise	1	11		5	1	6
Malignant hypertension		1				1
Mania		1				1
Marasmus		1				1
Mediastinal haemorrhage		1				1
Melaena		1				1
Metastases to peritoneum		1				1
Middle insomnia		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Moaning	1	1			1	1
Mobility decreased		1		1		
Monoparesis		1				1
Motor dysfunction		1		1		
Multiple fractures		1				1
Muscle spasms		3		1		2
Muscular weakness	1	2	1	1		1
Musculoskeletal stiffness		5		3		2
Myalgia	2	8	1	4	1	4
Myocardial infarction	1	2			1	2
Myopia	1	1			1	1
Nasal pruritus		1				1
Nasopharyngitis		1				1
Nausea	3	22	1	10	2	12
Neck pain		2		1		1
Neuropathy peripheral		1				1
Neutropenia		1				1
N-terminal prohormone brain natriuretic peptide increased	1	2			1	2
Obstructive airways disorder		1				1
Oedema peripheral		3		2		1
Ophthalmic herpes zoster		1				1
Oral pruritus		1				1
Oropharyngeal pain		2		1		1
Orthostatic hypotension	1	1			1	1
Oxygen saturation decreased	2	12	1	1	1	11
Pain	2	8	2	6		2
Pain in extremity		3		3		
Pallor		3				3
Paralysis		1				1
Paresis	1	1	1	1		
Pericardial effusion		2				2
Pericardial haemorrhage		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericarditis	1	2			1	2
Peripheral coldness		1				1
Peripheral swelling	1	4	1	2		2
Personality change		1				1
Petechiae	1	1			1	1
Photophobia		1				1
Pleural effusion		2				2
Pleurisy		1				1
Pneumonia	2	17			2	17
Pneumonia aspiration		1				1
Pneumonia bacterial	1	1			1	1
Pneumonitis	1	1			1	1
Presyncope	2	5			2	5
Productive cough		4				4
Pruritus		5		1		4
Psychomotor hyperactivity		1				1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	2	4			2	4
Pulmonary oedema		1				1
Pupil fixed		2				2
Pyelonephritis		1				1
Pyrexia	6	38	3	11	3	27
Rales		3		1		2
Rash	1	6		4	1	2
Rash erythematous		2		2		
Rash pruritic		1		1		
Red blood cell sedimentation rate increased	1	1	1	1		
Renal impairment		1				1
Respiratory acidosis	1	1			1	1
Respiratory arrest		4				4
Respiratory disorder		1				1
Respiratory failure	4	9			4	9
Respiratory rate increased	1	7	1	4		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract congestion		1				1
Respiratory tract infection		1				1
Restlessness		7		3		4
Retching		2		1		1
Rhinorrhoea		2		2		
Secretion discharge		2				2
Sepsis		2				2
Shock		1				1
Skin haemorrhage		1		1		
Snoring	1	1			1	1
Somnolence		9		3		6
Speech disorder		3		2		1
Sputum increased		1		1		
Stridor		1				1
Sudden death		7				7
Swelling face		1				1
Syncope	3	12			3	12
Tachycardia	1	4	1	1		3
Tachypnoea		1				1
Tendon pain		1		1		
Terminal state		1				1
Thirst		1				1
Throat tightness		1				1
Thrombocytopenia	2	2			2	2
Thrombophlebitis	2	2	1	1	1	1
Thrombotic stroke		1				1
Transfusion reaction	1	1	1	1		
Transient ischaemic attack	1	2			1	2
Tremor		4		1		3
Troponin increased		1				1
Tubulointerstitial nephritis		1				1
Unresponsive to stimuli	1	2			1	2
Urinary incontinence		2		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary retention		2				2
Urinary tract infection		3		3		
Urticaria		3				3
Vaccination failure	1	1			1	1
Vaccination site erythema		2		1		1
Vaccination site pain		7		5		2
Vaccination site pruritus		1				1
Vaccination site reaction		2		1		1
Vaccination site swelling		2				2
Vaccination site warmth		1				1
Vaccine breakthrough infection	1	1			1	1
Ventricular tachycardia		1				1
Vertigo	1	1			1	1
Vision blurred	2	2			2	2
Visual impairment	1	1			1	1
Vomiting	2	22	1	7	1	15
Weight decreased		1		1		
Wheezing	1	2			1	2
	156	965	44	254	112	711

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred  
**OMAN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Therapeutic response unexpected		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PANAMA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Rash erythematous		1		1
Rash pruritic		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PERU**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Arthralgia	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	1			1	1
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Pain	1	1	1	1		
Pyrexia	1	1	1	1		
	8	8	6	6	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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Country Where Event Occurred  
**POLAND**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	2			1	2
Abdominal pain upper		1		1		
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Ageusia		1		1		
Allergic reaction to excipient		2		2		
Anaphylactic reaction		1				1
Angioedema	1	1			1	1
Angiopathy		1				1
Anosmia		1		1		
Anuria		2				2
Anxiety		1		1		
Apnoea	1	1			1	1
Arteriosclerosis	1	1	1	1		
Arthralgia	1	7		5	1	2
Asthenia	4	11	2	6	2	5
Atrial fibrillation	1	2			1	2
Atrial flutter	1	2			1	2
Back pain		1		1		
Balance disorder		1		1		
Basophil count decreased		1		1		
Bladder cancer		1				1
Bladder disorder		1		1		
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased		2				2
Blood pressure increased	1	2			1	2
Blood smear test abnormal		1		1		
Body temperature decreased		1		1		
Body temperature increased	1	2		1	1	1
Bone density decreased	1	1	1	1		
Bone pain	1	1			1	1
Brain oedema		1				1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation		2		2		
Bursitis		1		1		
Cardiac arrest	3	5			3	5
Cardiogenic shock		1				1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest discomfort		2		2		
Chest pain		1				1
Chills	1	3		2	1	1
Choking sensation		1				1
Coma		1				1
Contusion	1	2	1	1		1
Cough	2	3			2	3
COVID-19	3	11		1	3	10
C-reactive protein increased		1		1		
Death	3	7			3	7
Decreased activity		1		1		
Decreased appetite		1				1
Depressed level of consciousness		1				1
Diarrhoea	3	3	2	2	1	1
Disease recurrence		1				1
Dizziness		3		3		
Drug hypersensitivity	1	1			1	1
Drug ineffective	2	5			2	5
Dysarthria	1	1			1	1
Dyspnoea	2	4		1	2	3
Emphysema	1	1	1	1		
Eosinophil count decreased		1		1		
Erythema	2	3			2	3
Exposure during pregnancy	1	1	1	1		
Faeces soft	1	1			1	1
Fall	2	3			2	3
Fatigue		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot		1		1		
Flatulence	1	1			1	1
Gait disturbance		1				1
General physical health deterioration		1				1
Haematuria		1		1		
Haemoptysis	1	1	1	1		
Haemorrhagic diathesis	1	1			1	1
Headache	1	6		4	1	2
Head discomfort		1		1		
Head injury	1	1			1	1
Heart rate increased	1	1			1	1
Hyperhidrosis		4		3		1
Hyperpyrexia	2	2			2	2
Hypoaesthesia		1		1		
Hypotonia		1				1
Hypotonic-hyporesponsive episode	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1		1		
Inflammation		3		2		1
Influenza like illness		3		2		1
Iritis		1		1		
Ischaemic stroke	1	1			1	1
Joint effusion		1		1		
Joint injury		1				1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling		2		1		1
Lethargy	1	1			1	1
Lividity		1				1
Loss of consciousness	1	4			1	4
Lung disorder	1	1	1	1		
Lung opacity	1	1	1	1		
Lymphadenopathy		2		2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Lymphocyte count decreased		1		1			
Malaise		4		2			2
Monocyte count decreased		1		1			
Muscular weakness		1					1
Musculoskeletal chest pain		1		1			
Musculoskeletal pain	1	1			1		1
Musculoskeletal stiffness		1		1			
Myalgia	1	6		4	1		2
Nausea	1	3		1	1		2
Neck pain		1		1			
Neutrophil count increased		1		1			
Off label use		2		2			
Oliguria		1		1			
Oxygen saturation decreased	1	1			1		1
Pain		3		3			
Pain in extremity	3	11	3	11			
Paraparesis		1					1
Parosmia	1	2	1	2			
Peripheral swelling	2	2	1	1	1		1
Phlebitis	1	1	1	1			
Photophobia		1		1			
Pleural effusion		1		1			
Pneumonia	1	2			1		2
Pneumonia viral	1	1			1		1
Poor quality product administered		1		1			
Presyncope	1	1			1		1
Product use issue		1		1			
Protein urine present		2		2			
Pruritus	1	1			1		1
Pulmonary calcification	1	1	1	1			
Pulmonary congestion	1	1			1		1
Pulmonary mass	1	1	1	1			
Pyrexia	1	9		7	1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	1	1	1	1		
Rash erythematous	1	2		1	1	1
Rash macular		1		1		
Reaction to excipient		1		1		
Renal pain		1		1		
Respiratory failure		1				1
Rhinorrhoea		2		2		
Speech disorder		1		1		
Sudden cardiac death	1	1			1	1
Syncope	2	3			2	3
Synovial disorder		1		1		
Systemic lupus erythematosus		1				1
Tachycardia	1	2			1	2
Tachypnoea		1				1
Taste disorder		1		1		
Therapeutic response unexpected	1	2	1	2		
Thrombophlebitis	1	1	1	1		
Thrombosis		1				1
Tinnitus	1	1			1	1
Transaminases increased		1				1
Tremor		1		1		
Urticaria	2	2	1	1	1	1
Vaccination complication		1		1		
Vaccination failure		2				2
Vaccination site extravasation		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	1	7		6	1	1
Vaccination site pruritus		1		1		
Vaccination site reaction	1	1			1	1
Vaccination site warmth		1		1		
Venous thrombosis	1	1			1	1
Vision blurred		1		1		
Vomiting	1	3	1	1		2

\* I=Interval, C=Cumulative  
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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	95	301	25	152	70	149

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PORTUGAL**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3			1	3
Abdominal pain upper	1	2	1	1		1
Aborted pregnancy		1				1
Acidosis	1	1			1	1
Acute myocardial infarction		2				2
Altered state of consciousness	1	1			1	1
Anaphylactic reaction	1	4			1	4
Anaphylactoid reaction		1				1
Angioedema		1				1
Anxiety		1		1		
Apathy	1	1			1	1
Arrhythmia		3				3
Arteriosclerosis	1	1	1	1		
Arthralgia	4	17			4	17
Asthenia	2	6			2	6
Atrial fibrillation	1	1			1	1
Atrioventricular block complete		2				2
Autonomic nervous system imbalance		1				1
Axillary pain		3		1		2
Back pain		1				1
Bacterial infection		1				1
Balance disorder		1				1
Bedridden		1				1
Blood glucose fluctuation		1		1		
Blood pressure decreased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure increased		1				1
Blood pressure systolic increased		1		1		
Blood thyroid stimulating hormone increased		1				1
Body temperature increased		1				1
Bradycardia	1	3			1	3
Bradyphrenia		1				1
Bradypnoea	1	1			1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1				1
Breast swelling	1	1			1	1
Bronchospasm	1	5			1	5
Cardiac failure		1				1
Cardio-respiratory arrest		2				2
Cerebrovascular accident	1	2			1	2
Chest discomfort		5		1		4
Chest pain		2				2
Chills	4	20	1	2	3	18
Choking sensation		1				1
Cholinergic syndrome		1				1
Circumoral oedema		1				1
Computerised tomogram thorax abnormal		1		1		
Condition aggravated	1	3			1	3
Cough	3	8			3	8
COVID-19	1	6		2	1	4
COVID-19 pneumonia		1				1
Crohn's disease		1				1
Cutaneous vasculitis		1				1
Cyanosis		1				1
Deafness		1				1
Deafness neurosensory	1	1			1	1
Deafness unilateral	1	2			1	2
Death	3	4			3	4
Decreased appetite	4	8			4	8
Deep vein thrombosis	1	1			1	1
Diarrhoea	1	13		1	1	12
Diplopia	1	1	1	1		
Discomfort	1	1			1	1
Disease recurrence		1				1
Disorientation	2	2			2	2
Dizziness	2	16		2	2	14
Drug-induced liver injury	1	1			1	1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective		1				1
Drug interaction	1	1			1	1
Dry mouth		2				2
Dry skin	1	1			1	1
Dysgeusia		2		1		1
Dysphagia		1				1
Dysphonia		1				1
Dyspnoea	5	13		1	5	12
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	1			1	1
Ecchymosis	1	1			1	1
Epistaxis	1	1			1	1
Erythema	1	5		1	1	4
Exposure during pregnancy		1		1		
Extrasystoles		1		1		
Eye irritation		1		1		
Face oedema		1				1
Fall		1		1		
Fatigue	8	23			8	23
Feeling abnormal		1				1
Feeling cold	1	2	1	1		1
Feeling hot	1	3	1	1		2
Fibrin D dimer increased	2	2	2	2		
Flushing		1		1		
Gait inability	1	1			1	1
Gastric disorder		1				1
Generalised tonic-clonic seizure		1				1
Glossodynia		1		1		
Haematoma	1	1			1	1
Haemorrhagic transformation stroke	1	1			1	1
Headache	8	52	2	4	6	48
Head discomfort	1	1	1	1		
Heart rate decreased		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparesis	1	1			1	1
Hydrocephalus	1	1			1	1
Hyperglycaemia		3				3
Hyperhidrosis	2	3			2	3
Hyperlactacidaemia	1	1			1	1
Hypersensitivity		1				1
Hypertension	1	5			1	5
Hypertensive crisis		1				1
Hyperthermia		1				1
Hypoacusis		2				2
Hypoaesthesia		1				1
Hypoaesthesia oral		1		1		
Hypoglycaemia		1				1
Hypopnoea	1	1			1	1
Hypotension		4				4
Hypothyroidism		1				1
Impetigo	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		2		2		
Influenza like illness		1		1		
International normalised ratio increased	1	1			1	1
Ischaemic stroke	1	1			1	1
Lacunar stroke	1	1			1	1
Laryngeal oedema		1				1
Leukaemoid reaction		1				1
Limb mass		1		1		
Lip oedema	1	3	1	1		2
Localised oedema		2				2
Loss of personal independence in daily activities		1				1
Lung infiltration	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	6	21	2	4	4	17
Lymphoedema		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphoproliferative disorder	1	1			1	1
Malaise	2	11			2	11
Migraine	2	2	1	1	1	1
Mobility decreased	1	1			1	1
Monocyte count increased	1	1	1	1		
Movement disorder	1	1	1	1		
Muscle fatigue	1	2		1	1	1
Muscle rigidity		1				1
Muscular weakness	2	4	1	1	1	3
Musculoskeletal disorder	1	1			1	1
Musculoskeletal stiffness		3		1		2
Myalgia	7	48		4	7	44
Myalgia intercostal		1				1
Myocarditis		1				1
Myoclonus		1				1
Nasal congestion		1				1
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction		1				1
Nausea	8	23	2	3	6	20
Night sweats		2				2
Occupational exposure to SARS-CoV-2		1		1		
Odynophagia		2				2
Oedema peripheral	1	2			1	2
Off label use		3		3		
Oropharyngeal discomfort		3				3
Overdose		1		1		
Oxygen saturation decreased	3	4			3	4
Pain	2	9	1	3	1	6
Pain in extremity	1	8		2	1	6
Pain in jaw		1				1
Pallor		1				1
Palmar-plantar erythrodysesthesia syndrome		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		3		1		2
Paraesthesia		5		1		4
Paraesthesia oral		2				2
Paralysis		1				1
Perineal pain		1				1
Peripheral artery occlusion	1	1			1	1
Peripheral artery stenosis	1	1			1	1
Peripheral coldness		1				1
Phlebitis		1				1
Platelet count increased	1	1	1	1		
PO2 decreased	1	1			1	1
Postural orthostatic tachycardia syndrome		1				1
Presyncope		5				5
Product use issue		3		3		
Pruritus	1	9	1	3		6
Pulmonary embolism	3	3			3	3
Purpura		2				2
Pyrexia	7	41	1	4	6	37
Rash	3	12	1	1	2	11
Rash erythematous		1				1
Rash macular	3	6			3	6
Rash maculo-papular		1				1
Rash papular		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory failure	1	1			1	1
Respiratory tract infection	1	1			1	1
Rhinorrhoea		1				1
SARS-CoV-2 test positive		1				1
Sciatica		1				1
Seizure	1	2			1	2
Sensory loss		2				2
Shock	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Sinus tachycardia		1					1
Skin burning sensation		1					1
Skin exfoliation	1	1			1		1
Skin lesion		1					1
Skin reaction	1	1			1		1
Skin warm		1		1			
Sleep disorder		1					1
Sneezing		1					1
Soft tissue haemorrhage		1		1			
Somnolence	3	8	1	2	2		6
Stroke in evolution		1					1
Sudden cardiac death	1	1			1		1
Sudden hearing loss		1					1
Swelling	1	2	1	1			1
Syncope		2					2
Synovial cyst		1					1
Tachyarrhythmia		1					1
Tachycardia	2	7			2		7
Tachypnoea	1	2			1		2
Taste disorder		4		1			3
Tenosynovitis		1		1			
Throat tightness		1					1
Thrombocytopenia		1					1
Thrombophlebitis	1	2			1		2
Thyroid function test abnormal		1		1			
Tinnitus	2	2			2		2
Tongue discomfort		1					1
Tongue dry		1					1
Tongue oedema	1	2	1	1			1
Tremor		2		1			1
Upper gastrointestinal haemorrhage	1	1			1		1
Urinary tract infection		1					1
Urticaria		3					3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Urticaria papular		1				1	
Vaccination failure	1	2			1	2	
Vaccination site erythema	5	9	3	3	2	6	
Vaccination site haematoma	1	1	1	1			
Vaccination site hypoaesthesia	1	1	1	1			
Vaccination site induration		1				1	
Vaccination site inflammation		2		1		1	
Vaccination site oedema	5	6	2	2	3	4	
Vaccination site pain	11	39	7	12	4	27	
Vaccination site paraesthesia		1				1	
Vaccination site pruritus	3	5	2	3	1	2	
Vaccination site rash		1				1	
Vaccination site swelling		3				3	
Vaccination site warmth		4		1		3	
Vaginal haemorrhage		1				1	
Vasculitis	1	1			1	1	
Ventricular extrasystoles		1				1	
Vertigo		1				1	
Vision blurred		1				1	
Vomiting	3	10	1	2	2	8	
Vulvovaginal burning sensation		1				1	
Vulvovaginal swelling		1				1	
Wheezing	3	4			3	4	
	210	795	46	122	164	673	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**PUERTO RICO**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal discomfort		1		1			
Abdominal pain		1		1			
Arthralgia		2		2			
Balance disorder		1		1			
Blood pressure increased		1		1			
Burning sensation		1		1			
Chest pain		1		1			
Chills		1		1			
Death	1	1			1		1
Deep vein thrombosis	1	1			1		1
Diarrhoea		1		1			
Discomfort		1		1			
Dizziness		2		2			
Dysgeusia		1		1			
Dyskinesia		1					1
Dyspnoea		1					1
Facial paralysis	1	2			1		2
Fatigue	1	3	1	3			
Feeling cold	1	1			1		1
Flushing		1		1			
Gait disturbance		1		1			
Headache	1	5	1	5			
Heart rate decreased		1					1
Heart rate increased		1		1			
Hyperhidrosis	1	1			1		1
Hypertension		2		2			
Hypoaesthesia	1	2	1	2			
Illness		1					1
Injection site discomfort		1		1			
Injection site pruritus		1		1			
Injection site swelling		1		1			
Injection site warmth		1		1			
Insomnia	1	1	1	1			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased		1		1		
Limb discomfort		1		1		
Lymphadenopathy	1	3	1	3		
Migraine		1				1
Musculoskeletal stiffness		1		1		
Myalgia		3		3		
Nausea		1		1		
Neuralgia		1		1		
Night sweats		1				1
Oral discomfort		1		1		
Pain		1		1		
Pain in extremity	1	3	1	3		
Palpitations		1		1		
Photophobia		1		1		
Pneumonia		1				1
Productive cough		1		1		
Pruritus	1	1	1	1		
Pyrexia	1	4	1	4		
Rash	2	3	2	3		
Rhinorrhoea		1		1		
Sinus arrhythmia		1				1
Somnolence		1		1		
Tachycardia		1		1		
Thrombosis	1	1			1	1
Urinary tract infection		1				1
Vaccination site induration		1		1		
Vaccination site pain	1	2	1	2		
Vaccination site swelling	1	3	1	3		
	18	86	12	70	6	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**QATAR**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
Asthenia	1	2		1	1	1
Blood pressure decreased		1		1		
Disturbance in attention	1	1	1	1		
Dizziness		1				1
Dyspnoea		1				1
Erythema	1	1	1	1		
Feeling hot		1				1
Heart rate increased		1		1		
Hyperhidrosis		1				1
Muscle spasticity	1	1			1	1
Pyrexia	1	1	1	1		
	5	13	3	6	2	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ROMANIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	1	2		1	1	1
Acute coronary syndrome		1				1
Acute pulmonary oedema		2				2
Administration site pain	1	1	1	1		
Administration site swelling	1	1	1	1		
Anaphylactic reaction		1				1
Angina pectoris		1				1
Anxiety		1				1
Arrhythmia		2				2
Arthralgia	2	7	1	4	1	3
Asphyxia	1	2			1	2
Asthenia	2	5	2	3		2
Asthma		1				1
Asthmatic crisis		1				1
Autoimmune disorder	1	1			1	1
Back disorder		1		1		
Back pain	4	5		1	4	4
Blood glucose decreased	1	1			1	1
Blood pressure fluctuation		2				2
Blood pressure increased	1	3		1	1	2
Blood pressure systolic increased		1				1
Breast inflammation	2	2			2	2
Breast pain	1	1			1	1
Bronchospasm	2	5	1	2	1	3
Cardiac arrest		1				1
Cardio-respiratory arrest		1				1
Cataract	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	1	1	1		
Chest pain	1	4			1	4
Chills	11	19	3	8	8	11
Coma		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Condition aggravated	1	3		1	1	2
Cough		4		2		2
COVID-19	2	3			2	3
Cyanosis		2		1		1
Decreased appetite	1	1	1	1		
Deep vein thrombosis	1	1			1	1
Dementia	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea	1	1			1	1
Discomfort		1		1		
Dizziness	8	12	2	5	6	7
Drug eruption		1				1
Drug ineffective	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	2	5		1	2	4
Dyspnoea exertional	1	1			1	1
Dysstasia	1	1			1	1
Erythema		2		1		1
Eye haemorrhage	1	1			1	1
Eye pain	1	1			1	1
Eye pruritus		1		1		
Facial paralysis		1				1
Fatigue	9	16	6	11	3	5
Feeling cold		1		1		
Feeling hot	2	2			2	2
Flatulence	1	1			1	1
Flushing		1		1		
Gait disturbance		1				1
General physical condition abnormal		1		1		
General physical health deterioration		2		2		
Goitre		1				1
Headache	14	25	5	10	9	15
Heart rate increased	3	4			3	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperglycaemia		2				2	
Hyperhidrosis	4	5			4	5	
Hyperkalaemia		2				2	
Hypertension	6	8			6	8	
Hypertensive crisis	1	1			1	1	
Hypoaesthesia	3	7		3	3	4	
Hypokinesia		1		1			
Hypotension		3		1		2	
Hypothyroidism		1				1	
Hypoxic-ischaemic encephalopathy		1				1	
Incomplete course of vaccination	1	1	1	1			
Influenza like illness	1	2	1	2			
Insomnia	1	1			1	1	
Laboratory test abnormal		1		1			
Lip dry	1	1			1	1	
Lip oedema		2				2	
Loss of consciousness	1	3			1	3	
Loss of personal independence in daily activities	1	1	1	1			
Lung disorder		1		1			
Lymphadenitis	1	2	1	1		1	
Lymphadenopathy	4	6			4	6	
Lymph node palpable	1	1	1	1			
Malaise	4	8		2	4	6	
Maternal exposure during pregnancy		1		1			
Mean cell haemoglobin increased		1		1			
Metabolic acidosis		1				1	
Migraine		1				1	
Mobility decreased		1		1			
Muscle rigidity	1	1			1	1	
Myalgia	8	23	3	10	5	13	
Myocardial infarction	1	1			1	1	
Myocardial ischaemia		1				1	
Nausea	5	12	3	6	2	6	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuronal neuropathy	1	1			1	1
Obstructive airways disorder		1				1
Ocular discomfort	1	1			1	1
Ocular hyperaemia		1		1		
Oedema		1				1
Off label use		1		1		
Oxygen saturation abnormal	1	1			1	1
Oxygen saturation decreased	2	3			2	3
Pain	2	3		1	2	2
Pain in extremity	1	3		2	1	1
Pain of skin	1	1			1	1
Pallor	1	2			1	2
Palpitations		2				2
Paraesthesia	3	5		1	3	4
Parkinson's disease	1	1			1	1
Pelvic pain	1	1			1	1
Polyuria	1	1			1	1
Presyncope	1	1			1	1
Productive cough		1				1
Product use issue		1		1		
Pulse volume decreased		1		1		
Pyrexia	11	18	3	7	8	11
Rales		1				1
Rash	1	3		1	1	2
Rash erythematous		1				1
Rash pruritic		1		1		
Raynaud's phenomenon		1				1
Renal pain		1				1
Respiration abnormal		1				1
Respiratory disorder		2		1		1
Respiratory distress		2				2
Respiratory failure		1				1
Rheumatic disorder		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinalgia		1				1
SARS-CoV-2 ant body test negative		1		1		
Sensory loss		1		1		
Shock		1				1
Sialoadenitis	1	1			1	1
Somnolence	6	7	3	4	3	3
Stomatitis	1	1			1	1
Stress		1		1		
Stridor		1		1		
Supraventricular tachycardia	1	1			1	1
Syncope	3	5			3	5
Systolic hypertension		1				1
Tachycardia	1	6		2	1	4
Tachypnoea		1				1
Tendon pain	1	1			1	1
Throat tightness		1		1		
Thrombosis	1	1			1	1
Tinnitus	1	1			1	1
Tremor	1	1			1	1
Type 2 diabetes mellitus	1	1			1	1
Urinary incontinence	1	1			1	1
Urticaria		2		1		1
Use of accessory respiratory muscles		1		1		
Vaccination failure	1	2			1	2
Vaccination site erythema		2		1		1
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	5	14	2	7	3	7
Vaccination site urticaria		1		1		
Vertigo	3	5	2	3	1	2
Visual acuity reduced		1				1
Visual impairment	1	1			1	1
Vomiting	2	7	1	1	1	6
Weight increased		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wheezing		2		1		1
	194	427	46	144	148	283

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SAUDI ARABIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		1				1
Cardiac arrest		1				1
Carotid artery stenosis		1				1
Fatigue		2		2		
Gait disturbance		1		1		
Gait inability		1				1
Headache		1		1		
Heart rate decreased		1				1
Hyperhidrosis		1				1
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Nasopharyngitis		1		1		
Pain		1		1		
Pyrexia		1				1
Rhinorrhoea		1		1		
Sitting disability		1				1
Somnolence		1		1		
Syncope		1				1
Vaccination site pain		1		1		
Vomiting		1				1
		21		11		10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SERBIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Abscess		1				1
Arthralgia		1		1		
Axillary pain		1				1
Body temperature increased		2		2		
Chills		1				1
COVID-19	1	1	1	1		
C-reactive protein increased	1	1	1	1		
Drug ineffective	1	1			1	1
Facial paralysis		1				1
Fatigue	1	1	1	1		
Fibrin D dimer increased	1	1	1	1		
Headache		2		2		
Influenza like illness		1		1		
Lymphadenitis		1				1
Lymphadenopathy		1				1
Malaise		1		1		
Pain		2		1		1
Pain in extremity		1		1		
Phlebitis		1				1
Pulmonary pain		1		1		
Pyrexia		3		2		1
Red blood cell count increased	1	1	1	1		
Swelling		1				1
Vaccination site pain		2		2		
Wrong product administered		1		1		
	7	32	6	21	1	11

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SINGAPORE**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute kidney injury	1	1			1	1
Acute psychosis	1	1			1	1
Anaphylactic reaction	8	9			8	9
Anaphylactic shock		1				1
Angioedema	2	2			2	2
Arthritis	1	1			1	1
Asthma	2	2			2	2
Bicytopenia	1	1			1	1
Blood pressure increased	1	1			1	1
Blood pressure systolic increased	2	2			2	2
Breath sounds abnormal	1	1			1	1
Chest discomfort	3	3			3	3
Chills		1		1		
Complement factor C3 increased	1	1			1	1
Confusional state	1	1			1	1
Diarrhoea	1	2		1	1	1
Disease recurrence	1	1			1	1
Dizziness	6	6			6	6
Dry eye	1	1			1	1
Dyskinesia	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia	2	2	1	1	1	1
Dyspnoea	8	8	1	1	7	7
Eye movement disorder	1	1			1	1
Eye pruritus	1	1	1	1		
Eye swelling	1	1			1	1
Fatigue	1	1	1	1		
Feeding disorder	1	1			1	1
Flushing	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Haematuria	1	1			1	1
Headache	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort		1		1		
Hypoaesthesia	2	2			2	2
Hypotension	1	1			1	1
Influenza like illness	1	1	1	1		
Lacrimation increased	1	1			1	1
Mental status changes	1	1			1	1
Muscular weakness	1	1			1	1
Musculoskeletal stiffness	1	1			1	1
Myalgia	1	1	1	1		
Nausea	3	3	1	1	2	2
Nerve injury	1	1			1	1
Odynophagia	1	1			1	1
Oedema peripheral	1	1	1	1		
Optic neuritis	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Palatal oedema	1	1			1	1
Palpitations	2	2			2	2
Parosmia	1	1	1	1		
Periorbital swelling	3	3	1	1	2	2
Pharyngeal mass	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Pneumonia aspiration	1	1			1	1
Proteinuria	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	3	3	1	1	2	2
Radiculopathy	1	1			1	1
Rash	3	3			3	3
Rash erythematous	1	1	1	1		
Rash macular	1	1			1	1
Rash maculo-papular	1	1			1	1
Renal impairment	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Secretion discharge	1	1	1	1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	1	1			1	1
Sensation of foreign body	1	1			1	1
Status epilepticus	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachycardia	2	2			2	2
Tenosynovitis	1	1			1	1
Throat irritation	3	3	2	2	1	1
Throat tightness	2	2	1	1	1	1
Troponin increased	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Urticaria	2	2			2	2
Vaccination site erythema	1	1	1	1		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site pain	2	2			2	2
Vaccination site paraesthesia	1	1			1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	1			1	1
Vision blurred	1	1			1	1
Vomiting	4	4	1	1	3	3
Wheezing	3	3	1	1	2	2
	132	137	22	25	110	112

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**SLOVAKIA**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Acute myocardial infarction		1				1
Altered state of consciousness	1	1			1	1
Amnesia	1	1			1	1
Anaphylactic reaction		1				1
Angioedema		1				1
Arthralgia		2		2		
Asphyxia	1	1			1	1
Asthenia	1	3	1	2		1
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Blood glucose increased	2	2	2	2		
Blood pressure increased	2	3	1	1	1	2
Body temperature increased	1	1			1	1
Bone pain	1	1	1	1		
Cardiac failure		1				1
Chest discomfort	1	1			1	1
Chills	2	3	2	3		
COVID-19	2	2			2	2
Deafness	1	1			1	1
Dehydration	1	1	1	1		
Diarrhoea	1	2		1	1	1
Dizziness	3	4	2	3	1	1
Drug ineffective	2	2			2	2
Dyspnoea	1	1			1	1
Erysipelas		1				1
Fall	1	1	1	1		
Fatigue	1	2	1	2		
Feeling hot	1	1	1	1		
Feeling of body temperature change		1		1		
Flatulence		1		1		
Headache	1	1	1	1		
Head discomfort	1	1	1	1		

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	1	1	1		
Hypoaesthesia		1		1		
Incorrect dose administered		1		1		
Insulin resistance		1				1
Limb discomfort		1		1		
Lip oedema		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy		2		2		
Malaise	2	4	2	3		1
Medication error		1		1		
Movement disorder		1		1		
Myalgia	1	2	1	2		
Myocardial ischaemia		1				1
Nausea		2		2		
No adverse event		1		1		
Pain in extremity	1	3	1	3		
Paraesthesia		1		1		
Product administered at inappropriate site		1		1		
Pruritus		1		1		
Pyrexia	2	4	2	3		1
Rash		2		2		
Rash pruritic		2		2		
Retching	1	1	1	1		
Somnolence		1		1		
Speech disorder	1	1			1	1
Sudden hearing loss	1	1			1	1
Syncope	1	2			1	2
Thirst	1	1	1	1		
Tinnitus	1	1	1	1		
Tissue infiltration		1		1		
Urticaria		1				1
Vaccination failure		1				1
Vaccination site erythema		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	1	1	1	1		
Vaccination site pain	2	6	2	6		
Vaccination site pruritus		1		1		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria		1		1		
Venous thrombosis limb	1	1			1	1
Vertigo	1	1	1	1		
Vomiting	1	2		1	1	1
Wheezing	1	1			1	1
	52	110	31	74	21	36

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SLOVENIA**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain		1		1			
Acute myocardial infarction		1					1
Anaphylactic reaction		1					1
Angioedema		1					1
Aphasia	1	1			1		1
Asthenia		2		2			
Asymptomatic bacteriuria		1					1
Atrial fibrillation		1					1
Basilar artery thrombosis		1					1
Blood pressure increased		1		1			
Body temperature increased		1					1
Cardiac arrest		1					1
Cardiac failure congestive	1	1			1		1
Cardiopulmonary failure		1					1
Cerebral haemorrhage	1	1			1		1
Cerebrovascular accident		1					1
Chest discomfort	1	2		1	1		1
Chest pain		2		1			1
Chills		1		1			
Cough		1					1
COVID-19		2					2
COVID-19 pneumonia		1					1
Dementia		1					1
Diarrhoea		1		1			
Disease recurrence		1					1
Dysarthria	1	1			1		1
Dyspnoea		4		1			3
Erythema		1		1			
Eyelid oedema		1		1			
Eye pruritus		1		1			
Fall	1	1			1		1
Fatigue		3		3			
Feeling hot	1	3		1	1		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General physical health deterioration		1				1
Headache		2		2		
Hot flush	1	1			1	1
Hypertension		1				1
Infection		1				1
Ischaemic cerebral infarction		1				1
Ischaemic stroke	1	1			1	1
Lip oedema	1	1			1	1
Lip swelling		1		1		
Loss of consciousness		1				1
Lower respiratory tract infection	1	1			1	1
Malaise		4		1		3
Migraine		1		1		
Miosis		1				1
Monoparesis	1	1			1	1
Myalgia		2		1		1
Myocardial infarction		1				1
Nausea		2		1		1
Oropharyngeal pain		1		1		
Oxygen saturation decreased		2				2
Pain		1		1		
Pain in extremity		2		1		1
Paraesthesia		1		1		
Paraesthesia oral	1	1			1	1
Pharyngeal erythema		1		1		
Pneumonia		1				1
Pneumothorax spontaneous	1	1			1	1
Pulmonary embolism		1				1
Pulmonary oedema	1	1			1	1
Pyrexia		2				2
Quadriparesis		1				1
Rash pruritic		1		1		
Restlessness		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body	1	1			1	1
Skin disorder		1				1
Somnolence		2		1		1
Sudden cardiac death	1	1			1	1
Sudden death		2				2
Swollen tongue		2		2		
Syncope		1				1
Tachycardia		1		1		
Tongue movement disturbance		1		1		
Tongue pruritus		2		2		
Total lung capacity decreased	1	1			1	1
Unresponsive to stimuli	1	3			1	3
Vaccination failure		1				1
Vaccination site pain		2		2		
Vaccination site warmth	1	1			1	1
Ventricular extrasystoles		1		1		
Vertebral artery thrombosis		1				1
Vertigo		3		2		1
Vomiting		1				1
White blood cell count increased		1		1		
	20	115		43	20	72

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**SPAIN**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3		2	1	1
Abdominal pain	3	9	3	3		6
Abdominal pain lower		1		1		
Abdominal pain upper		4		2		2
Abnormal faeces		1		1		
Abortion spontaneous		1				1
Activated partial thromboplastin time shortened	1	1	1	1		
Acute coronary syndrome	1	1			1	1
Acute hepatic failure	1	1			1	1
Acute kidney injury	1	3			1	3
Acute leukaemia		1				1
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome		1				1
Acute respiratory failure	5	10			5	10
Adrenal mass		1		1		
Ageusia		1				1
Agitation	2	3			2	3
Allergy to vaccine	1	4		1	1	3
Amaurosis fugax	1	1			1	1
Amnesia	1	3		2	1	1
Anaemia	2	2			2	2
Anal incontinence	1	1	1	1		
Anal sphincter atony		1				1
Anaphylactic reaction		16				16
Anaphylactic shock		2				2
Angina pectoris		1				1
Angioedema	1	5			1	5
Angular cheilitis		1		1		
Anosmia		1				1
Antibody test abnormal		1		1		
Antipsychotic drug level increased		1				1
Anxiety	1	3		2	1	1
Apathy	1	1			1	1

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		4		1		3
Aphthous ulcer		1				1
Apnoea		1				1
Appendicitis		1				1
Arrhythmia	1	2			1	2
Arthralgia	5	18	1	8	4	10
Arthritis reactive	1	1			1	1
Asphyxia		2				2
Aspiration		1				1
Asthenia	9	33	2	7	7	26
Asthenopia		1				1
Asthma		4		1		3
Asthmatic crisis		2				2
Asymptomatic COVID-19	1	7		1	1	6
Ataxia	1	1			1	1
Atelectasis		2				2
Atrial fibrillation		4				4
Atrioventricular block first degree		1		1		
Atypical haemolytic uraemic syndrome	1	1			1	1
Autoantibody negative		1				1
Autoimmune demyelinating disease		1				1
Autoimmune haemolytic anaemia	1	1			1	1
Autoimmune hepatitis	1	2			1	2
Axillary pain		1				1
Back pain		6		5		1
Bacteraemia	1	1			1	1
Bacterial test	1	1			1	1
Balance disorder	2	4	1	2	1	2
Base excess decreased	1	1	1	1		
Basilar artery thrombosis	1	1			1	1
Bedridden	1	1			1	1
Biliary cyst	1	1	1	1		
Blepharitis		1		1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral	1	1			1	1
Blister		1				1
Blood bicarbonate decreased	1	1			1	1
Blood bicarbonate increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood chloride decreased		1		1		
Blood creatinine increased	1	1	1	1		
Blood fibrinogen decreased	1	1	1	1		
Blood fibrinogen increased	1	1	1	1		
Blood gases abnormal	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood lactate dehydrogenase increased	2	2	1	1	1	1
Blood pressure decreased		2		1		1
Blood pressure diastolic decreased		1				1
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased		5		4		1
Blood sodium decreased		1		1		
Blood urea increased	1	1			1	1
Body temperature decreased	1	2		1	1	1
Bradycardia		1				1
Bradykinesia		2		1		1
Bradyphrenia	2	4	1	2	1	2
Breast mass		1		1		
Breath sounds abnormal		1				1
Bronchial hyperreactivity		1				1
Bronchospasm	2	12			2	12
Bundle branch block left	1	1			1	1
Cardiac arrest	1	3			1	3
Cardiac disorder	1	2	1	1		1
Cardiac failure	7	14			7	14
Cardiac failure acute	1	5			1	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure congestive	2	2			2	2
Cardiac tamponade		1				1
Cardiomegaly	1	1			1	1
Cardio-respiratory arrest	2	11			2	11
Cardio-respiratory distress		1				1
Carotid bruit		1				1
Cell death	1	1			1	1
Cellulitis	1	1			1	1
Cellulitis staphylococcal		1				1
Cephalhaematoma	1	1			1	1
Cerebellar infarction	1	1			1	1
Cerebral disorder		1				1
Cerebral haematoma	1	2			1	2
Cerebral haemorrhage	4	4			4	4
Cerebral infarction	2	2			2	2
Cerebral venous sinus thrombosis	1	1			1	1
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Cerebrovascular disorder	1	1			1	1
Chest discomfort		3		1		2
Chest injury		1				1
Chest pain	2	7			2	7
Chills	6	26	4	15	2	11
Choking		1				1
Choking sensation		3		1		2
Cholestasis	1	1			1	1
Chronic kidney disease	2	2			2	2
Chronic obstructive pulmonary disease	1	1			1	1
Chronic respiratory failure		2				2
Circadian rhythm sleep disorder	1	1			1	1
Citrobacter infection		1				1
Cognitive disorder	2	2			2	2
Cold sweat		2		1		1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis ulcerative		1				1
Concomitant disease aggravated	1	3			1	3
Condition aggravated	1	11		1	1	10
Confusional state	2	3			2	3
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia	1	1			1	1
Conjunctival laceration		1		1		
Constipation	4	5	2	3	2	2
Contusion	2	4		2	2	2
Coombs positive haemolytic anaemia	1	1			1	1
Coordination abnormal	1	1			1	1
Costochondritis		1				1
Cough		9		3		6
COVID-19	5	19	1	2	4	17
COVID-19 pneumonia	1	7			1	7
Craniocerebral injury	2	4			2	4
C-reactive protein increased	1	3	1	3		
Cyanosis		4		1		3
Death	1	6			1	6
Decreased appetite	3	7	1	2	2	5
Decreased nasolabial fold		1				1
Deep vein thrombosis	7	9			7	9
Dehydration		1		1		
Delirium	3	3			3	3
Delusion	1	1			1	1
Demyelination	1	2			1	2
Depressed level of consciousness	3	10			3	10
Depressed mood		1		1		
Dermatitis allergic	1	2			1	2
Diabetes mellitus		2				2
Diabetes mellitus inadequate control		1				1
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	9	33	6	18	3	15
Diarrhoea haemorrhagic		1				1
Diplopia	2	4			2	4
Discomfort	2	4		1	2	3
Disease recurrence	2	3			2	3
Disorganised speech		1				1
Disorientation	4	9	1	3	3	6
Disturbance in attention		1				1
Dizziness	6	36	2	11	4	25
Dizziness postural	1	1			1	1
Drowning		1				1
Drug ineffective	1	10			1	10
Drug interaction		2		1		1
Dry eye		1		1		
Dysarthria	2	6		2	2	4
Dysgeusia	1	5		2	1	3
Dyskinesia		1				1
Dyspepsia	1	1			1	1
Dysphagia	4	6	1	1	3	5
Dysphonia	1	3	1	1		2
Dyspnoea	9	52	2	7	7	45
Dyspnoea at rest		1				1
Dyspnoea exertional	1	7	1	3		4
Dystonia		1				1
Dysuria	2	3	1	2	1	1
Ear pain		1		1		
Eating disorder		1		1		
Ecchymosis		1				1
Eczema		2		1		1
Electrocardiogram normal	1	1			1	1
Electrocardiogram QRS complex prolonged		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST-T change		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Embolitic stroke	1	1			1	1
Embolism		1				1
Encephalitis		3				3
Encephalopathy		1				1
Enterococcal infection	1	1			1	1
Epigastric discomfort		1				1
Epilepsy	1	3			1	3
Episcleritis		1				1
Epistaxis	2	3	1	1	1	2
Erythema	4	11	3	5	1	6
Escherichia infection	1	2			1	2
Essential tremor		1				1
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Eyelid oedema		2				2
Eye pain	2	4			2	4
Eye swelling		1				1
Face injury		1				1
Face oedema		5				5
Facial paralysis	4	15			4	15
Faeces soft		1		1		
Fall	2	8		3	2	5
Fatigue	4	17	2	7	2	10
Febrile convulsion	1	2			1	2
Feeling abnormal	1	1	1	1		
Feeling cold		1				1
Feeling hot	2	5	2	4		1
Fibrin D dimer increased	4	5	1	1	3	4
Fluid overload	1	1			1	1
Formication		1		1		
Gait disturbance	1	7		1	1	6
Gait inability	1	4		1	1	3
Gal bladder enlargement		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gamma-glutamyltransferase increased		1		1			
Gastritis	1	1			1		1
Gastrointestinal disorder	1	1	1	1			
Gastrointestinal haemorrhage	2	3			2		3
Gastrooesophageal reflux disease		1		1			
Generalised oedema		1					1
Generalised tonic-clonic seizure	1	4			1		4
General physical health deterioration		5		2			3
Giant cell arteritis	1	1			1		1
Glomerular filtration rate decreased	1	1	1	1			
Glossitis		1					1
Glossodynia		1					1
Granulomatous liver disease		1					1
Guillain-Barre syndrome	1	2			1		2
Haematocrit decreased		1		1			
Haematoma	2	5	2	4			1
Haematoma muscle	2	3			2		3
Haematuria	2	3		1	2		2
Haemoglobin decreased	1	3	1	3			
Haemoglobin increased	1	1	1	1			
Haemophagocytic lymphohistiocytosis		1					1
Haemoptysis	1	2			1		2
Haemorrhage		1					1
Haemorrhage intracranial	1	1			1		1
Haemorrhagic diathesis		1					1
Haemorrhagic stroke	1	1			1		1
Hallucination	2	2			2		2
Hallucination, auditory	1	1			1		1
Hallucinations, mixed	1	1			1		1
Hallucination, visual	1	1			1		1
Headache	12	59	4	21	8		38
Head injury	2	3		1	2		2
Heart rate increased		2		1			1

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\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemidysaesthesia		1				1
Hemiparaesthesia		4				4
Hemiparesis	1	3			1	3
Hemiplegia	2	2			2	2
Hepatic cyst	1	2	1	2		
Hepatic failure		1				1
Hepatic steatosis	1	1			1	1
Hepatitis acute	1	3			1	3
Hepatitis B virus test positive	1	1	1	1		
Herpes ophthalmic		1				1
Herpes zoster	6	12		1	6	11
Herpes zoster cutaneous disseminated	1	1			1	1
Hiatus hernia	2	2			2	2
Hypercholesterolaemia	1	1	1	1		
Hyperglycaemia	4	8		1	4	7
Hyperhidrosis		4		2		2
Hyperkalaemia	1	1			1	1
Hypernatraemia		2				2
Hypersensitivity	1	7	1	1		6
Hypersensitivity vasculitis	1	1			1	1
Hypertension	2	14		2	2	12
Hypertensive crisis	1	10			1	10
Hypertensive encephalopathy	1	1			1	1
Hypertensive urgency	1	2			1	2
Hyperthyroidism		1				1
Hypoacusis		1				1
Hypoaesthesia	1	6			1	6
Hypoaesthesia eye	1	1			1	1
Hypoaesthesia oral		2		1		1
Hypocalcaemia	1	1			1	1
Hypoglycaemia		4		1		3
Hypokalaemia		1				1
Hyponatraemia	2	2			2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyporeflexia		1		1		
Hypotension	6	11	1	3	5	8
Hypotonia		1		1		
Hypoxia	1	11			1	11
Ileus paralytic	1	1			1	1
Ill-defined disorder	1	1			1	1
Immobilisation syndrome	1	1	1	1		
Immune system disorder		1				1
Immune thrombocytopenia	2	4			2	4
Inappropriate schedule of product administration	1	4	1	4		
Incoherent	1	2			1	2
Incorrect dose administered	1	2	1	2		
Incorrect route of product administration	1	2	1	2		
Increased bronchial secretion		1				1
Infection	1	1	1	1		
Infective exacerbation of bronchiectasis	1	1			1	1
Inflammatory bowel disease	1	2			1	2
Influenza like illness		1		1		
Injury	1	1	1	1		
Insomnia	1	1			1	1
Insulin resistance		1		1		
Interstitial lung disease		2				2
Intestinal ischaemia		1				1
Intestinal obstruction	1	1			1	1
Iridocyclitis	1	1			1	1
Ischaemic cerebral infarction		1				1
Ischaemic stroke	5	11			5	11
Joint injury	1	1			1	1
Kaposi's sarcoma AIDS related		1				1
Keratitis	1	1			1	1
Labyrinthitis		1				1
Lacunar stroke		1				1
Large intestine infection	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal disorder		1				1
Laryngeal oedema		3				3
Larynx irritation		1				1
Leukoencephalopathy		1				1
Limb discomfort	1	2	1	1		1
Lipase decreased	1	1	1	1		
Lip oedema	1	7			1	7
Liver function test abnormal	1	1			1	1
Localised infection		1				1
Localised oedema	1	1			1	1
Local reaction	2	2			2	2
Loss of consciousness	2	9			2	9
Lower respiratory tract infection		1				1
Lung disorder		2				2
Lung infiltration		3		2		1
Lymphadenopathy	3	20	1	7	2	13
Lymphocyte count decreased	1	1	1	1		
Lymphocyte count increased	1	1	1	1		
Lymphocyte percentage decreased		1		1		
Lymphopenia		1		1		
Macular oedema		1				1
Malaise	12	46	6	12	6	34
Maternal exposure during pregnancy		2		2		
Maternal exposure timing unspecified	1	1	1	1		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Medication error		1		1		
Melaena		1				1
Meningitis herpes	1	1			1	1
Mental disorder		1				1
Micturition urgency	1	1			1	1
Migraine	1	2			1	2
Migraine with aura		1				1
Mobility decreased	2	5	1	3	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monoparesis	1	1			1	1
Monoplegia		1				1
Morganella infection	1	1			1	1
Mouth swelling		1				1
Mouth ulceration		1				1
Movement disorder		2				2
Multiple organ dysfunction syndrome		4				4
Multiple sclerosis		1				1
Muscle rigidity	1	1			1	1
Muscle spasms		2		1		1
Muscle tightness		1				1
Muscular weakness		3		1		2
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort		1				1
Musculoskeletal pain	3	8		2	3	6
Musculoskeletal stiffness		2		1		1
Myalgia	16	38	7	15	9	23
Myocardial infarction		1				1
Myocarditis		1				1
Myoclonic dystonia		1				1
Myositis	1	1			1	1
Nasal congestion		1				1
Nasal disorder	1	1	1	1		
Nasal herpes		1				1
Nasopharyngitis		1		1		
Nausea	5	34	4	16	1	18
Neck mass		1		1		
Neck pain		3				3
Neoplasm		1		1		
Nervous system disorder	1	1			1	1
Neuralgia		3		1		2
Neutrophil count increased	2	4	2	4		
Neutrophilia	1	1			1	1

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophilic dermatosis	1	1			1	1
Neutrophil percentage increased		1		1		
Nodule		1		1		
N-terminal prohormone brain natriuretic peptide increased	1	1			1	1
Odynophagia		3				3
Oedema		1		1		
Oedema peripheral	4	6	2	2	2	4
Off label use	2	8	2	8		
Ophthalmic herpes zoster		1				1
Oral disorder		1				1
Oral pruritus		2				2
Oropharyngeal discomfort		1				1
Oropharyngeal pain	1	1	1	1		
Ovarian cyst		1				1
Overdose	1	1	1	1		
Oxygen saturation decreased	3	13	1	2	2	11
Pain	1	4	1	2		2
Pain in extremity	1	8	1	4		4
Palatal oedema		3				3
Pallor		5		2		3
Palpitations	1	6	1	2		4
Pancreatitis chronic	1	1			1	1
Pancytopenia		1				1
Paraesthesia	7	16	1	4	6	12
Paraesthesia oral		3				3
Paraparesis		2				2
Parosmia	1	1			1	1
Partial seizures		2				2
PCO2 decreased	1	1	1	1		
Pericarditis	3	5			3	5
Periorbital haematoma		1				1
Peripheral coldness	2	2	2	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Peripheral ischaemia		1				1	
Peripheral swelling	1	2	1	2			
Peripheral venous disease	1	1			1	1	
Persistent depressive disorder		1				1	
Persistent generalised lymphadenopathy	1	1			1	1	
Petechiae	3	7	1	2	2	5	
Petit mal epilepsy		3				3	
Pharyngeal inflammation	1	1	1	1			
Pharyngotonsillitis		1				1	
Phlebitis	1	1			1	1	
Photophobia		2		1		1	
Platelet count decreased	1	1			1	1	
Platelet count increased		1		1			
Pleural effusion	1	4		1	1	3	
Pleuritic pain		1				1	
Pleuropericarditis		1				1	
Pneumonia	3	8			3	8	
Pneumonia aspiration	2	3			2	3	
Pneumonitis	1	2			1	2	
PO2 decreased	3	3	3	3			
Pollakiuria	1	1			1	1	
Poor quality sleep		1				1	
Portal vein thrombosis	1	1			1	1	
Positron emission tomogram	1	1			1	1	
Post thrombotic syndrome	1	1			1	1	
Prerenal failure	1	1			1	1	
Presyncope	2	4			2	4	
Proctalgia		1		1			
Productive cough		1		1			
Product use issue		4		4			
Prothrombin level decreased	1	1			1	1	
Prothrombin time prolonged	2	3	1	2	1	1	
Pruritus	4	12	3	4	1	8	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Psoriatic arthropathy		1					1
Psychomotor hyperactivity		2					2
Pulmonary embolism	18	27			18		27
Pulmonary haemorrhage	1	1			1		1
Pulmonary infarction	1	2			1		2
Pulmonary sepsis	1	1			1		1
Pulmonary thrombosis	1	2			1		2
Pulse abnormal		1					1
Purpura		1					1
Pyrexia	36	114	17	41	19		73
Rash	2	9	1	3	1		6
Rash erythematous		2					2
Rash maculo-papular		2		1			1
Rash papular		1					1
Rash pruritic		5		1			4
Raynaud's phenomenon		1					1
Rectal haemorrhage	1	3			1		3
Rectal tenesmus		1					1
Renal cyst	1	2	1	2			
Renal failure	2	3			2		3
Renal impairment	1	2			1		2
Respiratory acidosis	1	2			1		2
Respiratory arrest		1					1
Respiratory distress	2	7			2		7
Respiratory failure	3	7			3		7
Respiratory tract infection	3	5			3		5
Restlessness	1	3		2	1		1
Retinal artery occlusion	1	1			1		1
Retinal vein occlusion		1					1
Retinal vein thrombosis	1	1			1		1
Rhinorrhoea		1		1			
SARS-CoV-2 ant body test positive		1		1			
SARS-CoV-2 test positive	1	1	1	1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Scleritis		1					1
Scoliosis	1	1			1		1
Seizure	3	7			3		7
Sensation of foreign body		2					2
Sense of oppression		1					1
Sensory disturbance		2					2
Sepsis		2					2
Septic shock	2	2			2		2
Serum ferritin abnormal		1		1			
Shock		1					1
Silent thyroiditis	1	1			1		1
Sinus bradycardia		1		1			
Sinusitis		1		1			
Sinus tachycardia	2	3		1	2		2
Skin exfoliation		1					1
Skin lesion		2					2
Skin ulcer	2	4	2	3			1
SLE arthritis		1					1
Slow speech	1	2	1	1			1
Sneezing	1	1	1	1			
Somnolence	1	4	1	2			2
Spasmodic dysphonia		1		1			
Speech disorder	1	3		1	1		2
Spinal cord injury		1					1
Spinal osteoarthritis	1	1			1		1
Staphylococcal infection	1	1			1		1
Status epilepticus		1					1
Stomatitis		1		1			
Stridor		1					1
Subarachnoid haemorrhage	1	1			1		1
Subcutaneous haematoma	1	1			1		1
Sudden death	3	12			3		12
Suicide attempt		1					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling		1		1		
Swollen tongue	1	2			1	2
Syncope	7	24			7	24
Systemic lupus erythematosus		1				1
Tachyarrhythmia		1				1
Tachycardia	2	16		3	2	13
Tachypnoea		6		2		4
Temperature regulation disorder	1	4	1	4		
Tension headache		2				2
Thalamic infarction	1	1			1	1
Throat irritation		5				5
Thrombocytopenia	2	3			2	3
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial	4	4	1	1	3	3
Thrombosis	1	1			1	1
Tinnitus		1				1
Tongue oedema		3				3
Tongue pruritus		2				2
Tonic clonic movements		1				1
Toxicity to various agents		1				1
Transaminases increased		1				1
Transferrin abnormal		1		1		
Transient global amnesia		1				1
Transient ischaemic attack	2	4			2	4
Tremor		6		3		3
Troponin I increased	1	1			1	1
Troponin T increased		1				1
Upper gastrointestinal haemorrhage	1	1			1	1
Upper limb fracture		1		1		
Urinary incontinence	1	1	1	1		
Urinary retention		1				1
Urinary sediment present		1		1		
Urinary tract infection	2	6		1	2	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Urinary tract infection bacterial		1				1	
Urinary tract infection pseudomonal	1	1			1	1	
Urosepsis	1	1			1	1	
Urticaria	2	9	2	3		6	
Uvulitis		1				1	
Vaccination complication		1				1	
Vaccination failure	5	13			5	13	
Vaccination site erythema	2	2	2	2			
Vaccination site haematoma		2				2	
Vaccination site induration	1	2	1	1		1	
Vaccination site inflammation	1	2	1	1		1	
Vaccination site joint erythema	1	2	1	2			
Vaccination site joint swelling	1	1	1	1			
Vaccination site movement impairment		2		1		1	
Vaccination site pain	4	21	4	13		8	
Vaccination site paraesthesia	1	1			1	1	
Vaccination site pruritus		3		1		2	
Vaccination site rash	1	2			1	2	
Vaccination site swelling	1	1	1	1			
Vaccination site warmth	2	3	2	3			
Vaginal discharge		1		1			
Vaginal haemorrhage		1				1	
Vasculitis	1	1			1	1	
Vasoplegia syndrome	1	1			1	1	
Venous thrombosis limb	4	5			4	5	
Ventricular dysfunction	1	1			1	1	
Ventricular enlargement	1	1			1	1	
Ventricular extrasystoles		1				1	
Ventricular fibrillation	1	1			1	1	
Vertigo		5		2		3	
Viral keratouveitis	1	1			1	1	
Vision blurred		6		1		5	
Visual impairment	1	1			1	1	

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vitamin B12 decreased		1		1		
Vitamin D decreased		1		1		
Vomiting	10	34	5	13	5	21
Wheezing	1	4	1	1		3
White blood cell count increased		2		2		
	646	2,051	175	535	471	1516

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Country Where Event Occurred  
**SWEDEN**

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	6		1	1	5
Abdominal pain lower		1				1
Abdominal pain upper		4		2		2
Abdominal symptom		1				1
Abnormal behaviour		3		1		2
Acute kidney injury	1	4			1	4
Acute left ventricular failure		1				1
Acute myocardial infarction	1	4			1	4
Adrenocortical insufficiency acute		1				1
Ageusia		2		1		1
Aggression		1				1
Agitation		1				1
Allergy to vaccine		1				1
Anaemia	1	1			1	1
Anaphylactic reaction	1	9			1	9
Anaphylactic shock	1	3			1	3
Angina pectoris	1	2			1	2
Angioedema		3				3
Anosmia		3		1		2
Anxiety		6		1		5
Aortic arteriosclerosis	1	2		1	1	1
Aphasia	1	2			1	2
Apnoea		2				2
Arrhythmia	1	3			1	3
Arterial thrombosis	1	1			1	1
Arteriosclerosis		2				2
Arteriosclerosis coronary artery		1				1
Arthralgia		7		5		2
Arthritis		3				3
Ascites		1				1
Aspiration	1	1			1	1
Asthenia	2	13	1	4	1	9
Asthenopia		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Atelectasis		1				1
Atrial fibrillation	3	6			3	6
Atrial flutter	1	1			1	1
Atrial septal defect		1				1
Atrial thrombosis		1				1
Atrioventricular block complete		2				2
Autonomic nervous system imbalance		1				1
Axillary pain	1	1			1	1
Back pain	2	4		1	2	3
Balance disorder	3	5			3	5
Basedow's disease		1				1
Basilar artery thrombosis	1	1			1	1
Bedridden		1		1		
Biliary colic	1	1			1	1
Biliary dilatation	1	1			1	1
Biliary tract disorder		1				1
Blister		1				1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatinine increased	1	2	1	2		
Blood fibrinogen decreased	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased		3		1		2
Blood lactate dehydrogenase increased	1	1			1	1
Blood phosphorus decreased		1		1		
Blood potassium increased	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure decreased	2	8	1	2	1	6
Blood pressure diastolic decreased		1		1		
Blood pressure systolic increased		1				1
Body temperature decreased		2				2
Body temperature increased	1	3		1	1	2

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorder		1		1		
Bradycardia	1	1			1	1
Brain herniation	1	1			1	1
Brain injury		1				1
Brain scan abnormal		1				1
Breath sounds abnormal		1				1
Bronchial haemorrhage		1				1
Bronchitis		1				1
Bundle branch block left	1	2	1	1		1
Bundle branch block right		1				1
Cachexia		1				1
Cardiac arrest	9	18			9	18
Cardiac death	1	1			1	1
Cardiac disorder		3				3
Cardiac failure	4	14			4	14
Cardiac failure acute		2				2
Cardiac failure chronic		1				1
Cardiac fibrillation		1				1
Cardiac murmur	1	1			1	1
Cardiogenic shock	1	2			1	2
Cardiopulmonary failure		1				1
Cardiovascular disorder	1	1			1	1
Catheter site haemorrhage		1		1		
Cerebellar haemorrhage	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral atrophy		1				1
Cerebral haemorrhage	4	5			4	5
Cerebral infarction	2	2			2	2
Cerebrovascular accident	2	10			2	10
Cerebrovascular disorder		1				1
Chest discomfort	2	6	1	3	1	3
Chest pain	4	15		4	4	11
Chills	2	23		10	2	13

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic gastritis		1				1
Chronic obstructive pulmonary disease		5				5
Chronic respiratory failure		1				1
Circulatory collapse	1	6			1	6
Coagulopathy	1	1			1	1
Coeliac artery stenosis		1				1
Cognitive disorder		1				1
Cold sweat		2		1		1
Condition aggravated	3	11		1	3	10
Confusional state	3	12	1	1	2	11
Constipation		1		1		
Contusion	1	1			1	1
Coronary artery stenosis		1				1
Cor pulmonale acute		1				1
Cough	4	17	2	10	2	7
COVID-19	4	13			4	13
COVID-19 pneumonia		1				1
Cranial nerve disorder		1				1
C-reactive protein increased	5	12	2	6	3	6
Crepitations		2		1		1
Crying		1		1		
Cyanosis	1	4	1	2		2
Death	3	34			3	34
Decreased appetite	2	11		4	2	7
Decubitus ulcer		1		1		
Deep vein thrombosis	10	14			10	14
Dehydration	2	6		1	2	5
Delirium	1	1			1	1
Delusional disorder, unspecified type		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	1	11			1	11
Depression		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis		2		1		1
Device related infection		1				1
Diarrhoea	1	22		9	1	13
Discomfort		1		1		
Disease recurrence	2	6		1	2	5
Disorganised speech		1				1
Disorientation		1				1
Dissociation		1				1
Disturbance in attention		1		1		
Diverticulitis		1				1
Diverticulum		1		1		
Dizziness	6	26	1	7	5	19
Drug eruption		1				1
Drug ineffective	1	6			1	6
Dry mouth		1				1
Dry skin		1		1		
Dysarthria	1	3		1	1	2
Dysgeusia		3				3
Dysphagia	3	9	1	4	2	5
Dysphonia		1				1
Dyspnoea	12	60	1	8	11	52
Dyspnoea exertional	1	1			1	1
Dysstasia		2				2
Dystonia	1	1			1	1
Ear swelling	1	1			1	1
Eating disorder	1	1			1	1
Eczema		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram T wave inversion		1				1
Embolic cerebral infarction	1	1			1	1
Embolism	1	2			1	2
Embolism arterial	1	1			1	1
Encephalitis	1	1			1	1

\* I=Interval, C=Cumulative

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy		1				1
Epistaxis	2	4		2	2	2
Erysipelas	2	3			2	3
Erythema	5	15	2	8	3	7
Escherichia infection		1				1
Escherichia sepsis		1				1
Extrasystoles		2				2
Eye disorder		1				1
Eye irritation		1				1
Eye pain		5				5
Face injury		1				1
Facial neuralgia		1				1
Facial paralysis		5				5
Facial paresis	2	6			2	6
Fall	5	11	2	3	3	8
Fatigue	12	73	6	31	6	42
Feeling abnormal	1	6	1	3		3
Feeling cold	1	3	1	2		1
Feeling hot	1	5	1	2		3
Feeling of body temperature change		1				1
Femoral neck fracture		1				1
Fluid intake reduced		1				1
Food refusal		1				1
Gait disturbance		1		1		
Gamma-glutamyltransferase increased		1				1
Gastric disorder		1		1		
Gastric haemorrhage	1	1			1	1
Gastroenteritis	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Generalised oedema		2				2
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration	8	39	2	9	6	30
Glomerular filtration rate decreased	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glossodynia		1		1		
Goitre		1				1
Gout		1				1
Graft versus host disease		1				1
Haematemesis	2	4			2	4
Haematochezia		1				1
Haematoma	1	5			1	5
Haematuria	1	1			1	1
Haemoglobin decreased		2				2
Haemolytic anaemia	1	2			1	2
Haemoptysis		1				1
Haemorrhage	3	4			3	4
Haemorrhage intracranial	1	1			1	1
Hallucination		2				2
Hallucination, visual	1	2			1	2
Headache	10	53	3	25	7	28
Head injury	1	3	1	2		1
Heart rate decreased		2		1		1
Heart rate increased	1	4			1	4
Heart rate irregular		2		2		
Hemiparesis	3	4			3	4
Herpes zoster		4		1		3
Hiccups		1				1
Hip fracture		1				1
Hot flush		1				1
Hydrothorax		1				1
Hyperacusis		1				1
Hypercalcaemia		1				1
Hyperglycaemia		1				1
Hyperhidrosis	1	9	1	3		6
Hypernatraemia		1				1
Hyperparathyroidism primary		1		1		
Hypersensitivity	1	11		1	1	10

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	2	5			2	5
Hyperventilation		2				2
Hypoacusis		1				1
Hypoaesthesia	2	10		3	2	7
Hypoaesthesia oral		4				4
Hypoalbuminaemia		1		1		
Hypoglycaemia		3				3
Hypokalaemia		1				1
Hypokinesia		1				1
Hypoperfusion	1	1			1	1
Hypophagia		2				2
Hypopnoea		1				1
Hypotension	5	18	1	2	4	16
Hypothermia		3				3
Idiopathic pulmonary fibrosis		1				1
Illness		1				1
Immune thrombocytopenia		1				1
Immunisation reaction		1				1
Inappropriate schedule of product administration	2	2	2	2		
Incontinence		1		1		
Incorrect route of product administration	2	4	2	4		
Increased upper airway secretion		2		2		
Infection	2	9			2	9
Influenza like illness	1	4	1	2		2
Infrequent bowel movements		1		1		
Insomnia		3		1		2
Intestinal haemorrhage		2				2
Intestinal ischaemia		2				2
Irregular breathing		1		1		
Ischaemic stroke	3	5			3	5
Jaundice		1				1
Jaw disorder		1				1
Lacrimation increased		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lactic acidosis		1				1
Laryngeal oedema		1				1
Left ventricular hypertrophy		1				1
Lethargy		1				1
Leukocytosis		1				1
Leukopenia	2	2			2	2
Lip swelling		1				1
Livedo reticularis		1		1		
Liver disorder		1				1
Loss of consciousness	4	13			4	13
Lung disorder	1	2			1	2
Lung infiltration	1	1			1	1
Lung transplant rejection		1				1
Lymphadenitis		1				1
Lymphadenopathy		4		2		2
Lymphoedema		1				1
Malaise	3	19	2	9	1	10
Memory impairment		2		2		
Meningism	1	1			1	1
Meningitis		1				1
Mesenteric artery embolism		1				1
Metabolic disorder	1	1	1	1		
Metastasis	1	1			1	1
Migraine	2	4		1	2	3
Motor dysfunction		1				1
Multiple sclerosis	1	2			1	2
Muscle spasms	2	6	1	3	1	3
Muscle tone disorder		1				1
Muscular weakness	2	4			2	4
Musculoskeletal stiffness		4				4
Myalgia	3	19	1	8	2	11
Myelitis		1				1
Myelosuppression		1				1

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Myocardial fibrosis		1					1
Myocardial infarction		9					9
Myocardial ischaemia		3					3
Myocardial rupture		1					1
Myocarditis		1					1
Nail discolouration		1					1
Nasal congestion		4		1			3
Nasopharyngitis	2	5	1	1	1		4
Nausea	8	37	3	15	5		22
Neck pain	1	2		1	1		1
Neoplasm progression		1					1
Neuropathy peripheral		1					1
Nightmare		1					1
Obstructive airways disorder	1	2			1		2
Ocular discomfort		1		1			
Oedema peripheral	1	1	1	1			
Off label use	2	3	2	3			
Oral herpes		2		2			
Oral pain		1		1			
Oral pruritus	1	2	1	2			
Oropharyngeal pain	1	10		6	1		4
Oropharyngeal spasm		1					1
Orthostatic hypotension		1					1
Oxygen saturation abnormal		1		1			
Oxygen saturation decreased	3	22		3	3		19
Pain	5	22	2	8	3		14
Pain in extremity	4	19	3	9	1		10
Pain in jaw		1					1
Pain of skin		1		1			
Pallor	1	7	1	4			3
Palpitations	2	9		4	2		5
Pancytopenia	1	1			1		1
Paraesthesia	1	10	1	3			7

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parkinson's disease	1	1			1	1
Parosmia		1				1
Pemphigoid		2				2
Pericardial effusion		1				1
Pericardial haemorrhage		1				1
Pericarditis		1				1
Periorbital oedema		2				2
Peripheral coldness		1				1
Peripheral embolism	1	1			1	1
Peripheral motor neuropathy		1				1
Peripheral sensory neuropathy		1				1
Peripheral swelling	5	9	1	2	4	7
Petechiae	3	4	1	1	2	3
Petit mal epilepsy		2				2
Pharyngeal disorder		1				1
Pharyngeal hypoaesthesia		1				1
Pharyngeal swelling		3				3
Pharyngitis		1		1		
Phlebitis	1	1			1	1
Photophobia		1				1
Platelet count decreased	1	1			1	1
Pleural effusion		1				1
Pneumonia	2	10			2	10
Pneumonia aspiration	2	3			2	3
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pneumonia streptococcal		1				1
Polyarthritis	1	1			1	1
Polyneuropathy	1	1			1	1
Postoperative wound complication		1				1
Post stroke epilepsy	1	1			1	1
Presyncope		2		1		1
Procalcitonin increased	2	2			2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Productive cough	2	5			2	5
Product use issue		1		1		
Pruritus	3	9	1	3	2	6
Psoriasis		1		1		
Psychotic disorder		1				1
Pulmonary artery thrombosis		1				1
Pulmonary embolism	22	30			22	30
Pulmonary hypertension	1	1			1	1
Pulmonary infarction	1	1			1	1
Pulmonary oedema		7				7
Pulmonary pain		1		1		
Pulmonary thrombosis	1	2			1	2
Pulse abnormal		2		2		
Pyrexia	20	97	8	35	12	62
Rash	1	8	1	5		3
Rash erythematous		2				2
Rash pruritic		1				1
Red blood cell sedimentation rate increased		1				1
Renal failure		1				1
Renal haemorrhage	1	1			1	1
Renal impairment		1				1
Renal infarct		1				1
Renal pain		1		1		
Respiration abnormal		1				1
Respiratory arrest	1	5			1	5
Respiratory distress	1	8			1	8
Respiratory failure	2	3			2	3
Respiratory rate increased		6		1		5
Restless legs syndrome		1				1
Retinal vein occlusion	1	1			1	1
Rhinitis		1		1		
Rhinorrhoea		2		2		
Rib fracture	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Scapula fracture	1	1			1	1
Sciatica		1		1		
Seizure	3	7			3	7
Seizure like phenomena		2				2
Sensation of foreign body		1				1
Sepsis		6				6
Septic shock	1	2			1	2
Skin discolouration		2				2
Skin turgor decreased		1				1
Slow speech		1				1
Solar dermatitis	1	1			1	1
Somnolence		4				4
Speech disorder	2	3	1	1	1	2
Spinal pain		1		1		
Spleen disorder	1	1			1	1
Status epilepticus	1	1			1	1
Stevens-Johnson syndrome		1				1
Streptococcal bacteraemia		1				1
Stress		1		1		
Subarachnoid haemorrhage	1	2			1	2
Subdural haematoma	2	2			2	2
Sudden death	1	4			1	4
Sudden visual loss	1	1			1	1
Swelling		4		1		3
Swelling face	1	4		1	1	3
Swollen tongue		1				1
Syncope	2	6			2	6
Systemic inflammatory response syndrome		1				1
Systemic lupus erythematosus	1	1			1	1
Tachycardia		4		1		3
Tachypnoea		3		2		1
Taste disorder		1				1
Temperature regulation disorder		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tenderness	1	1			1	1
Tenosynovitis		1				1
Throat irritation		1		1		
Throat tightness		3				3
Thrombocytopenia	9	9			9	9
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	2	4			2	4
Tinnitus	1	5			1	5
Toxic epidermal necrolysis		1				1
Tracheal haemorrhage		1				1
Transaminases increased		1				1
Transient ischaemic attack	3	4			3	4
Tremor		3				3
Troponin increased	1	1	1	1		
Unresponsive to stimuli		2				2
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract infection		1				1
Urinary incontinence		1				1
Urinary retention		1				1
Urinary tract infection	3	9	1	4	2	5
Urine output decreased		2				2
Urosepsis		3				3
Urticaria		7		2		5
Vaccination failure	2	4			2	4
Vaccination site bruising		1				1
Vaccination site erythema	2	12	1	9	1	3
Vaccination site haematoma		2				2
Vaccination site induration	1	3	1	2		1
Vaccination site lymphadenopathy		1				1
Vaccination site pain	1	23	1	16		7
Vaccination site pruritus		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Vaccination site reaction		2		1		1	
Vaccination site swelling	3	12	3	9		3	
Vaccination site warmth	1	5	1	5			
Vascular dementia		1				1	
Vasculitis		1				1	
Vasodilatation	1	1	1	1			
Ventricular fibrillation	2	2			2	2	
Ventricular tachycardia		1				1	
Vertigo		2		2			
Vision blurred		1				1	
Vomiting	8	36	2	6	6	30	
Wheezing	3	9	1	2	2	7	
White blood cell count increased	1	2	1	2			
White blood cells urine positive		1		1			
Wound	1	2		1	1	1	
	446	1,861	88	461	358	1400	

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Country Where Event Occurred

**SWITZERLAND**

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\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	4		1	2	3
Acute kidney injury	2	2			2	2
Acute myocardial infarction	1	2			1	2
Acute pulmonary oedema	1	2			1	2
Alanine aminotransferase increased		1		1		
Altered state of consciousness		1				1
Anaemia		1				1
Anal haemorrhage		1		1		
Anaphylactic reaction	1	5			1	5
Anaphylactic shock		1				1
Angioedema		3				3
Aphasia		1				1
Aphthous ulcer	1	1			1	1
Apnoea	1	1			1	1
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia		3				3
Ascites		1				1
Asthenia	2	6	1	2	1	4
Asthma		2				2
Atrial f brillation	1	1			1	1
Atrophy		1				1
Back pain	1	3		2	1	1
Blood alkaline phosphatase increased		1		1		
Blood pressure decreased		1				1
Blood pressure increased	1	2			1	2
Brain hypoxia		1				1
Cardiac arrest	1	2			1	2
Cardiac failure	3	4			3	4
Cardiac failure acute	1	1			1	1
Cardiac failure chronic		1				1
Cardiac fibrillation		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cardio-respiratory arrest		1					1
Cerebral infarction		1					1
Cerebrovascular accident	1	2			1		2
Chills	1	6		1	1		5
Cholecystitis acute	1	1			1		1
Cholestasis	1	2			1		2
Chronic obstructive pulmonary disease		2					2
Circulatory collapse	1	1			1		1
Coma		2					2
Condition aggravated	2	2			2		2
Confusional state	1	2			1		2
Cough		2		1			1
COVID-19	4	10		1	4		9
COVID-19 pneumonia	1	1			1		1
C-reactive protein increased	1	4	1	1			3
CSF test abnormal		1					1
Cystitis	1	1			1		1
Death	1	6			1		6
Decreased appetite	1	2			1		2
Deep vein thrombosis	1	1			1		1
Dehydration	1	2			1		2
Delirium	1	3			1		3
Diabetic ketoacidosis		1					1
Diabetic metabolic decompensation		1					1
Diarrhoea	2	6		1	2		5
Disease recurrence	1	1			1		1
Disorientation		1					1
Disturbance in attention		1					1
Dizziness	3	7		2	3		5
Drug ineffective	1	1			1		1
Dysphonia		1		1			
Dyspnoea	4	8	1	2	3		6
Embolism		1					1

\* I=Interval, C=Cumulative  
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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enuresis	1	1			1	1
Eosinophilia		1		1		
Epilepsy		3				3
Epistaxis		1		1		
Erythema		1				1
Erythema annulare	1	1			1	1
Eyelid oedema		1				1
Facial paralysis		1				1
Facial paresis	1	1			1	1
Fall		2				2
Fatigue	4	6		1	4	5
Feeding disorder	1	2	1	1		1
Feeling cold		1		1		
Feeling hot	1	1			1	1
Fluid overload	1	1			1	1
Gastric disorder		1				1
Gastritis	1	1			1	1
Gastrointestinal disorder		1				1
Gastrooesophageal reflux disease	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	3	4	2	2	1	2
Haematemesis	1	1			1	1
Haemophagocytic lymphohistiocytosis	1	1			1	1
Headache	1	9		3	1	6
Heart rate decreased		1				1
Hemiplegia		1				1
Hepatic cirrhosis		1				1
Hepatocellular injury	1	1			1	1
Herpes zoster	4	5			4	5
Hyperglycaemia		1				1
Hypersensitivity		4				4
Hypertension	2	6		2	2	4
Hypertensive emergency		1				1

\* I=Interval, C=Cumulative  
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Hyperthermia		1		1			
Hypoglycaemic coma		1					1
Hypotension	3	4		1	3		3
Immune thrombocytopenia		1					1
Immunisation anxiety related reaction	1	1			1		1
Incorrect route of product administration	4	6	4	6			
Infection		1		1			
Inflammation		2					2
Influenza like illness		2					2
Ischaemic cerebral infarction		1					1
Joint swelling		1					1
Lethargy		1		1			
Liver disorder	1	1			1		1
Liver injury		1					1
Loss of consciousness	1	2			1		2
Lung disorder	1	1			1		1
Lymphadenopathy	1	1			1		1
Lymphangiectasia	1	1			1		1
Lymphopenia		1					1
Malaise	3	9		3	3		6
Meniere's disease	1	1			1		1
Meningioma	1	1			1		1
Mobility decreased	1	1	1	1			
Monocytosis		1		1			
Muscular weakness		1					1
Myalgia	1	5	1	2			3
Myelitis	1	1			1		1
Nausea	5	10		2	5		8
Nervous system disorder		1					1
Neutrophilia		1					1
Odynophagia		1					1
Oesophageal perforation		1					1
Oropharyngeal pain		1		1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	1	3			1	3
Pain	2	2			2	2
Palpitations		1				1
Pancreatitis		1				1
Paraesthesia	1	1			1	1
Paranoia		1				1
Performance status decreased	1	1			1	1
Peripheral swelling		1				1
Peripheral vascular disorder		1				1
Pleural effusion		1		1		
Pneumonia	2	4			2	4
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Polyneuropathy		1				1
Presyncope	1	1			1	1
Pruritus		2				2
Pulmonary embolism	3	3			3	3
Pulmonary fibrosis	1	1			1	1
Purpura	1	1			1	1
Pyrexia	7	20	2	3	5	17
Rash	1	3	1	2		1
Rash erythematous		1				1
Rash maculo-papular	1	1			1	1
Renal failure		2				2
Renal impairment	1	1			1	1
Respiratory depression		1				1
Respiratory distress		1				1
Respiratory failure	1	3			1	3
Respiratory paralysis		1				1
Rheumatoid arthritis		2				2
Rhinitis		1		1		
Sedation	1	1			1	1
Sensory disturbance		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis		2				2
Septic shock		1				1
Skin lesion		1				1
Skin reaction	1	1			1	1
Somnolence		2				2
Sudden death	2	3			2	3
Syncope		1				1
Tachycardia	2	3			2	3
Tachypnoea		1				1
Thrombocytopenia	1	2			1	2
Transient ischaemic attack		1				1
Tremor		1				1
Urinary tract infection	1	1			1	1
Urinary tract infection bacterial		1				1
Urticaria		2				2
Vaccination failure	3	3			3	3
Vaccination site erythema		2		1		1
Vaccination site haematoma		1				1
Vaccination site oedema		1		1		
Vaccination site pain		4		3		1
Vaccination site pruritus		1		1		
Vaccination site reaction	1	1			1	1
Vaccination site swelling	1	2			1	2
Vaccination site urticaria		1				1
Vaccination site warmth		1		1		
Vascular encephalopathy		1				1
Ventricular fibrillation		1				1
Vertigo		1				1
Visual impairment	1	2			1	2
Vomiting	6	16		3	6	13
Weight decreased	1	1	1	1		
White matter lesion		1		1		
	147	404	17	70	130	334

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**TUNISIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Cough	1	1	1	1
Fatigue	1	1	1	1
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	5	5	5	5

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Country Where Event Occurred

**TURKEY**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Dizziness	2	2	2	2		
Drug ineffective	1	1			1	1
Dyspnoea	1	1	1	1		
Erythema	1	1	1	1		
Headache	2	2	2	2		
Herpes zoster	1	1	1	1		
Invasive ductal breast carcinoma	1	1			1	1
Vaccination site pain	2	2	2	2		
	12	12	9	9	3	3

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Country Where Event Occurred

**TURKS AND CAICOS ISLANDS**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Myalgia		1		1		
Nodule		1		1		
Seizure		1				1
		5		3		2

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Country Where Event Occurred  
**UKRAINE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
	1	1	1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED ARAB EMIRATES**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Arthralgia		1		1			
Back pain		1		1			
Chest pain	1	1			1	1	
Chills		1		1			
Cough		1		1			
COVID-19		1					1
Decreased appetite		1		1			
Drug ineffective	1	1			1	1	
Dyspnoea		2		1		1	
Erythropeia		1					1
Fatigue		3		3			
Feeling abnormal		1		1			
Fibromyalgia		1		1			
Headache	1	1	1	1			
Head injury	1	1			1	1	
Hypoxia		1					1
Injection site pain		1		1			
Loss of consciousness	1	1			1	1	
Nausea		1		1			
Off label use		1		1			
Product use issue		1		1			
Pyrexia		3		3			
Sleep deficit		1		1			
Somnolence		1		1			
Suspected COVID-19	1	1			1	1	
Tachypnoea		1		1			
Thrombosis	1	1			1	1	
	7	32	1	22	6	10	

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Country Where Event Occurred

**UNITED KINGDOM**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	12	59		1	6	14	6	45
Abdominal distension	9	44			4	14	5	30
Abdominal infection	1	1					1	1
Abdominal migraine	1	1					1	1
Abdominal pain	39	132			11	32	28	100
Abdominal pain lower	4	11			2	2	2	9
Abdominal pain upper	44	188			12	43	32	145
Abdominal rigidity		1						1
Abdominal tenderness		1						1
Abnormal behaviour	2	3					2	3
Abnormal dreams	4	12			3	5	1	7
Abnormal sensation in eye	1	3			1	1		2
Abnormal weight gain		1						1
Abortion spontaneous	6	11					6	11
Abscess		2				1		1
Abscess oral		2						2
Accident		1				1		
Acidosis	1	3				1	1	2
Acne	4	6					4	6
Acne pustular		1						1
Acquired haemophilia		1						1
Activated partial thromboplastin time prolonged	2	2					2	2
Acute abdomen	1	1					1	1
Acute cardiac event		1						1
Acute coronary syndrome	2	2					2	2
Acute disseminated encephalomyelitis	1	1					1	1
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	6	24					6	24
Acute leukaemia		1						1
Acute myocardial infarction	1	7					1	7
Acute respiratory distress syndrome		1						1
Acute respiratory failure		1						1
Addison's disease		1						1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site joint movement impairment		1						1
Adrenocortical insufficiency acute	3	8					3	8
Adverse drug reaction	1	10			1	8		2
Adverse reaction				1				
Affective disorder	1	1					1	1
Affect lability	1	3					1	3
African trypanosomiasis	1	1					1	1
Ageusia	9	36			5	11	4	25
Aggression	2	5				1	2	4
Agitation	2	14			1	5	1	9
Airway burns		1						1
Alanine aminotransferase increased	2	4					2	4
A buminuria	1	1					1	1
Alcohol interaction		1						1
Alexia		1				1		
Alexithymia		1				1		
Allergic oedema		2						2
Allergic reaction to excipient		1						1
Allergic sinusitis		1						1
Allergy to vaccine	3	12			1	4	2	8
Allodynia	1	3					1	3
Alopecia	4	6					4	6
Alopecia areata	2	2					2	2
Alopecia totalis	1	1					1	1
Altered state of consciousness	2	4					2	4
Amblyopia	1	1					1	1
Amenorrhoea	1	1					1	1
Ammonia abnormal		1				1		
Amnesia	8	14			1	2	7	12
Anaemia	2	11				2	2	9
Anaemia vitamin B12 deficiency		1						1
Anal fissure		1						1
Anal haemorrhage	1	2					1	2

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anal incontinence	1	7		1		1	1	6
Anal pruritus	1	2				1	1	1
Anaphylactic reaction	8	75					8	75
Anaphylactic shock		4						4
Anaphylactoid reaction		3						3
Anaphylactoid shock	1	1					1	1
Androgenetic alopecia	1	1					1	1
Aneurysm	1	1					1	1
Anger		3				2		1
Angina bullosa haemorrhagica	1	1					1	1
Angina pectoris	4	10					4	10
Angina unstable		1						1
Angioedema	9	37					9	37
Ankylosing spondylitis	1	6					1	6
Anorectal discomfort	1	2			1	1		1
Anosmia	4	15			2	4	2	11
Anticoagulation drug level below therapeutic	1	1					1	1
Antiphospholipid syndrome	1	2					1	2
Anuria	1	2					1	2
Anxiety	18	65			3	16	15	49
Aortic arteriosclerosis		1						1
Aortic dissection		1						1
Aortic embolus	2	2					2	2
Aortic stenosis		1						1
Apathy	1	2			1	1		1
Aphasia	5	10				1	5	9
Aphonia	1	9			1	1		8
Aphthous ulcer	2	4			1	1	1	3
Apnoea	1	1					1	1
Apparent death		1						1
Appetite disorder	1	2					1	2
Apraxia		1				1		
Arrhythmia	3	10					3	10

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arrhythmia supraventricular		1						1
Arterial stenosis		1						1
Arterial thrombosis	1	1					1	1
Arteriosclerosis coronary artery		1						1
Arthralgia	234	904	2	16	65	205	169	699
Arthritis	16	53			3	7	13	46
Arthritis reactive	1	3					1	3
Arthritis viral	1	1					1	1
Arthropathy	2	7				2	2	5
Arthropod sting	1	1			1	1		
Ascites		2						2
Aspartate aminotransferase increased		1						1
Aspiration		3						3
Asthenia	59	258		2	15	66	44	192
Asthenopia	2	11			1	2	1	9
Asthma	23	114			3	18	20	96
Asthma late onset		1						1
Asthma prophylaxis		1						1
Asymptomatic COVID-19	3	3					3	3
Ataxia	1	2					1	2
Atonic seizures		1						1
Atopy		1						1
Atrial fibrillation	7	30	1	1			7	30
Atrial flutter	1	2					1	2
Auditory disorder	2	3					2	3
Aura	2	3					2	3
Auricular swelling		2						2
Autoimmune disorder	1	9					1	9
Autoimmune neutropenia	1	1					1	1
Autonomic nervous system imbalance	1	1					1	1
Autoscopy	2	3					2	3
Axillary mass	11	20			2	7	9	13
Axillary pain	58	130			9	25	49	105

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Axonal neuropathy		1						1
Bacille Calmette-Guerin scar reactivation		2				1		1
Back pain	48	210		1	12	49	36	161
Bacterial infection		1						1
Balance disorder	13	55		1	1	10	12	45
Basal cell carcinoma	1	1					1	1
B-cell lymphoma		1						1
Bedridden		3						3
Behaviour disorder		3						3
Behcet's syndrome	2	5					2	5
Biliary colic		1						1
Bladder disorder		1						1
Bladder pain		1						1
Blepharitis	1	1					1	1
Blepharospasm	2	3					2	3
Blindness	4	12					4	12
Blindness transient	1	3					1	3
Blindness unilateral	2	3					2	3
Blister	11	29			1	5	10	24
Blood alkaline phosphatase increased		1						1
Blood blister	3	6			1	1	2	5
Blood creatine phosphokinase increased	1	2					1	2
Blood creatinine increased		2				1		1
Blood fibrinogen decreased	1	1					1	1
Blood glucose	1	2					1	2
Blood glucose abnormal		2				1		1
Blood glucose decreased	5	13				3	5	10
Blood glucose fluctuation	2	12			1	4	1	8
Blood glucose increased	7	53				17	7	36
Blood heavy metal increased		1				1		
Blood immunoglobulin E increased	1	1					1	1
Blood ketone body increased		1						1
Blood ketone body present		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood lactic acid increased	1	4			1	2		2
Blood magnesium decreased		1				1		
Blood pH	1	1					1	1
Blood potassium abnormal		1						1
Blood potassium decreased		2				1		1
Blood pressure abnormal	1	4			1	2		2
Blood pressure decreased	3	14				2	3	12
Blood pressure fluctuation	2	3					2	3
Blood pressure increased	7	41			2	9	5	32
Blood pressure systolic decreased		1						1
Blood pressure systolic increased		3				2		1
Blood sodium decreased	1	3					1	3
Blood test abnormal	3	3					3	3
Blood urea increased		1						1
Blood urine present	1	1			1	1		
Body temperature	2	2			1	1	1	1
Body temperature abnormal	4	18			2	5	2	13
Body temperature decreased	2	13				2	2	11
Body temperature fluctuation	3	9			1	2	2	7
Body temperature increased	19	76		2	9	28	10	48
Bone neoplasm	1	2			1	1		1
Bone pain	19	60	2	2	4	11	15	49
Bone swelling		2				1		1
Bowel movement irregularity		1						1
Bradycardia	1	9					1	9
Bradykinesia	1	1			1	1		
Bradyphrenia	3	4			1	1	2	3
Brain injury		1						1
Brain neoplasm	1	2					1	2
Brain oedema		1						1
Brain stem stroke		1						1
Breast cancer	5	8					5	8
Breast discomfort	2	2			1	1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breast disorder	1	1					1	1
Breast enlargement	1	2					1	2
Breast mass	1	5					1	5
Breast pain	11	22				2	11	20
Breast swelling	3	8				3	3	5
Breast tenderness	2	6				1	2	5
Breath odour	1	3				1	1	2
Breath sounds abnormal		1						1
Bronchial secretion retention	1	1			1	1		
Bronchiectasis	2	5					2	5
Bronchitis		1						1
Bronchopulmonary aspergillosis		1						1
Bronchospasm	2	7				1	2	6
Bulbar palsy	1	1					1	1
Bundle branch block right		1				1		
Burning feet syndrome		1						1
Burning sensation	16	50			4	11	12	39
Burn oesophageal		1						1
Burn oral cavity		1						1
Bursitis	2	3			1	1	1	2
Butterfly rash	1	2				1	1	1
Cachexia		1						1
Candida infection	2	2					2	2
Cardiac arrest	6	26					6	26
Cardiac disorder		4				1		3
Cardiac failure	5	12					5	12
Cardiac failure acute	2	2					2	2
Cardiac failure chronic	1	1					1	1
Cardiac failure congestive		3						3
Cardiac flutter	2	13					2	13
Cardiac murmur	1	2					1	2
Cardiac valve disease		1						1
Cardiomegaly		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		1						1
Cardiovascular disorder	1	2					1	2
Carotid artery occlusion	1	1					1	1
Carpal tunnel syndrome	1	2					1	2
Cataplexy	1	2					1	2
Catatonia		1						1
Cavernous sinus thrombosis	1	1					1	1
Cellulitis	7	24					7	24
Central nervous system lesion	1	1			1	1		
Central nervous system vasculitis	1	1					1	1
Central venous pressure abnormal	1	1			1	1		
Central vision loss	1	1					1	1
Cerebellar stroke		1						1
Cerebral artery thrombosis	2	2					2	2
Cerebral disorder		2				1		1
Cerebral haemorrhage	5	12					5	12
Cerebral infarction	6	13					6	13
Cerebral thrombosis	3	4					3	4
Cerebral venous sinus thrombosis	5	6					5	6
Cerebrospinal fluid leakage		1						1
Cerebrovascular accident	25	66					25	66
Change of bowel habit	2	2			1	1	1	1
Chapped lips		3						3
Charles Bonnet syndrome		1						1
Cheilitis		4				1		3
Chest discomfort	33	158			15	35	18	123
Chest injury	1	1					1	1
Chest pain	49	230		1	7	24	42	206
Chest X-ray abnormal		1				1		
Chillblains	6	8			5	5	1	3
Chills	218	879	2	8	86	239	132	640
Choking	1	4					1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Choking sensation		1						1
Cholangitis	1	1					1	1
Cholecystitis infective		1						1
Cholelithiasis	1	2					1	2
Chorea		2						2
Choroidal neovascularisation		1						1
Chromaturia	1	7				1	1	6
Chronic fatigue syndrome	6	13				1	6	12
Chronic gastritis	1	1					1	1
Chronic kidney disease	1	4					1	4
Chronic lymphocytic leukaemia	1	1					1	1
Chronic obstructive pulmonary disease	5	13					5	13
Chronic spontaneous urticaria		1						1
Circulatory collapse	2	21					2	21
Circumstance or information capable of leading to medication error		1				1		
Clostridium test positive	1	1					1	1
Clot retraction		1						1
Clumsiness	1	2					1	2
Cluster headache	8	16				1	8	15
Coagulopathy		1						1
Coeliac disease	1	3					1	3
Cognitive disorder	2	20				2	2	18
Cold-stimulus headache		1						1
Cold sweat	14	70			4	15	10	55
Colitis	5	10					5	10
Colitis ischaemic	1	1					1	1
Colitis microscopic		1						1
Colitis ulcerative	10	20	1	1			10	20
Colon cancer	1	1					1	1
Coma	2	4					2	4
Coma scale abnormal		2						2
Communication disorder	2	3					2	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Condition aggravated	41	138	1	1	9	23	32	115
Confusional arousal		1						1
Confusional state	33	124		1	5	23	28	101
Congenital cystic lung		1						1
Conjunctival haemorrhage	2	5					2	5
Conjunctival hyperaemia	1	1					1	1
Conjunctival oedema	1	1					1	1
Conjunctivitis	1	8					1	8
Constipation	5	22				4	5	18
Contrast media reaction		1						1
Contusion	21	50			4	10	17	40
Coordination abnormal	5	12				2	5	10
Corneal reflex decreased		1				1		
Coronary artery disease		2						2
Coronary artery stenosis		1						1
Coronavirus infection	1	1					1	1
Cortisol decreased		1						1
Costochondritis	2	6				1	2	5
Cough	62	248		1	19	70	43	178
Cough decreased		1				1		
COVID-19	24	125	1	1	9	23	15	102
COVID-19 immunisation	1	1					1	1
COVID-19 pneumonia	2	15					2	15
Cranial nerve disorder		1						1
C-reactive protein abnormal	1	1					1	1
C-reactive protein increased	4	9				1	4	8
Crohn's disease	3	15					3	15
Crying	2	9			1	3	1	6
Cyanosis	3	12			2	4	1	8
Cyanosis central		1						1
Cyst	1	1			1	1		
Cystitis	3	6			1	1	2	5
Cystitis interstitial	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dark circles under eyes	1	1					1	1
Deafness	10	24					10	24
Deafness neurosensory	1	5					1	5
Deafness unilateral	1	3					1	3
Death	8	39					8	39
Decreased activity	1	1			1	1		
Decreased appetite	49	212		2	14	48	35	164
Decreased immune responsiveness		2						2
Decreased insulin requirement	1	1					1	1
Decreased interest	1	2					1	2
Decubitus ulcer	1	1					1	1
Deep vein thrombosis	16	28		1			16	28
Defaecation urgency	2	5					2	5
Dehydration	6	24			2	7	4	17
Delirium	6	27					6	27
Delusion	2	3				1	2	2
Dementia	2	8					2	8
Dementia Alzheimer's type	1	1					1	1
Dementia with Lewy bodies		1						1
Demyelination	2	2					2	2
Dental caries	1	1					1	1
Dental discomfort		1						1
Depressed level of consciousness	2	6					2	6
Depressed mood	4	23			1	3	3	20
Depression	8	24				1	8	23
Dermatitis	3	10			1	3	2	7
Dermatitis allergic	4	17				5	4	12
Dermatitis atopic		3						3
Dermatitis bullous		1						1
Dermatitis contact	1	1					1	1
Dermatitis diaper	1	1			1	1		
Dermatitis exfoliative		1						1
Dermatomyositis		3						3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Device infusion issue		1							1
Diabetes mellitus	7	16					7		16
Diabetes mellitus inadequate control	2	7					2		7
Diabetic coma	1	1					1		1
Diabetic complication	1	2					1		2
Diabetic eye disease		1				1			
Diabetic ketoacidosis		5							5
Diaphragmalgia		1							1
Diaphragmatic disorder	1	1					1		1
Diarrhoea	112	480	2	5	39	100	73		380
Diarrhoea haemorrhagic	1	2					1		2
Diplegia	2	3					2		3
Diplopia	10	21			2	4	8		17
Discharge		1							1
Discoloured vomit		1							1
Discomfort	9	38		1	2	13	7		25
Disease recurrence	32	85			1	5	31		80
Disorganised speech		1							1
Disorientation	8	24			1	5	7		19
Disseminated intravascular coagulation	1	1					1		1
Disseminated varicella zoster virus infection		1							1
Dissociation	2	6			1	3	1		3
Disturbance in attention	18	59		1	5	14	13		45
Diverticulitis	1	3					1		3
Dizziness	173	715		6	58	159	115		556
Dizziness exertional	3	6			1	1	2		5
Dizziness postural	24	82		1	5	20	19		62
Dreamy state		1				1			
Drooling	1	3				1	1		2
Drooping shoulder syndrome		1				1			
Drug eruption	1	3					1		3
Drug hypersensitivity	1	6					1		6
Drug-induced liver injury	1	1					1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Drug ineffective	22	126	1	1			22	126
Drug interaction		1						1
Drug level decreased		1						1
Drug level fluctuating	1	1					1	1
Drug withdrawal syndrome		1						1
Dry eye	4	17				5	4	12
Dry mouth	8	56		1	1	13	7	43
Dry skin	9	19			2	5	7	14
Dry throat	6	18		1	4	8	2	10
Duodenal ulcer perforation		1						1
Duodenogastric reflux		1						1
Dysarthria	8	26				2	8	24
Dysgeusia	24	86			13	36	11	50
Dysgraphia		1						1
Dyshidrotic eczema		1						1
Dyskinesia	5	12			1	2	4	10
Dysmenorrhoea	2	7			1	3	1	4
Dysmorphism		1						1
Dyspepsia	6	21			2	5	4	16
Dysphagia	17	49			4	9	13	40
Dysphemia	1	2			1	1		1
Dysphonia	6	22			2	6	4	16
Dyspnoea	128	472			25	71	103	401
Dyspnoea at rest	1	4					1	4
Dyspnoea exertional	2	17				5	2	12
Dysstasia	8	19			1	6	7	13
Dystonia		2						2
Dysuria	1	9				2	1	7
Ear congestion		2						2
Ear discomfort	3	10			1	3	2	7
Ear disorder	1	4				1	1	3
Ear haemorrhage	1	1					1	1
Ear infection	8	11			1	3	7	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear infection bacterial		1						1
Ear pain	18	71			4	16	14	55
Ear pruritus		2				1		1
Ear swelling	1	3			1	2		1
Eating disorder	2	11				2	2	9
Eczema	5	15				3	5	12
Eczema eyelids	1	1			1	1		
Eczema herpeticum	1	2					1	2
Eczema weeping		1				1		
Electric shock	1	2					1	2
Electrocardiogram abnormal	1	2					1	2
Electrocardiogram ST segment elevation		1						1
Embolic cerebral infarction	1	1					1	1
Embolic stroke		1						1
Embolism	16	16					16	16
Emotional disorder	4	7			2	2	2	5
Emotional distress		4				1		3
Emphysema		1						1
Encephalitis	2	4					2	4
Encephalitis viral	1	1					1	1
Encephalopathy		2						2
Endometriosis		1						1
Energy increased	1	2					1	2
Enlarged uvula	1	2			1	1		1
Enteritis	1	2					1	2
Enthesopathy		1						1
Enuresis	2	2					2	2
Eosinophil count increased	1	1					1	1
Epicondylitis		2						2
Epigastric discomfort		2						2
Epiglottic oedema		1						1
Epiglottitis	2	2					2	2
Epilepsy	4	15					4	15

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Epileptic aura		1						1
Epileptic encephalopathy		1						1
Epiphyses premature fusion		1						1
Episcleritis		1						1
Epistaxis	18	45			5	8	13	37
Epstein-Barr virus infection		1						1
Erectile dysfunction		2						2
Eructation		5				1		4
Erythema	56	180			31	76	25	104
Erythema annulare	1	1					1	1
Erythema multiforme	2	7					2	7
Erythema nodosum	2	3			1	1	1	2
Erythema of eyelid	1	1					1	1
Erythroptosis		1						1
Essential hypertension		1						1
Euphoric mood	2	4			1	2	1	2
Excessive cerumen production	1	1					1	1
Exercise tolerance decreased	2	2			1	1	1	1
Exertional headache	1	1			1	1		
Exposure during pregnancy	3	6			1	4	2	2
Exposure to extreme temperature	1	1					1	1
Exposure to SARS-CoV-2		1						1
Exposure via breast milk	1	1			1	1		
Extensive swelling of vaccinated limb		3				3		
External ear cellulitis		1						1
External ear pain		1				1		
Extraocular muscle paresis		1						1
Extrasystoles	1	5				2	1	3
Extremity necrosis	1	1					1	1
Eye allergy		1						1
Eye colour change		1						1
Eye contusion		3				2		1
Eye discharge	1	4					1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Eye disorder	1	7				1	1	6
Eye haemorrhage	2	6					2	6
Eye infection		2						2
Eye inflammation	2	2			1	1	1	1
Eye irritation	1	11				1	1	10
Eyelid cyst		1						1
Eyelid disorder		1						1
Eyelid oedema	1	1					1	1
Eyelid pain		3				1		2
Eyelid ptosis	2	7				3	2	4
Eye movement disorder	1	4					1	4
Eye oedema	1	1			1	1		
Eye pain	24	102			8	17	16	85
Eye pruritus	4	20		1	2	7	2	13
Eye swelling	7	55		1	3	10	4	45
Eye symptom	1	1					1	1
Face oedema	1	4					2	2
Facial asymmetry		1				1		
Facial discomfort		1						1
Facial neuralgia	1	3			1	1		2
Facial pain	12	35			4	9	8	26
Facial paralysis	21	107		1			21	107
Facial paresis	3	14				3	3	11
Facial spasm	1	3			1	2		1
Faecal calprotectin		1						1
Faecaloma		2						2
Faeces discoloured	1	11				5	1	6
Failed in vitro fertilisation	1	1					1	1
Fall	15	51			3	11	12	40
Familial periodic paralysis		1						1
Fatigue	509	2,021	4	31	171	492	338	1529
Fear	2	5				1	2	4
Febrile convulsion	3	3			3	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Feeding disorder	2	11				1	2	10
Feeling abnormal	55	193		1	20	51	35	142
Feeling cold	56	184		1	18	52	38	132
Feeling drunk	1	10			1	3		7
Feeling hot	30	142			14	51	16	91
Feeling jittery	1	3					1	3
Feeling of body temperature change	18	57			6	18	12	39
Feeling of despair	1	2					1	2
Fibrin D dimer increased	3	5			1	2	2	3
Fibromyalgia		7				1		6
Fine motor skill dysfunction		1						1
Flank pain		2				1		1
Flashback	1	1					1	1
Flatulence	5	12			1	3	4	9
Fluid intake reduced		1						1
Fluid retention	2	5			1	1	1	4
Flushing	10	46			4	16	6	30
Foetal death	1	1					1	1
Food aversion	1	3					1	3
Food craving		1						1
Food refusal		2						2
Forced expiratory volume increased		1						1
Foreign body in gastrointestinal tract	1	1					1	1
Foreign body in mouth	1	1					1	1
Foreign body sensation in eyes	1	3			1	2		1
Formication	1	7				1	1	6
Foveal reflex abnormal	1	1					1	1
Fracture		1						1
Fractured skull depressed		1						1
Freezing phenomenon	1	3					1	3
Frequent bowel movements	2	9			1	3	1	6
Full blood count increased		1						1
Functional gastrointestinal disorder	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Furuncle	2	4					2	4
Gait disturbance	28	80		1	1	12	27	68
Gait inability	7	31				3	7	28
Galactorrhoea	2	2					2	2
Gastric antral vascular ectasia	1	2					1	2
Gastric cancer		1						1
Gastric dilatation		1						1
Gastric disorder		4				1		3
Gastric haemorrhage		1						1
Gastric varices haemorrhage		1						1
Gastritis	1	6				1	1	5
Gastroenteritis	3	8			1	1	2	7
Gastroenteritis norovirus	1	1					1	1
Gastroenteritis viral		1						1
Gastrointestinal carcinoma	1	1					1	1
Gastrointestinal disorder	3	6				3	3	3
Gastrointestinal pain	4	13			1	1	3	12
Gastrointestinal sounds abnormal	1	4				1	1	3
Gastrointestinal stoma complication		1						1
Gastrooesophageal reflux disease	1	12					1	12
Gastroschisis	1	1					1	1
Generalised oedema	1	1					1	1
Generalised tonic-clonic seizure	2	8					2	8
General physical health deterioration	1	5				1	1	4
Genital pain		1						1
Genital tract inflammation		1				1		
Giant cell arteritis		3						3
Gingival bleeding	1	2			1	1		1
Gingival blister		1				1		
Gingival discomfort		1						1
Gingival disorder		2				1		1
Gingival pain	2	11				2	2	9
Gingival swelling	1	2					1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Gingivitis		1				1			
Glaucoma	1	2					1	2	
Gliositis		1							1
Glomerulonephritis minimal lesion	1	2					1	2	
Glossitis		3				1			2
Glossodynia	6	24			1	7	5	17	
Glucose urine present		1							1
Goitre	1	2			1	1			1
Gout	2	9					2	9	
Graft versus host disease	1	1					1	1	
Grief reaction	1	1					1	1	
Grip strength decreased	1	8				2	1	6	
Groin pain	4	12			1	3	3	9	
Guillain-Barre syndrome	3	8					3	8	
Guttate psoriasis	1	1					1	1	
Habit cough	1	1			1	1			
Haemarthrosis	1	1					1	1	
Haematemesis		8							8
Haematochezia	5	10					5	10	
Haematocrit increased		1							1
Haematoma		5				2			3
Haematospermia	1	1					1	1	
Haematuria	4	6					4	6	
Haemodynamic instability		1							1
Haemoglobin decreased		6				3			3
Haemoglobin increased		1							1
Haemophilia		1							1
Haemoptysis	6	11			2	2	4	9	
Haemorrhage	13	23					13	23	
Haemorrhage intracranial	1	4					1	4	
Haemorrhage urinary tract	1	2					1	2	
Haemorrhagic stroke	1	2					1	2	
Haemorrhoids	1	2					1	2	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hair disorder	1	1			1	1		
Hair texture abnormal	2	2					2	2
Hallucination	7	22					7	22
Hallucination, auditory		2						2
Hallucination, olfactory		1						1
Hallucination, visual		2						2
Hand-arm vibration syndrome		1						1
Hand deformity	2	2					2	2
Hangover		4				1		3
Headache	552	2,170	1	19	194	561	358	1609
Head banging	1	1			1	1		
Head discomfort	16	43			3	9	13	34
Head injury	4	9				2	4	7
Heart injury		3						3
Heart rate	2	4					2	4
Heart rate abnormal	4	9		1	1	1	3	8
Heart rate decreased	3	8					3	8
Heart rate increased	19	96			10	27	9	69
Heart rate irregular	4	12					4	12
Heart sounds abnormal	1	1					1	1
Heat illness		1						1
Heat stroke		1				1		
Hemiparesis	3	11					3	11
Hemiplegia	2	3					2	3
Hemiplegic migraine	1	1					1	1
Hepatic artery embolism		1						1
Hepatic enzyme increased	1	2				1	1	1
Hepatic pain		2						2
Hepatitis	1	2					1	2
Hepatitis viral	1	1					1	1
Herpes simplex	2	5			1	2	1	3
Herpes virus infection		1						1
Herpes zoster	20	88			1	23	19	65

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Herpes zoster meningoencephalitis	1	1					1	1
Herpes zoster reactivation		1						1
Hiccups		1						1
Hip fracture		1						1
Hordeolum		1						1
Hot flush	21	80			11	21	10	59
Hyperacusis	4	10			1	1	3	9
Hyperaesthesia	4	14			1	6	3	8
Hyperaesthesia teeth		1						1
Hypercapnia		1						1
Hyperchlorhydria		4				1		3
Hypergeusia		1						1
Hyperglycaemia	6	25				3	6	22
Hyperhidrosis	45	187		1	13	33	32	154
Hyperkalaemia		2						2
Hyperoxia	1	1					1	1
Hyperpyrexia		1						1
Hypersensitivity	10	57			1	10	9	47
Hypersensitivity pneumonitis		1						1
Hypersomnia	15	48			6	15	9	33
Hypertension	12	63		1	3	14	9	49
Hypertensive crisis	1	1					1	1
Hypertensive heart disease		3						3
Hyperthermia		1						1
Hyperthyroidism	3	5					3	5
Hypertonia		2						2
Hypertonic bladder		1				1		
Hypertrophic cardiomyopathy		1						1
Hyperventilation		1						1
Hypervolaemia		1						1
Hyphaema		1						1
Hypoacusis	4	8			1	1	3	7
Hypoaesthesia	48	179		3	13	44	35	135

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hypoaesthesia eye	1	2					1	2
Hypoaesthesia oral	4	44			2	17	2	27
Hypocalcaemia	1	2					1	2
Hypoglycaemia	4	32				5	4	27
Hypoglycaemic coma		1						1
Hypokalaemic syndrome		2						2
Hypokinesia	9	16			1	2	8	14
Hypomenorrhoea		1						1
Hyponatraemia		2						2
Hyponatraemic syndrome	1	1					1	1
Hypophagia	5	9					5	9
Hypopnoea	5	11					5	11
Hyporeflexia		3				1		2
Hyporesponsive to stimuli		1						1
Hyposmia		2						2
Hyposomnia		1						1
Hypotension	6	42			1	7	5	35
Hypothermia	2	9					2	9
Hypothyroidism	5	7					5	7
Hypotonia	1	3					1	3
Hypoventilation	1	1					1	1
Hypovitaminosis		1						1
Hypovolaemic shock	1	1					1	1
Hypoxia	1	9					1	9
Idiopathic intracranial hypertension		1						1
IgA nephropathy	1	1					1	1
Illrd nerve disorder	1	2					1	2
Illrd nerve paralysis	1	1					1	1
Illness	52	166			18	35	34	131
Immobile	2	5					2	5
Immune system disorder	4	10			1	1	3	9
Immune thrombocytopenia	6	17					6	17
Immunisation anxiety related reaction		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Immunodeficiency		3							3
Immunodeficiency common variable	1	1					1		1
Impaired driving ability	1	3				2	1		1
Impaired gastric emptying		1							1
Impaired quality of life	1	1					1		1
Impaired work ability	1	3					1		3
Implant site pain		1							1
Inadequate analgesia	1	1					1		1
Inappropriate affect		1							1
Inappropriate schedule of product administration	99	124			97	122	2		2
Incoherent	2	5			1	2	1		3
Incontinence	2	6			1	3	1		3
Incorrect dose administered	1	1			1	1			
Incorrect route of product administration		10				10			
Increased insulin requirement		1							1
Increased upper airway secretion		2				1			1
Increased viscosity of upper respiratory secretion	1	3					1		3
Infarction	1	3					1		3
Infection	9	23			1	4	8		19
Infectious mononucleosis	1	2					1		2
Infectious pleural effusion		1							1
Inflammation	10	28			2	7	8		21
Inflammatory bowel disease	1	1					1		1
Inflammatory marker increased		2				1			1
Inflammatory pain	1	3			1	2			1
Influenza	45	140		1	13	30	32		110
Influenza like illness	76	302		2	21	93	55		209
Inhibitory drug interaction		1							1
Initial insomnia		1				1			
Injected limb mobility decreased		2				1			1
Injection related reaction	2	8					2		8
Injection site erythema	3	5			3	5			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Injection site mass		1				1			
Injection site muscle weakness	1	1					1	1	
Injection site pain	6	9			4	5	2	4	
Injection site pruritus		1				1			
Injection site pustule	1	1					1	1	
Injection site reaction		1						1	
Injection site swelling		2				2			
Injury corneal		1							1
Inner ear disorder	1	1					1	1	
Inner ear inflammation		1							1
Insomnia	42	168			10	48	32	120	
Insulin resistance		3				1			2
Intentional self-injury	1	1					1	1	
International normalised ratio abnormal	1	1			1	1			
International normalised ratio decreased		4							4
International normalised ratio increased	2	9				2	2	7	
Interstitial lung disease	1	1					1	1	
Intervertebral disc compression	1	1					1	1	
Intestinal haemorrhage	1	1					1	1	
Intestinal infarction	1	1					1	1	
Intestinal ischaemia		2							2
Intestinal obstruction	1	3					1	3	
Intestinal perforation		1							1
Intracranial aneurysm	1	1					1	1	
Intrusive thoughts	1	1					1	1	
Iodine uptake increased		1							1
Iridocyclitis		5							5
Iritis		2				1			1
Iron deficiency	1	2					1	2	
Irregular breathing		2							2
Irritability	1	9			1	3			6
Irritable bowel syndrome	2	13			1	2	1	11	
Ischaemic stroke	2	8					2	8	

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Itching scar		1				1			
Jaundice	2	3					2		3
Joint effusion		7				1			6
Joint range of motion decreased	13	30			2	9	11		21
Joint stiffness	11	48			1	7	10		41
Joint swelling	23	69			5	15	18		54
Joint warmth		1							1
Jugular vein thrombosis	2	2			1	1	1		1
Keratitis		2				1			1
Kidney infection	1	3					1		3
Kidney small		1							1
Kidney transplant rejection	1	1					1		1
Labile blood pressure		2							2
Labyrinthitis	2	8				1	2		7
Lacrimation increased	3	25			1	5	2		20
Language disorder	2	2					2		2
Laryngeal pain		1							1
Laryngitis		2							2
Latent autoimmune diabetes in adults		1							1
Left ventricular dysfunction	2	3					2		3
Left ventricular failure		2							2
Lethargy	52	210			19	59	33		151
Leukaemia		1							1
Leukopenia	1	1					1		1
Lichenoid keratosis	1	2					1		2
Ligament disorder	1	1					1		1
Ligamentitis	1	1					1		1
Limbal swelling	1	1					1		1
Limb discomfort	37	139	1	2	16	46	21		93
Limb immobilisation	1	3				2	1		1
Limb injury	2	4					2		4
Limb mass	1	6				2	1		4
Lip blister		2							2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Lip disorder		4				2			2
Lip dry	1	8				2	1		6
Lip oedema		2							2
Lip pain	1	6				2	1		4
Lip swelling	13	79		1	4	17	9		62
Listless	1	2					1		2
Livedo reticularis		2							2
Liver function test abnormal	1	4				1	1		3
Liver function test increased	1	5				1	1		4
Liver injury	1	1					1		1
Liver tenderness	1	1					1		1
Localised infection	2	6				1	2		5
Localised oedema	1	3			1	1			2
Local reaction	1	6			1	3			3
Logorrhoea		1							1
Long thoracic nerve palsy		1				1			
Loss of consciousness	19	67					19		67
Loss of control of legs		1							1
Loss of libido	1	1					1		1
Loss of personal independence in daily activities	12	42			2	15	10		27
Lower respiratory tract infection	15	52					15		52
Lung consolidation	1	2					1		2
Lung disorder	1	6				1	1		5
Lung neoplasm malignant	1	1					1		1
Lymphadenitis	8	15			1	3	7		12
Lymphadenopathy	188	495			59	139	129		356
Lymph gland infection	1	2				1	1		1
Lymph node pain	38	102			8	23	30		79
Lymphocyte count increased		1							1
Lymphoedema	6	17			2	4	4		13
Lymphoma	1	3					1		3
Lymphopenia		1				1			
Macular degeneration		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Macular rupture	1	1					1	1
Macule	1	2			1	1		1
MAGIC syndrome		1						1
Malaise	176	773		4	58	201	118	572
Mania		1						1
Mass	1	5			1	1		4
Mast cell activation syndrome		2						2
Mastication disorder	1	3					1	3
Mastitis	2	5					2	5
Mastocytosis		1						1
Maternal exposure before pregnancy	1	1					1	1
Maternal exposure during breast feeding	5	5			2	2	3	3
Maternal exposure during pregnancy	4	20	1	1	2	10	2	10
Medial tibial stress syndrome		1						1
Melaena	1	2					1	2
Memory impairment	8	26			2	4	6	22
Meniere's disease	2	4					2	4
Meningitis	1	2					1	2
Meningitis aseptic		1						1
Meningitis viral	1	1					1	1
Menopausal symptoms		1				1		
Menorrhagia	5	14			1	2	4	12
Menstrual disorder	2	6				1	2	5
Menstruation delayed	1	4			1	1		3
Menstruation irregular	2	4			1	3	1	1
Mental disorder	1	2				1	1	1
Mental fatigue	3	21				2	3	19
Mental impairment		5						5
Mental status changes		1						1
Mesenteric vein thrombosis	1	1					1	1
Metamorphopsia		3				1		2
Metastatic neoplasm	1	1					1	1
Metrorrhagia	1	2			1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Microvascular coronary artery disease		1						1
Micturition disorder		3				1		2
Micturition urgency		1						1
Middle ear inflammation		1						1
Middle insomnia	3	11			1	2	2	9
Migraine	65	212	1	1	12	33	53	179
Migraine with aura	5	20				2	5	18
Miliaria	3	8			1	2	2	6
Mini mental status examination abnormal		1						1
Miosis		2						2
Mitral valve incompetence	1	1					1	1
Moaning		1						1
Mobility decreased	16	68			3	14	13	54
Monoparesis	1	7					1	7
Monoplegia		8						8
Mood altered	1	2				1	1	1
Mood swings		3				1		2
Morning sickness		1						1
Morose		2				2		
Motion sickness	1	2				1	1	1
Mouth breathing		2						2
Mouth haemorrhage	2	2			1	1	1	1
Mouth swelling	2	16				1	2	15
Mouth ulceration	8	40			2	13	6	27
Movement disorder	5	24				2	5	22
Mucosal haemorrhage		1						1
Mucous stools	2	2					2	2
Multiple injuries		1						1
Multiple organ dysfunction syndrome		3						3
Multiple sclerosis	2	10					2	10
Multiple sclerosis relapse	4	20					4	20
Multiple sclerosis relapse prophylaxis	1	1					1	1
Mumps	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Muscle atrophy	1	1					1	1
Muscle contractions involuntary		2				1		1
Muscle disorder		2						2
Muscle fatigue	12	44			3	6	9	38
Muscle injury		1						1
Muscle rigidity		3						3
Muscle rupture	1	3					1	3
Muscle spasms	22	81			6	16	16	65
Muscle spasticity		1						1
Muscle strain	2	5					2	5
Muscle swelling	2	3			1	1	1	2
Muscle tightness	4	12			1	4	3	8
Muscle tone disorder		1						1
Muscle twitching	3	19			2	5	1	14
Muscular weakness	34	130			7	23	27	107
Musculoskeletal chest pain	8	22			1	3	7	19
Musculoskeletal discomfort	8	16			3	6	5	10
Musculoskeletal disorder	1	5				1	1	4
Musculoskeletal pain	3	9					3	9
Musculoskeletal stiffness	35	139		1	9	30	26	109
Mutism		1				1		
Myalgia	237	953	3	9	90	255	147	698
Myasthenia gravis	3	5					3	5
Myasthenia gravis crisis	1	1					1	1
Mydriasis		2						2
Myelitis transverse	2	5					2	5
Myelodysplastic syndrome		1						1
Myocardial haemorrhage		1						1
Myocardial infarction	7	24					7	24
Myocardial ischaemia		7						7
Myocarditis	2	4					2	4
Myoclonus	1	2					1	2
Myositis	2	4					2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Nail avulsion		1				1			
Nail discolouration		3				1			2
Nail pigmentation	1	1					1		1
Nail ridging	1	1					1		1
Narcolepsy		1							1
Nasal congestion	5	27			1	6	4		21
Nasal discharge discolouration		1				1			
Nasal discomfort	3	7					3		7
Nasal disorder		1				1			
Nasal dryness	1	2					1		2
Nasal obstruction		1							1
Nasal odour		1							1
Nasopharyngitis	27	89			9	23	18		66
Nausea	268	1,173		8	100	290	168		883
Neck mass		2							2
Neck pain	57	224		1	21	55	36		169
Necrotising fasciitis	1	2					1		2
Negative thoughts		1							1
Neoplasm	2	2					2		2
Nephrolithiasis		1							1
Nephrotic syndrome	2	7					2		7
Nerve compression	1	3			1	2			1
Nerve injury	3	6			2	2	1		4
Nervousness	6	30			2	7	4		23
Nervous system disorder		2				1			1
Neuralgia	13	35			2	8	11		27
Neurogenic shock		1							1
Neurological symptom	2	5					2		5
Neurologic neglect syndrome		1							1
Neuromuscular pain	1	1					1		1
Neuropathy peripheral	8	22					8		22
Neuropsychiatric symptoms		1				1			
Neutropenia	4	12					4		12

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Neutropenic sepsis		1						1
Neutrophil count decreased	1	2			1	2		
Neutrophilia		1						1
Nightmare	5	14			1	2	4	12
Night sweats	9	45		2	5	11	4	34
Nipple pain	2	5				1	2	4
Nipple swelling		1				1		
Nodule	3	5			2	2	1	3
Non-cardiac chest pain		2				1		1
Noninfective gingivitis		1						1
Noninfective sialoadenitis	1	1					1	1
Numb chin syndrome		1						1
Obsessive-compulsive symptom		1						1
Obstructive airways disorder		1						1
Obstructive pancreatitis	1	1					1	1
Occipital neuralgia	1	2					1	2
Occupational exposure to SARS-CoV-2		1				1		
Ocular discomfort	4	6			3	3	1	3
Ocular hyperaemia	6	25			3	7	3	18
Ocular myasthenia	1	1					1	1
Ocular sarcoidosis		1						1
Odynophagia	2	8			1	4	1	4
Oedema	4	7			1	2	3	5
Oedema mouth		1						1
Oedema peripheral	4	12				3	4	9
Oesophageal pain	1	2					1	2
Oesophageal varices haemorrhage		1						1
Oesophagitis	1	1			1	1		
Off label use	114	428			108	412	6	16
Oligodendroglioma	1	1					1	1
Oliguria	1	2					1	2
Onychoclasia	2	2			1	1	1	1
Ophthalmological examination abnormal	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ophthalmoplegia		1						1
Optic neuritis	1	4					1	4
Oral allergy syndrome		1						1
Oral blood blister	1	2			1	1		1
Oral candidiasis		3				1		2
Oral discomfort	1	12				2	1	10
Oral disorder	2	4				2	2	2
Oral dysaesthesia		1						1
Oral herpes	4	21			3	6	1	15
Oral lichen planus	2	2					2	2
Oral mucosal blistering	1	5			1	4		1
Oral mucosal erythema	2	4			1	1	1	3
Oral mucosal exfoliation		1				1		
Oral mucosal roughening		1						1
Oral pain	5	15			3	4	2	11
Oral pruritus	1	3			1	1		2
Orchitis		1						1
Oropharyngeal blistering		5						5
Oropharyngeal discomfort	7	10			3	3	4	7
Oropharyngeal oedema		1						1
Oropharyngeal pain	55	241		3	22	71	33	170
Oropharyngeal spasm		1						1
Orthopnoea		2				1		1
Orthostatic hypotension		2						2
Osmophobia		1						1
Osteoarthritis	1	6					1	6
Otitis externa		1						1
Otorrhoea		1				1		
Overdose		2				2		
Overflow diarrhoea		1				1		
Oversensing	1	1					1	1
Oxygen saturation	1	1					1	1
Oxygen saturation decreased	3	30				4	3	26

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pain	197	738	1	6	61	219	136	519
Painful respiration	6	9					6	9
Pain in extremity	288	1,073	2	17	100	320	188	753
Pain in jaw	10	28			1	4	9	24
Pain of skin	5	28			1	4	4	24
Palatal swelling		1						1
Palindromic rheumatism	1	1					1	1
Pallor	6	28			4	9	2	19
Palpitations	44	173		1	11	34	33	139
Pancreatic carcinoma	1	2					1	2
Pancreatic disorder		1						1
Pancreatitis acute	1	2					1	2
Pancytopenia	1	1					1	1
Panic attack	1	5			1	1		4
Panic disorder		2						2
Panic reaction	1	4					1	4
Papule	3	7			1	2	2	5
Paraesthesia	66	264		2	18	65	48	199
Paraesthesia oral	28	116		1	12	39	16	77
Parainfluenzae viral laryngotracheobronchitis	1	1					1	1
Paralysis	8	18		1			8	18
Paramnesia	1	2					1	2
Paranasal sinus discomfort		1						1
Paranoia		4				1		3
Paresis	1	2					1	2
Parkinsonism	1	4				1	1	3
Parkinson's disease	1	6					1	6
Parophthalmia	1	1					1	1
Parosmia	5	20			1	4	4	16
Parotid gland enlargement	1	1					1	1
Parotitis		1				1		
Partial seizures	1	3					1	3
Patellofemoral pain syndrome	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Patient elopement	1	1					1	1
Peak expiratory flow rate	1	1					1	1
Peak expiratory flow rate abnormal		1						1
Peak expiratory flow rate decreased		1						1
Pelvic discomfort		1						1
Pelvic pain	3	9				2	3	7
Pemphigoid	1	5					1	5
Pemphigus		2						2
Periarthritis	2	7				1	2	6
Pericardial effusion	1	1					1	1
Pericardial haemorrhage		1						1
Pericarditis	1	10					1	10
Periorbital cellulitis		1						1
Periorbital haematoma		1						1
Periorbital oedema		3						3
Periorbital swelling	2	13				3	2	10
Peripheral circulatory failure		1						1
Peripheral coldness	7	41			2	10	5	31
Peripheral embolism		1						1
Peripheral ischaemia	1	2			1	1		1
Peripheral sensory neuropathy		1						1
Peripheral swelling	85	252	1	1	26	68	59	184
Peripheral vascular disorder		1				1		
Peripheral vein stenosis	1	1					1	1
Peritonitis		1						1
Peroneal nerve palsy	1	3				1	1	2
Persistent postural-perceptual dizziness		2				1		1
Personality change		2						2
Petechiae	2	7			1	1	1	6
Petit mal epilepsy		4						4
Phantom limb syndrome		1						1
Pharyngeal erythema		1						1
Pharyngeal hypoaesthesia	1	4			1	1		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pharyngeal inflammation		3						3
Pharyngeal oedema	1	1					1	1
Pharyngeal paraesthesia	3	6			2	2	1	4
Pharyngeal swelling	8	41			4	7	4	34
Pharyngeal ulceration	1	2					1	2
Pharyngitis	1	2					1	2
Pharyngitis streptococcal		2						2
Phlebitis	2	4			1	1	1	3
Photophobia	11	43			1	4	10	39
Photopsia	3	8			2	3	1	5
Photosensitivity reaction	1	7				3	1	4
pH urine increased		1						1
Physical disability		1						1
Pigmentation disorder		1				1		
Piloerection	2	5					2	5
Pineal gland cyst	1	1					1	1
Pityriasis		1				1		
Pityriasis lichenoides et varioliformis acuta	1	1			1	1		
Plantar fasciitis	1	2			1	1		1
Platelet count abnormal	1	1			1	1		
Platelet count decreased	16	19			4	4	12	15
Platelet count increased	1	1					1	1
Pleural effusion	3	5					3	5
Pleurisy	1	6					1	6
Pleuritic pain	2	6				1	2	5
Plicated tongue		1						1
Pneumonia	4	24					4	24
Pneumonia aspiration		4						4
Pneumonitis	2	6					2	6
Pneumothorax	1	1					1	1
Pollakiuria	1	7				2	1	5
Polyarthrits	2	3					2	3
Polychondritis		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Polydipsia		1						1
Polymenorrhoea	2	4			1	2	1	2
Polymyalgia rheumatica	3	13					3	13
Polymyositis		1						1
Polyuria		2				1		1
Poor quality sleep	6	23		1	3	6	3	17
Portal vein thrombosis	1	1					1	1
Postmenopausal haemorrhage	1	1					1	1
Postprandial hypoglycaemia		1						1
Post procedural complication		1						1
Post-traumatic stress disorder	1	2					1	2
Postural orthostatic tachycardia syndrome	1	2					1	2
Posture abnormal		1						1
Post viral fatigue syndrome	8	17				1	8	16
Pre-existing condition improved		2				2		
Premenstrual syndrome	1	1					1	1
Pressure of speech		1						1
Presyncope	4	35			3	8	1	27
Primary biliary cholangitis		1						1
Primary gastrointestinal follicular lymphoma		1						1
Prion disease		1						1
Procedural dizziness	1	1					1	1
Procedural nausea		1						1
Proctalgia		4				2		2
Proctitis ulcerative		1						1
Product administered at inappropriate site	1	3			1	3		
Product administered to patient of inappropriate age		3				2		1
Productive cough	6	25				4	6	21
Product use issue	17	321			13	306	4	15
Prostatic abscess	1	1					1	1
Prostatic specific antigen increased		1				1		
Prostatomegaly		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Proteinuria		1						1
Pruritus	89	304			39	113	50	191
Psoriasis	11	25			2	7	9	18
Psoriatic arthropathy	5	12					5	12
Psychiatric symptom		1						1
Psychogenic seizure	1	2					1	2
Psychomotor hyperactivity	1	4					1	4
Psychotic behaviour		1						1
Psychotic disorder	1	4					1	4
Pulmonary artery dilatation		1						1
Pulmonary artery thrombosis		1						1
Pulmonary congestion		1						1
Pulmonary embolism	23	52					23	52
Pulmonary fibrosis	1	1					1	1
Pulmonary function test	1	1					1	1
Pulmonary haemorrhage	1	1					1	1
Pulmonary hypertension		1						1
Pulmonary oedema	2	6					2	6
Pulmonary pain	3	16				4	3	12
Pulmonary sarcoidosis		2				1		1
Pulmonary thrombosis	1	3					1	3
Pulse abnormal	1	2					1	2
Pulseless electrical activity		2						2
Pupillary disorder		1						1
Purging	1	1					1	1
Purple glove syndrome	1	1					1	1
Purpura	5	8			4	4	1	4
Pustular psoriasis		1						1
Pustule		1						1
Pyelonephritis		1						1
Pyrexia	263	1,180		8	102	326	161	854
Q fever		4						4
Radiculitis brachial		2				1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Radioisotope uptake increased		1							1
Rales		1							1
Rash	90	270			34	77	56		193
Rash erythematous	26	86	1	1	12	31	14		55
Rash macular	10	43			6	20	4		23
Rash maculo-papular	2	6			2	2			4
Rash papular	12	27			5	10	7		17
Rash pruritic	26	82			9	27	17		55
Rash pustular	1	1					1		1
Rash vesicular	2	7			1	2	1		5
Raynaud's phenomenon	3	8			1	3	2		5
Reaction to excipient		1							1
Reaction to preservatives		1							1
Reading disorder		1							1
Rectal abscess	1	1					1		1
Rectal haemorrhage	5	12					5		12
Red blood cell sedimentation rate increased	2	2					2		2
Reduced facial expression		2				2			
Reflux gastritis	1	1					1		1
Renal cancer	1	2					1		2
Renal cyst	2	2					2		2
Renal disorder		1							1
Renal failure	2	7					2		7
Renal haemorrhage		1							1
Renal impairment	5	9					5		9
Renal pain	5	23			1	5	4		18
Respiration abnormal	2	10			1	3	1		7
Respiratory acidosis		1							1
Respiratory arrest	1	6					1		6
Respiratory depression		1							1
Respiratory disorder	2	6					2		6
Respiratory distress	2	4					2		4
Respiratory failure		6							6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Respiratory muscle weakness		1						1
Respiratory rate increased	2	14					2	14
Respiratory symptom				1				
Respiratory tract infection		1						1
Respiratory tract irritation	1	1					1	1
Respiratory tract oedema		2						2
Restless legs syndrome	1	8				2	1	6
Restlessness	7	20			2	4	5	16
Retching	1	17				6	1	11
Reticulocyte count decreased	1	1					1	1
Retinal aneurysm	1	1					1	1
Retinal detachment	1	1					1	1
Retinal disorder	1	1			1	1		
Retinal exudates	1	1					1	1
Retinal fovea disorder	1	1					1	1
Retinal haemorrhage		1						1
Retinal migraine	1	4					1	4
Retinal toxicity		1						1
Retinal vasculitis	1	1					1	1
Retinopathy	1	1					1	1
Retroperitoneal haemorrhage		1						1
Rhabdomyolysis		2						2
Rheumatic disorder	1	1					1	1
Rheumatoid arthritis	21	52		1			21	52
Rhinalgia		1						1
Rhinitis	2	9			1	3	1	6
Rhinitis allergic		1						1
Rhinorrhoea	18	80	1	4	7	16	11	64
Rib fracture		1						1
Right ventricular enlargement		1				1		
Road traffic accident		1						1
Rotator cuff syndrome		2						2
Rubber sensitivity		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sacroiliitis	1	3				1	1	2
Salivary gland disorder		1						1
Salivary gland enlargement	1	2					1	2
Salivary gland pain	2	3					2	3
Salivary hypersecretion	1	6			1	3		3
Salt craving		1						1
Sarcoidosis	2	6					2	6
Sarcoma		1						1
SARS-CoV-2 ant body test negative	2	4				1	2	3
SARS-CoV-2 ant body test positive		1				1		
SARS-CoV-2 test		1						1
SARS-CoV-2 test negative	1	1					1	1
SARS-CoV-2 test positive	4	11			3	4	1	7
Scab	1	2				1	1	1
Sciatica	1	7				1	1	6
Sciatic nerve neuropathy		1						1
Scleral discolouration		3				1		2
Scleritis		1						1
Scleroderma associated digital ulcer		1						1
Scratch	1	4				1	1	3
Screaming	2	2			1	1	1	1
Seasonal allergy	1	3				1	1	2
Secretion discharge	1	4			1	1		3
Seizure	14	53					14	53
Senile dementia		1						1
Sensation of blood flow		1						1
Sensation of foreign body	4	8			1	1	3	7
Sense of a foreshortened future		2				2		
Sensitisation	1	1					1	1
Sensitive skin	5	17			2	6	3	11
Sensitivity to weather change	1	1					1	1
Sensory disturbance	4	15			2	6	2	9
Sensory loss	2	6				1	2	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sepsis	6	13					6	13
Sepsis syndrome		1						1
Septic shock	2	3					2	3
Serositis	1	1					1	1
Serotonin syndrome		1						1
Serum ferritin decreased	1	1					1	1
Serum sickness		1						1
Shock	1	4					1	4
Sight disability		1						1
Sinonasal obstruction	1	4			1	2		2
Sinus congestion	1	5					1	5
Sinus disorder		2						2
Sinus headache	13	38		1	8	14	5	24
Sinusitis	2	10				3	2	7
Sinus pain	3	14			1	3	2	11
Sinus tachycardia		2						2
Sjogren's syndrome	1	3					1	3
Skin abrasion	1	2			1	1		1
Skin burning sensation	3	15		2		4	3	11
Skin cancer		1						1
Skin depigmentation		1						1
Skin discolouration	7	17			2	5	5	12
Skin disorder	4	8			2	3	2	5
Skin erosion	2	6			1	2	1	4
Skin exfoliation	9	15			5	5	4	10
Skin hypertrophy		1				1		
Skin induration	1	3				2	1	1
Skin infection	3	3			1	1	2	2
Skin irritation	2	9			1	4	1	5
Skin laceration		3				2		1
Skin lesion	5	7			3	4	2	3
Skin mass		1						1
Skin odour abnormal		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin reaction	4	6			2	3	2	3
Skin sensitisation	1	2					1	2
Skin swelling		5				3		2
Skin temperature	1	2			1	1		1
Skin tightness	1	7				3	1	4
Skin ulcer		1						1
Skin warm	1	24		1		6	1	18
Skin weeping		2						2
Skin wrinkling	1	1					1	1
Skull fracture		1						1
Sleep apnoea syndrome		1						1
Sleep attacks		1						1
Sleep deficit		3				1		2
Sleep disorder	19	51			6	20	13	31
Sleep disorder due to a general medical condition		5				1		4
Sleep disorder due to general medical condition, insomnia type	2	7				2	2	5
Sleep terror	1	2					1	2
Slow speech	1	2					1	2
Sluggishness	1	4					1	4
Sneezing	5	31		1	2	12	3	19
Social avoidant behaviour		1						1
Soft tissue swelling	1	1			1	1		
Somnolence	29	134		1	8	33	21	101
Speech disorder	7	18			1	4	6	14
Spinal column injury		1						1
Spinal disorder		2				1		1
Spinal fracture	1	1					1	1
Spinal pain	1	12				2	1	10
Spleen atrophy		1						1
Splenic rupture	1	1					1	1
Splenomegaly	1	2					1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Spondylitis	1	1					1	1
Sputum abnormal		1						1
Sputum discoloured	1	3				1	1	2
Sputum increased		1						1
Staphylococcal infection	1	1					1	1
Staphylococcal sepsis	1	1					1	1
Status epilepticus	3	6					3	6
Steatorrhoea	1	1			1	1		
Stevens-Johnson syndrome		2						2
Stoma site discharge		1						1
Stomatitis	1	8		1	1	2		6
Stress	2	5					2	5
Stress cardiomyopathy	1	1					1	1
Stridor	1	3					1	3
Subarachnoid haemorrhage	1	4					1	4
Subcutaneous haematoma	1	1			1	1		
Subdural haematoma		1						1
Sudden death	3	14					3	14
Sudden hearing loss	1	2					1	2
Suffocation feeling		1				1		
Suicidal ideation	5	7					5	7
Sunburn		2						2
Suprapubic pain		1				1		
Supraventricular tachycardia	1	2					1	2
Suspected COVID-19	17	82			12	28	5	54
Sweating fever	2	9					2	9
Swelling	69	148			22	47	47	101
Swelling face	20	94		1	6	19	14	75
Swelling of eyelid	5	12			1	3	4	9
Swollen tongue	14	55			6	11	8	44
Symptom recurrence	1	1					1	1
Syncope	28	101					28	101
Synovial cyst		2				1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Synovitis		3							3
Systemic immune activation	1	1					1		1
Systemic inflammatory response syndrome		1							1
Systemic lupus erythematosus	4	9		1			4		9
Systemic lupus erythematosus rash	1	4				1	1		3
Systolic hypertension		2							2
Tachycardia	14	96	1	1	5	25	9		71
Tachyphrenia		1							1
Tachypnoea		8				2			6
Taste disorder	8	28			5	12	3		16
Tearfulness	3	6			1	1	2		5
Telangiectasia	1	1					1		1
Temperature difference of extremities		1							1
Temperature intolerance	2	2					2		2
Temperature regulation disorder		3				1			2
Temporomandibular joint syndrome		1				1			
Tenderness	12	27		1	9	20	3		7
Tendonitis		2							2
Tendon pain		1							1
Tenosynovitis stenosaurs	1	2					1		2
Tension	2	2					2		2
Tension headache	15	34		1	5	8	10		26
Testicular pain		2				1			1
Testicular swelling		1				1			
Therapeutic product ineffective		1							1
Therapeutic response unexpected	9	18			6	12	3		6
Thermal burn	1	3					1		3
Thermal burns of eye		2							2
Thinking abnormal	2	6				2	2		4
Thirst	7	34			2	7	5		27
Throat clearing		1							1
Throat irritation	8	38			3	8	5		30
Throat tightness	5	50				4	5		46

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Thrombocytopenia	21	29					21	29
Thrombophlebitis	1	1					1	1
Thrombophlebitis superficial	1	1			1	1		
Thrombosis	22	41					22	41
Thrombosis in device	1	1					1	1
Thrombotic stroke	1	1					1	1
Thrombotic thrombocytopenic purpura	1	2					1	2
Thyroid function test abnormal		1				1		
Thyroiditis subacute		1				1		
Thyroid pain		1						1
Tinnitus	33	91			5	15	28	76
Tongue blistering	1	3				1	1	2
Tongue coated	1	3			1	2		1
Tongue discolouration	3	4			1	1	2	3
Tongue discomfort		6				2		4
Tongue disorder	1	10				1	1	9
Tongue dry		1						1
Tongue eruption		2						2
Tongue erythema		1				1		
Tongue movement disturbance		1				1		
Tongue oedema		3						3
Tongue paralysis		1						1
Tongue pruritus		1						1
Tongue spasm	1	1					1	1
Tongue ulceration		3				1		2
Tonic convulsion		1						1
Tonsillar hypertrophy	1	5					1	5
Tonsillar inflammation		1						1
Tonsillitis	3	4					3	4
Toothache	3	11				1	3	10
Tooth disorder		1				1		
Toxic epidermal necrolysis		1						1
Toxicity to various agents		1		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Transient global amnesia	1	1					1	1
Transient ischaemic attack	8	14					8	14
Traumatic haemorrhage		1						1
Tremor	34	182		1	9	36	25	146
Trichodynia		1						1
Trigeminal neuralgia		1						1
Trigger finger		1						1
Tri-iodothyronine decreased		1						1
Trismus	3	4					3	4
Troponin increased	1	2					1	2
Tubulointerstitial nephritis		1						1
Tunnel vision	2	4					2	4
Tympanic membrane hyperaemia	1	1					1	1
Type 1 diabetes mellitus	1	3					1	3
Type III immune complex mediated reaction	1	1					1	1
Type IV hypersensitivity reaction		2						2
Typical aura without headache	1	2					1	2
Ulcer		4				1		3
Ulcerative keratitis		3						3
Underdose	1	2			1	2		
Unresponsive to stimuli	2	14					2	14
Upper-airway cough syndrome		1				1		
Upper airway obstruction		1						1
Upper respiratory tract congestion	1	1					1	1
Upper respiratory tract infection		2						2
Urinary incontinence	4	12			2	2	2	10
Urinary retention	2	10					2	10
Urinary tract disorder		1						1
Urinary tract infection	8	21			1	4	7	17
Urinary tract infection bacterial		1						1
Urine abnormality	1	2				1	1	1
Urine analysis abnormal		1						1
Urine flow decreased	1	2					1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urine ketone body present	1	1					1	1
Urine odour abnormal		2						2
Urine output		1						1
Urine output decreased	1	2					1	2
Urosepsis		2						2
Urticaria	26	111			11	29	15	82
Uterine haemorrhage	1	1					1	1
Uveitis	1	9					1	9
Vaccination complication	2	5				1	2	4
Vaccination failure		1						1
Vaccination site bruising	12	28			6	11	6	17
Vaccination site cellulitis		4				2		2
Vaccination site discolouration		4				1		3
Vaccination site discomfort	2	19			1	10	1	9
Vaccination site dryness		1						1
Vaccination site erythema	32	130			15	58	17	72
Vaccination site haemorrhage	2	8				2	2	6
Vaccination site hyperaesthesia		2				1		1
Vaccination site hypoaesthesia		4				1		3
Vaccination site induration	6	19			2	10	4	9
Vaccination site infection		5				1		4
Vaccination site inflammation	6	13			5	9	1	4
Vaccination site irritation		3				1		2
Vaccination site joint erythema	1	1			1	1		
Vaccination site joint movement impairment		4				2		2
Vaccination site joint pain		4				2		2
Vaccination site joint swelling	1	1			1	1		
Vaccination site joint warmth	1	1			1	1		
Vaccination site lymphadenopathy	3	9			1	3	2	6
Vaccination site mass	22	59			7	20	15	39
Vaccination site movement impairment	5	17			2	7	3	10
Vaccination site oedema	1	3				1	1	2
Vaccination site pain	168	670		5	77	270	91	400

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vaccination site paraesthesia		7				3			4
Vaccination site pruritus	20	54			13	22	7		32
Vaccination site rash	6	27			4	10	2		17
Vaccination site reaction	3	14			1	6	2		8
Vaccination site swelling	48	167			23	62	25		105
Vaccination site ulcer		1							1
Vaccination site urticaria	2	4			1	2	1		2
Vaccination site vesicles	1	1					1		1
Vaccination site warmth	19	76			9	26	10		50
Vaccine breakthrough infection	1	1					1		1
Vaginal cyst		1							1
Vaginal disorder	1	1					1		1
Vaginal haemorrhage	5	8			2	2	3		6
Varicella	2	2					2		2
Varicose vein	2	3					2		3
Vascular dementia	1	4					1		4
Vascular headache		5				1			4
Vascular pain	1	2				1	1		1
Vascular stent thrombosis	1	1					1		1
Vasculitic rash	1	2			1	1			1
Vasculitis	9	16			4	5	5		11
Vasoconstriction		1							1
Vasodilatation	1	2					1		2
Vein disorder	1	1					1		1
Vein rupture		1							1
Venous injury	1	1					1		1
Venous thrombosis	1	1					1		1
Ventricular extrasystoles		6							6
Ventricular fibrillation		2							2
Ventricular tachycardia	2	2					2		2
Vertebral artery stenosis	1	1					1		1
Vertigo	28	100			6	16	22		84
Vertigo positional	4	10					4		10

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vestibular disorder		1				1			
Vestibular migraine	1	2					1		2
Vestibular neuritis	2	4					2		4
Viral infection	2	4					2		4
Viral labyrinthitis		3						3	
Viral rash		2					1		1
Virologic failure		1							1
Vision blurred	23	84			6	15	17		69
Visual acuity reduced	1	2					1		2
Visual field defect	2	3					2		3
Visual impairment	12	37			3	12	9		25
Visual snow syndrome	1	1					1		1
Vital capacity		1							1
Vitamin D deficiency		1							1
Vlth nerve paralysis	1	2					1		2
Vitiligo	1	1					1		1
Vitreous detachment	1	2					1		2
Vitreous floaters		2						1	1
Vocal cord disorder		1							1
Vomiting	91	373	1	1	27	86	64		287
Vomiting projectile	3	7			2	4	1		3
Vomiting psychogenic		1							1
Vulval haemorrhage		1							1
Vulvovaginal candidiasis	1	5			1	2			3
Vulvovaginal pain		2						1	1
Vulvovaginal ulceration		1							1
Weight bearing difficulty		2						1	1
Weight decreased	3	14			1	6	2		8
Weight increased	1	2			1	1			1
Weight loss diet		1							1
Wheat-free diet	1	1					1		1
Wheezing	15	84			4	15	11		69
White blood cell count abnormal	1	1					1		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
White blood cell count decreased		2							2
White blood cell count increased	3	7				1		3	6
Withdrawal syndrome	1	2			1	2			
Wound	1	3					1		3
Wound complication		1							1
Wound secretion	1	1					1		1
Wrist fracture		1							1
Wrong product administered	2	2			2	2			
Yawning	1	1					1		1
	1	4			1	4			
	9,517	35,403	32	225	2894	9017	6623		26386

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED STATES**

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	18	66			16	62	2	4
Abdominal distension	4	12			3	10	1	2
Abdominal infection	1	1					1	1
Abdominal pain	19	81			15	64	4	17
Abdominal pain lower	4	11			3	8	1	3
Abdominal pain upper	32	100			27	87	5	13
Abdominal rigidity	1	2			1	1		1
Abnormal behaviour	3	7			3	6		1
Abnormal dreams	2	5			2	4		1
Abnormal faeces		2				2		
Abnormal sensation in eye	2	4			2	4		
Abortion spontaneous	2	5					2	5
Abscess	1	1					1	1
Accidental exposure to product		4				4		
Accidental overdose		2				2		
Accidental underdose		1				1		
Acetonaemia		1				1		
Achlorhydria	1	1			1	1		
Acne	3	5			3	5		
Acute coronary syndrome		1						1
Acute disseminated encephalomyelitis		1						1
Acute febrile neutrophilic dermatosis	1	2					1	2
Acute hepatic failure		1						1
Acute kidney injury	1	6					1	6
Acute myeloid leukaemia		3						3
Acute myocardial infarction	2	4					2	4
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		1						1
Acute respiratory failure	1	1					1	1
Adrenal disorder		2				1		1
Adrenal insufficiency		2						2
Adrenocortical insufficiency acute		2						2
Adverse drug reaction		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Affective disorder		1				1			
Ageusia	12	53			10	48	2	5	
Aggression		2				1		1	
Agitation	3	10			3	9		1	
Alanine aminotransferase abnormal		1				1			
Alanine aminotransferase decreased		1						1	
Alanine aminotransferase increased	1	4			1	4			
Allergic cough	1	1			1	1			
Allergy test positive		1				1			
Allergy to chemicals	1	1			1	1			
Allergy to vaccine	6	26			2	13	4	13	
Alopecia	6	15			6	12		3	
Alopecia areata		1				1			
Altered state of consciousness	1	4					1	4	
Altered visual depth perception	1	1			1	1			
Amnesia	5	14			4	11	1	3	
Amyloidosis		1						1	
Anaemia	2	8			1	4	1	4	
Anal haemorrhage	1	2				1	1	1	
Anal incontinence	2	4			2	4			
Anaphylactic reaction	34	119					34	119	
Anaphylactic shock	5	8					5	8	
Anaphylactoid reaction		2						2	
Anger		6				4		2	
Angina pectoris	7	12					7	12	
Angioedema	6	27			1	1	5	26	
Angiokeratoma	1	1			1	1			
Angiopathy	1	3				2	1	1	
Angle closure glaucoma	1	1					1	1	
Anion gap decreased		1				1			
Ankylosing spondylitis		1						1	
Anomalous pulmonary venous connection		1						1	
Anorectal discomfort		1				1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anosmia	9	38			6	30	3	8
Anterior chamber cell		1						1
Antibody test abnormal	1	2			1	2		
Antibody test negative		2				2		
Anti Kell antibody test positive	1	1			1	1		
Antinuclear antibody positive		1				1		
Anxiety	26	88			21	74	5	14
Aortic arteriosclerosis	1	1			1	1		
Apathy	2	2			1	1	1	1
Aphasia	10	17			4	7	6	10
Aphonia	3	11			2	5	1	6
Aphthous ulcer		1				1		
Apnoea	1	2					1	2
Appendicitis	7	15					7	15
Appendicitis perforated	1	1					1	1
Appendix disorder	1	1					1	1
Appetite disorder		4				4		
Application site haemorrhage		1						1
Aptyalism		1				1		
Arachnoid cyst		1						1
Areflexia	1	2			1	1		1
Arrhythmia	10	26					10	26
Arterial occlusive disease	1	1					1	1
Arterial thrombosis		1						1
Arteriosclerosis		2						2
Arteriosclerosis coronary artery	1	1			1	1		
Arthralgia	134	558	1	1	121	510	13	48
Arthritis	7	29			7	27		2
Arthritis allergic		1				1		
Arthropathy	5	14			5	14		
Arthropod bite		1				1		
Arthropod sting	2	2			2	2		
Aspartate aminotransferase increased	1	3			1	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aspiration	1	1					1	1
Asthenia	116	398			93	329	23	69
Asthenopia	6	11			5	9	1	2
Asthma	20	52			10	34	10	18
Asymptomatic COVID-19	2	6				1	2	5
Ataxia		2						2
Atelectasis	2	4			1	1	1	3
Atrial fibrillation	12	43				1	12	42
Atrial flutter	2	2			1	1	1	1
Atrioventricular block complete	1	1					1	1
Aura	1	1					1	1
Autoimmune disorder	7	14					7	14
Autoimmune haemolytic anaemia		1						1
Autoimmune thyroid disorder	1	1					1	1
Autoimmune thyroiditis		2						2
Autonomic nervous system imbalance		3				2		1
Autoscopy		1				1		
Axillary mass		4				4		
Axillary pain	5	33			5	33		
Back disorder	1	4			1	4		
Back injury		1				1		
Back pain	55	180			42	148	13	32
Bacteraemia		1						1
Bacterial infection	1	1			1	1		
Balance disorder	22	63			18	50	4	13
Band neutrophil count increased		1						1
Basal ganglia haemorrhage		1						1
Basedow's disease	2	2					2	2
Basophil count abnormal		1				1		
Bed rest	2	2			2	2		
Bedridden	5	13			4	10	1	3
Belligerence		1						1
Biliary tract disorder	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Biopsy	1	1			1	1		
Bladder disorder		2				2		
Blast cell count increased		1						1
Blast cell crisis		1						1
Blepharitis		1				1		
Blepharospasm		1				1		
Blindness	4	13					4	13
Blindness transient		1						1
Blindness unilateral		3						3
Blister	5	15			4	11	1	4
Blood albumin decreased		2				2		
Blood bilirubin decreased		1				1		
Blood bilirubin increased		3				2		1
Blood blister		1						1
Blood calcium decreased		1				1		
Blood calcium increased		3				2		1
Blood chloride decreased		2				1		1
Blood chloride increased		3				3		
Blood cholesterol abnormal	2	2			2	2		
Blood cholesterol increased	2	6			2	6		
Blood copper increased	1	1			1	1		
Blood creatine increased		1						1
Blood creatine phosphokinase abnormal	1	1			1	1		
Blood creatine phosphokinase increased	1	4				1	1	3
Blood creatinine abnormal	1	1					1	1
Blood creatinine decreased		1				1		
Blood creatinine increased	1	4			1	3		1
Blood disorder	2	3			2	3		
Blood electrolytes decreased	1	1					1	1
Blood folate increased	1	1			1	1		
Blood follicle stimulating hormone increased	1	1					1	1
Blood glucose abnormal	1	5				3	1	2
Blood glucose decreased	7	20			4	11	3	9

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Blood glucose fluctuation		2				2			
Blood glucose increased	11	59			7	42	4		17
Blood immunoglobulin E increased		1							1
Blood immunoglobulin G decreased		1				1			
Blood insulin increased	1	1			1	1			
Blood iron decreased	1	4				1	1		3
Blood ketone body increased		1							1
Blood lactic acid increased	2	4				1	2		3
Blood magnesium decreased		1							1
Blood phosphorus decreased	1	1					1		1
Blood potassium decreased	4	10			2	6	2		4
Blood potassium increased	1	2					1		2
Blood pressure abnormal	2	10			2	7			3
Blood pressure decreased	8	25			4	11	4		14
Blood pressure diastolic decreased		2							2
Blood pressure diastolic increased		2							1
Blood pressure fluctuation	3	9			2	6	1		3
Blood pressure increased	33	135			24	89	9		46
Blood pressure systolic increased	2	6			1	2	1		4
Blood sodium decreased	2	4			2	3			1
Blood test abnormal	2	2			2	2			
Blood thyroid stimulating hormone increased		2							1
Blood triglycerides abnormal	1	1			1	1			
Blood triglycerides increased	1	2			1	1			1
Blood urea increased		1							1
Blood urine present	4	9			4	6			3
Blue toe syndrome	2	2					2		2
Body height decreased	3	13			3	13			
Body temperature	1	1			1	1			
Body temperature abnormal	1	7			1	6			1
Body temperature decreased	5	9			3	7	2		2
Body temperature fluctuation		2							2
Body temperature increased	9	47			8	43	1		4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Body tinea		1				1			
Bone density abnormal	1	1			1	1			
Bone disorder	1	2				1	1	1	
Bone pain	11	36			10	31	1	5	
Bone swelling		1							1
Bowel movement irregularity	2	5			2	5			
Brachial plexopathy		1							1
Bradycardia	3	4					3	4	
Bradykinesia	1	3			1	3			
Bradyphrenia		2							2
Brain cancer metastatic	1	1					1	1	
Brain injury		2							2
Brain oedema		1							1
Brain stem haemorrhage		1							1
Brain stem infarction	1	1					1	1	
Brain stem syndrome		1							1
Breast cancer		1							1
Breast discharge		1				1			
Breast discomfort		1							1
Breast disorder	1	2			1	2			
Breast mass	1	1					1	1	
Breast pain	12	26			10	23	2	3	
Breast swelling	2	4			2	4			
Breast tenderness	1	2			1	2			
Bronchial disorder	1	1			1	1			
Bronchitis	5	10			3	8	2	2	
Bronchospasm	3	15			1	7	2	8	
Burning mouth syndrome		1				1			
Burning sensation	29	81			22	63	7	18	
Burn oral cavity		1							1
Bursitis	1	2			1	2			
Butterfly rash		1							1
Candida infection		2				2			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Carbohydrate antigen 125 increased		1				1			
Cardiac arrest	6	19					6		19
Cardiac discomfort		1				1			
Cardiac disorder	10	18			7	11	3		7
Cardiac failure	1	2					1		2
Cardiac failure congestive	1	6					1		6
Cardiac flutter	7	15					7		15
Cardiac neoplasm unspecified		1							1
Cardiac pacemaker insertion		1				1			
Cardiac valve disease		1				1			
Cardiac valve vegetation		1							1
Cardiogenic shock		1							1
Cardiomyopathy	1	3					1		3
Cardio-respiratory arrest		2							2
Cardiospasm	1	1			1	1			
Cardiovascular disorder	1	3			1	3			
Carpal tunnel syndrome	1	1			1	1			
Cataract	2	2					2		2
Cataract nuclear		1							1
Cellulitis	4	11					4		11
Central nervous system lesion		1							1
Cerebellar stroke	1	2					1		2
Cerebral artery embolism	1	1					1		1
Cerebral disorder		3				3			
Cerebral haemorrhage	1	4					1		4
Cerebral infarction		1							1
Cerebral thrombosis		1							1
Cerebral venous sinus thrombosis	3	3					3		3
Cerebrospinal fluid leakage	1	1					1		1
Cerebrovascular accident	29	57					29		57
Cerumen impaction	1	1			1	1			
Change in sustained attention	1	1			1	1			
Cheilitis	1	3			1	2			1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Chest discomfort	46	158			36	108	10	50
Chest injury		2						2
Chest pain	45	147			29	104	16	43
Chest X-ray abnormal		1						1
Chillblains	1	2			1	2		
Chills	194	943			176	857	18	86
Choking	4	9					4	9
Choking sensation	2	4			1	2	1	2
Cholestasis	1	3					1	3
Chondritis		1				1		
Chorea		1						1
Chromatopsia		1				1		
Chromaturia	1	3			1	3		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	2					1	2
Chronic kidney disease		2						2
Chronic lymphocytic leukaemia	1	1					1	1
Chronic myeloid leukaemia recurrent		1						1
Chronic obstructive pulmonary disease	3	5	1	1	1	1	2	4
Circadian rhythm sleep disorder		1				1		
Circulatory collapse	1	3					1	3
Circumstance or information capable of leading to device use error		1				1		
Circumstance or information capable of leading to medication error	9	43			9	43		
Claustrophobia		1				1		
Clumsiness		1				1		
Coagulation time prolonged		1				1		
Coagulopathy	3	4			1	2	2	2
Cognitive disorder	2	8			2	5		3
Cold sweat	10	34			7	28	3	6
Cold urticaria		1				1		
Colitis	2	5			1	3	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Colitis ulcerative	4	4					4	4
Colon cancer		1						1
Coma		3						3
Communication disorder		3				2		1
Complex regional pain syndrome		1				1		
Complication associated with device		1						1
Computerised tomogram normal		1				1		
Concussion		3				1		2
Condition aggravated	45	132			23	81	22	51
Confusional state	15	54			11	36	4	18
Conjunctival haemorrhage	2	5					2	5
Conjunctival hyperaemia		1						1
Conjunctivitis	1	3			1	3		
Conjunctivitis allergic		1				1		
Consciousness fluctuating	1	1					1	1
Constipation	9	20			6	17	3	3
Contraindicated product administered		1				1		
Contusion	14	35			10	28	4	7
Conversion disorder	1	1			1	1		
Coordination abnormal	2	6				2	2	4
Corneal disorder		1						1
Corneal graft rejection		1						1
Corneal infection		1						1
Corneal infiltrates		1						1
Coronary artery occlusion		1						1
Coronavirus infection		1				1		
Cor pulmonale acute	1	1					1	1
Costochondritis		1				1		
Cough	61	233			48	185	13	48
COVID-19	84	237	2	3	20	62	64	175
COVID-19 pneumonia	5	16					5	16
C-reactive protein increased		8				4		4
Crohn's disease		3				1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Crying	2	10				7	2	3
Crystal urine		1				1		
CSF protein increased		1						1
Culture urine positive		1				1		
Cutaneous lupus erythematosus		1						1
Cutaneous vasculitis	1	1			1	1		
Cyanosis	3	10			1	6	2	4
Cystitis	1	5				1	1	4
Cystitis escherichia	1	1					1	1
Daydreaming		2				2		
Deafness	8	20					8	20
Deafness bilateral		1						1
Deafness neurosensory		5						5
Deafness unilateral	3	14					3	14
Death	10	41	1	1			10	41
Decreased appetite	45	154			39	135	6	19
Decreased interest		1				1		
Deep vein thrombosis	15	21					15	21
Defaecation disorder	1	1			1	1		
Degenerative bone disease		1				1		
Dehydration	11	41			7	23	4	18
Delirium	5	18					5	18
Delirium febrile	1	1					1	1
Delusion	2	4				1	2	3
Delusional perception		2				1		1
Dementia	1	7					1	7
Demyelinating polyneuropathy		1						1
Dental caries	1	1			1	1		
Depersonalisation/derealisation disorder		1				1		
Depressed level of consciousness		4						4
Depressed mood	2	6		1	2	6		
Depression	5	11			3	9	2	2
Dermatitis	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Dermatitis acneiform		2				2			
Dermatitis allergic		1				1			
Dermatitis contact	1	1			1	1			
Dermatitis diaper		1							1
Dermatomyositis	1	3					1		3
Device leakage	1	1			1	1			
Diabetes mellitus		7							7
Diabetes mellitus inadequate control		3							3
Diabetic coma	1	1					1		1
Diabetic foot infection		1				1			
Diabetic ketoacidosis		1							1
Diaphragmatic disorder		1				1			
Diarrhoea	82	339			71	300	11		39
Diarrhoea haemorrhagic	3	8					3		8
Diet refusal		1							1
Diplopia	4	10			3	6	1		4
Discomfort	10	42			9	38	1		4
Discouragement	1	1			1	1			
Disease progression		2				1			1
Disease recurrence	14	54			5	29	9		25
Disorganised speech	1	1					1		1
Disorientation	10	24			6	17	4		7
Disseminated intravascular coagulation		1							1
Disseminated varicella zoster virus infection	1	1					1		1
Dissociation		1				1			
Disturbance in attention	2	23			2	21			2
Disturbance in social behaviour		1				1			
Diverticulitis	4	6					4		6
Diverticulum intestinal		1							1
Dizziness	167	672	1	1	139	566	28		106
Dizziness postural	1	11				8	1		3
Drainage	1	1			1	1			
Drooling		1				1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Drug effective for unapproved indication	1	1			1	1		
Drug eruption		1				1		
Drug hypersensitivity	4	13			3	10	1	3
Drug ineffective	49	159	1	2			49	159
Drug interaction	4	14			2	10	2	4
Dry eye	1	13			1	12		1
Dry mouth	10	43			7	35	3	8
Dry skin		7				5		2
Dry throat	1	5			1	5		
Dumping syndrome	1	1			1	1		
Duodenogastric reflux	1	1			1	1		
Dupuytren's contracture		1						1
Dysaesthesia		3				2		1
Dysarthria	5	13			3	8	2	5
Dysentery		1						1
Dysgeusia	13	64			13	59		5
Dysgraphia	1	1					1	1
Dyskinesia	5	12			4	9	1	3
Dyslexia		1				1		
Dyslipidaemia		1				1		
Dysmenorrhoea	2	5			2	5		
Dyspepsia	8	20			7	19	1	1
Dysphagia	22	66	1	1	17	45	5	21
Dysphemia		3				1		2
Dysphonia	20	62			12	35	8	27
Dyspnoea	146	429	2	2	81	247	65	182
Dyspnoea at rest	2	2					2	2
Dyspnoea exertional	1	9				6	1	3
Dysstasia	13	42			8	26	5	16
Dystonia	5	6			1	1	4	5
Dysuria	3	10			1	7	2	3
Ear congestion	1	2			1	1		1
Ear discomfort	8	26			8	24		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorder	1	7			1	4		3
Ear haemorrhage		1				1		
Ear infection	1	6				4	1	2
Ear pain	13	46			11	41	2	5
Ear pruritus	3	5			2	4	1	1
Ear swelling		6				5		1
Eating disorder	8	23			8	20		3
Eczema	1	2			1	2		
Ejection fraction decreased		1						1
Electrocardiogram abnormal	1	4			1	3		1
Electrocardiogram QT prolonged		2						2
Electrocardiogram T wave abnormal	1	1			1	1		
Embolic stroke		2						2
Emotional disorder		5				5		
Emotional distress	3	3			3	3		
Encephalitis		2						2
Encephalopathy		1						1
Endocarditis		2						2
Endocrine ophthalmopathy	1	2					1	2
Endometriosis	1	1					1	1
Energy increased	1	6			1	6		
Enlarged uvula	1	3				1	1	2
Eosinophil count increased		2				1		1
Eosinophilia		1				1		
Epicondylitis		1				1		
Epilepsy	2	2					2	2
Epistaxis	14	33			9	22	5	11
Erectile dysfunction		3						3
Eructation	1	2				1	1	1
Erythema	48	203			39	164	9	39
Erythema marginatum		1				1		
Erythema multiforme	1	2					1	2
Erythema nodosum		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Erythema of eyelid	1	4				3	1	1
Escherichia urinary tract infection	1	1					1	1
Euphoric mood	1	2			1	2		
Eustachian tube dysfunction		1						1
Excessive cerumen production		1				1		
Exercise tolerance decreased		1				1		
Exophthalmos	2	3					2	3
Expired product administered		1				1		
Exposure during pregnancy	2	7			2	6		1
Exposure to SARS-CoV-2	2	8			2	8		
Exposure via skin contact		3				3		
Extensive swelling of vaccinated limb		1				1		
Extraocular muscle disorder	1	1			1	1		
Extraocular muscle paresis	1	2					1	2
Extrasystoles	4	6			4	5		1
Eye colour change	1	1					1	1
Eye contusion	1	3			1	3		
Eye discharge		2				2		
Eye disorder	8	20			7	17	1	3
Eye haemorrhage	4	12					4	12
Eye infection		2				2		
Eye inflammation	1	5			1	3		2
Eye injury	1	1					1	1
Eye irritation		10				9		1
Eyelid disorder	1	3			1	3		
Eyelid function disorder	2	4				2	2	2
Eyelid haematoma		1				1		
Eyelid irritation		2				2		
Eyelid oedema		2				2		
Eyelid pain	1	2			1	2		
Eyelid ptosis	1	3			1	2		1
Eyelid sensory disorder	1	1			1	1		
Eyelids pruritus	2	5			1	3	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Eye movement disorder	3	5			3	4		1
Eye oedema	1	3			1	3		
Eye pain	7	40			6	33	1	7
Eye paraesthesia		2				1		1
Eye pruritus	3	23			2	17	1	6
Eye swelling	9	42			5	30	4	12
Eye ulcer		1				1		
Face injury	1	1			1	1		
Face oedema		2						2
Facial bones fracture	1	2					1	2
Facial discomfort	1	3			1	3		
Facial nerve disorder		3				2		1
Facial neuralgia	1	1			1	1		
Facial pain	5	24			4	20	1	4
Facial paralysis	34	108				1	34	107
Facial paresis	1	6			1	3		3
Facial spasm	1	1					1	1
Faeces discoloured	2	5			2	4		1
Faeces soft	1	2			1	1		1
Fall	25	79			10	39	15	40
False positive investigation result		1				1		
Fatigue	318	1,250	1	2	290	1156	28	94
Fear	3	17			2	14	1	3
Fear of injection	1	1			1	1		
Febrile convulsion		2						2
Feeding disorder	4	17			3	14	1	3
Feeling abnormal	102	338			90	307	12	31
Feeling cold	10	69			7	59	3	10
Feeling drunk	2	9			2	8		1
Feeling hot	37	172			30	143	7	29
Feeling jittery	3	9			3	5		4
Feeling of body temperature change	5	19			3	16	2	3
Femur fracture		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Fibrin D dimer increased	1	5				4	1	1
Fibromyalgia	3	6			3	4		2
Flank pain		3				2		1
Flatulence	2	11			2	10		1
Fluid intake reduced		3				2		1
Fluid overload		1						1
Fluid retention	2	3			1	2	1	1
Flushing	19	113			16	84	3	29
Foaming at mouth	2	2			2	2		
Food allergy	1	1			1	1		
Food aversion	1	2			1	2		
Food poisoning	1	2			1	2		
Foot deformity	1	1			1	1		
Foot fracture	1	1					1	1
Foreign body aspiration		1						1
Foreign body in throat		1						1
Foreign body sensation in eyes		2				2		
Formication	1	2			1	2		
Freezing phenomenon	1	1			1	1		
Frequent bowel movements	1	7				6	1	1
Frustration tolerance decreased	1	3			1	3		
Full blood count abnormal		2				2		
Functional gastrointestinal disorder	1	1			1	1		
Furuncle		1				1		
Gait disturbance	42	125			25	80	17	45
Gait inability	6	26			2	14	4	12
Gal bladder disorder		3				1		2
Gal bladder polyp		1				1		
Gastric disorder	4	8			3	7	1	1
Gastric infection		1						1
Gastritis	1	1			1	1		
Gastroenteritis viral	3	6			3	5		1
Gastrointestinal disorder	5	22			4	19	1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gastrointestinal haemorrhage	2	5					2	5
Gastrointestinal hypomotility		1						1
Gastrointestinal inflammation		1				1		
Gastrointestinal motility disorder		2				2		
Gastrointestinal pain	1	5			1	5		
Gastrointestinal sounds abnormal		1				1		
Gastrointestinal stoma complication		1				1		
Gastrointestinal viral infection		1				1		
Gastrooesophageal reflux disease	6	17			6	15		2
Generalised anxiety disorder		1				1		
Generalised tonic-clonic seizure	4	6					4	6
General physical health deterioration	2	6			1	1	1	5
Genital herpes simplex		1				1		
Gingival bleeding	1	4				2	1	2
Gingival discomfort	1	2			1	1		1
Gingival disorder		1				1		
Gingival erythema		2				2		
Gingival pain		5				4		1
Gingival recession		1				1		
Gingival swelling	1	3			1	3		
Glassy eyes	1	4				3	1	1
Glomerular filtration rate abnormal		1				1		
Glomerular filtration rate decreased	1	3				2	1	1
Glossitis		3				3		
Glossodynia	2	10			2	9		1
Glycosylated haemoglobin increased	2	3			1	1	1	2
Goitre		1				1		
Gout		1						1
Granuloma skin		1						1
Grip strength decreased	4	6			4	6		
Groin pain	1	5			1	3		2
Growing pains		1				1		
Grunting	1	5			1	4		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Guillain-Barre syndrome	1	7				1	1	6
Haematemesis	1	2					1	2
Haematochezia	2	8					2	8
Haematocrit decreased		3				2		1
Haematoma	2	3			2	3		
Haematuria		4				2		2
Haemoglobin abnormal		1						1
Haemoglobin decreased	1	12				4	1	8
Haemolysis	1	1					1	1
Haemolytic anaemia		2						2
Haemophagocytic lymphohistiocytosis		1						1
Haemoptysis	3	7			1	2	2	5
Haemorrhage	6	13					6	13
Haemorrhage subcutaneous		1						1
Haemorrhage urinary tract		3						3
Haemorrhagic stroke		3						3
Haemorrhagic urticaria	1	1					1	1
Haemorrhagic varicella syndrome		1						1
Haemorrhoids	1	3				2	1	1
Hair injury		1				1		
Hallucination	6	17					6	17
Hallucination, auditory		4						4
Hallucination, visual		5						5
Hand fracture		3						3
Hangover		3				3		
Haptoglobin increased	1	1			1	1		
Headache	319	1,459			288	1323	31	136
Head discomfort	13	49			10	39	3	10
Head injury	4	9			3	6	1	3
Heart injury		1						1
Heart rate abnormal	5	12			4	11	1	1
Heart rate decreased	4	14			3	8	1	6
Heart rate increased	36	203			22	150	14	53

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Heart rate irregular	5	17			3	13	2	4
Heat illness	1	1			1	1		
Hemiparesis	3	5					3	5
Hemiplegia		3						3
Henoch-Schonlein purpura	1	2					1	2
Heparin-induced thrombocytopenia		1						1
Hepatic enzyme abnormal	2	3					2	3
Hepatic enzyme increased	4	5			3	3	1	2
Hepatic pain		1				1		
Hepatitis		1						1
Hepatitis acute		1						1
Hepatitis A virus test positive	1	1			1	1		
Hepatomegaly		1				1		
Herpes simplex		1				1		
Herpes virus infection	1	2				1	1	1
Herpes zoster	13	43			9	35	4	8
Herpes zoster oticus		1						1
Hiccups		1				1		
Hip fracture	1	4					1	4
Histamine level increased		1				1		
Hordeolum		3				2		1
Hot flush	13	55			10	47	3	8
Hunger	1	4			1	4		
Hydronephrosis		1						1
Hyperactive pharyngeal reflex		1				1		
Hyperacusis	3	8			3	8		
Hyperaesthesia	2	13			2	12		1
Hyperaesthesia teeth		1				1		
Hyperbilirubinaemia	1	1					1	1
Hypercholesterolaemia		1				1		
Hyperglycaemia	2	6				2	2	4
Hyperhidrosis	37	170			32	145	5	25
Hyperpyrexia	3	4					3	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hypersensitivity	20	97			14	59	6	38
Hypersensitivity vasculitis	2	3					2	3
Hypersomnia	11	36			11	34		2
Hypertension	26	101	1	1	10	53	16	48
Hypertensive crisis		1						1
Hypertensive emergency		4						4
Hypertensive heart disease		1						1
Hyperthyroidism	1	1					1	1
Hypertonia		1						1
Hypertrichosis		1				1		
Hyperventilation	4	9			4	7		2
Hypervigilance		1				1		
Hypoacusis	7	18			6	14	1	4
Hypoaesthesia	60	252			40	183	20	69
Hypoaesthesia eye	2	3			2	3		
Hypoaesthesia oral	12	80			9	57	3	23
Hypoaesthesia teeth		1				1		
Hypocalcaemia		1						1
Hypogeusia	1	3				2	1	1
Hypoglycaemia		6				3		3
Hypokalaemia	1	3					1	3
Hypokalaemic syndrome	1	1			1	1		
Hypokinesia	5	11			2	6	3	5
Hypomagnesaemia		1						1
Hyponatraemic syndrome	1	1			1	1		
Hypophagia		3				1		2
Hypopnoea	1	5			1	4		1
Hyporeflexia		1						1
Hyporesponsive to stimuli		1						1
Hyposmia		1				1		
Hypotension	9	37			4	16	5	21
Hypothermia		4						4
Hypothyroidism	1	3				1	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Hypovolaemic shock		1							1
Hypoxia	2	3					2		3
Idiosyncratic drug reaction		1				1			
IIIrd nerve paralysis		2							2
Ileus		1							1
III-defined disorder		1				1			
Illness	44	124	1	1	40	113	4		11
Immobile	2	3					2		3
Immune system disorder	5	13			3	10	2		3
Immune thrombocytopenia	2	7					2		7
Immunisation		2				2			
Immunisation reaction	1	1					1		1
Immunodeficiency		1							1
Impaired driving ability		1							1
Impaired healing		2				1			1
Impaired quality of life		1							1
Impaired self-care	1	1					1		1
Impaired work ability		4				4			
Inappropriate schedule of product administration	24	118			22	116	2		2
Incision site haemorrhage		1							1
Incoherent	1	5					2	1	3
Incomplete course of vaccination		2					2		
Incontinence		1							1
Incorrect dose administered		2					2		
Incorrect route of product administration	3	18			3	17			1
Increased tendency to bruise		1					1		
Increased upper airway secretion		3					1		2
Increased viscosity of bronchial secretion		1							1
Increased viscosity of upper respiratory secretion		1							1
Infection	4	8			1	4	3		4
Infectious mononucleosis	1	1			1	1			
Infertility female	1	1					1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Inflammation	14	29			12	24	2	5
Inflammatory marker increased		1				1		
Inflammatory pain		2				2		
Influenza	11	38			9	34	2	4
Influenza B virus test positive		1				1		
Influenza like illness	39	126			35	113	4	13
Initial insomnia		2				2		
Injected limb mobility decreased	1	2			1	2		
Injection site bruising	1	2			1	2		
Injection site erythema	4	11			4	11		
Injection site extravasation		1				1		
Injection site haematoma		1						1
Injection site haemorrhage		3				3		
Injection site inflammation		1				1		
Injection site mass		2				2		
Injection site pain	7	43			7	42		1
Injection site papule		1				1		
Injection site pruritus	1	3			1	3		
Injection site rash		3				3		
Injection site reaction	1	2			1	2		
Injection site swelling	5	13			5	13		
Injection site urticaria		2				2		
Injection site warmth	1	3			1	3		
Injury	2	3			2	2		1
Inner ear disorder		1						1
Insomnia	37	121			34	109	3	12
Instillation site pain		1				1		
Insulin resistance	1	1			1	1		
Intentional product misuse		1				1		
Internal haemorrhage	1	2					1	2
International normalised ratio decreased		3				2		1
International normalised ratio increased		4				2		2
Intervertebral disc protrusion	1	3				1	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Intestinal obstruction		1						1
Intestinal perforation		1						1
Intra-abdominal haematoma		1						1
Intracardiac thrombus	1	1					1	1
Intracranial aneurysm	1	1					1	1
Intracranial pressure increased	2	3					2	3
Intranasal hypoaesthesia		1				1		
Intranasal paraesthesia		2				2		
Intraocular pressure increased		1						1
Intrusive thoughts		1				1		
Iridocyclitis	1	2					1	2
Iritis		1				1		
Irregular breathing		1				1		
Irritability	2	7			2	6		1
Irritable bowel syndrome	2	4			2	3		1
Ischaemic stroke	2	5					2	5
IVth nerve paralysis		1						1
Jaundice	1	1					1	1
Jaw clicking	1	1			1	1		
Jaw disorder		3	1	1		3		
Job dissatisfaction	1	1			1	1		
Joint dislocation		4				1		3
Joint effusion		2				2		
Joint injury	3	5			3	4		1
Joint instability		4				1		3
Joint lock	2	2			2	2		
Joint range of motion decreased	3	18			1	15	2	3
Joint stiffness	6	19			6	17		2
Joint swelling	12	46			10	42	2	4
Joint warmth		1				1		
Keratic precipitates		2						2
Keratitis		1						1
Kidney infection	2	3					2	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Labile hypertension		1				1			
Laboratory test abnormal	1	2				1	1	1	
Laboratory test normal		1				1			
Labyrinthitis		1							1
Lack of spontaneous speech		1							1
Lacrimal disorder		1				1			
Lacrimation increased	3	21			2	18	1	3	
Lactic acidosis		1							1
Lacunar infarction		1							1
Laryngeal oedema		3							3
Laryngitis	1	5			1	4			1
Laryngospasm		3							3
Latent autoimmune diabetes in adults		1							1
Laziness		1				1			
Lethargy	19	65			17	56	2	9	
Leukaemia		3				1			2
Leukaemia recurrent	1	1					1		1
Leukocytosis		3				2			1
Lichen planus		1				1			
Ligament rupture		1				1			
Ligament sprain	2	4			2	4			
Limb discomfort	15	63			12	54	3	9	
Limb injury	1	12			1	12			
Limb mass	1	1			1	1			
Lip blister		1				1			
Lip disorder	1	3			1	3			
Lip dry		1				1			
Lip erythema	1	4			1	4			
Lip haemorrhage	1	1					1		1
Lipids increased		1				1			
Lip injury	1	2			1	2			
Lip oedema		2				1			1
Lipoma	1	1					1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Lip pain		3				3			
Lip pruritus		6				3			3
Lip swelling	11	62			8	35	3		27
Listless		1				1			
Livedo reticularis		4				2			2
Liver disorder	1	2			1	2			
Liver function test abnormal		2				1			1
Liver injury	1	2					1		2
Liver tenderness		1				1			
Localised infection		2				2			
Localised oedema		2				1			1
Loose body in joint	1	1					1		1
Loss of consciousness	42	96					42		96
Loss of control of legs		2							2
Loss of personal independence in daily activities	12	38			7	29	5		9
Loss of proprioception		1							1
Low density lipoprotein increased	1	1			1	1			
Lower gastrointestinal haemorrhage		1							1
Lower respiratory tract congestion		1				1			
Lower respiratory tract infection	2	3					2		3
Lumbar puncture abnormal		1							1
Lumbar radiculopathy		1				1			
Lung disorder	3	6		1	2	4	1		2
Lung hyperinflation		1				1			
Lung infiltration	1	2				1	1		1
Lung neoplasm malignant	1	1					1		1
Lung opacity		1							1
Lupus myositis	1	1					1		1
Lymphadenitis		3				1			2
Lymphadenopathy	59	263	1	1	54	241	5		22
Lymph gland infection		1				1			
Lymph node pain	10	56			8	51	2		5
Lymphocyte count abnormal		1				1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Lymphocyte count decreased		4				4			
Lymphocytosis		1				1			
Lymphoedema		6				6			
Lymphoma		1							1
Macular degeneration		2							2
Macular oedema		1							1
Macule		1				1			
Malaise	103	429			92	393	11		36
Mammogram abnormal	1	1			1	1			
Mania		1				1			
Mass	1	10			1	9			1
Mastication disorder		5				3			2
Maternal exposure during pregnancy	2	6			2	6			
May-Thurner syndrome		1							1
Measles	2	2					2		2
Mechanical urticaria		1				1			
Medication error		1				1			
Melaena	1	1					1		1
Melanoma recurrent	2	2					2		2
Memory impairment	7	24			7	19			5
Meniere's disease	2	2					2		2
Meningitis aseptic		1							1
Meningitis noninfective		1							1
Menorrhagia	6	9			4	7	2		2
Menstrual disorder	3	7			2	6	1		1
Menstruation delayed		1							1
Menstruation irregular	1	5			1	5			
Mental disorder	1	6			1	3			3
Mental impairment	5	21					5		21
Mental status changes	1	4			1	3			1
Meralgia paraesthetica		1							1
Metabolic encephalopathy		1							1
Metabolic function test abnormal		2				2			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Metamorphopsia		1						1
Metamyelocyte count increased		1						1
Metrorrhagia		3				3		
Microangiopathic haemolytic anaemia	1	1					1	1
Microembolism		1						1
Micturition disorder		1				1		
Micturition urgency	2	4			1	3	1	1
Middle insomnia	2	8			2	7		1
Migraine	24	85			14	67	10	18
Migraine with aura	2	5			2	5		
Miliaria		2				2		
Mitral valve disease	1	1					1	1
Mitral valve prolapse		1						1
Moaning		1				1		
Mobility decreased	11	33			8	25	3	8
Monoclonal gammopathy	1	1			1	1		
Monocyte count abnormal		1				1		
Monocyte count increased		3				2		1
Monoplegia		2						2
Mood altered		1				1		
Mood swings		1						1
Morning sickness	1	1					1	1
Motion sickness		1				1		
Motor dysfunction	3	6			1	2	2	4
Mouth haemorrhage		2				2		
Mouth swelling	1	12			1	8		4
Mouth ulceration	3	6			3	6		
Movement disorder	12	31			6	24	6	7
Mucosal disorder		4				4		
Mucous stools		1				1		
Multi-organ disorder	2	2			1	1	1	1
Multiple organ dysfunction syndrome		3						3
Multiple sclerosis	2	4					2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Multiple sclerosis relapse	4	6					4	6
Muscle atrophy		1				1		
Muscle contractions involuntary	2	4			2	3		1
Muscle discomfort	1	7			1	7		
Muscle disorder		1						1
Muscle fatigue	1	1			1	1		
Muscle injury	1	1			1	1		
Muscle rigidity	1	2			1	1		1
Muscle rupture		1						1
Muscle spasms	28	100			20	79	8	21
Muscle spasticity	1	3			1	2		1
Muscle strain		2				2		
Muscle swelling	2	4			2	4		
Muscle tightness	7	35			4	26	3	9
Muscle twitching	5	18			3	11	2	7
Muscular weakness	29	90			13	59	16	31
Musculoskeletal chest pain	3	20			3	17		3
Musculoskeletal discomfort	8	27			8	26		1
Musculoskeletal disorder	2	3			1	2	1	1
Musculoskeletal pain	3	10			2	8	1	2
Musculoskeletal stiffness	23	88			22	79	1	9
Mutism		1						1
Myalgia	99	503	1	1	88	466	11	37
Myasthenia gravis	1	2					1	2
Mydriasis	1	2			1	2		
Myelitis transverse	1	4					1	4
Myelocyte count increased		1						1
Myelopathy		1						1
Myocardial infarction	12	33					12	33
Myocardial necrosis marker increased		2						2
Myocardial strain	1	1					1	1
Myocarditis	2	5					2	5
Myoclonus		2						2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Myositis		2							2
Narcolepsy	1	1					1		1
Nasal congestion	13	75			11	68	2		7
Nasal discomfort	1	6			1	4			2
Nasal disorder	1	2				1	1		1
Nasal dryness		1				1			
Nasal injury	1	1			1	1			
Nasal oedema	3	6			2	3	1		3
Nasal pruritus	1	1					1		1
Nasopharyngitis	24	58			22	55	2		3
Nausea	177	809	1	1	149	707	28		102
Near death experience	3	8					3		8
Neck injury		1				1			
Neck mass		3				3			
Neck pain	29	132			23	114	6		18
Neoplasm	1	2			1	2			
Neoplasm malignant	1	1					1		1
Neoplasm progression	1	2					1		2
Nephrolithiasis		5							5
Nephropathy	1	2				1	1		1
Nerve compression	1	6			1	6			
Nerve injury	2	3			2	3			
Nervousness	11	44			10	40	1		4
Nervous system disorder	2	10			2	7			3
Neuralgia	6	30			4	28	2		2
Neuralgic amyotrophy		1				1			
Neuritis		3				3			
Neurological examination normal		1				1			
Neurological symptom	2	5			1	3	1		2
Neuromyelitis optica spectrum disorder	1	1					1		1
Neuropathy peripheral	18	44			1	2	17		42
Neutropenia		2							2
Neutrophil count abnormal		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Neutrophil count decreased		2				1			1
Neutrophil count increased		2				1			1
Nightmare	1	10			1	9			1
Night sweats	6	28			5	27	1		1
Nipple pain		3				3			
Nipple swelling		1				1			
No adverse event	5	5			5	5			
Nocturia		1				1			
Nodule	2	4			2	4			
Non-Hodgkin's lymphoma		1							1
Noninfective encephalitis		3							3
Non-pitting oedema	1	1					1		1
Normocytic anaemia		1				1			
Nuchal rigidity		2				1			1
Nystagmus	1	3			1	2			1
Obsessive thoughts		1							1
Obstructive airways disorder		1							1
Occipital neuralgia		1							1
Ocular discomfort	5	16			5	14			2
Ocular hyperaemia	3	28			3	25			3
Odynophagia	1	8			1	7			1
Oedema		5				4			1
Oedema peripheral	3	8			2	5	1		3
Oesophageal disorder		1							1
Oesophageal pain		1				1			
Off label use	20	149			19	145	1		4
Oligodipsia		1							1
Optic neuritis	1	3					1		3
Oral blood blister	1	1					1		1
Oral candidiasis	1	1			1	1			
Oral discomfort	1	15				12	1		3
Oral disorder		1							1
Oral fungal infection	1	1			1	1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Oral herpes	4	15			3	14	1	1
Oral lichen planus	1	1			1	1		
Oral mucosal blistering	1	2				1	1	1
Oral mucosal eruption		1						1
Oral mucosal erythema		2				2		
Oral mucosal exfoliation		1				1		
Oral pain	2	8			2	8		
Oral pruritus	4	10			3	6	1	4
Oral viral infection		1				1		
Organising pneumonia		1						1
Oromandibular dystonia		1				1		
Oropharyngeal blistering	1	2					1	2
Oropharyngeal cobble stone mucosa		1				1		
Oropharyngeal discomfort	8	25			6	19	2	6
Oropharyngeal pain	27	136			25	123	2	13
Oropharyngeal spasm		2						2
Orthopnoea		1						1
Orthostatic hypotension		1						1
Osteoarthritis		3				3		
Osteochondritis		1				1		
Osteomyelitis		1						1
Osteopenia		1				1		
Otitis media	1	1			1	1		
Ovarian disorder	1	1					1	1
Overdose	1	9			1	8		1
Overweight		2				2		
Oxygen consumption		1				1		
Oxygen saturation abnormal		4				4		
Oxygen saturation decreased	8	34			3	14	5	20
Pain	179	879	1	1	160	797	19	82
Painful respiration	1	5				2	1	3
Pain in extremity	239	799	2	3	216	740	23	59
Pain in jaw	7	28	1	1	6	22	1	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pain of skin	4	14			3	12	1	2
Palatal disorder		1				1		
Palatal swelling		3				1		2
Pallor	6	21			3	15	3	6
Palmar erythema		2				1		1
Palpable purpura		1				1		
Palpitations	32	158			28	122	4	36
Pancreatic disorder	1	1			1	1		
Pancreatitis		4						4
Pancreatitis acute	1	3					1	3
Pancytopenia		1						1
Panic attack	4	7			2	5	2	2
Panic reaction	1	6			1	5		1
Paraesthesia	47	254			35	200	12	54
Paraesthesia oral	11	82			8	60	3	22
Paralysis	1	7					1	7
Paranasal sinus discomfort	1	8			1	8		
Paranoia		2				2		
Paraplegia	1	1					1	1
Parkinsonism	2	2			1	1	1	1
Parkinson's disease		2						2
Parosmia	4	15			3	13	1	2
Patient elopement		1				1		
Pelvic pain	1	2			1	2		
Pemphigoid		1						1
Penile haemorrhage		1						1
Periarthritis		1						1
Pericardial effusion		4						4
Pericarditis	1	7					1	7
Periorbital cellulitis		1						1
Periorbital discomfort		1				1		
Periorbital pain		1				1		
Periorbital swelling	1	12			1	11		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Peripheral artery thrombosis	1	1			1	1		
Peripheral coldness	7	25			4	20	3	5
Peripheral nerve injury		1						1
Peripheral sensory neuropathy		1						1
Peripheral swelling	45	162	1	1	35	138	10	24
Peripheral venous disease	1	2			1	2		
Perivascular dermatitis		1				1		
Peroneal nerve palsy	1	5			1	3		2
Petechiae	3	12			1	4	2	8
Pharyngeal disorder	1	3				2	1	1
Pharyngeal erythema	2	5			2	5		
Pharyngeal hypoaesthesia	2	6			1	3	1	3
Pharyngeal inflammation	1	2			1	2		
Pharyngeal mass	1	3			1	2		1
Pharyngeal oedema		1						1
Pharyngeal paraesthesia	1	14			1	9		5
Pharyngeal swelling	20	72			11	31	9	41
Pharyngitis	2	2			1	1	1	1
Pharyngitis streptococcal		1				1		
Phlebitis		1				1		
Photophobia	2	18			1	16	1	2
Photopsia		4				2		2
Photosensitivity reaction	2	4			1	2	1	2
Physical deconditioning		1				1		
Pigmentation disorder		2				1		1
Piloerection	1	3			1	3		
Pituitary tumour benign		1						1
Plantar fasciitis	1	1			1	1		
Plasma cell myeloma		1						1
Platelet count decreased	9	22			2	3	7	19
Platelet count increased		4				2		2
Platelet disorder	2	3			1	1	1	2
Pleural effusion	4	6			1	2	3	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Pleurisy		3				1			2
Pleuritic pain		2				2			
Plicated tongue		1				1			
Pneumocystis jirovecii pneumonia		1							1
Pneumonia	10	33					10		33
Pneumonia aspiration	2	3					2		3
Pneumonia staphylococcal	1	1					1		1
Pneumonia viral	1	1					1		1
Pneumonitis	1	1					1		1
Pneumothorax	3	3					3		3
PO2 decreased		1							1
Pollakiuria	5	15			5	15			
Polychondritis		1							1
Polycythaemia		1				1			
Polydipsia		1				1			
Polymyalgia rheumatica	2	7					2		7
Polymyositis		1							1
Polyneuropathy	1	1					1		1
Polyserositis		1							1
Polyuria	1	3			1	2			1
Poor peripheral circulation		2							2
Poor quality product administered	2	4			2	4			
Poor quality sleep	1	12			1	12			
Poor venous access	1	1			1	1			
Post herpetic neuralgia		1				1			
Postmenopausal haemorrhage	3	4					3		4
Postoperative wound infection		1							1
Post procedural complication				1					
Post procedural infection		1							1
Post procedural oedema		1				1			
Post-traumatic neck syndrome		3							3
Postural orthostatic tachycardia syndrome		1		1					1
Posturing		1							1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pre-existing condition improved	2	3			2	3		
Premature delivery		1						1
Premature labour		1						1
Premature rupture of membranes		1						1
Premenstrual syndrome		1				1		
Pressure of speech		1				1		
Presyncope	17	54			8	33	9	21
Prinzmetal angina	1	2					1	2
Procedural pain		2				1		1
Procedural site reaction		1						1
Product administered at inappropriate site	9	17			8	15	1	2
Product administration error		2				1		1
Product colour issue	1	1			1	1		
Product complaint	1	1			1	1		
Product confusion		1				1		
Product dose omission issue	4	5			4	5		
Productive cough	4	16			4	14		2
Product preparation error		4				4		
Product preparation issue		1				1		
Product storage error		1				1		
Product supply issue	2	2			2	2		
Product temperature excursion issue	1	1			1	1		
Product use in unapproved indication	1	1			1	1		
Product use issue	4	108			4	105		3
Prostate cancer	2	2					2	2
Prostate infection		1						1
Prostatic specific antigen increased		1				1		
Protein total decreased	1	2			1	2		
Protein urine present	1	1			1	1		
Prothrombin time prolonged	1	1			1	1		
Pruritus	75	309			60	247	15	62
Pruritus genital		1						1
Psoriasis	2	6			1	5	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Psoriatic arthropathy	2	5					2	5
Psychiatric symptom		1				1		
Psychomotor hyperactivity	1	3			1	2		1
Psychotic disorder	1	1					1	1
Pulmonary artery occlusion	1	1					1	1
Pulmonary artery thrombosis		1						1
Pulmonary congestion	6	9					6	9
Pulmonary embolism	18	31					18	31
Pulmonary fibrosis	1	4					1	4
Pulmonary hypertension		1						1
Pulmonary infarction		1						1
Pulmonary mass		1				1		
Pulmonary oedema	5	12					5	12
Pulmonary pain	1	10				8	1	2
Pulmonary thrombosis	7	9					7	9
Pulse abnormal	1	5				1	1	4
Pulse absent	1	1					1	1
Pulseless electrical activity	1	1					1	1
Pulse pressure decreased	1	1					1	1
Pulse pressure increased		1				1		
Pupil fixed	1	1					1	1
Pupillary disorder		1				1		
Purpura		1				1		
Pustule	1	4				1	1	3
Pyrexia	212	932			188	829	24	103
Quality of life decreased	1	2				1	1	1
Rash	74	296			57	233	17	63
Rash erythematous	7	53			5	42	2	11
Rash macular	5	33			3	25	2	8
Rash maculo-papular		5				5		
Rash morbilliform	3	7			2	4	1	3
Rash papular	5	21			2	17	3	4
Rash pruritic	5	50			3	41	2	9

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rash vesicular	1	3				2	1	1
Raynaud's phenomenon	1	4			1	4		
Reaction to excipient		4				1		3
Rectal haemorrhage	2	4					2	4
Rectal tenesmus		1				1		
Red blood cell count abnormal		1				1		
Red blood cell count decreased	1	5				2	1	3
Red blood cell sedimentation rate abnormal		1				1		
Red blood cell sedimentation rate increased		4				1		3
Red cell distribution width increased		1						1
Red ear syndrome		1				1		
Reduced facial expression		1				1		
Regurgitation		1				1		
Renal atrophy	1	2					1	2
Renal disorder	3	7			1	4	2	3
Renal failure	2	5					2	5
Renal impairment		4						4
Renal pain	1	5			1	5		
Respiration abnormal	1	4			1	4		
Respiratory arrest	3	6					3	6
Respiratory disorder	4	20			2	11	2	9
Respiratory distress	5	22					5	22
Respiratory failure		4						4
Respiratory rate decreased	2	3			1	1	1	2
Respiratory rate increased	2	8					2	8
Respiratory symptom	1	3				2	1	1
Respiratory tract congestion	7	11			3	7	4	4
Respiratory tract infection		3						3
Respiratory tract irritation	1	1					1	1
Respiratory tract oedema	1	3					1	3
Restless legs syndrome	3	6			2	5	1	1
Restlessness	4	16			3	12	1	4
Restrictive pulmonary disease		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retching	2	19			2	17		2
Retinal artery occlusion		2						2
Retinal detachment		1						1
Retinal disorder		1				1		
Retinal vein occlusion		2						2
Retinitis		1						1
Rhabdomyolysis		1						1
Rheumatoid arthritis	15	30	1	1		1	15	29
Rhinalgia	1	5				4	1	1
Rhinitis		3				2		1
Rhinitis allergic		1						1
Rhinorrhoea	22	83			20	72	2	11
Rosacea		2				2		
Salivary gland enlargement		1				1		
Salivary hypersecretion	2	4			1	3	1	1
SARS-CoV-2 ant body test negative	6	15			5	13	1	2
SARS-CoV-2 ant body test positive		2				2		
SARS-CoV-2 test false positive	1	1					1	1
SARS-CoV-2 test negative		1				1		
SARS-CoV-2 test positive	5	30			4	10	1	20
Scab		3				2		1
Scar	2	3			1	1	1	2
Sciatica	2	6			2	4		2
Scleral discolouration		1				1		
Scleritis	1	2					1	2
Scleroderma	2	2					2	2
Scratch	1	4			1	3		1
Screaming	1	2				1	1	1
Scrotal pain	1	1			1	1		
Seasonal allergy	2	3			2	3		
Secretion discharge	4	5			3	3	1	2
Sedation		3				2		1
Seizure	22	45					22	45

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Seizure like phenomena	1	2					1	2
Sensation of foreign body	1	14			1	12		2
Sensitive skin		8				8		
Sensitivity to weather change		2				2		
Sensory disturbance	3	8			2	7	1	1
Sensory loss	3	4			1	2	2	2
Sepsis	3	9					3	9
Seronegative arthritis		2						2
Serum ferritin decreased		2						2
Serum sickness	1	1			1	1		
Shock	2	8			1	1	1	7
Shock symptom		1						1
Shoulder injury related to vaccine administration		1				1		
Sialoadenitis		2						2
Sinus bradycardia		2				1		1
Sinus congestion	1	5			1	5		
Sinus disorder	8	14			7	12	1	2
Sinus headache	1	4			1	4		
Sinusitis	7	17			7	17		
Sinusitis bacterial		1						1
Sinus pain		4				4		
Sinus tachycardia		4				2		2
Sitting disability		2				1		1
Sjogren's syndrome	1	3					1	3
Skin abrasion		2				2		
Skin bacterial infection	1	1					1	1
Skin burning sensation	3	12			3	12		
Skin depigmentation		1				1		
Skin discolouration	6	25			5	21	1	4
Skin disorder	6	17			5	13	1	4
Skin exfoliation	2	6			2	6		
Skin fissures	1	2			1	1		1
Skin haemorrhage	2	2			1	1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin indentation	1	1			1	1		
Skin infection	2	2			1	1	1	1
Skin injury		2				2		
Skin irritation		3				3		
Skin laceration	2	5			1	2	1	3
Skin laxity		1				1		
Skin lesion	1	3			1	3		
Skin mass	1	1			1	1		
Skin reaction		1				1		
Skin swelling	1	3				2	1	1
Skin tightness	1	1					1	1
Skin turgor decreased	1	1					1	1
Skin ulcer		2				2		
Skin warm	1	3			1	3		
Sleep apnoea syndrome	1	1					1	1
Sleep attacks	1	1			1	1		
Sleep deficit	2	3			2	3		
Sleep disorder	11	32			11	31		1
Sleep disorder due to a general medical condition		1				1		
Sleep disorder due to general medical condition, insomnia type		1				1		
Sleep paralysis		1				1		
Sleep talking		1				1		
Sleep terror		1				1		
Slow speech	1	2			1	2		
Sluggishness	4	8			4	8		
Small fibre neuropathy		1						1
Small intestinal obstruction		2						2
Sneezing	8	28			7	26	1	2
Snoring		2				2		
Soft tissue injury		1				1		
Somnolence	24	98			22	86	2	12

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Speech disorder	13	41			5	19	8	22
Speech sound disorder	1	1			1	1		
Spinal cord disorder		1						1
Spinal disorder		1				1		
Spinal fusion surgery		1						1
Spinal osteoarthritis		1				1		
Spinal pain	1	7			1	6		1
Splenic vein thrombosis		1						1
Splenomegaly		2				1		1
Splinter	1	1			1	1		
Splinter haemorrhages		1				1		
Sputum discoloured	2	3					2	3
Staphylococcal infection		1						1
Staring	1	3				1	1	2
Status asthmaticus		1						1
Stevens-Johnson syndrome		1						1
Stiff tongue		1						1
Stoma site haemorrhage		1						1
Stomatitis	2	13			1	11	1	2
Strabismus		1						1
Stress	4	15			4	15		
Stress urinary incontinence	1	1			1	1		
Stridor	1	5			1	2		3
Subarachnoid haemorrhage		2						2
Subdural haemorrhage		1						1
Sudden cardiac death		2						2
Sudden death	1	2					1	2
Sudden hearing loss	2	3					2	3
Sudden visual loss	1	1					1	1
Suicidal ideation	1	5					1	5
Suicide attempt		1						1
Sunburn		1				1		
Superficial injury of eye		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Superior sagittal sinus thrombosis	1	1					1	1
Supraventricular extrasystoles	1	3			1	2		1
Supraventricular tachycardia		1						1
Suspected COVID-19	5	16			3	6	2	10
Suture related complication		1						1
Swelling	31	120			25	96	6	24
Swelling face	27	113			22	83	5	30
Swelling of eyelid	2	12			1	11	1	1
Swollen tongue	17	63	1	1	7	31	10	32
Syncope	34	76				1	34	75
Synovial cyst		1				1		
Systemic inflammatory response syndrome		1						1
Systemic lupus erythematosus	2	6					2	6
Systemic scleroderma		1						1
Tachycardia	9	98			3	57	6	41
Tachyphrenia		2				2		
Tachypnoea	1	18				11	1	7
Tardive dyskinesia	1	1					1	1
Taste disorder	8	30			6	24	2	6
Temperature intolerance	1	4			1	2		2
Temperature regulation disorder		1				1		
Temporomandibular joint syndrome		1				1		
Tenderness	4	11			4	11		
Tendon pain	1	1					1	1
Tension		1				1		
Tension headache	2	4			2	3		1
Testicular swelling	1	1			1	1		
Tetanus	1	1					1	1
Tetany		1						1
Thalamic infarction		1						1
Therapeutic response unexpected	14	32			14	32		
Thinking abnormal	2	11			2	11		
Thirst	7	21			7	19		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Thoracic vertebral fracture		1						1	
Throat clearing	1	4					1		4
Throat irritation	19	69			12	47	7		22
Throat tightness	22	93			11	41	11		52
Thrombocytopenia	4	8					4		8
Thrombophlebitis	2	2			2	2			
Thrombophlebitis superficial	3	3			2	2	1		1
Thrombosis	33	47				1	33		46
Thrombotic microangiopathy	1	1					1		1
Thrombotic stroke	1	1					1		1
Thyroid disorder	2	6			2	6			
Thyroid function test abnormal	1	2			1	2			
Thyroid hormones increased	1	1			1	1			
Thyroiditis subacute		1				1			
Thyroid mass		1				1			
Thyroid pain	1	2			1	2			
Thyrotoxic crisis	3	3					3		3
Thyroxine decreased		1				1			
Tic		1							1
Tinnitus	32	81			23	58	9		23
T-lymphocyte count increased		1				1			
Tongue blistering		3				3			
Tongue discolouration	1	2				1	1		1
Tongue discomfort	4	13			2	11	2		2
Tongue disorder	3	8			2	6	1		2
Tongue dry		2				2			
Tongue eruption	2	4			2	2			2
Tongue erythema	1	4			1	4			
Tongue movement disturbance	1	1			1	1			
Tongue oedema		2				1			1
Tongue paralysis	1	1					1		1
Tongue pruritus	1	6				3	1		3
Tongue ulceration		2				2			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tonic clonic movements		1						1
Tonsillar hypertrophy		1				1		
Tooth abscess	1	1			1	1		
Toothache	2	12			2	10		2
Tooth discolouration	1	1			1	1		
Tooth disorder		3				2		1
Tooth injury		1						1
Torsade de pointes		1						1
Torticollis		1				1		
Tourette's disorder	1	1					1	1
Tracheal obstruction	1	1					1	1
Tracheomalacia		1						1
Transaminases decreased	1	1					1	1
Transaminases increased		2				1		1
Transient ischaemic attack	4	13					4	13
Transplant failure		1						1
Tremor	39	139		1	30	108	9	31
Trigeminal nerve disorder		1				1		
Trigeminal neuralgia	1	4			1	2		2
Trigger finger	4	4			4	4		
Tri-iodothyronine decreased		1				1		
Trismus		1				1		
Troponin I increased	1	1			1	1		
Troponin increased	3	10			1	3	2	7
Tryptase increased		1				1		
Tumour marker abnormal		1						1
Tunnel vision	5	7					5	7
Type 1 diabetes mellitus	1	1					1	1
Type III immune complex mediated reaction		1						1
Type V hyperlipidaemia		1						1
Ulcer		2				2		
Ulcer haemorrhage		1						1
Underdose	1	9			1	9		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Undifferentiated connective tissue disease		1						1
Unresponsive to stimuli	4	19					4	19
Upper-airway cough syndrome		8				6		2
Upper airway obstruction	1	1					1	1
Upper respiratory tract congestion	4	9			3	7	1	2
Upper respiratory tract infection	1	3			1	3		
Urethral disorder		1				1		
Urinary assistance device user		1				1		
Urinary incontinence	3	9				5	3	4
Urinary retention		1						1
Urinary tract infection	3	18			2	10	1	8
Urinary tract infection bacterial		2						2
Urine analysis abnormal	1	4			1	4		
Urine output decreased	1	1			1	1		
Urine output increased		2				2		
Urosepsis		1						1
Urticaria	43	201			28	145	15	56
Use of accessory respiratory muscles		4				4		
Uterine disorder		1				1		
Uterine haemorrhage	1	1					1	1
Uterine inflammation		1						1
Uveitis		4						4
Vaccination complication	2	2	1	1	1	1	1	1
Vaccination error	1	1			1	1		
Vaccination failure	16	26	1	1			16	26
Vaccination site bruising	1	15			1	15		
Vaccination site cellulitis		3				2		1
Vaccination site coldness	1	2			1	2		
Vaccination site discolouration		8				8		
Vaccination site discomfort	3	11			3	10		1
Vaccination site erythema	24	138			24	127		11
Vaccination site extravasation		1				1		
Vaccination site haemorrhage	4	9			4	9		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vaccination site hypoaesthesia		3				3			
Vaccination site induration	3	14			3	13			1
Vaccination site infection		2				2			
Vaccination site inflammation		5				5			
Vaccination site injury		1				1			
Vaccination site irritation	1	1			1	1			
Vaccination site joint movement impairment	1	4			1	4			
Vaccination site joint pain	1	3			1	3			
Vaccination site lymphadenopathy		3				3			
Vaccination site macule		1				1			
Vaccination site mass	7	25			6	21	1		4
Vaccination site movement impairment	2	14			2	14			
Vaccination site nodule	1	2			1	2			
Vaccination site oedema		4				2			2
Vaccination site pain	117	632	2	2	113	601	4		31
Vaccination site pallor		1				1			
Vaccination site papule		3				3			
Vaccination site paraesthesia	1	3			1	2			1
Vaccination site pruritus	17	76			17	69			7
Vaccination site rash	8	29			7	25	1		4
Vaccination site reaction	2	6			1	4	1		2
Vaccination site scab		1				1			
Vaccination site streaking	1	1			1	1			
Vaccination site swelling	25	138			25	133			5
Vaccination site urticaria	4	17			3	14	1		3
Vaccination site vesicles		1				1			
Vaccination site warmth	11	57			11	52			5
Vaginal discharge		2				2			
Vaginal haemorrhage	2	5			2	4			1
Varicella		1				1			
Varicella zoster virus infection		1				1			
Varicocele	1	1			1	1			
Varicose vein	1	1					1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Vascular dementia		1							1
Vascular occlusion	1	1					1		1
Vascular pain	1	1			1	1			
Vasculitic rash		1				1			
Vein discolouration		1				1			
Vein disorder	1	2			1	2			
Venous thrombosis limb	1	2					1		2
Ventricular arrhythmia		1							1
Ventricular extrasystoles	3	9			2	4	1		5
Ventricular fibrillation		1							1
Vertigo	26	76			13	56	13		20
Vertigo positional	1	2					1		2
Vestibular disorder		1				1			
Vestibular migraine	1	1			1	1			
Viral myocarditis		1							1
Viral upper respiratory tract infection		2				1			1
Vision blurred	15	62			12	42	3		20
Visual acuity reduced	2	4			2	4			
Visual field defect	2	5			1	4	1		1
Visual impairment	6	36			3	22	3		14
Vitamin B12 decreased	1	2					1		2
Vitamin B12 increased	1	1			1	1			
Vitamin D decreased	2	2			1	1	1		1
Vitamin D deficiency		1				1			
Vlth nerve paralysis		1							1
Vitreous degeneration		1							1
Vitreous detachment		1							1
Vitreous floaters	1	3			1	1			2
Vocal cord disorder		2							2
Vomiting	76	273	1	1	48	210	28		63
Vomiting projectile	1	6			1	6			
Vulvovaginal mycotic infection	1	2			1	2			
Vulvovaginal pain	1	1			1	1			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vulvovaginal pruritus		1						1
Vulvovaginal rash		1						1
Vulvovaginal swelling		1						1
Walking aid user	2	3			1	2	1	1
Walking disability	1	1			1	1		
Weight decreased	14	46			11	40	3	6
Weight fluctuation	1	2			1	2		
Weight increased	7	10			6	9	1	1
Wheezing	29	70			19	45	10	25
White blood cell count decreased	1	8			1	6		2
White blood cell count increased	3	18			2	10	1	8
White matter lesion		1						1
Winged scapula		1				1		
Wound	2	4			1	3	1	1
Wound haemorrhage	1	1			1	1		
Wound secretion		1						1
Wrong product administered	3	4			3	4		
Wrong technique in device usage process		1				1		
Wrong technique in product usage process	1	3			1	3		
Yellow skin	1	3				1	1	2
	7,492	28,896	30	38	5309	21986	2183	6910

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

## APPENDIX 2.6: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Sources Organized per MedDRA System Organ Class by High Level Term

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

Total Number of Adverse Events (PT): 112,695 (Interval) / 414,597 (Cumulative)

MedDRA Version: v.23.1J

*System Organ Class*

**Blood and lymphatic system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia deficiencies	4	8			4	4		4
Anaemias haemolytic immune	6	12					6	12
Anaemias haemolytic mechanical factor	2	3					2	3
Anaemias haemolytic NEC	8	16					8	16
Anaemias NEC	39	89			9	26	30	63
Bleeding tendencies	20	33				7	20	26
Coagulation factor deficiencies	2	4					2	4
Coagulopathies	33	64			3	9	30	55
Eosinophilic disorders	5	11				3	5	8
Haematological disorders	5	16			4	6	1	10
Haemolyses NEC	2	5					2	5
Leukocytoses NEC	27	81		1	8	25	19	56
Leukopenias NEC	27	74		1	7	19	20	55
Lymphatic system disorders NEC	1,880	6,780	17	26	898	3826	982	2954
Marrow depression and hypoplastic anaemias	14	29					14	29
Neutropenias	17	56		1			17	56
Platelet disorders NEC	4	7			1	2	3	5
Polycythaemia (excl rubra vera)		1				1		
Red blood cell abnormal findings NEC	2	7				1	2	6
Sickle cell trait and disorders	3	3					3	3
Spleen disorders	12	23			1	3	11	20
Thrombocytopenias	176	314	1	2	2	3	174	311
Thrombocytoses	2	5			1	2	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell abnormal findings NEC	2	2					2	2
	2,292	7,643	18	31	938	3937	1354	3706

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic valvular disorders	6	10					6	10
Cardiac conduction disorders	25	70			3	11	22	59
Cardiac disorders NEC	85	245			37	91	48	154
Cardiac hypertensive complications	4	8					4	8
Cardiac signs and symptoms NEC	542	1,883		5	257	885	285	998
Cardiac valve disorders NEC	2	7			1	2	1	5
Cardiomyopathies	8	27				1	8	26
Coronary artery disorders NEC	24	49			1	1	23	48
Heart failure signs and symptoms	6	7			1	1	5	6
Heart failures NEC	139	391					139	391
Ischaemic coronary artery disorders	262	697			1	2	261	695
Left ventricular failures	3	14					3	14
Mitral valvular disorders	9	17					9	17
Myocardial disorders NEC	27	56			4	9	23	47
Noninfectious myocarditis	83	157					83	157
Noninfectious pericarditis	63	148					63	148
Pericardial disorders NEC	29	62			1	1	28	61
Rate and rhythm disorders NEC	729	3,215	3	16	244	1207	485	2008
Right ventricular failures	5	10					5	10
Supraventricular arrhythmias	247	763	3	3	16	69	231	694
Tricuspid valvular disorders	5	6					5	6
Ventricular arrhythmias and cardiac arrest	169	506			9	28	160	478
	2,472	8,348	6	24	575	2308	1897	6040

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial disorders congenital		1				1
Cardiac disorders congenital NEC		2				2
Cardiac septal defects congenital	1	6			1	6
Cerebral disorders congenital	4	4			4	4
Coagulation disorders congenital	2	5	1	1	1	4
Congenital disorders NEC	1	3			1	3
Connective tissue disorders congenital		1				1
Corneal and scleral disorders congenital	1	1			1	1
Gastrointestinal tract disorders congenital NEC	1	1			1	1
Gene mutations and other alterations NEC		1				1
Haematological disorders congenital NEC		1				1
Immune system abnormalities congenital		1				1
Inborn errors of amino acid metabolism	1	2	1	1		1
Inborn errors of lipid metabolism	1	2			1	2
Inborn errors of porphyrin metabolism	1	2			1	2
Lymphatic system disorders congenital		1				1
Musculoskeletal and connective tissue disorders of limbs congenital		1				1
Musculoskeletal disorders congenital NEC	1	2			1	2
Neurological disorders congenital NEC	2	10	1	1	1	9
Ocular disorders congenital NEC		1		1		
Peripheral nervous system disorders congenital NEC	1	1			1	1
Pulmonary and bronchial disorders congenital		1				1
Retinal disorders congenital		2				2
Skin and subcutaneous tissue disorders congenital NEC		2		1		1
Thyroid disorders congenital	1	1			1	1
Tongue disorders congenital	3	8			3	8
Venous disorders congenital		1				1
	21	64	3	5	18	59

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	269	947			150	549	119	398
Eustachian tube disorders	1	6			1	2		4
External ear disorders NEC	10	28			6	19	4	9
External ear infections and inflammations		2				1		1
Hearing disorders NEC	5	13			2	4	3	9
Hearing losses	247	606			33	104	214	502
Hyperacusia	23	64			11	32	12	32
Inner ear disorders NEC	21	58			3	12	18	46
Inner ear infections and inflammations		1						1
Inner ear signs and symptoms	793	2,412	3	6	331	1154	462	1258
Mastoid disorders	1	2			1	1		1
Middle ear disorders NEC		2				1		1
Middle ear infections and inflammations		1						1
Tympanic membrane disorders (excl infections)	1	3				2	1	1
	1,371	4,145	3	6	538	1881	833	2264

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	13	39	3	12	10	27
Adrenal cortical hypofunctions	6	19			6	19
Adrenal gland disorders NEC	3	9	3	7		2
Endocrine abnormalities of puberty	1	1	1	1		
Female gonadal function disorders		1				1
Hyperparathyroid disorders		2		2		
Hypothalamic and pituitary disorders NEC		1				1
Posterior pituitary disorders		1				1
Thyroid disorders NEC	18	45	9	26	9	19
Thyroid hyperfunction disorders	20	35			20	35

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroid hypofunction disorders	11	23		1	11	22
Thyroid neoplasms		1				1
	72	177	16	49	56	128

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amblyopic vision impairment	1	2				1	1	1
Cataract conditions	7	11				1	7	10
Chambers (anterior and posterior) and lens infections and inflammations		1						1
Choroid and vitreous haemorrhages and vascular disorders	5	8					5	8
Choroid and vitreous structural change, deposit and degeneration	17	61		1	2	13	15	48
Colour blindness (incl acquired)	2	4			1	3	1	1
Conjunctival and corneal bleeding and vascular disorders	30	83		2			30	83
Conjunctival infections, irritations and inflammations	23	61			11	32	12	29
Conjunctival structural change, deposit and degeneration		1						1
Corneal disorders NEC		3						3
Corneal infections, oedemas and inflammations	3	15				5	3	10
Corneal structural change, deposit and degeneration	3	10					3	10
Eyelid movement disorders	40	129			18	56	22	73
Glaucomas (excl congenital)	7	18					7	18
Iris and ciliary body structural change, deposit and degeneration	1	4				1	1	3

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\* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Iris and uveal tract infections, irritations and inflammations	17	57
Lacrimation disorders	73	339
Lid bleeding and vascular disorders	2	4
Lid, lash and lacrimal infections, irritations and inflammations	95	335
Lid, lash and lacrimal structural disorders	5	11
Ocular bleeding and vascular disorders NEC	53	100
Ocular disorders NEC	415	1,568
Ocular infections, inflammations and associated manifestations	185	755
Ocular nerve and muscle disorders	33	83
Ocular sensation disorders	120	515
Optic disc abnormalities NEC	2	7
Optic nerve bleeding and vascular disorders	8	9
Orbital infections, inflammations and irritations	2	2
Orbital structural change, deposit and degeneration	3	6
Pupil disorders	22	61
Refractive and accommodative disorders	5	12
Retinal bleeding and vascular disorders (excl retinopathy)	53	70
Retinal, choroid and vitreous infections and inflammations	6	13
Retinal structural change, deposit and degeneration	18	40
Retinopathies NEC	5	8
Scleral infections, irritations and inflammations	5	21
Scleral structural change, deposit and degeneration	1	8
Structural change, deposit and degeneration of eye NEC	8	13
Visual colour distortions	2	10
Visual disorders NEC	363	1,082

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	16	53
		46	207	27	132
		1	3	1	1
	1	47	173	48	162
		4	5	1	6
		2	2	51	98
	3	240	843	175	725
	3	117	469	68	286
		8	18	25	65
		59	249	61	266
				2	7
				8	9
				2	2
				3	6
		15	27	7	34
		4	8	1	4
	1	1	1	52	69
				6	13
				18	40
				5	8
			5	5	16
			3	1	5
			1	8	12
		1	6	1	4
		174	515	189	567

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment and blindness (excl colour blindness)	244	643	1	4	69	195	175	448
Visual pathway disorders	1	5					1	5
	1,885	6,188	1	15	821	2846	1064	3342

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	9	27			6	16	3	11
Abdominal hernias NEC	1	1					1	1
Abdominal wall conditions NEC	1	4					1	4
Acute and chronic pancreatitis	21	61					21	61
Anal and rectal disorders NEC	1	10				2	1	8
Anal and rectal pains	2	9			1	6	1	3
Anal and rectal signs and symptoms	5	18			3	11	2	7
Anal and rectal ulcers and perforation		1						1
Benign neoplasms gastrointestinal (excl oral cavity)		2				2		
Benign oral cavity neoplasms	2	4				2	2	2
Colitis (excl infective)	56	112	1	1	10	17	46	95
Dental and periodontal infections and inflammations	2	3			1	2	1	1
Dental disorders NEC	8	21			6	15	2	6
Dental pain and sensation disorders	50	160			34	113	16	47
Dental surface disorders	1	1			1	1		
Diaphragmatic hernias	3	6			1	3	2	3
Diarrhoea (excl infective)	1,168	4,682	4	21	701	2666	467	2016
Diverticula	5	9			1	4	4	5
Duodenal and small intestinal stenosis and obstruction	2	6					2	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Duodenal ulcers and perforation	1	4
Dyspeptic signs and symptoms	92	324
Faecal abnormalities NEC	41	137
Flatulence, bloating and distension	117	379
Gastric and oesophageal haemorrhages	4	13
Gastric and pyloric stenosis and obstruction		2
Gastric ulcers and perforation	7	10
Gastritis (excl infective)	14	43
Gastrointestinal and abdominal pains (excl oral and throat)	812	3,086
Gastrointestinal atonic and hypomotility disorders NEC	98	306
Gastrointestinal disorders NEC	74	224
Gastrointestinal dyskinetic disorders	15	44
Gastrointestinal inflammatory disorders NEC	9	24
Gastrointestinal mucosal dystrophies and secretion disorders	3	11
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	3	8
Gastrointestinal signs and symptoms NEC	358	1,321
Gastrointestinal spastic and hypermotility disorders	27	121
Gastrointestinal stenosis and obstruction NEC	17	41
Gastrointestinal vascular malformations	2	3
Gastrointestinal vascular occlusion and infarction	26	53
Gingival disorders, signs and symptoms NEC	32	135
Gingival haemorrhages	17	34
Haemorrhoids and gastrointestinal varices (excl oesophageal)	6	23
Intestinal haemorrhages	40	102
Intestinal ulcers and perforation NEC	2	4
Large intestinal stenosis and obstruction		1
Malabsorption syndromes	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
		48	188	44	136
		24	87	17	50
	1	68	219	49	160
				4	13
					2
				7	10
		6	21	8	22
2	7	422	1656	390	1430
		54	165	44	141
1	1	50	152	24	72
		13	36	2	8
		3	6	6	18
		1	3	2	8
				3	8
2	8	207	699	151	622
		16	55	11	66
		1	1	16	40
				2	3
				26	53
	1	17	71	15	64
		7	17	10	17
		3	9	3	14
		3	6	37	96
				2	4
					1
		1	1	1	7

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nausea and vomiting symptoms	4,366	17,287
Non-mechanical ileus	3	8
Non-site specific gastrointestinal haemorrhages	86	249
Oesophageal disorders NEC		5
Oesophageal stenosis and obstruction	1	2
Oesophageal ulcers and perforation	1	3
Oesophagitis (excl infective)	4	7
Oral dryness and saliva altered	140	620
Oral soft tissue disorders NEC	48	163
Oral soft tissue haemorrhages	19	36
Oral soft tissue infections	1	4
Oral soft tissue signs and symptoms	544	2,664
Oral soft tissue swelling and oedema	205	978
Pancreatic disorders NEC	2	5
Peptic ulcers and perforation	1	3
Peritoneal and retroperitoneal disorders	1	8
Peritoneal and retroperitoneal fibrosis and adhesions	1	2
Peritoneal and retroperitoneal haemorrhages	2	4
Rectal inflammations NEC	2	4
Salivary gland disorders NEC	5	15
Salivary gland enlargements	9	26
Salivary gland infections and inflammations	1	3
Salivary gland stenosis and obstruction		2
Stomatitis and ulceration	89	303
Tongue disorders	26	149
Tongue signs and symptoms	263	1,101
Tooth missing		1
	8,976	35,250

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
10	90	2557	9616	1809	7671
				3	8
		1	1	85	248
			1		4
				1	2
				1	3
		3	5	1	2
	2	83	349	57	271
		28	92	20	71
		6	16	13	20
			3	1	1
3	7	371	1578	173	1086
2	4	113	429	92	549
		1	1	1	4
				1	3
				1	8
				1	2
				2	4
		2	2		2
		2	8	3	7
		4	16	5	10
			1	1	2
					2
1	2	47	156	42	147
		14	88	12	61
2	3	129	474	134	627
					1
28	148	5070	19088	3906	16162

System Organ Class

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\* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site reactions NEC	17	105			15	96	2	9
Adverse effect absent	44	125			44	125		
Application and instillation site reactions	4	19			3	14	1	5
Asthenic conditions	8,395	32,978	29	219	5222	19940	3173	13038
Body temperature altered	67	325			21	102	46	223
Complications associated with device NEC	1	6			1	4		2
Death and sudden death	277	1,107	1	2			277	1107
Eye complications associated with device		1						1
Febrile disorders	4,364	19,631	23	89	2767	11895	1597	7736
Feelings and sensations NEC	4,661	19,523	9	63	2989	12595	1672	6928
Fibrosis NEC	1	1			1	1		
Gait disturbances	309	990		2	108	437	201	553
General signs and symptoms NEC	3,151	10,280	7	22	1555	5042	1596	5238
Healing abnormal NEC	3	7			1	3	2	4
Hernias NEC		1						1
Implant and catheter site reactions		2				1		1
Inflammations	152	471			98	291	54	180
Infusion site reactions	1	4			1	4		
Injection site reactions	208	2,089		1	178	1997	30	92
Interactions	28	75			12	44	16	31
Mass conditions NEC	108	299			82	242	26	57
Mucosal findings abnormal	12	48			7	26	5	22
Necrosis NEC	2	5					2	5
Oedema NEC	245	916	2	3	120	475	125	441
Pain and discomfort NEC	3,933	14,290	7	31	2227	8662	1706	5628
Therapeutic and nontherapeutic responses	1,055	3,766	5	9	74	183	981	3583
Trophic disorders	1	2			1	1		1
Ulcers NEC	1	12				6	1	6
Vaccination site reactions	5,595	23,046	7	89	4371	17310	1224	5736
Vascular complications associated with device	3	3					3	3
Withdrawal and rebound effects	1	5			1	2		3
	32,639	130,132	90	530	19899	79498	12740	50634

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	5	10			5	10
Cholecystitis and cholelithiasis	8	19		2	8	17
Cholestasis and jaundice	28	74	4	12	24	62
Gal bladder disorders NEC	5	16	1	6	4	10
Hepatic and hepatobiliary disorders NEC	10	22	4	10	6	12
Hepatic enzymes and function abnormalities	11	21	4	6	7	15
Hepatic failure and associated disorders	3	13			3	13
Hepatic fibrosis and cirrhosis	1	5			1	5
Hepatic vascular disorders	11	16			11	16
Hepatobiliary signs and symptoms	8	28	2	11	6	17
Hepatocellular damage and hepatitis NEC	38	87	1	3	37	84
Obstructive bile duct disorders (excl neoplasms)		1				1
Structural and other bile duct disorders	4	6	2	2	2	4
	132	318	18	52	114	266

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute and chronic sarcoidosis	6	13					6	13
Allergic conditions NEC	411	1,493		7	212	614	199	879
Allergies to foods, food additives, drugs and other chemicals	79	373		1	40	188	39	185
Amyloidoses		1						1
Anaphylactic and anaphylactoid responses	830	2,249	1	5	3	4	827	2245
Atopic disorders	14	31			11	22	3	9
Autoimmune disorders NEC	20	47					20	47
Immune and associated conditions NEC	31	93			8	35	23	58
Immunodeficiency disorders NEC	4	13					4	13
Primary immunodeficiency syndromes	1	1					1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Transplant rejections	2	4					2	4
Vasculitides		1						1
	1,398	4,319	1	13	274	863	1124	3456

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	99	369	5	7	6	17	93	352
Aspergillus infections		1						1
Babesia infections		1						1
Bacterial infections NEC	132	390			14	34	118	356
Blastocystis infections		1						1
Bone and joint infections	3	11					3	11
Bordetella infections		3						3
Borrelial infections	3	9					3	9
Breast infections	16	37			1	1	15	36
Caliciviral infections	1	1					1	1
Candida infections	19	61			7	30	12	31
Cardiac infections	1	8					1	8
Central nervous system and spinal infections	30	85					30	85
Clostridia infections	4	8					4	8
Coccidioides infections		2						2
Coronavirus infections	2,100	6,106	7	14	552	1423	1548	4683
Coxiella infections	3	16					3	16
Coxsackie viral infections	1	1			1	1		
Cytomegaloviral infections	1	3					1	3
Dental and oral soft tissue infections	26	84			13	45	13	39
Ear infections	49	132			20	53	29	79
Ectoparasitic infestations	1	4				1	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Enterococcal infections	2	4
Enteroviral infections NEC		1
Epstein-Barr viral infections	4	19
Escherichia infections	9	20
Eye and eyelid infections	27	136
Female reproductive tract infections	4	12
Filovirus viral infections		1
Fungal infections NEC	10	26
Helicobacter infections		2
Hepatitis viral infections	3	5
Hepatobiliary and spleen infections	1	5
Herpes viral infections	408	1,500
Infections NEC	152	392
Infectious disorders carrier		1
Infectious transmissions	1	1
Inflammatory disorders following infection		1
Influenza viral infections	243	789
Klebsiella infections		5
Legionella infections		1
Listeria infections		1
Lower respiratory tract and lung infections	199	649
Male reproductive tract infections	2	11
Moraxella infections		2
Mumps viral infections	1	3
Muscle and soft tissue infections	2	8
Neisseria infections		2
Nematode infections	2	2
Parainfluenzae viral infections	1	1
Parvoviral infections	1	1
Pneumocystis infections		1
Prion-associated disorders	3	5
Pseudomonal infections	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
					1
		2	3	2	16
				9	20
		16	77	11	59
		1	6	3	6
					1
		7	18	3	8
					2
			1	3	4
				1	5
2	3	147	721	261	779
	1	44	126	108	266
					1
				1	1
			1		
1	4	109	324	134	465
					5
					1
					1
		10	31	189	618
			1	2	10
					2
				1	3
				2	8
					2
				2	2
				1	1
		1	1		
					1
				3	5
				4	4

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System Organ Class

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Retroviral infections	1	2
Rhinoviral infections	1	4
Rotaviral infections	1	1
Rubeola viral infections	5	5
Sepsis, bacteraemia, viraemia and fungaemia NEC	52	169
Skin structures and soft tissue infections	29	98
Staphylococcal infections	17	45
Streptobacillus infections		1
Streptococcal infections	24	67
Tinea infections	2	4
Toxoplasma infections	1	1
Treponema infections	1	3
Trypanosomal infections	1	2
Tuberculous infections	8	16
Upper respiratory tract infections	338	1,104
Urinary tract infections	116	343
Vascular infections	10	29
Viral infections NEC	89	275
	4,264	13,113

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	3		1
				1	1
				5	5
				52	169
	1	14	48	15	50
		1	6	16	39
					1
1	1		8	24	59
		2	4		
		1	1		
				1	3
				1	2
				8	16
2	4	226	723	112	381
1	1	40	125	76	218
				10	29
1	1	16	60	73	215
20	37	1252	3893	3012	9220

System Organ Class

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Abdominal and gastrointestinal injuries NEC	20	34
Accidental exposures to product	6	50
Anaesthetic and allied procedural complications	3	3
Atmospheric pressure injuries		1
Bone and joint injuries NEC	13	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	19	8	15
		6	49		1
		1	1	2	2
			1		
		7	19	6	14

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System Organ Class

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiac and vascular procedural complications	5	7
Cardiovascular injuries	11	20
Cerebral injuries NEC	29	53
Chemical injuries	1	1
Chest and respiratory tract injuries NEC	11	29
Conditions caused by cold	35	56
Cranial nerve injuries		1
Ear injuries NEC	1	1
Exposures associated with pregnancy, delivery and lactation	213	855
Exposures to agents or circumstances NEC	44	111
Eye injuries NEC	14	59
Fractures and dislocations NEC	5	24
Gastrointestinal and hepatobiliary procedural complications	1	8
Heat injuries (excl thermal burns)	2	13
Intentional product misuses	4	8
Intentional product use issues	2	7
Limb fractures and dislocations	38	88
Medication errors, product use errors and issues NEC	243	1,820
Muscle, tendon and ligament injuries	35	103
Musculoskeletal procedural complications		1
Nerve injuries NEC	18	42
Neurological and psychiatric procedural complications	3	7
Non-occupational environmental exposures	2	2
Non-site specific injuries NEC	323	847
Non-site specific procedural complications	9	43
Occupational exposures	6	25
Off label uses	617	1,921
Overdoses NEC	145	383
Pathways and sources of exposure	6	42

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	7
		1	1	10	19
		2	7	27	46
				1	1
			2	11	27
		30	42	5	14
					1
		1	1		
4	4	152	731	61	124
	1	42	92	2	19
	1	5	33	9	26
		2	3	3	21
		1	3		5
		1	6	1	7
		4	8		
		2	7		
		2	3	36	85
		232	1772	11	48
	1	14	48	21	55
					1
		11	20	7	22
		1	1	2	6
		1	1	1	1
1	1	115	312	208	535
	1	1	8	8	35
		6	24		1
1	1	590	1861	27	60
		141	371	4	12
		6	42		

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pelvic fractures and dislocations	2	6					2	6
Peripheral nerve injuries	2	12					2	12
Poisoning and toxicity	9	21		1			9	21
Product administration errors and issues	1,035	3,572	1	1	1004	3497	31	75
Product confusion errors and issues	1	8			1	8		
Product dispensing errors and issues	1	1			1	1		
Product preparation errors and issues	141	571			141	565		6
Product prescribing errors and issues	1	4			1	4		
Product storage errors and issues in the product use system	24	45			24	45		
Product transcribing errors and communication issues		2				2		
Radiation injuries	3	12			3	8		4
Reproductive system and breast injuries		1				1		
Reproductive tract and breast procedural complications	3	3			1	1	2	2
Respiratory tract and thoracic cavity procedural complications		1						1
Site specific injuries NEC	81	225			29	94	52	131
Skin injuries NEC	220	527		2	115	292	105	235
Skin procedural complications	2	2			2	2		
Skull fractures, facial bone fractures and dislocations	10	20					10	20
Spinal cord injuries NEC		3						3
Spinal fractures and dislocations	3	6					3	6
Stoma complications		8				3		5
Thermal burns	12	37			4	8	8	29
Thoracic cage fractures and dislocations	8	15				1	8	14
Transfusion related complications	1	1			1	1		
Transplantation complications		2						2
Underdoses NEC	41	336			41	334		2
Vaccination related complications	430	787	3	6	9	88	421	699
	3,895	12,926	10	20	2766	10443	1129	2483

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adrenal cortex tests		2
Adrenal medulla tests		2
Auditory function diagnostic procedures	1	3
Autoimmunity analyses	6	16
Bacteria identification and serology (excl mycobacteria)	10	20
Blood counts NEC	7	18
Blood gas and acid base analyses	161	663
Blood grouping and cross-matching analyses	1	1
Bone marrow and immune tissue imaging procedures		2
Carbohydrate tolerance analyses (incl diabetes)	80	332
Cardiac auscultatory investigations	5	13
Cardiac function diagnostic procedures	3	9
Cardiac imaging procedures	1	1
Cell marker analyses	3	11
Central nervous system imaging procedures	2	5
Cerebrospinal fluid tests (excl microbiology)	3	6
Chemistry analyses NEC	1	19
Cholesterol analyses	11	24
Coagulation and bleeding analyses	102	220
Digestive enzymes	5	18
ECG investigations	28	77
Endocrine analyses and imaging NEC	1	6
Faecal analyses NEC	2	3
Foetal and neonatal diagnostic procedures	1	4
Gastrointestinal and abdominal imaging procedures	1	1
Gastrointestinal function diagnostic procedures	1	3
Gastrointestinal, pancreatic and APUD hormone analyses	1	1
Haematological analyses NEC	11	43
Haem metabolism analyses	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		1
		1	3		
		2	6	4	10
		3	8	7	12
		2	9	5	9
1	2	43	154	118	509
		1	1		
					2
		35	183	45	149
			2	5	11
		1	2	2	7
				1	1
		2	6	1	5
			1	2	4
				3	6
			6	1	13
		9	19	2	5
		29	72	73	148
		4	10	1	8
	1	8	18	20	59
			2	1	4
				2	3
				1	4
				1	1
		1	3		
		1	1		
		3	22	8	21
		1	2	1	3

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate and pulse investigations	440	1,761
Histopathology procedures NEC	1	2
Imaging procedures NEC	3	5
Immune response protein analyses NEC	2	5
Immunoglobulin analyses	4	16
Immunology analyses NEC	8	50
Investigations NEC	25	49
Lipoprotein and lipid tests NEC		2
Liver function analyses	85	226
Metabolism tests NEC	12	29
Microbiology and serology tests NEC	3	6
Mineral and electrolyte analyses	43	133
Musculoskeletal and soft tissue histopathology procedures		1
Musculoskeletal and soft tissue imaging procedures	2	2
Musculoskeletal and soft tissue tests NEC		2
Mycobacteria identification and serology		1
Neurologic diagnostic procedures	7	25
Ophthalmic function diagnostic procedures	6	18
Parasite identification and serology	1	1
Parathyroid analyses	1	1
Physical examination procedures and organ system status	495	1,739
Pituitary analyses anterior	8	25
Platelet analyses	76	141
Protein analyses NEC	86	271
Psychiatric investigations		1
Red blood cell analyses	46	148
Renal function analyses	25	76
Reproductive hormone analyses	1	4
Reproductive organ and breast imaging procedures	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	227	947	213	814
		1	2		
			1	3	4
			2	2	3
		1	11	3	5
		8	49		1
		11	25	14	24
			2		
	1	43	114	42	112
		5	11	7	18
		2	4	1	2
		24	81	19	52
					1
		2	2		
					2
			1		
		3	8	4	17
		2	8	4	10
		1	1		
		1	1		
1	3	316	1129	179	610
		5	17	3	8
		27	55	49	86
		40	131	46	140
					1
		27	89	19	59
		17	50	8	26
		1	3		1
		1	1		

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory and pulmonary function diagnostic procedures	9	21
Respiratory tract and thoracic histopathology procedures		2
Respiratory tract and thoracic imaging procedures	2	7
Skeletal and cardiac muscle analyses	45	119
Therapeutic drug monitoring analyses	6	11
Thyroid analyses	8	26
Tissue enzyme analyses NEC	12	30
Toxicology laboratory analyses	3	5
Triglyceride analyses	3	6
Urinalysis NEC	38	101
Urinary tract function analyses NEC	8	24
Vascular auscultatory investigations		3
Vascular tests NEC (incl blood pressure)	523	1,734
Virus identification and serology	173	842
Vitamin analyses	13	20
Water and electrolyte analyses NEC	1	3
White blood cell analyses	75	250
	2,750	9,473

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	7	17
					2
			2	2	5
		10	28	35	91
		2	2	4	9
		5	17	3	9
		7	15	5	15
		2	3	1	2
		2	3	1	3
		25	63	13	38
		6	13	2	11
			1		2
	4	227	792	296	942
		82	398	91	444
		6	12	7	8
			2	1	1
		49	152	26	98
2	12	1336	4783	1414	4690

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Appetite disorders	441	1,764
Calcium metabolism disorders	7	23
Cell metabolism disorders NEC	5	5
Chloride imbalance	1	1
Diabetes mellitus (incl subtypes)	52	122

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	5	240	944	201	820
		3	5	4	18
				5	5
				1	1
				52	122

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System Organ Class

**Metabolism and nutrition disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diabetic complications NEC	3	27
Diabetic complications neurological		1
Disorders of purine metabolism	15	57
Electrolyte imbalance NEC	3	12
Elevated cholesterol	1	3
Elevated triglycerides	1	1
Fat soluble vitamin deficiencies and disorders	4	12
Fluid intake decreased	3	17
Fluid intake increased	3	16
Food malabsorption and intolerance syndromes (excl sugar intolerance)	7	11
General nutritional disorders NEC	52	186
Hyperglycaemic conditions NEC	33	113
Hyperlipidaemias NEC		1
Hypervitaminoses NEC		1
Hypoglycaemic conditions NEC	16	107
Iron deficiencies	3	5
Iron excess	1	2
Lipid metabolism and deposit disorders NEC	2	6
Magnesium metabolism disorders		1
Metabolic acidoses (excl diabetic acidoses)	6	31
Metabolic alkaloses		1
Metabolic disorders NEC	2	4
Mixed acid-base disorders	4	8
Phosphorus metabolism disorders		1
Potassium imbalance	18	60
Protein metabolism disorders NEC	1	3
Sodium imbalance	17	47
Sugar intolerance (excl glucose intolerance)		1
Total fluid volume decreased	86	279
Total fluid volume increased	16	42
Vitamin deficiencies NEC	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	27
					1
		6	23	9	34
		1	3	2	9
		1	3		
				1	1
		2	6	2	6
		1	7	2	10
			7	3	9
		2	3	5	8
		25	95	27	91
		9	26	24	87
					1
					1
		5	31	11	76
		1	2	2	3
			1	1	1
		2	6		
					1
			3	6	28
			1		
		1	1	1	3
		1	2	3	6
			1		
		1	1	17	59
			2	1	1
		4	12	13	35
			1		
		31	117	55	162
		8	17	8	25
		1	1	1	2

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Water soluble vitamin deficiencies		2				1			1
	805	2,976	1	5	345	1322	460	1654	

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	98	300			37	128	61	172
Bone disorders NEC	15	41	1	1	6	23	9	18
Bone related signs and symptoms	241	981	3	4	135	573	106	408
Bursal disorders	17	41		1	5	14	12	27
Cartilage disorders	10	31			1	6	9	25
Connective tissue disorders NEC	27	61					27	61
Crystal arthropathic disorders	2	3					2	3
Epiphyseal disorders		1						1
Extremity deformities	5	14			2	8	3	6
Intervertebral disc disorders NEC	9	18			6	11	3	7
Joint related disorders NEC	28	102		1	7	37	21	65
Joint related signs and symptoms	2,678	10,546	9	56	1539	6223	1139	4323
Ligament disorders	3	6			1	3	2	3
Lupus erythematosus (incl subtypes)	14	32		1	1	1	13	31
Metabolic bone disorders	1	4			1	3		1
Muscle infections and inflammations	10	38		1	2	10	8	28
Muscle pains	3,101	13,073	16	76	1994	8017	1107	5056
Muscle related signs and symptoms NEC	395	1,451	2	3	216	804	179	647
Muscle tone abnormalities	21	114		1	11	59	10	55
Muscle weakness conditions	319	1,105			126	493	193	612
Musculoskeletal and connective tissue conditions NEC	473	1,702	1	3	263	888	210	814

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\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	8	14			1	4	7	10
Musculoskeletal and connective tissue infections and inflammations NEC	5	15			2	4	3	11
Musculoskeletal and connective tissue pain and discomfort	4,204	15,776	11	59	2622	9925	1582	5851
Myopathies	11	26			1	1	10	25
Osteoarthropathies	13	37			7	20	6	17
Psoriatic arthropathies	12	25					12	25
Rheumatoid arthropathies	63	139	2	3		1	63	138
Soft tissue disorders NEC	83	248	2	2	34	124	49	124
Spine and neck deformities	2	6				2	2	4
Spondyloarthropathies	15	48		1			15	48
Synovial disorders	7	30			3	9	4	21
Tendon disorders	34	91			15	43	19	48
Trunk deformities		1				1		
	11,924	46,120	47	213	7038	27435	4886	18685

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aural neoplasms malignant and unspecified		1		1		
B-cell lymphomas NEC	1	3			1	3
Bladder neoplasms malignant		1				1
Bone neoplasms unspecified malignancy	2	4	1	2	1	2
Breast and nipple neoplasms benign		1		1		
Breast and nipple neoplasms malignant	10	17			10	17
Cardiovascular neoplasms benign		2		1		1
Cardiovascular neoplasms malignant and unspecified		1				1

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system neoplasms malignant NEC	1	1			1	1
Colorectal neoplasms malignant	1	2			1	2
Diffuse large B-cell lymphomas	1	1			1	1
Endocrine neoplasms benign NEC		1				1
Follicle centre lymphomas, follicular grade I, II, III		1				1
Gastric neoplasms malignant		1				1
Gastrointestinal neoplasms malignant NEC	1	1			1	1
Islet cell neoplasms and APUDoma NEC		1				1
Kaposi's sarcomas		1				1
Leukaemias acute lymphocytic	1	2			1	2
Leukaemias acute myeloid	2	7			2	7
Leukaemias acute NEC		4				4
Leukaemias chronic lymphocytic	4	5			4	5
Leukaemias chronic myeloid		1				1
Leukaemias NEC	5	11		1	5	10
Lymphomas unspecified NEC	6	19			6	19
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)	1	1			1	1
Mediastinal neoplasms malignancy unspecified NEC		1				1
Metastases to specified sites		10				10
Metastases to unknown and unspecified sites	1	2			1	2
Myelodysplastic syndromes	1	3			1	3
Myeloproliferative disorders (excl leukaemias)		2				2
Neoplasms benign site unspecified NEC		3		3		
Neoplasms malignant site unspecified NEC	8	18			8	18
Neoplasms unspecified malignancy and site unspecified NEC	12	20	6	10	6	10
Nervous system neoplasms unspecified malignancy NEC	4	7			4	7
Neuromas	3	4			3	4
Non-Hodgkin's lymphomas NEC	1	4			1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oncologic complications and emergencies	1	2			1	2
Ovarian neoplasms malignant (excl germ cell)		1				1
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	2	3			2	3
Plasma cell myelomas		2				2
Plasma cell neoplasms NEC	3	4	1	1	2	3
Prostatic neoplasms malignant	3	6			3	6
Renal neoplasms malignant	1	2			1	2
Reproductive neoplasms male unspecified malignancy	1	1			1	1
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	3	8			3	8
Skin melanomas (excl ocular)	2	3			2	3
Skin neoplasms benign		3				3
Skin neoplasms malignant and unspecified (excl melanoma)	2	8	1	3	1	5
Soft tissue neoplasms benign NEC	3	8	2	3	1	5
Soft tissue sarcomas histology unspecified		1				1
Thyroid neoplasms malignant	1	1			1	1
Urinary tract neoplasms unspecified malignancy NEC	1	1			1	1
	89	218	11	26	78	192

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	8	37			4	14	4	23
Abnormal sleep-related events	1	8			1	6		2
Absence seizures	10	42					10	42
Acute polyneuropathies	53	113				1	53	112

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alzheimer's disease (incl subtypes)	2	12
Auditory nerve disorders		4
Autonomic nervous system disorders	12	35
Central nervous system aneurysms and dissections	8	15
Central nervous system haemorrhages and cerebrovascular accidents	740	1,484
Central nervous system inflammatory disorders NEC	1	2
Central nervous system vascular disorders NEC	16	32
Cerebrovascular venous and sinus thrombosis	39	51
Cervical spinal cord and nerve root disorders	7	27
Choreiform movements		5
Chronic polyneuropathies	3	12
Coma states	14	47
Coordination and balance disturbances	281	857
Cortical dysfunction NEC	103	235
Cranial nerve disorders NEC	2	18
Dementia (excl Alzheimer's type)	14	57
Demyelinating disorders NEC	11	26
Disturbances in consciousness NEC	1,699	5,910
Disturbances in sleep phase rhythm	5	8
Dyskinesias and movement disorders NEC	238	658
Dystonias	12	26
Encephalitis NEC	2	10
Encephalopathies NEC	8	27
Encephalopathies toxic and metabolic		1
Eye movement disorders	21	49
Facial cranial nerve disorders	493	1,570
Generalised tonic-clonic seizures	29	106
Glossopharyngeal nerve disorders	1	1
Headaches NEC	6,371	25,872

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	12
			1		3
		5	8	7	27
				8	15
2	2			740	1484
				1	2
			1	16	31
				39	51
		2	13	5	14
			1		4
			1	3	11
				14	47
3	4	102	335	179	522
1	1	18	62	85	173
			5	2	13
				14	57
				11	26
4	18	394	1478	1305	4432
		4	7	1	1
		92	319	146	339
		1	3	11	23
				2	10
				8	27
					1
		1	1	20	48
2	4	34	113	459	1457
				29	106
				1	1
14	121	4011	15882	2360	9990

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hydrocephalic conditions	3	3
Hypoglossal nerve disorders	6	10
Increased intracranial pressure disorders	13	31
Lumbar spinal cord and nerve root disorders	12	64
Memory loss (excl dementia)	128	350
Meningitis NEC	1	1
Mental impairment (excl dementia and memory loss)	162	598
Migraine headaches	442	1,637
Mixed cranial nerve disorders	1	1
Mononeuropathies	31	81
Motor neurone diseases		1
Multiple sclerosis acute and progressive	29	95
Muscle tone abnormal	27	91
Myelitis (incl infective)	9	34
Narcolepsy and hypersomnia	84	308
Nervous system cysts and polyps	2	3
Nervous system disorders NEC	39	133
Neurological signs and symptoms NEC	2,787	10,570
Neurologic visual problems NEC	29	90
Neuromuscular disorders NEC	20	116
Neuromuscular junction dysfunction	10	23
Olfactory nerve disorders	144	567
Optic nerve disorders NEC	11	32
Paraesthesias and dysaesthesias	1,875	7,287
Paralysis and paresis (excl cranial nerve)	229	627
Parkinson's disease and parkinsonism	20	51
Partial complex seizures	5	9
Peripheral neuropathies NEC	117	312
Seizures and seizure disorders NEC	365	1,093
Sensory abnormalities NEC	643	2,502
Sleep disturbances NEC	43	190

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
				6	10
				13	31
		9	32	3	32
		57	150	71	200
					1
2	4	50	221	112	377
5	8	155	713	287	924
				1	1
		14	40	17	41
					1
			4	29	91
		14	41	13	50
				9	34
		44	176	40	132
				2	3
		14	44	25	89
1	63	1569	5776	1218	4794
		4	19	25	71
		9	43	11	73
				10	23
2	2	88	386	56	181
				11	32
2	17	1042	4116	833	3171
	1	7	22	222	605
		4	13	16	38
		1	2	4	7
	1	9	40	108	272
		16	40	349	1053
5	8	392	1557	251	945
	1	24	109	19	81

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Speech and language abnormalities	202	587	2	3	63	213	139	374
Spinal cord and nerve root disorders NEC	11	40			1	12	10	28
Structural brain disorders NEC	8	29			1	4	7	25
Transient cerebrovascular events	159	266	1	1	1	1	158	265
Tremor (excl congenital)	412	1,718		6	232	809	180	909
Trigeminal disorders	25	91			12	35	13	56
Vagus nerve disorders	1	6					1	6
	18,308	67,004	46	265	8501	32869	9807	34135

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion related conditions and complications	2	2			2	2
Abortions not specified as induced or spontaneous	9	16			9	16
Abortions spontaneous	59	134			59	134
Amniotic fluid and cavity disorders of pregnancy NEC		1				1
Foetal complications NEC	2	2			2	2
Foetal growth complications	1	4			1	4
Gestational age and weight conditions	6	11			6	11
Haemorrhagic complications of pregnancy	1	1			1	1
Labour onset and length abnormalities	2	7		1	2	6
Maternal complications of labour NEC		2		1		1
Maternal complications of pregnancy NEC	1	14		1	1	13
Multiple pregnancies		1		1		
Neonatal disorders due to birth trauma (excl intracranial haemorrhages)	1	1			1	1
Normal pregnancy, labour and delivery	1	6		4	1	2
Postpartum complications NEC		1		1		

\* I=Interval, C=Cumulative  
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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pregnancy complicated by maternal disorders	1	2			1	2
Stillbirth and foetal death	7	12			7	12
Unintended pregnancies	2	2			2	2
	95	219		9	95	210

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products	4	7	4	7		
Device issues NEC	2	2	1	1	1	1
Device malfunction events NEC	6	14	1	3	5	11
Device physical property and chemical issues	5	29	5	26		3
Product contamination and sterility issues	1	4	1	4		
Product distribution and storage issues	63	468	63	466		2
Product label issues		1		1		
Product packaging issues		25		25		
Product physical issues	6	101	6	101		
Product quality issues NEC	19	65	18	62	1	3
Product supply and availability issues	12	28	12	28		
	118	744	111	724	7	20

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour NEC	20	50			5	15	15	35
Abnormal food elimination	1	1					1	1

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System Organ Class

**Psychiatric disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Adjustment disorders	2	2
Affect alterations NEC	8	17
Amnesic symptoms	1	2
Anxiety disorders NEC	2	7
Anxiety symptoms	332	1,276
Attention deficit and disruptive behaviour disorders	3	3
Behaviour and socialisation disturbances	25	85
Bipolar disorders	2	5
Cognitive and attention disorders and disturbances NEC	23	87
Communications disorders	9	33
Confusion and disorientation	350	1,152
Decreased physical activity levels		4
Deliria	62	171
Delusional disorders		1
Delusional symptoms	9	24
Dementia NEC		1
Depressive disorders	45	140
Dissociative states	8	35
Disturbances in initiating and maintaining sleep	414	1,641
Dyssomnias	2	2
Eating disorders NEC	30	90
Emotional and mood disturbances NEC	124	384
Factitious disorders	1	1
Fear symptoms and phobic disorders (incl social phobia)	24	88
Fluctuating mood symptoms	2	15
Hallucinations (excl sleep-related)	88	292
Impulse control disorders	1	2
Increased physical activity levels	57	212
Learning disorders		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		4	7	4	10
				1	2
		2	5		2
	1	200	757	132	519
		1	1	2	2
		10	32	15	53
				2	5
		8	23	15	64
		5	17	4	16
4	9	115	404	235	748
			2		2
				62	171
					1
		1	10	8	14
					1
		15	46	30	94
		4	21	4	14
		230	993	184	648
		2	2		
		16	53	14	37
		79	244	45	140
				1	1
		12	58	12	30
		1	5	1	10
				88	292
		1	2		
		24	114	33	98
					4

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mental disorders due to a general medical condition NEC		3
Mental disorders NEC	18	50
Mood alterations with depressive symptoms	60	205
Mood alterations with manic symptoms	2	10
Mood disorders NEC	31	97
Narcolepsy and associated conditions	1	6
Obsessive-compulsive disorders and symptoms		4
Orgasmic disorders and disturbances		1
Panic attacks and disorders	50	148
Parasomnias	61	226
Perception disturbances NEC	28	71
Personality disorders NEC		1
Pervasive developmental disorders NEC	1	1
Psychiatric elimination disorders	3	8
Psychiatric symptoms NEC	5	14
Psychotic disorder NEC	11	27
Schizophrenia NEC	2	3
Sexual desire disorders	3	10
Sleep disorders NEC	141	452
Somatic symptom disorders	9	20
Speech and language usage disturbances	5	17
Speech articulation and rhythm disturbances	12	31
Stereotypies and automatisms	4	16
Stress disorders	2	7
Substance related and addictive disorders	1	3
Suicidal and self-injurious behaviour	19	45
Thinking disturbances	32	113
Tic disorders	2	10
	2,148	7,426

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		11	32	7	18
	1	27	85	33	120
		1	2	1	8
		19	48	12	49
		1	2		4
					4
					1
		32	81	18	67
		39	144	22	82
		5	19	23	52
			1		
				1	1
			2	3	6
		3	7	2	7
		2	3	9	24
				2	3
		2	5	1	5
1	2	81	267	60	185
		6	10	3	10
			4	5	13
		2	9	10	22
		1	5	3	11
			2	2	5
				1	3
		1	1	18	44
		18	65	14	48
			4	2	6
5	13	986	3610	1162	3816

System Organ Class

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System Organ Class

**Renal and urinary disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Bladder and urethral symptoms	138	438
Bladder disorders NEC	6	16
Bladder infections and inflammations	4	10
Genital and urinary tract disorders NEC	1	5
Genitourinary tract infections and inflammations NEC	1	5
Glomerulonephritis and nephrotic syndrome	10	32
Myoneurogenic bladder disorders	2	13
Nephritis NEC		3
Nephropathies and tubular disorders NEC	5	7
Renal disorders NEC	11	34
Renal failure and impairment	108	307
Renal failure complications		3
Renal lithiasis	16	30
Renal neoplasms	4	8
Renal obstructive disorders		2
Renal structural abnormalities and trauma	1	3
Renal vascular and ischaemic conditions	4	9
Structural and obstructive urethral disorders (excl congenital)		1
Ureteric disorders NEC		2
Urethral disorders NEC		2
Urinary abnormalities	54	156
Urinary tract lithiasis (excl renal)		1
Urinary tract signs and symptoms NEC	55	209
	420	1,296

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		51	171	87	267
		2	6	4	10
			1	4	9
			1	1	4
		1	1		4
				10	32
			4	2	9
			1	5	6
		3	12	8	22
	1	1	5	107	302
					3
				16	30
		1	3	3	5
					2
				1	3
				4	9
					1
					2
			1		1
		22	76	32	80
			1		
		20	92	35	117
		1	101	319	921

System Organ Class

**Reproductive system and breast disorders**

*Interval Total #*      *Cumulative Total #*

Non Interventional Study		Spontaneous	
Serious		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Reproductive system and breast disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Benign and malignant breast neoplasms	1	4
Breast disorders NEC	23	47
Breast infections and inflammations	4	6
Breast signs and symptoms	153	400
Cervix disorders NEC	2	4
Erection and ejaculation conditions and disorders	13	39
Lactation disorders	6	18
Menopausal effects NEC	2	6
Menopausal effects on the genitourinary tract	12	18
Menstruation and uterine bleeding NEC	89	238
Menstruation with decreased bleeding	34	91
Menstruation with increased bleeding	69	142
Ovarian and fallopian tube cysts and neoplasms	2	3
Ovarian and fallopian tube disorders NEC	2	3
Pelvis and broad ligament disorders NEC	1	16
Penile and scrotal infections and inflammations		1
Penile disorders NEC (excl erection and ejaculation)	1	6
Prostate and seminal vesicles infections and inflammations	5	8
Prostatic neoplasms and hypertrophy	2	2
Prostatic signs, symptoms and disorders NEC	4	6
Reproductive tract disorders NEC (excl neoplasms)	3	12
Reproductive tract infections and inflammations NEC		2
Reproductive tract signs and symptoms NEC	20	63
Scrotal disorders NEC	4	15
Sexual function and fertility disorders NEC	2	4
Spermatogenesis and semen disorders	2	2
Testicular and epididymal disorders NEC	12	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		2
		8	22	15	25
			2	4	4
	1	59	194	94	206
			1	2	3
				13	39
		2	8	4	10
			3	2	3
				12	18
2	2	48	151	41	87
		12	36	22	55
1	1	38	73	31	69
		1	1	1	2
		1	1	1	2
		1	7		9
			1		
			1	1	5
		2	2	3	6
		1	1	1	1
		1	3	3	3
		1	5	2	7
			2		
		10	32	10	31
		3	7	1	8
		1	2	1	2
				2	2
		9	16	3	12

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Testicular and epididymal infections and inflammations		1				1			
Uterine disorders NEC	9	19			1	3	8	16	
Uterine infections and inflammations (excl cervix)		2				1		1	
Uterine tone disorders		2				1		1	
Vaginal and vulval infections and inflammations		1						1	
Vulvovaginal cysts and neoplasms	1	2					1	2	
Vulvovaginal disorders NEC	45	121			15	45	30	76	
Vulvovaginal signs and symptoms	10	38			5	24	5	14	
	533	1,370	3	4	220	648	313	722	

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	1,794	6,867	5	16	622	2268	1172	4599
Bronchial conditions NEC	6	20			2	6	4	14
Bronchospasm and obstruction	323	1,186	3	5	117	377	206	809
Conditions associated with abnormal gas exchange	45	158			1	2	44	156
Coughing and associated symptoms	907	3,125	2	6	520	1763	387	1362
Diaphragmatic disorders	2	7			1	3	1	4
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	5	26			1	3	4	23
Laryngeal spasm, oedema and obstruction	46	266			4	16	42	250
Lower respiratory tract inflammatory and immunologic conditions	34	125				6	34	119
Lower respiratory tract signs and symptoms	55	219			19	81	36	138
Mediastinal disorders		1						1
Nasal congestion and inflammations	138	547		1	105	421	33	126

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Nasal disorders NEC	206	541		1	93	271	113	270
Neonatal hypoxic conditions		1						1
Newborn respiratory disorders NEC	1	1					1	1
Paranasal sinus disorders (excl infections and neoplasms)	33	136			23	102	10	34
Parenchymal lung disorders NEC	36	91			7	14	29	77
Pharyngeal disorders (excl infections and neoplasms)	202	851		2	101	355	101	496
Pleural infections and inflammations	3	25			1	2	2	23
Pneumothorax and pleural effusions NEC	43	89			4	10	39	79
Pulmonary hypertensions	9	14					9	14
Pulmonary oedemas	70	197					70	197
Pulmonary thrombotic and embolic conditions	488	772	2	3			488	772
Respiratory failures (excl neonatal)	61	212					61	212
Respiratory signs and symptoms NEC	36	146		1	11	59	25	87
Respiratory tract disorders NEC	126	383		1	44	124	82	259
Thoracic musculoskeletal disorders		1						1
Tracheal disorders (excl infections and neoplasms)	3	10				3	3	7
Upper respiratory tract neoplasms	1	1			1	1		
Upper respiratory tract signs and symptoms	1,636	6,259	6	20	1054	3815	582	2444
Vascular pulmonary disorders NEC	2	4					2	4
	6,311	22,281	18	56	2731	9702	3580	12579

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acnes	23	53			17	41	6	12
Alopecias	39	90			15	44	24	46
Angioedemas	123	504			6	15	117	489

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Apocrine and eccrine gland disorders	779	3,145
Bullous conditions	121	386
Connective tissue disorders	4	12
Dermal and epidermal conditions NEC	639	2,025
Dermatitis and eczema	137	445
Dermatitis ascribed to specific agent	24	54
Erythemas	778	2,823
Exfoliative conditions	35	99
Granulomatous and deep cutaneous inflammatory conditions	3	5
Hyperkeratoses	2	4
Hyperpigmentation disorders	3	5
Hypertrichoses		2
Hypopigmentation disorders	2	6
Lipodystrophies		1
Nail and nail bed conditions (excl infections and infestations)	8	24
Panniculitides	15	26
Papulosquamous conditions	12	33
Photosensitivity and photodermatitis conditions	14	57
Pigmentation changes NEC	3	9
Pilar disorders NEC	12	38
Pruritus NEC	1,075	3,851
Psoriatic conditions	25	60
Purpura and related conditions	99	231
Pustular conditions	2	3
Rashes, eruptions and exanthems NEC	1,668	5,855
Rosaceas	1	9
Scaly conditions	1	7
Sebaceous gland disorders	1	2
Skin and subcutaneous conditions NEC	11	37
Skin and subcutaneous tissue ulcerations	11	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	6	419	1714	360	1431
1	1	35	127	86	259
			1	4	11
	3	401	1291	238	734
	1	67	220	70	225
		7	19	17	35
1	5	524	1796	254	1027
		19	44	16	55
		2	2	1	3
		1	1	1	3
		1	2	2	3
			2		
		1	3	1	3
					1
		5	15	3	9
		4	7	11	19
		5	15	7	18
		4	26	10	31
		1	6	2	3
		7	17	5	21
1	5	682	2380	393	1471
		5	24	20	36
	2	47	103	52	128
				2	3
1	11	1002	3403	666	2452
			5	1	4
		1	5		2
			1	1	1
		9	21	2	16
		5	12	6	21

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin cysts and polyps	1	5			1	3		2
Skin dystrophies	4	5			3	3	1	2
Skin haemorrhages	28	42			8	12	20	30
Skin hyperplasias and hypertrophies	2	5				3	2	2
Skin hypoplasias and atrophies	2	3			1	2	1	1
Skin injuries and mechanical dermatoses	4	8			1	3	3	5
Skin preneoplastic conditions NEC		1				1		
Skin vascular conditions NEC		3				3		
Skin vasculitides	21	42			4	10	17	32
Skin vasomotor conditions	12	55		1	8	21	4	34
Telangiectasia and related conditions	2	2			1	1	1	1
Urticarias	619	2,181		3	403	1302	216	879
	6,365	22,286	4	38	3722	12726	2643	9560

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Age related issues	2	2	1	1	1	1
Dietary and nutritional issues	1	1	1	1		
Disability issues	186	584	81	273	105	311
Educational issues		1				1
Employment issues	1	1	1	1		
Non-occupational and unspecified environmental problems	2	3		1	2	2
Pregnancy related circumstances		1				1
Social issues NEC	9	18	6	13	3	5
Tobacco use	1	1	1	1		
	202	612	91	291	111	321

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	7	31	7	31
	7	31	7	31

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaesthesia and allied procedures		1		1		
Arterial therapeutic procedures (excl aortic)	1	1			1	1
Breast therapeutic procedures NEC	3	3			3	3
Bronchial and pulmonary therapeutic procedures		1				1
Cardiac device therapeutic procedures		1		1		
Contraceptive methods female	1	1	1	1		
Cranial nerve therapeutic procedures		1				1
Dental and gingival therapeutic procedures	3	3	2	2	1	1
Dietary and nutritional therapies	1	3			1	3
Gastrointestinal therapeutic procedures NEC	1	2			1	2
Haematological therapeutic procedures NEC	1	1			1	1
Hernia repairs	1	1	1	1		
Immunisations	5	12	1	7	4	5
Induced abortions	1	3	1	1		2
Joint therapeutic procedures	1	2	1	2		
Limb therapeutic procedures	2	9		6	2	3
Nervous system therapeutic procedures NEC	2	3			2	3
Prophylactic procedures NEC	1	1			1	1
Respiratory tract therapeutic procedures NEC		1				1
Skin and subcutaneous tissue therapeutic procedures NEC	1	2	1	2		
Skin lesion excisions		1		1		
Small intestine therapeutic procedures	1	1			1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spine and spinal cord therapeutic procedures		1				1
Therapeutic procedures NEC	7	14	4	9	3	5
Thyroid therapeutic procedures	1	1	1	1		
Uterine therapeutic procedures	1	1			1	1
Vascular therapeutic procedures NEC	1	1			1	1
	36	72	13	35	23	37

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	105	431		2			105	431
Aneurysms and dissections non-site specific	3	9					3	9
Aortic aneurysms and dissections	8	20					8	20
Aortic embolism and thrombosis	3	3					3	3
Aortic infections and inflammations	1	2					1	2
Aortic necrosis and vascular insufficiency	4	12			1	3	3	9
Arterial infections and inflammations	11	21					11	21
Blood pressure disorders NEC	21	85			12	45	9	40
Bruising, ecchymosis and purpura		1				1		
Circulatory collapse and shock	102	331		1	5	6	97	325
Haemorrhages NEC	169	338	1	2	22	57	147	281
Lymphangiopathies	2	2					2	2
Lymphoedemas	23	85		1	4	41	19	44
Non-site specific embolism and thrombosis	348	528	1	2	3	4	345	524
Non-site specific necrosis and vascular insufficiency NEC	36	69			7	11	29	58
Non-site specific vascular disorders NEC	42	105			21	58	21	47
Peripheral embolism and thrombosis	429	602	2	4	48	56	381	546
Peripheral vascular disorders NEC	418	1,800		2	257	1035	161	765

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	168	510		2	88	269	80	241
Phlebitis NEC	38	56			25	29	13	27
Site specific necrosis and vascular insufficiency NEC	1	2					1	2
Site specific vascular disorders NEC	87	424		1	40	181	47	243
Varicose veins NEC	9	18			3	10	6	8
Vascular hypertensive disorders NEC	569	1,917	1	5	152	587	417	1330
Vascular hypotensive disorders	218	938	2	4	77	292	141	646
Vascular malformations and acquired anomalies	1	1					1	1
Vasculitides NEC	39	74			18	26	21	48
Vena caval embolism and thrombosis	2	5					2	5
	2,857	8,389	7	26	783	2711	2074	5678

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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### APPENDIX 2.6.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by High Level Term per Country

Cumulative Reporting Period: Through 29-APR-2021

Interval Reporting Period: 01-APR-2021 Through 29-APR-2021

Total Number of Cases: 30,752 (Interval) / 109,692 (Cumulative)

Total Number of Adverse Events (PT): 112,695 (Interval) / 414,597 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

#### AFGHANISTAN

System Organ Class

##### General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC		2		2
General signs and symptoms NEC		1		1
		3		3

System Organ Class

##### Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle related signs and symptoms NEC		1		1
		1		1

System Organ Class

##### Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders		1			1	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesias and dysaesthesias		1		1		
		2		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythemas		1		1
Pruritus NEC		1		1
Rashes, eruptions and exanthems NEC		1		1
		3		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ALBANIA**

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections		2		2
		2		2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC	1	1	1	1
Off label uses	1	1	1	1
	2	2	2	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AMERICAN SAMOA**

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC		1		1
Pain and discomfort NEC		1		1
		2		2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ANDORRA**

*System Organ Class*

**Injury, poisoning and procedural complications**

*High Level Term*

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**ANGOLA**

*System Organ Class*

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms		1		1
Tongue signs and symptoms		1		1
		2		2

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Febrile disorders		1		1
		1		1

*System Organ Class*

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Upper respiratory tract infections		1		1
		1		1

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total #	Cumulative Total #	Spontaneous	
	Spontaneous AE	Spontaneous AE	I	C
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ARGENTINA**

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Intentional product misuses	1	1	1	1
Medication errors, product use errors and issues NEC		1		1
	1	2	1	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Virus identification and serology		1		1
		1		1

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diabetes mellitus (incl subtypes)	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue pain and discomfort		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRALIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematological disorders	1	1	1	1		
Lymphatic system disorders NEC	8	8	7	7	1	1
	9	9	8	8	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	4	6	4	6		
Ischaemic coronary artery disorders	1	2			1	2
Rate and rhythm disorders NEC	13	17	8	8	5	9
Ventricular arrhythmias and cardiac arrest	3	5			3	5
	21	30	12	14	9	16

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	2	2	2		
Hearing losses	5	5			5	5
Inner ear signs and symptoms	3	4	3	3		1
	10	11	5	5	5	6

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal cortical hypofunctions	1	1	1	1
Thyroid hyperfunction disorders	2	2	2	2
	3	3	3	3

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	2	2			2	2
Iris and uveal tract infections, irritations and inflammations	1	1			1	1
Ocular disorders NEC	3	4	3	4		
Ocular infections, inflammations and associated manifestations	4	6	4	6		
Ocular sensation disorders	2	2	2	2		
Pupil disorders	1	6			1	6
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Visual disorders NEC	1	1	1	1		
Visual impairment and blindness (excl colour blindness)	3	3	3	3		
	18	26	13	16	5	10

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Diarrhoea (excl infective)	10	10	10	10		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	9	9	8	8	1	1
Gastrointestinal signs and symptoms NEC	3	5	3	3		2
Intestinal haemorrhages	4	4	1	1	3	3
Nausea and vomiting symptoms	45	59	39	47	6	12
Non-site specific gastrointestinal haemorrhages	1	2			1	2
Oral soft tissue signs and symptoms	9	10	8	8	1	2
Oral soft tissue swelling and oedema	3	3	3	3		
Tongue signs and symptoms	3	4	2	3	1	1
	88	107	74	83	14	24

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	40	48	35	41	5	7
Death and sudden death	3	6			3	6
Febrile disorders	36	41	33	36	3	5
Feelings and sensations NEC	26	33	26	30		3
Gait disturbances	2	3	2	3		
General signs and symptoms NEC	10	19	6	8	4	11
Inflamations	2	2	2	2		
Injection site reactions	1	1	1	1		
Oedema NEC	2	3	2	2		1
Pain and discomfort NEC	18	19	17	18	1	1
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	40	51	39	47	1	4
	181	227	163	188	18	39

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatocellular damage and hepatitis NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	1	1	1		
Anaphylactic and anaphylactoid responses	33	54			33	54
	34	55	1	1	33	54

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	1			1	1
Bacterial infections NEC	3	3	1	1	2	2
Coronavirus infections	1	2		1	1	1
Herpes viral infections	3	3	3	3		
Infections NEC	1	1			1	1
Lower respiratory tract and lung infections	6	11			6	11
Rhinoviral infections	1	1	1	1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	7			1	7
Upper respiratory tract infections	1	1	1	1		
Viral infections NEC		1				1
	18	31	6	7	12	24

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Medication errors, product use errors and issues NEC	4	5	4	5		
Nerve injuries NEC	1	1	1	1		
Non-site specific injuries NEC	2	5	1	2	1	3
Off label uses	2	2	2	2		
Pelvic fractures and dislocations		1				1
Product administration errors and issues	1	3	1	3		
Product preparation errors and issues		2		2		
Skin injuries NEC	6	7	6	6		1
Vaccination related complications	2	2			2	2
	19	29	16	22	3	7

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	6	1	2	1	4
Heart rate and pulse investigations	3	5	3	3		2
Liver function analyses	1	1	1	1		
Neurologic diagnostic procedures		1				1
Physical examination procedures and organ system status	1	5		2	1	3
Skeletal and cardiac muscle analyses	1	1			1	1
Vascular tests NEC (incl blood pressure)	5	8	5	6		2
White blood cell analyses	2	2	2	2		
	15	29	12	16	3	13

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	7	1	4	1	3
Diabetes mellitus (incl subtypes)	1	1			1	1
Diabetic complications NEC		1				1
Diabetic complications neurological		1				1
Hyperglycaemic conditions NEC		1				1
	3	11	1	4	2	7

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	1	1	1		
Joint related signs and symptoms	16	18	16	18		
Muscle pains	26	30	26	29		1
Muscle related signs and symptoms NEC	4	5	4	5		
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	1	2	1	2		
Musculoskeletal and connective tissue pain and discomfort	10	11	10	11		
	59	68	59	67		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes	1	1			1	1
Central nervous system haemorrhages and cerebrovascular accidents	5	10			5	10

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 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination and balance disturbances	1	2	1	1		1
Cortical dysfunction NEC		1				1
Demyelinating disorders NEC	1	1			1	1
Disturbances in consciousness NEC	66	89	23	30	43	59
Dyskinesias and movement disorders NEC		1		1		
Facial cranial nerve disorders	10	14		1	10	13
Headaches NEC	55	61	54	59	1	2
Mental impairment (excl dementia and memory loss)		1				1
Migraine headaches	3	4	3	4		
Multiple sclerosis acute and progressive	3	3			3	3
Neurological signs and symptoms NEC	39	52	29	33	10	19
Paraesthesias and dysaesthesias	20	22	20	22		
Paralysis and paresis (excl cranial nerve)	2	3			2	3
Peripheral neuropathies NEC	1	1			1	1
Seizures and seizure disorders NEC	8	10			8	10
Sensory abnormalities NEC	3	4	3	4		
Speech and language abnormalities	2	4	1	1	1	3
Transient cerebrovascular events	2	2			2	2
Tremor (excl congenital)	5	9	5	9		
Trigeminal disorders	1	1	1	1		
	228	296	140	166	88	130

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	8	1	2	1	6
Confusion and disorientation	4	6	4	5		1
Deliria	1	2			1	2

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in initiating and maintaining sleep	2	2	2	2		
Hallucinations (excl sleep-related)	2	3			2	3
Mood alterations with depressive symptoms		1		1		
Panic attacks and disorders	1	1	1	1		
Somatic symptom disorders		1				1
	12	24	8	11	4	13

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	2	1	1		1
Renal failure and impairment	1	2			1	2
	2	4	1	1	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	26	32	14	16	12	16
Bronchospasm and obstruction	4	7	4	6		1
Conditions associated with abnormal gas exchange	1	3			1	3
Coughing and associated symptoms	23	30	22	28	1	2
Lower respiratory tract inflammatory and immunologic conditions	2	3			2	3
Lower respiratory tract signs and symptoms	1	2	1	1		1
Nasal congestion and inflammations	3	3	3	3		

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal disorders (excl infections and neoplasms)	1	2			1	2
Pulmonary oedemas	2	3			2	3
Pulmonary thrombotic and embolic conditions	5	5			5	5
Respiratory failures (excl neonatal)	2	3			2	3
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	31	39	29	37	2	2
	101	133	73	91	28	42

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	3	3			3	3
Apocrine and eccrine gland disorders	12	18	11	14	1	4
Dermal and epidermal conditions NEC	2	2	2	2		
Erythemas	4	7	4	7		
Pruritus NEC	10	13	10	13		
Rashes, eruptions and exanthems NEC	24	28	22	25	2	3
Urticarias	9	11	9	11		
	64	82	58	72	6	10

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock	1	2			1	2
Non-site specific embolism and thrombosis	1	1	1	1		

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System Organ Class

**Vascular disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism and thrombosis	4	5	2	2	2	3
Peripheral vascular disorders NEC	12	16	11	15	1	1
Peripheral vasoconstriction, necrosis and vascular insufficiency	2	2	2	2		
Site specific vascular disorders NEC	1	2	1	1		1
Vascular hypertensive disorders NEC	13	13	12	12	1	1
Vascular hypotensive disorders	8	12	8	9		3
	42	53	37	42	5	11

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Country Where Event Occurred

**AUSTRIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic immune		1				1
Anaemias NEC	1	1			1	1
Bleeding tendencies	1	1			1	1
Coagulopathies	1	2			1	2
Haematological disorders		1				1
Leukocytoses NEC		3				3
Leukopenias NEC	1	5		1	1	4
Lymphatic system disorders NEC	4	39	1	20	3	19
Marrow depression and hypoplastic anaemias	1	1			1	1
Neutropenias		2				2
Spleen disorders	1	1			1	1
Thrombocytopenias	2	5			2	5
	12	62	1	21	11	41

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	2			1	2
Cardiac disorders NEC	2	11	1	9	1	2
Cardiac signs and symptoms NEC	6	21	3	7	3	14
Cardiomyopathies		1				1
Coronary artery disorders NEC		1				1
Heart failures NEC	3	10			3	10
Ischaemic coronary artery disorders	6	12			6	12
Left ventricular failures	1	3			1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial disorders NEC		2		1		1
Noninfectious myocarditis		3				3
Noninfectious pericarditis		1				1
Pericardial disorders NEC	2	2			2	2
Rate and rhythm disorders NEC	8	31		3	8	28
Supraventricular arrhythmias	4	11			4	11
Ventricular arrhythmias and cardiac arrest	3	8			3	8
	36	119	4	20	32	99

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Gene mutations and other alterations NEC		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		4		4		
External ear disorders NEC	1	1			1	1
Hearing losses	3	3			3	3
Inner ear signs and symptoms	8	28	3	14	5	14
	12	36	3	18	9	18

System Organ Class

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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous haemorrhages and vascular disorders	2	2			2	2
Conjunctival and corneal bleeding and vascular disorders	2	2			2	2
Eyelid movement disorders		2				2
Lacrimation disorders		1		1		
Lid, lash and lacrimal infections, irritations and inflammations		2				2
Ocular bleeding and vascular disorders NEC		1				1
Ocular disorders NEC	1	5		3	1	2
Ocular infections, inflammations and associated manifestations		5		4		1
Ocular nerve and muscle disorders		2		1		1
Ocular sensation disorders	1	4	1	4		
Pupil disorders		2				2
Refractive and accommodative disorders	1	1	1	1		
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Retinal structural change, deposit and degeneration	1	1			1	1
Retinopathies NEC	1	1			1	1
Structural change, deposit and degeneration of eye NEC	1	1			1	1
Visual disorders NEC	1	8	1	5		3

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment and blindness (excl colour blindness)	5	9		1	5	8
	17	50	3	20	14	30

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis (excl infective)		1				1
Dental pain and sensation disorders	1	1			1	1
Diarrhoea (excl infective)	6	29	5	19	1	10
Flatulence, bloating and distension	2	2	2	2		
Gastrointestinal and abdominal pains (excl oral and throat)	3	11	1	3	2	8
Gastrointestinal disorders NEC		2		2		
Gastrointestinal dyskinetic disorders		1		1		
Gastrointestinal signs and symptoms NEC	3	10		3	3	7
Gastrointestinal spastic and hypermotility disorders		2		2		
Gastrointestinal vascular occlusion and infarction		1				1
Nausea and vomiting symptoms	32	111	27	71	5	40
Non-site specific gastrointestinal haemorrhages		2				2
Oral dryness and saliva altered	1	10	1	7		3
Oral soft tissue disorders NEC	1	2	1	1		1
Oral soft tissue signs and symptoms	1	21	1	5		16
Oral soft tissue swelling and oedema	1	9			1	9
Stomatitis and ulceration	2	2	2	2		
Tongue disorders		1		1		
Tongue signs and symptoms		15		3		12
	53	233	40	122	13	111

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	2	1	2		
Application and instillation site reactions		1		1		
Asthenic conditions	32	176	24	131	8	45
Complications associated with device NEC		1		1		
Death and sudden death	4	19			4	19
Febrile disorders	30	143	20	87	10	56
Feelings and sensations NEC	22	125	20	73	2	52
Gait disturbances	2	8	1	5	1	3
General signs and symptoms NEC	15	67	7	26	8	41
Inflamations		2				2
Injection site reactions	1	5		4	1	1
Mucosal findings abnormal		1		1		
Oedema NEC	1	9		2	1	7
Pain and discomfort NEC	13	45	4	20	9	25
Therapeutic and nontherapeutic responses	3	32		1	3	31
Vaccination site reactions	29	187	18	134	11	53
	153	823	95	488	58	335

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	1	1			1	1
Cholestasis and jaundice		1				1
Hepatic vascular disorders		1				1
Hepatobiliary signs and symptoms	1	2		1	1	1
Hepatocellular damage and hepatitis NEC		1		1		
	2	6		2	2	4

System Organ Class

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	4	17		1	4	16
Anaphylactic and anaphylactoid responses	2	16			2	16
Autoimmune disorders NEC		1				1
	6	34		1	6	33

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1		1		
Bacterial infections NEC		5				5
Central nervous system and spinal infections		1				1
Coronavirus infections	19	63	1	5	18	58
Dental and oral soft tissue infections	1	2	1	2		
Ear infections		1				1
Escherichia infections		1				1
Eye and eyelid infections		1				1
Helicobacter infections		1				1
Herpes viral infections	4	12		5	4	7
Infections NEC	1	1			1	1
Influenza viral infections		1		1		
Lower respiratory tract and lung infections	4	11			4	11
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	3			1	3
Skin structures and soft tissue infections		5		3		2
Streptococcal infections		1				1
Upper respiratory tract infections	1	3	1	3		
Urinary tract infections	1	1			1	1
Viral infections NEC	1	4		1	1	3
	33	118	3	21	30	97

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	3	3			3	3
Chest and respiratory tract injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Eye injuries NEC	2	2			2	2
Medication errors, product use errors and issues NEC	1	9	1	9		
Non-site specific injuries NEC	8	11		1	8	10
Off label uses	1	9	1	9		
Overdoses NEC		1				1
Poisoning and toxicity		1				1
Product administration errors and issues	2	16	2	16		
Product preparation errors and issues		1		1		
Site specific injuries NEC		1				1
Skin injuries NEC	2	2			2	2
Skull fractures, facial bone fractures and dislocations	1	1			1	1
Thoracic cage fractures and dislocations	1	1			1	1
Underdoses NEC		1		1		
Vaccination related complications	15	18			15	18
	37	79	5	38	32	41

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	1	1			1	1
Blood gas and acid base analyses	3	9		2	3	7
Carbohydrate tolerance analyses (incl diabetes)	1	2			1	2
Coagulation and bleeding analyses	1	3		1	1	2

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
ECG investigations	2	4		1	2	3
Faecal analyses NEC	1	1			1	1
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	1	6	1	2		4
Immune response protein analyses NEC		1				1
Immunology analyses NEC		3		3		
Liver function analyses	1	4		3	1	1
Metabolism tests NEC	1	2	1	1		1
Mineral and electrolyte analyses		3		3		
Neurologic diagnostic procedures	2	3			2	3
Ophthalmic function diagnostic procedures		1				1
Physical examination procedures and organ system status	4	20	3	16	1	4
Platelet analyses		1		1		
Protein analyses NEC		6		4		2
Renal function analyses		1		1		
Respiratory and pulmonary function diagnostic procedures	1	1	1	1		
Skeletal and cardiac muscle analyses	2	9		1	2	8
Therapeutic drug monitoring analyses		1				1
Tissue enzyme analyses NEC		1		1		
Toxicology laboratory analyses		1				1
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	3	19	1	6	2	13
Virus identification and serology	3	9		1	3	8
White blood cell analyses		3		1		2
	27	117	7	50	20	67

System Organ Class

**Metabolism and nutrition disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	7	1	5	1	2
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1				1
General nutritional disorders NEC	1	3			1	3
Hyperglycaemic conditions NEC		2				2
Hypoglycaemic conditions NEC		1				1
Mixed acid-base disorders	1	1	1	1		
Potassium imbalance	1	1			1	1
Sodium imbalance		1				1
Total fluid volume decreased	1	1			1	1
	6	18	2	6	4	12

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1		1		
Bone related signs and symptoms	1	5		3	1	2
Bursal disorders		2		1		1
Intervertebral disc disorders NEC	1	1			1	1
Joint related signs and symptoms	14	64	6	34	8	30
Muscle pains	6	54	6	35		19
Muscle related signs and symptoms NEC	3	11	1	6	2	5
Muscle tone abnormalities		2		1		1
Muscle weakness conditions	3	10		2	3	8
Musculoskeletal and connective tissue conditions NEC	3	3	1	1	2	2
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	22	91	11	59	11	32

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myopathies	1	1			1	1
Rheumatoid arthropathies		1				1
Soft tissue disorders NEC		1		1		
Tendon disorders		1		1		
	55	249	25	145	30	104

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasms malignant site unspecified NEC		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Absence seizures		1				1
Central nervous system haemorrhages and cerebrovascular accidents	14	23			14	23
Central nervous system vascular disorders NEC	1	1			1	1
Cerebrovascular venous and sinus thrombosis	1	1			1	1
Coordination and balance disturbances	1	6	1	3		3
Cortical dysfunction NEC	3	5		2	3	3
Demyelinating disorders NEC	1	3			1	3
Disturbances in consciousness NEC	9	59	4	18	5	41
Dyskinesias and movement disorders NEC	1	7		4	1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Encephalopathies NEC	1	1			1	1
Facial cranial nerve disorders	9	20	1	1	8	19
Generalised tonic-clonic seizures		3				3
Glossopharyngeal nerve disorders	1	1			1	1
Headaches NEC	26	167	17	116	9	51
Hypoglossal nerve disorders	1	1			1	1
Memory loss (excl dementia)	3	6	2	3	1	3
Mental impairment (excl dementia and memory loss)	3	7	2	3	1	4
Migraine headaches	3	7	1	5	2	2
Mononeuropathies	2	2			2	2
Multiple sclerosis acute and progressive		2				2
Muscle tone abnormal		5		3		2
Narcolepsy and hypersomnia		3		2		1
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC	23	101	14	51	9	50
Neurologic visual problems NEC	1	4			1	4
Neuromuscular disorders NEC	1	4		1	1	3
Olfactory nerve disorders		4		3		1
Paraesthesias and dysaesthesias	21	84	5	31	16	53
Paralysis and paresis (excl cranial nerve)	5	10			5	10
Parkinson's disease and parkinsonism		1		1		
Peripheral neuropathies NEC		3				3
Seizures and seizure disorders NEC	4	11		1	4	10
Sensory abnormalities NEC	6	23	3	12	3	11
Speech and language abnormalities	4	8	1	2	3	6
Spinal cord and nerve root disorders NEC		1				1
Transient cerebrovascular events	1	1			1	1
Tremor (excl congenital)	1	4		2	1	2
Trigeminal disorders	1	2			1	2
	148	594	51	264	97	330

\* I=Interval, C=Cumulative  
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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
		1		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	7		5	1	2
Behaviour and socialisation disturbances		1				1
Cognitive and attention disorders and disturbances NEC		1				1
Confusion and disorientation	4	10	1	3	3	7
Deliria	1	1			1	1
Disturbances in initiating and maintaining sleep		6		4		2
Hallucinations (excl sleep-related)		1				1
Increased physical activity levels		5		4		1
Mood alterations with manic symptoms		1				1
Mood disorders NEC		2		2		
Narcolepsy and associated conditions		1		1		
Panic attacks and disorders		2		1		1
Psychotic disorder NEC		1				1
Sleep disorders NEC	1	3		1	1	2
Somatic symptom disorders		1				1
Speech and language usage disturbances		1		1		
Speech articulation and rhythm disturbances	1	1			1	1
Stereotypies and automatisms		1				1
Thinking disturbances		1				1
	8	47	1	22	7	25

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	2	4	1	2	1	2
Renal disorders NEC		1		1		
Renal failure and impairment	2	3			2	3
Urinary abnormalities	1	2			1	2
Urinary tract signs and symptoms NEC	1	3			1	3
	6	13	1	3	5	10

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		1		1		
Menstruation and uterine bleeding NEC	1	2			1	2
Menstruation with decreased bleeding		1				1
Menstruation with increased bleeding	1	1			1	1
Vulvovaginal disorders NEC	1	2			1	2
Vulvovaginal signs and symptoms		1		1		
	3	8		2	3	6

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	20	64	4	12	16	52
Bronchospasm and obstruction	2	6	1	2	1	4
Coughing and associated symptoms	2	14	2	11		3
Laryngeal spasm, oedema and obstruction		2				2

\* I=Interval, C=Cumulative  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions		4				4
Lower respiratory tract signs and symptoms		2		1		1
Nasal congestion and inflammations		1				1
Nasal disorders NEC	1	3	1	2		1
Paranasal sinus disorders (excl infections and neoplasms)		1		1		
Parenchymal lung disorders NEC		4		1		3
Pharyngeal disorders (excl infections and neoplasms)	2	8	1	3	1	5
Pleural infections and inflammations		1				1
Pneumothorax and pleural effusions NEC	2	4			2	4
Pulmonary hypertensions	1	1			1	1
Pulmonary oedemas		4				4
Pulmonary thrombotic and embolic conditions	12	25			12	25
Respiratory failures (excl neonatal)		2				2
Respiratory signs and symptoms NEC	1	2	1	2		
Respiratory tract disorders NEC		2		2		
Upper respiratory tract signs and symptoms	4	24	4	11		13
	47	174	14	48	33	126

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias		2		2		
Angioedemas	2	3			2	3
Apocrine and eccrine gland disorders	4	8	4	5		3
Bullous conditions	1	3			1	3
Dermal and epidermal conditions NEC		8		3		5
Dermatitis and eczema	2	7	1	2	1	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dermatitis ascribed to specific agent		2				2	
Erythemas	3	16	2	9	1	7	
Exfoliative conditions	1	2	1	1		1	
Hypertrichoses		1		1			
Nail and nail bed conditions (excl infections and infestations)		1		1			
Pruritus NEC	4	33		7	4	26	
Psoriatic conditions	1	1			1	1	
Purpura and related conditions		3		1		2	
Rashes, eruptions and exanthems NEC	8	45	4	10	4	35	
Skin dystrophies	1	1	1	1			
Skin hypoplasias and atrophies		1		1			
Skin vasomotor conditions		1		1			
Urticarias	3	18	1	2	2	16	
	30	156	14	47	16	109	

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Disability issues	4	16	2	6	2	10	
Social issues NEC	1	1			1	1	
	5	17	2	6	3	11	

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	2	11			2	11
Aneurysms and dissections non-site specific		1				1
Circulatory collapse and shock	9	25			9	25
Haemorrhages NEC	2	3			2	3
Non-site specific embolism and thrombosis	4	4			4	4
Non-site specific necrosis and vascular insufficiency NEC	1	2			1	2
Peripheral embolism and thrombosis	9	15	1	2	8	13
Peripheral vascular disorders NEC	2	17	1	4	1	13
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	4	1	3		1
Site specific vascular disorders NEC	1	7		2	1	5
Varicose veins NEC	1	1			1	1
Vascular hypertensive disorders NEC	2	12		1	2	11
Vascular hypotensive disorders	1	12		3	1	9
Vasculitides NEC		1				1
	35	115	3	15	32	100

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Country Where Event Occurred

**BAHRAIN**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders	1	3		2	1	1
Feelings and sensations NEC	1	3		2	1	1
General signs and symptoms NEC	1	1			1	1
Pain and discomfort NEC	2	3		1	2	2
Vaccination site reactions		1		1		
	5	11		6	5	5

System Organ Class

**Investigations**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart rate and pulse investigations	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle pains		2		2		
Muscle related signs and symptoms NEC	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort		1		1		
	1	4		3	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC		1		1		
Paraesthesias and dysaesthesias	1	1			1	1
	1	2		1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
	1	1	1	1

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1			1	1
Pruritus NEC		1		1		
	1	2		1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral vascular disorders NEC		1		1
		1		1

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Country Where Event Occurred

**BELGIUM**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathies	9	17		3	9	14
Leukocytoses NEC		2				2
Lymphatic system disorders NEC	20	45	6	7	14	38
Neutropenias		1				1
Thrombocytopenias		2				2
	29	67	6	10	23	57

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		3				3
Cardiac disorders NEC	17	59	4	8	13	51
Cardiac signs and symptoms NEC	4	14	3	5	1	9
Cardiomyopathies		1		1		
Coronary artery disorders NEC		1				1
Heart failures NEC	2	6			2	6
Ischaemic coronary artery disorders		4				4
Myocardial disorders NEC	1	1			1	1
Noninfectious pericarditis	1	1			1	1
Pericardial disorders NEC		1				1
Rate and rhythm disorders NEC	12	44		2	12	42
Supraventricular arrhythmias	1	5			1	5
Ventricular arrhythmias and cardiac arrest	2	14	1	1	1	13
	40	154	8	17	32	137

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	4	8	2	3	2	5
Hearing disorders NEC	1	1			1	1
Hearing losses	1	5			1	5
Hyperacusia		2				2
Inner ear disorders NEC		2				2
Inner ear signs and symptoms	11	36	5	8	6	28
	17	54	7	11	10	43

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glaucomas (excl congenital)		2				2
Lacrimation disorders	1	2		1	1	1
Lid, lash and lacrimal infections, irritations and inflammations		1				1
Ocular disorders NEC	4	12	4	6		6
Ocular infections, inflammations and associated manifestations	1	2		1	1	1
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders	2	5	1	2	1	3
Pupil disorders	1	1	1	1		
Retinopathies NEC		1				1
Scleral structural change, deposit and degeneration		1				1
Structural change, deposit and degeneration of eye NEC	1	1			1	1
Visual disorders NEC	5	12	3	5	2	7
Visual impairment and blindness (excl colour blindness)	4	9	2	2	2	7
	19	50	11	18	8	32

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders		1				1
Diarrhoea (excl infective)	12	31	3	7	9	24
Dyspeptic signs and symptoms	1	1			1	1
Faecal abnormalities NEC		1				1
Flatulence, bloating and distension	2	4	2	3		1
Gastrointestinal and abdominal pains (excl oral and throat)	5	21	1	3	4	18
Gastrointestinal atonic and hypomotility disorders NEC	4	5	1	1	3	4
Gastrointestinal disorders NEC	1	3			1	3
Gastrointestinal signs and symptoms NEC	4	13	4	6		7
Gastrointestinal stenosis and obstruction NEC	1	1			1	1
Gastrointestinal vascular occlusion and infarction		2				2
Gingival disorders, signs and symptoms NEC		2				2
Nausea and vomiting symptoms	102	360	22	38	80	322
Oral dryness and saliva altered	1	5		1	1	4
Oral soft tissue signs and symptoms	2	9	2	3		6
Oral soft tissue swelling and oedema		5		1		4
Stomatitis and ulceration	1	4			1	4
Tongue signs and symptoms	1	9		1	1	8
	137	477	35	64	102	413

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	271	812	60	111	211	701
Body temperature altered	4	6	2	2	2	4
Death and sudden death	5	20			5	20
Febrile disorders	152	405	47	71	105	334

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feelings and sensations NEC	148	430	29	53	119	377
Gait disturbances		3				3
General signs and symptoms NEC	44	157	14	28	30	129
Inflamations	1	3	1	1		2
Injection site reactions	9	16	5	8	4	8
Oedema NEC	2	4	1	2	1	2
Pain and discomfort NEC	30	71	9	18	21	53
Therapeutic and nontherapeutic responses	16	70	1	1	15	69
Vaccination site reactions	167	410	77	116	90	294
	849	2,407	246	411	603	1996

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations		1				1
Hepatic and hepatobiliary disorders NEC	3	4	2	2	1	2
Hepatic failure and associated disorders		1				1
Hepatocellular damage and hepatitis NEC	1	2			1	2
	4	8	2	2	2	6

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	7	21	1	3	6	18
Allergies to foods, food additives, drugs and other chemicals	2	3			2	3

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic and anaphylactoid responses	6	39			6	39
Autoimmune disorders NEC	5	6			5	6
	20	69	1	3	19	66

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2				2
Bacterial infections NEC		1				1
Coronavirus infections	28	120	6	17	22	103
Herpes viral infections	2	15		5	2	10
Infections NEC	2	7	1	2	1	5
Influenza viral infections	2	5	1	3	1	2
Lower respiratory tract and lung infections		3				3
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	5			1	5
Skin structures and soft tissue infections		1				1
Streptococcal infections		2				2
Upper respiratory tract infections	1	8		1	1	7
Urinary tract infections	1	3		1	1	2
Viral infections NEC		1				1
	37	173	8	29	29	144

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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*System Organ Class*

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Cerebral injuries NEC		1					1
Conditions caused by cold		1					1
Exposures associated with pregnancy, delivery and lactation	1	4	1	4			
Medication errors, product use errors and issues NEC	36	116	36	116			
Muscle, tendon and ligament injuries	7	11	1	2	6	9	
Non-site specific injuries NEC	3	12		2	3	10	
Non-site specific procedural complications	1	1			1	1	
Occupational exposures		1		1			
Off label uses	2	4	2	4			
Pathways and sources of exposure		1		1			
Product administration errors and issues	38	136	37	134	1	2	
Product preparation errors and issues		1		1			
Skin injuries NEC	2	3	1	1	1	2	
Skull fractures, facial bone fractures and dislocations		1					1
Underdoses NEC		1		1			
Vaccination related complications	2	17			2	17	
	92	311	78	267	14	44	

*System Organ Class*

**Investigations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	3	28	1	1	2	27
Carbohydrate tolerance analyses (incl diabetes)		2		2		
Coagulation and bleeding analyses	1	3			1	3
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	1	14		4	1	10
Investigations NEC	1	1			1	1

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liver function analyses	4	7	4	4		3
Metabolism tests NEC	1	2			1	2
Mineral and electrolyte analyses	1	1	1	1		
Physical examination procedures and organ system status	7	17	4	6	3	11
Protein analyses NEC	1	4	1	2		2
Skeletal and cardiac muscle analyses	1	4			1	4
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	8	22	2	4	6	18
Virus identification and serology		2		1		1
White blood cell analyses		1		1		
	29	110	13	27	16	83

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	5	14	2	4	3	10
Calcium metabolism disorders		1				1
Diabetic complications NEC		1				1
Fat soluble vitamin deficiencies and disorders		1				1
Hypoglycaemic conditions NEC		5				5
Metabolic acidoses (excl diabetic acidoses)	1	6			1	6
Potassium imbalance		1				1
Sodium imbalance		1				1
Total fluid volume decreased		1				1
	6	31	2	4	4	27

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	4		1	1	3
Bone disorders NEC	1	1	1	1		
Bone related signs and symptoms		8		2		6
Joint related signs and symptoms	61	180	9	15	52	165
Muscle pains	124	389	28	51	96	338
Muscle related signs and symptoms NEC	3	7	1	2	2	5
Muscle weakness conditions	1	5		1	1	4
Musculoskeletal and connective tissue conditions NEC	26	60	19	33	7	27
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1			1	1
Musculoskeletal and connective tissue infections and inflammations NEC		1				1
Musculoskeletal and connective tissue pain and discomfort	34	92	21	40	13	52
Soft tissue disorders NEC		1				1
	252	749	79	146	173	603

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	8	17			8	17
Coma states		1				1
Coordination and balance disturbances	4	10			4	10
Cortical dysfunction NEC	2	3			2	3
Disturbances in consciousness NEC	7	69		2	7	67
Dystonias		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders	6	21	2	2	4	19
Generalised tonic-clonic seizures	1	3			1	3
Headaches NEC	169	515	37	78	132	437
Memory loss (excl dementia)	1	3		1	1	2
Mental impairment (excl dementia and memory loss)	2	2	1	1	1	1
Migraine headaches	3	17			3	17
Narcolepsy and hypersomnia		2				2
Nervous system disorders NEC	12	38	3	6	9	32
Neurological signs and symptoms NEC	21	74	5	13	16	61
Neurologic visual problems NEC		2				2
Neuromuscular disorders NEC	1	1			1	1
Olfactory nerve disorders	1	3	1	1		2
Paraesthesias and dysaesthesias	17	42	7	15	10	27
Paralysis and paresis (excl cranial nerve)	1	7			1	7
Parkinson's disease and parkinsonism		2				2
Peripheral neuropathies NEC	1	5			1	5
Seizures and seizure disorders NEC	4	22			4	22
Sensory abnormalities NEC	4	21	3	9	1	12
Sleep disturbances NEC		5		2		3
Speech and language abnormalities	1	3	1	3		
Structural brain disorders NEC	1	1			1	1
Transient cerebrovascular events	1	1			1	1
Tremor (excl congenital)	3	13	1	2	2	11
	271	906	61	135	210	771

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
		1		1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC		1				1
Anxiety symptoms	2	14	2	2		12
Confusion and disorientation	2	7	2	2		5
Deliria		1				1
Disturbances in initiating and maintaining sleep	6	21	2	6	4	15
Emotional and mood disturbances NEC		1				1
Hallucinations (excl sleep-related)	1	5			1	5
Increased physical activity levels	1	3		1	1	2
Mood disorders NEC	1	3		1	1	2
Parasomnias	1	2			1	2
Perception disturbances NEC		1				1
Psychotic disorder NEC	1	1			1	1
Sleep disorders NEC	2	7	2	3		4
Thinking disturbances		1				1
	17	68	8	15	9	53

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		1				1

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 \* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorders NEC	2	5			2	5
Renal failure and impairment	1	6			1	6
Urinary abnormalities		1		1		
Urinary tract signs and symptoms NEC		3				3
	3	16		1	3	15

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	3	3	1	1	2	2
Lactation disorders	1	1			1	1
Vulvovaginal disorders NEC		1				1
	4	5	1	1	3	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	21	74	2	5	19	69
Bronchial conditions NEC		1				1
Bronchospasm and obstruction	1	9			1	9
Conditions associated with abnormal gas exchange	1	2			1	2
Coughing and associated symptoms	6	18	2	4	4	14
Laryngeal spasm, oedema and obstruction		2				2
Lower respiratory tract inflammatory and immunologic conditions	1	4			1	4
Lower respiratory tract signs and symptoms	1	3			1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Nasal congestion and inflammations		1		1			
Nasal disorders NEC	1	2		1	1	2	
Parenchymal lung disorders NEC		1				1	
Pharyngeal disorders (excl infections and neoplasms)	1	8			1	8	
Pneumothorax and pleural effusions NEC		2				2	
Pulmonary hypertensions	1	1			1	1	
Pulmonary oedemas	1	4			1	4	
Pulmonary thrombotic and embolic conditions	4	10			4	10	
Respiratory failures (excl neonatal)		5				5	
Respiratory signs and symptoms NEC	2	5			2	5	
Respiratory tract disorders NEC	25	57	1	3	24	54	
Upper respiratory tract signs and symptoms	7	36	4	15	3	21	
	73	245	9	28	64	217	

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Angioedemas		4				4	
Apocrine and eccrine gland disorders	4	18	1	4	3	14	
Dermal and epidermal conditions NEC	20	51	6	8	14	43	
Dermatitis and eczema	1	1	1	1			
Erythemas	6	21	5	6	1	15	
Pruritus NEC	9	25	5	8	4	17	
Psoriatic conditions		1		1			
Rashes, eruptions and exanthems NEC	8	19	7	8	1	11	
Skin and subcutaneous conditions NEC	1	1			1	1	
Skin vasculitides	1	1			1	1	
Skin vasomotor conditions		1				1	

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticarias	1	6			1	6
	51	149	25	36	26	113

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	3	2	2		1
	2	3	2	2		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Circulatory collapse and shock		3				3
Haemorrhages NEC	1	3	1	1		2
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	1	2			1	2
Peripheral embolism and thrombosis	4	6			4	6
Peripheral vascular disorders NEC	3	16	1	3	2	13
Peripheral vasoconstriction, necrosis and vascular insufficiency		1				1
Phlebitis NEC		1				1
Site specific vascular disorders NEC		3				3
Vascular hypertensive disorders NEC	11	36	2	3	9	33
Vascular hypotensive disorders	2	19	1	3	1	16
Vasculitides NEC		2		1		1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	22	94	5	11	17	83

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Country Where Event Occurred

**BERMUDA**

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	2	2	2	2
	2	2	2	2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Visual impairment and blindness (excl colour blindness)		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders		1		1		

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feelings and sensations NEC		2		2		
General signs and symptoms NEC	1	1			1	1
Pain and discomfort NEC	1	1			1	1
	2	5		3	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coordination and balance disturbances		1		1
Neurological signs and symptoms NEC		1		1
Paraesthesias and dysaesthesias		1		1
		3		3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1		1		

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas	1	1			1	1
Rashes, eruptions and exanthems NEC	1	1	1	1		
	2	3	1	2	1	1

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Country Where Event Occurred

**BOSNIA AND HERZEGOVINA**

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**BRAZIL**

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pain and discomfort NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**BULGARIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenias NEC	1	1			1	1
Lymphatic system disorders NEC	4	20	4	19		1
	5	21	4	19	1	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	2	4	1	3	1	1
Ischaemic coronary artery disorders		1				1
Rate and rhythm disorders NEC	4	7	2	4	2	3
Ventricular arrhythmias and cardiac arrest		1				1
	6	13	3	7	3	6

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses		1				1
Inner ear signs and symptoms	4	14	3	10	1	4
	4	15	3	10	1	5

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctival infections, irritations and inflammations		1		1
Lacrimation disorders	1	2	1	2
Ocular disorders NEC		2		2
Ocular sensation disorders		1		1
	1	6	1	6

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)		2		2		
Dyspeptic signs and symptoms		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)		3		1		2
Gastrointestinal disorders NEC		1		1		
Gastrointestinal signs and symptoms NEC		1		1		
Nausea and vomiting symptoms	4	20	4	18		2
Oral dryness and saliva altered		2		2		
Oral soft tissue signs and symptoms		1		1		
Oral soft tissue swelling and oedema		1				1
Tongue signs and symptoms		1				1
	4	34	4	28		6

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	17	58	17	56		2
Body temperature altered		1				1
Febrile disorders	10	32	10	30		2
Feelings and sensations NEC	9	31	9	28		3
Gait disturbances	1	3		2	1	1
General signs and symptoms NEC	3	9	3	9		
Injection site reactions		12		12		
Oedema NEC	1	2	1	2		
Pain and discomfort NEC	3	9	3	9		
Therapeutic and nontherapeutic responses	4	11			4	11
Vaccination site reactions	14	101	12	93	2	8
	62	269	55	241	7	28

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1		
Anaphylactic and anaphylactoid responses		1				1
	1	3	1	2		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	5	17	1	4	4	13

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections		1		1		
Infections NEC		1				1
Lower respiratory tract and lung infections	2	2	1	1	1	1
Upper respiratory tract infections	5	5	5	5		
Viral infections NEC		1				1
	12	27	7	11	5	16

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC	1	1			1	1
Off label uses		1		1		
Overdoses NEC	2	2	2	2		
Product administration errors and issues		1		1		
Skull fractures, facial bone fractures and dislocations	1	1			1	1
	4	6	2	4	2	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		2		1		1
Carbohydrate tolerance analyses (incl diabetes)	2	2	1	1	1	1
Heart rate and pulse investigations	1	2	1	2		
Immunology analyses NEC	1	1	1	1		
Physical examination procedures and organ system status	1	32	1	30		2

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Protein analyses NEC	1	1			1	1
Thyroid analyses		1				1
Vascular tests NEC (incl blood pressure)	5	10	2	6	3	4
Virus identification and serology	1	2	1	1		1
White blood cell analyses		1		1		
	12	54	7	43	5	11

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders		3		2		1
		3		2		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1		1		
Bone related signs and symptoms	1	2	1	2		
Joint related signs and symptoms	7	28	7	28		
Muscle pains	6	37	6	37		
Muscle related signs and symptoms NEC		1		1		
Muscle tone abnormalities		1		1		
Musculoskeletal and connective tissue conditions NEC		4		3		1
Musculoskeletal and connective tissue pain and discomfort	11	21	11	21		
Rheumatoid arthropathies		1				1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	25	96	25	94		2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Demyelinating disorders NEC		1				1
Disturbances in consciousness NEC	3	3	1	1	2	2
Dyskinesias and movement disorders NEC	1	2	1	1		1
Facial cranial nerve disorders	1	3			1	3
Headaches NEC	11	47	11	43		4
Mental impairment (excl dementia and memory loss)		1		1		
Myelitis (incl infective)		1				1
Neurological signs and symptoms NEC	4	20	4	18		2
Olfactory nerve disorders		2		2		
Paraesthesias and dysaesthesias	5	10	5	9		1
Peripheral neuropathies NEC		1		1		
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC		2		2		
Tremor (excl congenital)	1	5		4	1	1
	26	99	22	82	4	17

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms		2		2

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Communications disorders		1		1
Disturbances in initiating and maintaining sleep		2		2
		5		5

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary tract signs and symptoms NEC		1		1
		1		1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	1	1	1	1		
Erection and ejaculation conditions and disorders		1				1
	1	2	1	1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	6	3	4		2
Coughing and associated symptoms	3	6	3	6		
Nasal disorders NEC	1	1	1	1		

\* I=Interval, C=Cumulative  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Parenchymal lung disorders NEC		1				1	
Respiratory signs and symptoms NEC		1		1			
Upper respiratory tract signs and symptoms	6	10	6	10			
	13	25	13	22			3

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Apocrine and eccrine gland disorders		7		5		2	
Dermatitis ascribed to specific agent		1		1			
Erythemas	2	5	2	5			
Pruritus NEC	3	3	2	2	1	1	
Rashes, eruptions and exanthems NEC	3	7	2	6	1	1	
Urticarias		3		2		1	
	8	26	6	21	2	5	

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood pressure disorders NEC		2		2			
Circulatory collapse and shock	1	1			1	1	
Haemorrhages NEC	1	1			1	1	
Non-site specific necrosis and vascular insufficiency NEC		1				1	
Non-site specific vascular disorders NEC	1	1	1	1			
Peripheral vascular disorders NEC		1		1			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1		
Site specific vascular disorders NEC		2		1		1
Vascular hypertensive disorders NEC	2	3	1	2	1	1
	5	13	2	8	3	5

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**CANADA**

*System Organ Class*

**Blood and lymphatic system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	1	28		24	1	4
Spleen disorders	1	1			1	1
Thrombocytopenias		2				2
	2	31		24	2	7

*System Organ Class*

**Cardiac disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1			1	1
Cardiac signs and symptoms NEC	2	6	2	5		1
Ischaemic coronary artery disorders	2	2			2	2
Noninfectious myocarditis	2	2			2	2
Noninfectious pericarditis		1				1
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	7	19	2	6	5	13
Supraventricular arrhythmias	2	3			2	3
Ventricular arrhythmias and cardiac arrest		1				1
	17	36	4	11	13	25

*System Organ Class*

**Ear and labyrinth disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	7	3	7		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
External ear disorders NEC		2		2		
Hearing losses	3	6	1	3	2	3
Inner ear signs and symptoms	7	16	3	11	4	5
	13	31	7	23	6	8

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thyroid disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		2		1		1
Eyelid movement disorders	1	2			1	2
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders	3	4	3	4		
Lid, lash and lacrimal infections, irritations and inflammations		3		2		1
Lid, lash and lacrimal structural disorders	1	1	1	1		
Ocular disorders NEC	4	9	4	8		1
Ocular infections, inflammations and associated manifestations	1	3	1	2		1
Ocular sensation disorders		2		2		

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual disorders NEC	3	8	2	5	1	3
Visual impairment and blindness (excl colour blindness)	1	3		1	1	2
	14	38	11	26	3	12

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis (excl infective)	1	1			1	1
Dental pain and sensation disorders		1		1		
Diaphragmatic hernias	1	1	1	1		
Diarrhoea (excl infective)	7	27	5	24	2	3
Faecal abnormalities NEC	1	1	1	1		
Flatulence, bloating and distension	1	2	1	2		
Gastric ulcers and perforation	2	2			2	2
Gastrointestinal and abdominal pains (excl oral and throat)	3	14	2	12	1	2
Gastrointestinal atonic and hypomotility disorders NEC		1		1		
Gastrointestinal disorders NEC	1	2	1	2		
Gastrointestinal dyskinetic disorders		1		1		
Gastrointestinal signs and symptoms NEC	6	13	4	11	2	2
Gastrointestinal spastic and hypermotility disorders		1		1		
Intestinal haemorrhages	1	1			1	1
Malabsorption syndromes		1				1
Nausea and vomiting symptoms	30	87	21	72	9	15
Non-site specific gastrointestinal haemorrhages		1				1
Oesophageal disorders NEC		1				1
Oesophagitis (excl infective)	1	1			1	1

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 \* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral dryness and saliva altered	4	4	3	3	1	1
Oral soft tissue disorders NEC	1	3	1	3		
Oral soft tissue haemorrhages		1		1		
Oral soft tissue signs and symptoms	6	27	5	19	1	8
Oral soft tissue swelling and oedema	4	8	4	5		3
Stomatitis and ulceration		3		3		
Tongue disorders	1	5	1	4		1
Tongue signs and symptoms	3	10	3	8		2
	74	220	53	175	21	45

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	2	3	2	3		
Asthenic conditions	37	148	28	129	9	19
Death and sudden death	1	2			1	2
Febrile disorders	14	61	11	56	3	5
Feelings and sensations NEC	21	85	19	80	2	5
Gait disturbances	3	3	1	1	2	2
General signs and symptoms NEC	18	49	9	32	9	17
Inflammations	1	1	1	1		
Infusion site reactions	1	1	1	1		
Injection site reactions	4	19	4	19		
Interactions	2	2			2	2
Mass conditions NEC		1		1		
Mucosal findings abnormal	1	2	1	2		
Necrosis NEC		1				1
Oedema NEC		4		2		2
Pain and discomfort NEC	15	70	10	59	5	11

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\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Therapeutic and nontherapeutic responses	9	46	2	4	7	42
Vaccination site reactions	20	94	18	89	2	5
	149	592	107	479	42	113

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	6	20	3	6	3	14
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses	7	43			7	43
Autoimmune disorders NEC	1	1			1	1
	14	65	3	7	11	58

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1		1		
Bacterial infections NEC		1				1
Candida infections		1		1		
Central nervous system and spinal infections		1				1
Coronavirus infections	10	52	3	5	7	47
Ear infections		1				1
Eye and eyelid infections		1		1		
Female reproductive tract infections		1		1		
Fungal infections NEC		1		1		

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\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections	8	15	5	10	3	5
Infections NEC		1		1		
Inflammatory disorders following infection		1		1		
Lower respiratory tract and lung infections	2	3	1	1	1	2
Parvoviral infections	1	1	1	1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2			2	2
Skin structures and soft tissue infections	1	2	1	2		
Streptococcal infections		1				1
Upper respiratory tract infections		3		3		
Urinary tract infections		1		1		
Viral infections NEC		2		2		
	24	92	11	32	13	60

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product		1		1		
Exposures associated with pregnancy, delivery and lactation	6	64	5	61	1	3
Intentional product use issues		1		1		
Limb fractures and dislocations	1	1			1	1
Medication errors, product use errors and issues NEC	1	44	1	43		1
Muscle, tendon and ligament injuries	1	2	1	2		
Non-site specific injuries NEC	4	6		1	4	5
Off label uses	3	80	3	79		1
Overdoses NEC		11		11		
Poisoning and toxicity	1	1			1	1
Product administration errors and issues	4	59	4	59		

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation errors and issues		15		15		
Skin injuries NEC	4	8	4	6		2
Thoracic cage fractures and dislocations	1	1			1	1
Underdoses NEC	4	13	4	13		
Vaccination related complications		3				3
	30	310	22	292	8	18

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1				1
Carbohydrate tolerance analyses (incl diabetes)	1	3		1	1	2
Heart rate and pulse investigations	5	14	1	5	4	9
Liver function analyses	4	6	1	1	3	5
Physical examination procedures and organ system status		6		5		1
Protein analyses NEC	2	2	1	1	1	1
Red blood cell analyses	1	1	1	1		
Skeletal and cardiac muscle analyses	2	2	1	1	1	1
Therapeutic drug monitoring analyses	2	2	1	1	1	1
Urinalysis NEC	1	3	1	3		
Vascular tests NEC (incl blood pressure)	5	8	1	3	4	5
Virus identification and serology		1				1
Vitamin analyses	1	1			1	1
White blood cell analyses		4		4		
	24	54	8	26	16	28

System Organ Class

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	8	2	7		1
Diabetes mellitus (incl subtypes)	1	1			1	1
Disorders of purine metabolism	1	3	1	3		
Fluid intake increased		1		1		
Total fluid volume decreased		1		1		
Total fluid volume increased	1	3	1	3		
	5	17	4	15	1	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	3		2	1	1
Bursal disorders	1	1	1	1		
Joint related disorders NEC		1		1		
Joint related signs and symptoms	9	39	6	33	3	6
Lupus erythematosus (incl subtypes)		1				1
Muscle pains	7	49	6	46	1	3
Muscle related signs and symptoms NEC	1	6	1	5		1
Muscle weakness conditions	1	7	1	6		1
Musculoskeletal and connective tissue conditions NEC	4	12	4	12		
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	14	71	14	63		8
Rheumatoid arthropathies	2	4			2	4
Soft tissue disorders NEC		2		2		
Tendon disorders	1	3	1	3		
	42	200	35	175	7	25

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Soft tissue neoplasms benign NEC		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Central nervous system aneurysms and dissections		2				2
Central nervous system haemorrhages and cerebrovascular accidents	4	7			4	7
Cerebrovascular venous and sinus thrombosis	1	1			1	1
Coordination and balance disturbances	6	7	4	5	2	2
Cortical dysfunction NEC	1	2	1	2		
Disturbances in consciousness NEC	17	37		8	17	29
Dyskinesias and movement disorders NEC		2		2		
Eye movement disorders		1				1
Facial cranial nerve disorders	5	14			5	14
Generalised tonic-clonic seizures		1				1
Headaches NEC	31	113	25	104	6	9
Memory loss (excl dementia)	1	1			1	1
Mental impairment (excl dementia and memory loss)	5	9	3	7	2	2
Migraine headaches	2	11	1	9	1	2
Multiple sclerosis acute and progressive	2	2			2	2
Narcolepsy and hypersomnia	2	4	2	4		
Nervous system disorders NEC	1	1			1	1
Neurological signs and symptoms NEC	21	60	13	45	8	15
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	21	60	10	34	11	26

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis and paresis (excl cranial nerve)	3	3			3	3
Seizures and seizure disorders NEC	4	4			4	4
Sensory abnormalities NEC	8	21	8	18		3
Speech and language abnormalities	2	3	1	2	1	1
Transient cerebrovascular events	2	3	1	1	1	2
Tremor (excl congenital)	1	6	1	5		1
	141	377	71	247	70	130

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous	1	3			1	3
Foetal growth complications	1	3			1	3
Labour onset and length abnormalities		1		1		
Maternal complications of pregnancy NEC		1				1
Postpartum complications NEC		1		1		
Pregnancy complicated by maternal disorders		1				1
	2	10		2	2	8

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device malfunction events NEC		1		1
Product packaging issues		1		1
Product physical issues		1		1
Product quality issues NEC	4	5	4	5

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\* AE=Adverse Event  
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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues		2		2
	4	10	4	10

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect alterations NEC		1		1		
Anxiety symptoms	4	12	4	10		2
Cognitive and attention disorders and disturbances NEC		1		1		
Confusion and disorientation	1	2	1	2		
Deliria	1	1			1	1
Depressive disorders	1	2	1	2		
Disturbances in initiating and maintaining sleep	3	5	3	5		
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Psychotic disorder NEC		1				1
Sleep disorders NEC	2	3	2	3		
Suicidal and self-injurious behaviour	1	1			1	1
	13	30	11	25	2	5

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	6	1	3	2	3
Renal failure and impairment		1				1
Urinary abnormalities		1		1		

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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract signs and symptoms NEC	3	5		1	3	4
	6	13	1	5	5	8

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		3		2		1
Menstruation and uterine bleeding NEC	2	6	2	6		
Menstruation with decreased bleeding		1		1		
Menstruation with increased bleeding	3	6	2	5	1	1
Penile disorders NEC (excl erection and ejaculation)		1				1
Testicular and epididymal disorders NEC		2		1		1
Vulvovaginal disorders NEC		4		3		1
Vulvovaginal signs and symptoms		1		1		
	5	24	4	19	1	5

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	14	31	9	21	5	10
Bronchospasm and obstruction	1	6		3	1	3
Coughing and associated symptoms	4	13	3	10	1	3
Laryngeal spasm, oedema and obstruction		1				1
Lower respiratory tract signs and symptoms		1				1
Nasal congestion and inflammations	1	2		1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal disorders (excl infections and neoplasms)	1	9	1	5		4
Pneumothorax and pleural effusions NEC	1	1			1	1
Pulmonary oedemas	1	1			1	1
Pulmonary thrombotic and embolic conditions	1	4			1	4
Respiratory tract disorders NEC	2	3	1	1	1	2
Upper respiratory tract signs and symptoms	11	36	10	29	1	7
	37	108	24	70	13	38

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		1		1		
Angioedemas	1	2			1	2
Apocrine and eccrine gland disorders	4	11	2	7	2	4
Bullous conditions		2				2
Dermal and epidermal conditions NEC	3	9	3	9		
Dermatitis and eczema	1	2		1	1	1
Erythemas	6	12	4	8	2	4
Exfoliative conditions		1		1		
Pruritus NEC	9	27	6	20	3	7
Purpura and related conditions		3		3		
Rashes, eruptions and exanthems NEC	16	48	14	40	2	8
Skin preneoplastic conditions NEC		1		1		
Urticarias	10	31	7	25	3	6
	50	150	36	116	14	34

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	3	6	3	5		1
Social issues NEC	1	1	1	1		
	4	7	4	6		1

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Induced abortions	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Lymphoedemas		1		1		
Non-site specific embolism and thrombosis	5	7			5	7
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	2	7	1	5	1	2
Peripheral vasoconstriction, necrosis and vascular insufficiency	4	5	3	3	1	2
Site specific vascular disorders NEC	1	3	1	2		1
Vascular hypertensive disorders NEC	5	16	3	8	2	8
Vascular hypotensive disorders	2	9	1	5	1	4
	20	51	9	25	11	26

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**CAYMAN ISLANDS**

*System Organ Class*

**Cardiac disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC		1		1
		1		1

*System Organ Class*

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Dyspeptic signs and symptoms		1		1
		1		1

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
		1		1

*System Organ Class*

**Metabolism and nutrition disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle related signs and symptoms NEC		2		2
		2		2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
		1		1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Emotional and mood disturbances NEC		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CHILE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	2	10	2	9		1
Spleen disorders	1	1			1	1
	3	11	2	9	1	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	3	5	3	3		2
	4	6	3	3	1	3

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		1		1
Inner ear disorders NEC		1		1
Inner ear signs and symptoms	1	1	1	1
	1	3	1	3

System Organ Class

**Eye disorders**

Spontaneous

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	1	2	1	1		1
Ocular infections, inflammations and associated manifestations	1	3	1	1		2
Ocular nerve and muscle disorders	1	1			1	1
Ocular sensation disorders		1				1
	3	7	2	2	1	5

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Colitis (excl infective)	1	1	1	1		
Dental pain and sensation disorders	1	1	1	1		
Diarrhoea (excl infective)	3	9	3	9		
Faecal abnormalities NEC		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	6	8	6	7		1
Gastrointestinal disorders NEC		1				1
Gastrointestinal signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	12	18	12	17		1
Oral dryness and saliva altered		1				1
Tongue disorders		1		1		
Tongue signs and symptoms	1	2		1	1	1
	25	45	24	39	1	6

System Organ Class

**General disorders and administration site conditions**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	21	37	21	37		
Febrile disorders	21	30	21	29		1
Feelings and sensations NEC	10	17	10	16		1
Gait disturbances	4	5	2	3	2	2
General signs and symptoms NEC	4	8	3	5	1	3
Inflammations		1		1		
Mass conditions NEC	2	2	2	2		
Oedema NEC		4		1		3
Pain and discomfort NEC	14	22	14	20		2
Therapeutic and nontherapeutic responses	2	2	1	1	1	1
Vaccination site reactions	17	33	16	30	1	3
	95	161	90	145	5	16

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatocellular damage and hepatitis NEC	1	2		1	1	1
	1	2		1	1	1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	8	3	8		
Anaphylactic and anaphylactoid responses		3				3
	3	11	3	8		3

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	2	1	2
	1	2	1	2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	1	3	1	3		
Medication errors, product use errors and issues NEC	1	2	1	2		
Non-site specific injuries NEC		2				2
Off label uses	1	3	1	3		
Overdoses NEC		1		1		
Product administration errors and issues	3	14	3	14		
Product preparation errors and issues		1		1		
Site specific injuries NEC		1				1
Skin injuries NEC	2	2	2	2		
	9	30	8	26	1	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1	1	1		
Carbohydrate tolerance analyses (incl diabetes)	2	2	1	1	1	1
Immune response protein analyses NEC		1		1		
Investigations NEC		1		1		

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liver function analyses	1	2	1	1		1
Protein analyses NEC		1		1		
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	1	1	1	1		
Virus identification and serology		1		1		
White blood cell analyses		1		1		
	5	12	4	9	1	3

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		2		2
Fluid intake increased		1		1
		3		3

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1			1	
Bone related signs and symptoms	1	2	1	2		
Joint related signs and symptoms	3	10	3	8		2
Muscle pains	20	29	20	28		1
Muscle related signs and symptoms NEC	2	4	2	4		
Muscle weakness conditions		1		1		
Musculoskeletal and connective tissue pain and discomfort	13	18	13	18		

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\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myopathies		1				1
Soft tissue disorders NEC	1	1	1	1		
Synovial disorders		1		1		
	40	68	40	63		5

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		2				2
Cortical dysfunction NEC	1	1			1	1
Disturbances in consciousness NEC	4	6	2	3	2	3
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	26	42	26	41		1
Muscle tone abnormal	1	1	1	1		
Neurological signs and symptoms NEC	4	6	4	6		
Paraesthesias and dysaesthesias	10	17	9	13	1	4
Paralysis and paresis (excl cranial nerve)		2				2
Seizures and seizure disorders NEC	1	2			1	2
Sensory abnormalities NEC	1	3		1	1	2
	49	83	42	65	7	18

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues	1	1	1	1
	1	1	1	1

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	2	2	2	2
Behaviour and socialisation disturbances	1	1	1	1
Disturbances in initiating and maintaining sleep	3	3	3	3
Emotional and mood disturbances NEC	1	2	1	2
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1
Mental disorders NEC		1		1
Mood alterations with depressive symptoms	1	1	1	1
Panic attacks and disorders	2	2	2	2
	11	13	11	13

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast signs and symptoms	1	2	1	2
Lactation disorders	1	1	1	1
	2	3	2	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	7	1	2		5
Coughing and associated symptoms	1	2	1	2		
Nasal congestion and inflammations	1	2	1	2		
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	6	8	6	7		1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	9	20	9	13	7	

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		2				2
Apocrine and eccrine gland disorders	1	2	1	2		
Dermal and epidermal conditions NEC	2	3	2	3		
Dermatitis and eczema	1	5		4	1	1
Erythemas	1	3	1	3		
Panniculitides	1	1			1	1
Pruritus NEC	1	2	1	2		
Rashes, eruptions and exanthems NEC		3		1		2
Urticarias	1	2	1	1		1
	8	23	6	16	2	7

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues		2		2
		2		2

System Organ Class

**Vascular disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	1	1	1		
Haemorrhages NEC	1	1			1	1
Non-site specific embolism and thrombosis		1				1
Peripheral vascular disorders NEC	1	1	1	1		
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC	1	1	1	1		
Vascular hypotensive disorders		1				1
Vasculitides NEC	1	1			1	1
	5	8	3	3	2	5

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Country Where Event Occurred

**COLOMBIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukocytoses NEC		1		1
Lymphatic system disorders NEC	3	3	3	3
	3	4	3	4

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rate and rhythm disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular infections, inflammations and associated manifestations		1		1
		2		2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	2	1	1		1
Gastrointestinal and abdominal pains (excl oral and throat)		1		1		
Nausea and vomiting symptoms	2	5	2	4		1
Oral soft tissue signs and symptoms		1		1		
Stomatitis and ulceration		1		1		
	3	10	3	8		2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	1	1	1		
Asthenic conditions	7	17	7	14		3
Death and sudden death	1	1			1	1
Febrile disorders	3	6	3	5		1
Feelings and sensations NEC	3	10	3	9		1
Gait disturbances		1		1		
General signs and symptoms NEC	1	2	1	2		
Oedema NEC	1	1	1	1		
Pain and discomfort NEC	2	5	2	4		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reactions	4	8	4	8		
	23	52	22	45	1	7

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	4	2	4		
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1		
Anaphylactic and anaphylactoid responses		4				4
	3	9	3	5		4

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Candida infections		2		2		
Coronavirus infections	3	5	2	3	1	2
Dental and oral soft tissue infections		1		1		
Influenza viral infections	1	2	1	2		
	4	10	3	8	1	2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Medication errors, product use errors and issues NEC		1		1
Off label uses		1		1
Product administration errors and issues	1	1	1	1
Underdoses NEC	1	1	1	1
	3	5	3	5

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood gas and acid base analyses		1		1
Physical examination procedures and organ system status		1		1
Vascular tests NEC (incl blood pressure)		1		1
		3		3

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Spontaneous

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone related signs and symptoms		1		1
Joint related signs and symptoms	3	6	3	6
Muscle pains	1	4	1	4
Muscle related signs and symptoms NEC	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	2	1	2
	6	14	6	14

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC		1				1
Headaches NEC	5	15	5	13		2
Neurological signs and symptoms NEC	1	3	1	3		
Paraesthesias and dysaesthesias	1	5	1	5		
Seizures and seizure disorders NEC		1				1
	7	25	7	21		4

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anxiety symptoms		1		1
		1		1

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	5	2	3		2
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	2	6	2	5		1
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1		
Upper respiratory tract signs and symptoms	3	5	3	5		
	8	18	8	14		4

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1		1		
Bullous conditions		1		1		
Dermal and epidermal conditions NEC		2		2		
Erythemas	2	4	2	4		
Pruritus NEC		1		1		
Rashes, eruptions and exanthems NEC		5		3		2
Urticarias	2	4	2	4		
	4	18	4	16		2

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1	1	
		1	1	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC		1		1		
Vascular hypertensive disorders NEC		2		1		1
		3		2		1

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Country Where Event Occurred

**COSTA RICA**

*System Organ Class*

**Blood and lymphatic system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	1	5	1	5		
Spleen disorders		1				1
Thrombocytopenias	1	1			1	1
	2	7	1	5	1	2

*System Organ Class*

**Cardiac disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders	1	2			1	2
Rate and rhythm disorders NEC		3		3		
	1	5		3	1	2

*System Organ Class*

**Ear and labyrinth disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	1	1	1		
Hearing losses	1	1			1	1
Inner ear signs and symptoms	2	2	2	2		
	4	4	3	3	1	1

*System Organ Class*

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	1	1	1	1		
Lid, lash and lacrimal infections, irritations and inflammations	2	2	2	2		
Ocular disorders NEC		2		2		
Ocular infections, inflammations and associated manifestations		6		6		
Pupil disorders		1				1
Visual disorders NEC		2		2		
	3	14	3	13		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal		1		1		
Dental disorders NEC	1	1	1	1		
Diarrhoea (excl infective)	5	9	4	7	1	2
Dyspeptic signs and symptoms	1	2			1	2
Faecal abnormalities NEC		1		1		
Flatulence, bloating and distension	1	2		1	1	1
Gastritis (excl infective)		2		1		1
Gastrointestinal and abdominal pains (excl oral and throat)	2	6	1	3	1	3
Gastrointestinal atonic and hypomotility disorders NEC		2		2		
Gastrointestinal disorders NEC		1		1		
Gingival disorders, signs and symptoms NEC	2	2	2	2		
Gingival haemorrhages	1	1	1	1		
Nausea and vomiting symptoms	3	16	1	12	2	4
Oral dryness and saliva altered		1				1
Oral soft tissue signs and symptoms	1	1	1	1		

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral soft tissue swelling and oedema		1		1		
Stomatitis and ulceration		1		1		
	17	50	11	36	6	14

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application and instillation site reactions		4		4		
Asthenic conditions	19	50	18	44	1	6
Body temperature altered		2		1		1
Death and sudden death	2	2			2	2
Febrile disorders	8	25	7	23	1	2
Feelings and sensations NEC	3	27	2	22	1	5
General signs and symptoms NEC	2	8	2	6		2
Pain and discomfort NEC	10	25	10	22		3
Therapeutic and nontherapeutic responses	3	6			3	6
Vaccination site reactions	25	51	25	51		
	72	200	64	173	8	27

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Anaphylactic and anaphylactoid responses	1	3			1	3
	1	4		1	1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	6	12	1	3	5	9
Dental and oral soft tissue infections	1	1	1	1		
Infections NEC	1	2	1	2		
Influenza viral infections	1	2	1	2		
Upper respiratory tract infections		1		1		
Vascular infections		1				1
	9	19	4	9	5	10

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific injuries NEC		1				1
Product administration errors and issues		2		2		
Skin injuries NEC	1	2		1	1	1
Vaccination related complications	2	2			2	2
	3	7		3	3	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	5	1	1	1	4
Coagulation and bleeding analyses		1		1		
Haematological analyses NEC		1		1		
Heart rate and pulse investigations		2		1		1
Liver function analyses		1				1
Platelet analyses	2	2			2	2

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)	1	1		1		
Virus identification and serology		1		1		
	5	14	2	6	3	8

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		1		1		
Joint related signs and symptoms	2	10	2	9		1
Muscle pains	4	22	4	20		2
Muscle related signs and symptoms NEC		3		3		
Musculoskeletal and connective tissue conditions NEC	1	4	1	3		1
Musculoskeletal and connective tissue pain and discomfort	17	36	17	36		
	24	76	24	72		4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	3	3			3	3
Coordination and balance disturbances		1		1		
Disturbances in consciousness NEC	5	7	4	6	1	1
Encephalopathies NEC		1				1
Headaches NEC	9	37	8	33	1	4
Migraine headaches		4		3		1

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 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Narcolepsy and hypersomnia		1		1		
Nervous system disorders NEC		1		1		
Neurological signs and symptoms NEC	3	9	2	6	1	3
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	1	7	1	7		
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC		3		2		1
Speech and language abnormalities		1		1		
Tremor (excl congenital)		1		1		
	22	78	16	63	6	15

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Communications disorders		1		1
Depressive disorders		1		1
Disturbances in initiating and maintaining sleep		1		1
Emotional and mood disturbances NEC		1		1
Sleep disorders NEC		1		1
		5		5

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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Renal disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pelvis and broad ligament disorders NEC		2		2
		2		2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	11	3	8		3
Bronchospasm and obstruction	1	1	1	1		
Coughing and associated symptoms	3	4	3	4		
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms		1		1		
Nasal congestion and inflammations	1	1	1	1		
Nasal disorders NEC	2	2	1	1	1	1
Pneumothorax and pleural effusions NEC		1				1
Respiratory tract disorders NEC	3	4	2	2	1	2
Upper respiratory tract signs and symptoms	6	13	6	11		2
	19	39	17	29	2	10

System Organ Class

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 \* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		4		3		1
Dermal and epidermal conditions NEC		3		3		
Dermatitis and eczema		2		1		1
Erythemas		1		1		
Pruritus NEC	5	7	5	7		
Purpura and related conditions	3	3	2	2	1	1
Rashes, eruptions and exanthems NEC	2	5	2	5		
Urticarias		1		1		
	10	26	9	23	1	3

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	1	3	1	3
	1	3	1	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Haemorrhages NEC	1	1			1	1
Non-site specific embolism and thrombosis		1				1
Non-site specific necrosis and vascular insufficiency NEC	1	1	1	1		
Vascular hypertensive disorders NEC		1				1
Vasculitides NEC		1		1		

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	2	6	1	2	1	4

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Country Where Event Occurred

**CROATIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Leukopenias NEC		1		1		
Lymphatic system disorders NEC	3	14	2	10	1	4
Thrombocytopenias		1				1
	3	17	2	11	1	6

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1			1	1
Cardiac signs and symptoms NEC	4	12	2	5	2	7
Cardiomyopathies	1	2			1	2
Heart failures NEC	1	5			1	5
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	10	20	2	6	8	14
Supraventricular arrhythmias		2				2
Ventricular arrhythmias and cardiac arrest	1	2			1	2
	19	45	4	11	15	34

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	5	1	1		4

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	1	3		1	1	2
Inner ear signs and symptoms	3	11	1	6	2	5
	5	19	2	8	3	11

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		1				1
Conjunctival and corneal bleeding and vascular disorders	1	3			1	3
Conjunctival infections, irritations and inflammations		1				1
Eyelid movement disorders		3				3
Lacrimation disorders	2	3	1	2	1	1
Lid, lash and lacrimal infections, irritations and inflammations		2		1		1
Ocular bleeding and vascular disorders NEC		2				2
Ocular disorders NEC	3	6	3	6		
Ocular infections, inflammations and associated manifestations		1		1		
Structural change, deposit and degeneration of eye NEC		1		1		
Visual disorders NEC		1				1
Visual impairment and blindness (excl colour blindness)		1				1
	6	25	4	11	2	14

System Organ Class

**Gastrointestinal disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	3	6	2	4	1	2
Dyspeptic signs and symptoms	1	2	1	2		
Gastritis (excl infective)	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	5	1	4		1
Gastrointestinal signs and symptoms NEC		3				3
Gastrointestinal spastic and hypermotility disorders	1	2	1	2		
Gingival haemorrhages		1		1		
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	13	43	9	31	4	12
Non-site specific gastrointestinal haemorrhages	1	1			1	1
Oral dryness and saliva altered		3		1		2
Oral soft tissue disorders NEC		1				1
Oral soft tissue signs and symptoms	2	10	1	5	1	5
Oral soft tissue swelling and oedema	1	4			1	4
Stomatitis and ulceration		1		1		
Tongue disorders		1				1
Tongue signs and symptoms		6				6
	24	91	16	52	8	39

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application and instillation site reactions		1		1		
Asthenic conditions	21	89	16	71	5	18
Death and sudden death	1	3			1	3
Febrile disorders	20	89	12	64	8	25
Feelings and sensations NEC	14	66	11	54	3	12

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbances	1	2			1	2
General signs and symptoms NEC		11		3		8
Oedema NEC	1	4	1	2		2
Pain and discomfort NEC	8	22	4	13	4	9
Therapeutic and nontherapeutic responses	1	2			1	2
Vaccination site reactions	26	214	16	153	10	61
	93	503	60	361	33	142

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	25			1	25
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses		4				4
Immune and associated conditions NEC		1		1		
	1	31		2	1	29

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	14	18		2	14	16
Ear infections	1	1			1	1
Escherichia infections		1				1
Klebsiella infections		1				1
Lower respiratory tract and lung infections		3				3

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Staphylococcal infections		1				1
Upper respiratory tract infections		1		1		
Urinary tract infections		1				1
Viral infections NEC		1		1		
	15	28		4	15	24

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Medication errors, product use errors and issues NEC		3		3		
Non-site specific injuries NEC	2	3			2	3
Off label uses		1		1		
Overdoses NEC		1		1		
Product administration errors and issues	1	2	1	1		1
Product preparation errors and issues		1		1		
Underdoses NEC		1				1
Vaccination related complications	13	14			13	14
	17	27	2	8	15	19

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1		1		
Blood gas and acid base analyses		1				1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carbohydrate tolerance analyses (incl diabetes)	3	3	2	2	1	1
Heart rate and pulse investigations	1	4	1	2		2
Ophthalmic function diagnostic procedures		1		1		
Physical examination procedures and organ system status	3	20	2	17	1	3
Skeletal and cardiac muscle analyses	1	2	1	2		
Vascular tests NEC (incl blood pressure)	8	18	4	7	4	11
Virus identification and serology		1		1		
White blood cell analyses	2	2	2	2		
	18	53	12	35	6	18

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	6	1	5		1
Diabetes mellitus (incl subtypes)		1				1
General nutritional disorders NEC		1		1		
	1	8	1	6		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	2	8	2	8		
Joint related signs and symptoms	2	18		16	2	2
Muscle pains	9	52	5	45	4	7
Muscle related signs and symptoms NEC	2	5	2	3		2

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle weakness conditions	1	5	1	3		2
Musculoskeletal and connective tissue conditions NEC	1	2	1	1		1
Musculoskeletal and connective tissue pain and discomfort	5	34	3	26	2	8
	22	124	14	102	8	22

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes	1	1	1	1		
Abnormal sleep-related events		1		1		
Central nervous system haemorrhages and cerebrovascular accidents	5	8			5	8
Central nervous system vascular disorders NEC	1	1			1	1
Coma states	1	1			1	1
Coordination and balance disturbances	2	3			2	3
Disturbances in consciousness NEC	6	13		2	6	11
Dyskinesias and movement disorders NEC		3		1		2
Encephalitis NEC		1				1
Facial cranial nerve disorders	3	11		2	3	9
Headaches NEC	14	82	10	61	4	21
Memory loss (excl dementia)	1	1	1	1		
Mental impairment (excl dementia and memory loss)		2		2		
Migraine headaches		1		1		
Neurological signs and symptoms NEC	3	18	1	10	2	8
Neuromuscular disorders NEC		2		1		1
Olfactory nerve disorders	1	1			1	1
Paraesthesias and dysaesthesias	3	21	2	12	1	9

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis and paresis (excl cranial nerve)	3	5			3	5
Peripheral neuropathies NEC		1		1		
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC		5		2		3
Speech and language abnormalities	2	3	1	1	1	2
Transient cerebrovascular events	1	1			1	1
Tremor (excl congenital)	3	12	2	9	1	3
	50	199	18	108	32	91

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		1		1		
Communications disorders		1				1
Confusion and disorientation		4		2		2
Disturbances in initiating and maintaining sleep	2	5	2	5		
Fear symptoms and phobic disorders (incl social phobia)		1				1
Increased physical activity levels		1				1
Mental disorders due to a general medical condition NEC		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Panic attacks and disorders		2				2
Parasomnias		1		1		
Speech and language usage disturbances	1	1			1	1
	3	18	2	9	1	9

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		1				1
Urinary abnormalities		1		1		
Urinary tract signs and symptoms NEC		1		1		
		3		2		1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast signs and symptoms	1	1	1	1
Menstruation and uterine bleeding NEC		1		1
Menstruation with increased bleeding		1		1
	1	3	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	5	24	1	6	4	18
Bronchospasm and obstruction		9				9
Conditions associated with abnormal gas exchange	1	1			1	1
Coughing and associated symptoms	3	9	3	5		4
Diaphragmatic disorders		1				1
Laryngeal spasm, oedema and obstruction		2				2
Lower respiratory tract signs and symptoms		2		1		1
Nasal congestion and inflammations		1		1		
Pharyngeal disorders (excl infections and neoplasms)		2		1		1
Pneumothorax and pleural effusions NEC		1				1
Pulmonary thrombotic and embolic conditions	1	2			1	2
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC		3				3
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	8	17	4	9	4	8
	18	76	8	23	10	53

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		2				2
Apocrine and eccrine gland disorders	3	12	2	8	1	4
Bullous conditions		1				1
Dermal and epidermal conditions NEC	3	9		2	3	7
Dermatitis and eczema		2		1		1
Erythemas	2	21		4	2	17
Pruritus NEC	1	13		4	1	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Psoriatic conditions		1		1			
Rashes, eruptions and exanthems NEC	3	23	1	5	2	18	
Skin haemorrhages		1				1	
Skin hyperplasias and hypertrophies	1	1			1	1	
Skin vascular conditions NEC		1		1			
Skin vasomotor conditions		1				1	
Urticarias		6		1		5	
	13	94	3	27	10	67	

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues	2	2	2	2
	2	2	2	2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Haemorrhages NEC	1	1	1	1		
Non-site specific embolism and thrombosis	1	1			1	1
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	2	3			2	3
Peripheral vascular disorders NEC	1	6		1	1	5
Peripheral vasoconstriction, necrosis and vascular insufficiency	4	4	1	1	3	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Site specific vascular disorders NEC		3				3
Vascular hypertensive disorders NEC	5	11		1	5	10
Vascular hypotensive disorders		4		1		3
	15	35	2	6	13	29

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**CYPRUS**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC		6		5		1
		6		5		1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders	1	3			1	3
Rate and rhythm disorders NEC		4		1		3
	1	7		1	1	6

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		2		2
Hearing losses		1		1
Inner ear signs and symptoms		1		1
		4		4

System Organ Class

**Eye disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1		1		
Ocular disorders NEC		1		1		
Ocular sensation disorders		1				1
		3		2		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	2	1	2		
Gastric and oesophageal haemorrhages		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1		
Gastrointestinal signs and symptoms NEC		1		1		
Nausea and vomiting symptoms	6	17	5	16	1	1
Oral soft tissue signs and symptoms		3		1		2
Tongue signs and symptoms		2		2		
	8	27	7	23	1	4

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	9	36	9	36		
Death and sudden death	1	1			1	1
Febrile disorders	3	18	3	18		
Feelings and sensations NEC	3	18	3	18		
Gait disturbances		3		3		

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General signs and symptoms NEC	2	7	1	6	1	1
Inflamations		1		1		
Injection site reactions	1	1	1	1		
Interactions		1		1		
Oedema NEC		2		1		1
Pain and discomfort NEC	2	7	2	7		
Therapeutic and nontherapeutic responses	3	7	1	1	2	6
Vaccination site reactions	2	21	2	21		
	26	123	22	114	4	9

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Anaphylactic and anaphylactoid responses		2				2
		3		1		2

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	1			1	1
Bacterial infections NEC	1	1			1	1
Central nervous system and spinal infections		1				1
Coronavirus infections	2	13		1	2	12
Dental and oral soft tissue infections		1				1
Influenza viral infections		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper respiratory tract infections		1		1		
Viral infections NEC	1	1			1	1
	5	20		3	5	17

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Medication errors, product use errors and issues NEC		1		1		
Off label uses	1	2	1	2		
Overdoses NEC		1		1		
Product administration errors and issues	1	2	1	2		
Skin injuries NEC		2		2		
Vaccination related complications		1				1
	2	9	2	8		1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		3		1		2
Coagulation and bleeding analyses		1		1		
Physical examination procedures and organ system status		1		1		
Protein analyses NEC	1	1	1	1		
Vascular tests NEC (incl blood pressure)		1				1
Virus identification and serology		1				1
	1	8	1	4		4

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\* AE=Adverse Event  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sodium imbalance	1	2	1	2		
Total fluid volume decreased	1	1			1	1
	2	3	1	2	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		1		1		
Joint related signs and symptoms	3	17	3	17		
Muscle pains	9	31	9	31		
Muscle weakness conditions	1	2		1	1	1
Musculoskeletal and connective tissue conditions NEC		2		2		
Musculoskeletal and connective tissue pain and discomfort		4		4		
	13	57	12	56	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		1				1
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Coordination and balance disturbances		1		1		
Disturbances in consciousness NEC		3				3
Facial cranial nerve disorders		8				8

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised tonic-clonic seizures		1				1
Headaches NEC	2	17	2	17		
Migraine headaches		2		2		
Neurological signs and symptoms NEC	1	9		8	1	1
Paraesthesias and dysaesthesias	2	7	2	5		2
Sensory abnormalities NEC		2		2		
Tremor (excl congenital)		2		2		
	6	54	4	37	2	17

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation		2		2
Disturbances in initiating and maintaining sleep	1	3	1	3
	1	5	1	5

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	1	1	1	1
Renal failure and impairment	1	1	1	1
	2	2	2	2

System Organ Class

**Reproductive system and breast disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cervix disorders NEC		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	8	2	5		3
Coughing and associated symptoms		1		1		
Nasal congestion and inflammations		1		1		
Nasal disorders NEC		1				1
Paranasal sinus disorders (excl infections and neoplasms)		1		1		
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Pulmonary oedemas	2	2			2	2
Pulmonary thrombotic and embolic conditions	4	6			4	6
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms		2		2		
	8	24	2	11	6	13

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Apocrine and eccrine gland disorders		3		3
Dermatitis and eczema		2		2
Erythemas		1		1
Rashes, eruptions and exanthems NEC		3		3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		9		9

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections	1	1			1	1
Circulatory collapse and shock	1	1			1	1
Site specific vascular disorders NEC		1		1		
Vascular hypertensive disorders NEC	1	2	1	1		1
Vascular hypotensive disorders	1	3			1	3
Vasculitides NEC	1	2		1	1	1
	5	10	1	3	4	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**CZECH REPUBLIC**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		3		1		2
Coagulopathies		1				1
Leukocytoses NEC	1	2	1	2		
Leukopenias NEC	1	2			1	2
Lymphatic system disorders NEC	13	97	7	46	6	51
Neutropenias		1				1
Spleen disorders		1				1
Thrombocytopenias		1				1
	15	108	8	49	7	59

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	1			1	1
Cardiac disorders NEC	1	1			1	1
Cardiac signs and symptoms NEC	5	21	1	7	4	14
Cardiomyopathies		1				1
Heart failures NEC	4	5			4	5
Ischaemic coronary artery disorders	4	9		1	4	8
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	10	43	1	17	9	26
Supraventricular arrhythmias	4	9		1	4	8
Ventricular arrhythmias and cardiac arrest	3	6			3	6
	32	97	2	26	30	71

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	15	3	8		7
Hearing losses	4	9	1	2	3	7
Hyperacusia	1	1			1	1
Inner ear disorders NEC		1				1
Inner ear signs and symptoms	17	57	7	33	10	24
	25	83	11	43	14	40

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival infections, irritations and inflammations	1	1	1	1		
Eyelid movement disorders		1				1
Glaucomas (excl congenital)	1	1			1	1
Lacrimation disorders	2	4	1	2	1	2
Lid, lash and lacrimal infections, irritations and inflammations	3	6			3	6
Lid, lash and lacrimal structural disorders		1		1		
Ocular bleeding and vascular disorders NEC	3	3			3	3
Ocular disorders NEC	7	16	5	10	2	6
Ocular infections, inflammations and associated manifestations	2	7		3	2	4
Ocular nerve and muscle disorders		2		1		1
Ocular sensation disorders	2	5	1	4	1	1
Orbital structural change, deposit and degeneration	1	1			1	1
Pupil disorders		1				1
Visual disorders NEC	9	22	1	8	8	14
Visual impairment and blindness (excl colour blindness)		5		1		4

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	31	76	9	31	22	45

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders	2	5	2	4		1
Diarrhoea (excl infective)	10	42	6	29	4	13
Duodenal ulcers and perforation		1				1
Dyspeptic signs and symptoms	4	9	2	5	2	4
Flatulence, bloating and distension	1	3	1	2		1
Gastric ulcers and perforation	2	2			2	2
Gastrointestinal and abdominal pains (excl oral and throat)	8	25	5	14	3	11
Gastrointestinal atonic and hypomotility disorders NEC	1	4		2	1	2
Gastrointestinal disorders NEC	1	3	1	3		
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC	5	16	1	5	4	11
Gastrointestinal spastic and hypermotility disorders		2		1		1
Gastrointestinal vascular occlusion and infarction		4				4
Gingival disorders, signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	42	164	31	123	11	41
Non-site specific gastrointestinal haemorrhages		3				3
Oesophagitis (excl infective)		1		1		
Oral dryness and saliva altered	3	7	1	4	2	3
Oral soft tissue signs and symptoms	15	38	2	7	13	31
Oral soft tissue swelling and oedema	4	11		1	4	10
Pancreatic disorders NEC		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis and ulceration	2	4			2	4
Tongue signs and symptoms	7	17	1	2	6	15
	108	364	54	204	54	160

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		1		1		
Application and instillation site reactions	1	3	1	1		2
Asthenic conditions	91	348	71	272	20	76
Death and sudden death	1	6			1	6
Febrile disorders	72	276	38	171	34	105
Feelings and sensations NEC	47	213	37	175	10	38
Gait disturbances	6	13	1	5	5	8
General signs and symptoms NEC	66	156	45	86	21	70
Inflamations		2		1		1
Injection site reactions		4		3		1
Interactions	1	1			1	1
Mass conditions NEC	2	3		1	2	2
Mucosal findings abnormal		3		1		2
Oedema NEC	9	24	5	10	4	14
Pain and discomfort NEC	24	77	16	48	8	29
Therapeutic and nontherapeutic responses	9	18			9	18
Vaccination site reactions	82	388	52	242	30	146
	411	1,536	266	1017	145	519

System Organ Class

**Hepatobiliary disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholestasis and jaundice		1		1		
Gal bladder disorders NEC	1	1	1	1		
Hepatic enzymes and function abnormalities		1				1
Hepatic vascular disorders		1				1
Hepatocellular damage and hepatitis NEC		1				1
	1	5	1	2		3

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	22	49	5	14	17	35
Allergies to foods, food additives, drugs and other chemicals	4	10		2	4	8
Anaphylactic and anaphylactoid responses	5	14			5	14
Immune and associated conditions NEC		1				1
Transplant rejections	1	1			1	1
	32	75	5	16	27	59

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2		1		1
Bacterial infections NEC	2	3			2	3
Central nervous system and spinal infections		1				1
Coronavirus infections	24	55	2	11	22	44
Dental and oral soft tissue infections	1	3			1	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enterococcal infections	1	2			1	2
Escherichia infections		1				1
Eye and eyelid infections	1	1			1	1
Hepatobiliary and spleen infections		1				1
Herpes viral infections	10	20	1	2	9	18
Infections NEC	1	1	1	1		
Influenza viral infections		1		1		
Klebsiella infections		1				1
Lower respiratory tract and lung infections	4	8			4	8
Sepsis, bacteraemia, viraemia and fungaemia NEC		3				3
Skin structures and soft tissue infections	1	2	1	2		
Streptococcal infections	1	2			1	2
Upper respiratory tract infections	5	7	5	7		
Urinary tract infections	2	4		1	2	3
Viral infections NEC		3		1		2
	53	121	10	27	43	94

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation		2		2		
Medication errors, product use errors and issues NEC		7		7		
Muscle, tendon and ligament injuries		1				1
Non-site specific injuries NEC	4	10		4	4	6
Off label uses		11		11		
Overdoses NEC	1	4	1	4		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administration errors and issues	3	98	3	98		
Product preparation errors and issues	1	84	1	84		
Skin injuries NEC	2	3			2	3
Thermal burns		2				2
Vaccination related complications	9	16		2	9	14
	20	239	5	212	15	27

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteria identification and serology (excl mycobacteria)	1	1	1	1		
Blood gas and acid base analyses	2	6		3	2	3
Carbohydrate tolerance analyses (incl diabetes)		1		1		
Coagulation and bleeding analyses		2		1		1
ECG investigations	2	2	1	1	1	1
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	3	7	1	3	2	4
Immunoglobulin analyses		1		1		
Immunology analyses NEC		1		1		
Investigations NEC	1	1	1	1		
Liver function analyses		2		2		
Mineral and electrolyte analyses		1		1		
Physical examination procedures and organ system status	2	10	1	7	1	3
Protein analyses NEC		5		2		3
Renal function analyses		1		1		
Skeletal and cardiac muscle analyses		1				1
Urinalysis NEC	2	2	2	2		

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)	8	21		8	8	13
Virus identification and serology	2	6		2	2	4
	23	72	7	39	16	33

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	14	36	11	27	3	9
Disorders of purine metabolism		1		1		
Fluid intake decreased		1		1		
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1				1
Hyperglycaemic conditions NEC	3	5		1	3	4
Hypoglycaemic conditions NEC	1	2		1	1	1
Potassium imbalance	2	5			2	5
Total fluid volume decreased		2		1		1
	20	53	11	32	9	21

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	2	3			2	3
Bone disorders NEC		1				1
Bone related signs and symptoms	5	10	2	5	3	5
Joint related disorders NEC		1				1
Joint related signs and symptoms	53	177	39	130	14	47

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ligament disorders	1	1	1	1		
Muscle infections and inflammations	1	1			1	1
Muscle pains	26	116	22	87	4	29
Muscle related signs and symptoms NEC	6	12	2	5	4	7
Muscle tone abnormalities		1		1		
Muscle weakness conditions	5	15	2	10	3	5
Musculoskeletal and connective tissue conditions NEC	5	19	2	14	3	5
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	50	130	35	102	15	28
Rheumatoid arthropathies	2	2			2	2
Soft tissue disorders NEC	2	2	2	2		
Tendon disorders	1	1			1	1
	160	493	107	357	53	136

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostatic neoplasms malignant		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	1			1	1

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System Organ Class

**Nervous system disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		11	22
		2	2
			1
1	2	2	3
1	2	2	3
		1	2
		1	1
5	19	21	51
2	4	4	4
		6	14
35	173	7	32
		1	2
			3
	2	3	5
2	7	2	6
		1	1
			2
	1		
		3	6
8	32	7	21
		1	2
	1	1	1
1	6	3	4
7	36	14	50
		7	16
		1	4
		4	10
2	5	3	6
	1		1
	3	2	5

Central nervous system haemorrhages and cerebrovascular accidents	11	22
Cerebrovascular venous and sinus thrombosis	2	2
Coma states		1
Coordination and balance disturbances	3	5
Cortical dysfunction NEC	3	5
Cranial nerve disorders NEC	1	2
Dementia (excl Alzheimer's type)	1	1
Disturbances in consciousness NEC	26	70
Dyskinesias and movement disorders NEC	6	8
Facial cranial nerve disorders	6	14
Headaches NEC	42	205
Increased intracranial pressure disorders	1	2
Memory loss (excl dementia)		3
Mental impairment (excl dementia and memory loss)	3	7
Migraine headaches	4	13
Mononeuropathies	1	1
Multiple sclerosis acute and progressive		2
Muscle tone abnormal		1
Narcolepsy and hypersomnia	3	6
Neurological signs and symptoms NEC	15	53
Neurologic visual problems NEC	1	2
Neuromuscular disorders NEC	1	2
Olfactory nerve disorders	4	10
Paraesthesias and dysaesthesias	21	86
Paralysis and paresis (excl cranial nerve)	7	16
Peripheral neuropathies NEC	1	4
Seizures and seizure disorders NEC	4	10
Sensory abnormalities NEC	5	11
Sleep disturbances NEC		2
Speech and language abnormalities	2	8

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal cord and nerve root disorders NEC		2				2
Transient cerebrovascular events	1	2			1	2
Tremor (excl congenital)	6	16	1	8	5	8
	182	595	65	302	117	293

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
Stillbirth and foetal death		1		1
		2		2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	12	1	8		4
Attention deficit and disruptive behaviour disorders	1	1	1	1		
Communications disorders		1				1
Confusion and disorientation	4	16	1	5	3	11
Deliria		3				3
Depressive disorders	1	3		1	1	2
Disturbances in initiating and maintaining sleep	8	19	6	13	2	6
Eating disorders NEC		2		1		1
Emotional and mood disturbances NEC		1		1		
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1		

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucinations (excl sleep-related)	1	3			1	3
Increased physical activity levels	1	4	1	4		
Mental disorders NEC		1		1		
Mood alterations with depressive symptoms		1		1		
Mood disorders NEC	2	7	1	2	1	5
Parasomnias		3		3		
Perception disturbances NEC		1		1		
Sleep disorders NEC		4		2		2
Speech and language usage disturbances	1	2		1	1	1
Speech articulation and rhythm disturbances	1	1			1	1
Thinking disturbances		2		1		1
	22	88	12	47	10	41

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	2	3			2	3
Bladder infections and inflammations		1		1		
Genitourinary tract infections and inflammations NEC	1	3	1	1		2
Renal disorders NEC		1		1		
Renal failure and impairment	2	7			2	7
Urinary tract signs and symptoms NEC	2	2	2	2		
	7	17	3	5	4	12

System Organ Class

**Reproductive system and breast disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	2	6	1	3	1	3
Menstruation and uterine bleeding NEC		2		2		
Menstruation with decreased bleeding		1		1		
	2	9	1	6	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	29	89	6	23	23	66
Bronchospasm and obstruction	1	5		3	1	2
Conditions associated with abnormal gas exchange		3		1		2
Coughing and associated symptoms	14	36	7	24	7	12
Laryngeal spasm, oedema and obstruction	1	3		1	1	2
Lower respiratory tract inflammatory and immunologic conditions	1	3		1	1	2
Lower respiratory tract signs and symptoms	1	2		1	1	1
Nasal congestion and inflammations	3	4	3	4		
Nasal disorders NEC	4	8	1	4	3	4
Pharyngeal disorders (excl infections and neoplasms)	2	9			2	9
Pulmonary oedemas	1	1			1	1
Pulmonary thrombotic and embolic conditions	2	4			2	4
Respiratory failures (excl neonatal)	2	6			2	6
Respiratory tract disorders NEC	1	3			1	3
Upper respiratory tract signs and symptoms	16	45	9	27	7	18
	78	221	26	89	52	132

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	1	1	1		
Alopecias		2		1		1
Angioedemas	1	2			1	2
Apocrine and eccrine gland disorders	7	31	6	26	1	5
Bullous conditions	2	2			2	2
Dermal and epidermal conditions NEC	10	18	4	9	6	9
Dermatitis and eczema	8	12	1	2	7	10
Dermatitis ascribed to specific agent	2	4			2	4
Erythemas	9	33	4	20	5	13
Exfoliative conditions	1	2	1	1		1
Panniculitides	1	1			1	1
Photosensitivity and photodermatosis conditions		1		1		
Pruritus NEC	13	42	6	15	7	27
Purpura and related conditions	5	5			5	5
Rashes, eruptions and exanthems NEC	29	82	5	22	24	60
Skin and subcutaneous conditions NEC		1		1		
Skin vasomotor conditions	1	1	1	1		
Urticarias	5	11		2	5	9
	95	251	29	102	66	149

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues		4		2		2
Social issues NEC	1	1	1	1		
	1	5	1	3		2

System Organ Class

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 \* AE=Adverse Event  
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System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Limb therapeutic procedures		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysms and dissections non-site specific	1	1			1	1
Aortic necrosis and vascular insufficiency	1	2			1	2
Blood pressure disorders NEC		2		1		1
Circulatory collapse and shock	3	10			3	10
Haemorrhages NEC	3	5	1	1	2	4
Lymphoedemas		1		1		
Non-site specific embolism and thrombosis	1	1			1	1
Non-site specific necrosis and vascular insufficiency NEC		1				1
Non-site specific vascular disorders NEC		2		1		1
Peripheral embolism and thrombosis	4	4			4	4
Peripheral vascular disorders NEC	5	20	1	10	4	10
Peripheral vasoconstriction, necrosis and vascular insufficiency	2	10	1	8	1	2
Site specific vascular disorders NEC	3	9	2	6	1	3
Vascular hypertensive disorders NEC	20	37	3	10	17	27
Vascular hypotensive disorders	3	22		5	3	17
Vena caval embolism and thrombosis		1				1
	46	128	8	43	38	85

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Country Where Event Occurred

**DENMARK**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		2		1		1
Bleeding tendencies	1	1			1	1
Coagulopathies	1	1			1	1
Haemolyses NEC		1				1
Leukocytoses NEC		1		1		
Leukopenias NEC	1	4	1	1		3
Lymphatic system disorders NEC	1	35	1	25		10
Marrow depression and hypoplastic anaemias	1	2			1	2
Spleen disorders	2	2			2	2
Thrombocytopenias	3	5			3	5
Thrombocytoses	1	1			1	1
	11	55	2	28	9	27

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	2	2			2	2
Cardiac signs and symptoms NEC	2	28	2	16		12
Cardiomyopathies		1				1
Coronary artery disorders NEC	2	2			2	2
Heart failures NEC	1	2			1	2
Ischaemic coronary artery disorders	4	7			4	7
Noninfectious myocarditis		1				1
Noninfectious pericarditis	2	2			2	2
Rate and rhythm disorders NEC	3	12		2	3	10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular arrhythmias	5	13		2	5	11
Ventricular arrhythmias and cardiac arrest	8	9			8	9
	29	79	2	20	27	59

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		3		2		1
External ear disorders NEC		1		1		
Hearing losses	1	4		2	1	2
Hyperacusia		2		1		1
Inner ear disorders NEC		1				1
Inner ear signs and symptoms	1	9		5	1	4
	2	20		11	2	9

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal cortical hypofunctions		1		1
		1		1

System Organ Class

**Eye disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders		1				1
Conjunctival infections, irritations and inflammations		1		1		
Eyelid movement disorders		2				2
Lacrimation disorders		4		4		
Lid, lash and lacrimal infections, irritations and inflammations		3		2		1
Ocular disorders NEC	1	11		9	1	2
Ocular infections, inflammations and associated manifestations		7		6		1
Ocular sensation disorders	2	5		1	2	4
Pupil disorders		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Visual disorders NEC	2	10		2	2	8
Visual impairment and blindness (excl colour blindness)		2		1		1
	6	48		27	6	21

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Colitis (excl infective)	2	2	1	1	1	1
Diarrhoea (excl infective)	9	37	4	22	5	15
Dyspeptic signs and symptoms		1				1
Faecal abnormalities NEC		1		1		
Flatulence, bloating and distension		2		2		
Gastric ulcers and perforation	1	1			1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	6	29	1	13	5	16
Gastrointestinal atonic and hypomotility disorders NEC	1	3		2	1	1
Gastrointestinal disorders NEC		1		1		
Gastrointestinal mucosal dystrophies and secretion disorders		1		1		
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	1			1	1
Gastrointestinal signs and symptoms NEC	2	10	1	4	1	6
Gastrointestinal spastic and hypermotility disorders		1		1		
Gastrointestinal vascular occlusion and infarction	2	2			2	2
Nausea and vomiting symptoms	22	195	14	118	8	77
Non-mechanical ileus		1				1
Non-site specific gastrointestinal haemorrhages	3	3			3	3
Oral dryness and saliva altered		6		4		2
Oral soft tissue signs and symptoms	4	27	2	15	2	12
Oral soft tissue swelling and oedema	1	4			1	4
Salivary gland disorders NEC		1		1		
Salivary gland enlargements		1		1		
Stomatitis and ulceration		1		1		
Tongue signs and symptoms	1	15		4	1	11
	55	347	23	192	32	155

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	45	340	14	202	31	138
Body temperature altered		2				2

\* I=Interval, C=Cumulative  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death and sudden death	9	21			9	21
Febrile disorders	22	225	8	147	14	78
Feelings and sensations NEC	8	118	2	73	6	45
Gait disturbances	2	5		1	2	4
General signs and symptoms NEC	16	100	4	43	12	57
Inflammations		1				1
Injection site reactions		5		5		
Interactions		1				1
Oedema NEC	5	11	1	3	4	8
Pain and discomfort NEC	20	101	5	49	15	52
Therapeutic and nontherapeutic responses	1	10		1	1	9
Vaccination site reactions	36	341	34	306	2	35
	164	1,281	68	830	96	451

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatocellular damage and hepatitis NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	25	2	7		18
Allergies to foods, food additives, drugs and other chemicals	2	3			2	3

\* I=Interval, C=Cumulative  
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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic and anaphylactoid responses	7	29			7	29
Atopic disorders		1		1		
Immune and associated conditions NEC	2	4		1	2	3
	13	62	2	9	11	53

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		4				4
Bacterial infections NEC		4				4
Central nervous system and spinal infections		1				1
Coronavirus infections	5	23	3	4	2	19
Eye and eyelid infections		1				1
Fungal infections NEC		1		1		
Herpes viral infections		2		1		1
Infections NEC	2	5	1	2	1	3
Influenza viral infections	1	11		6	1	5
Lower respiratory tract and lung infections	8	21			8	21
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	5			2	5
Staphylococcal infections		1				1
Streptococcal infections		1				1
Upper respiratory tract infections		6		5		1
Urinary tract infections	1	4		1	1	3
Vascular infections	1	1			1	1
Viral infections NEC		1		1		
	20	92	4	21	16	71

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product		1		1		
Exposures associated with pregnancy, delivery and lactation	1	4	1	3		1
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC		7		7		
Non-site specific injuries NEC	4	11		1	4	10
Off label uses	2	10	2	10		
Pathways and sources of exposure		1		1		
Poisoning and toxicity	1	2			1	2
Product administration errors and issues	2	11	2	10		1
Product preparation errors and issues		1		1		
Site specific injuries NEC		2				2
Skin injuries NEC	2	4		1	2	3
Transplantation complications		1				1
Underdoses NEC		2		2		
Vaccination related complications		2		1		1
	12	60	5	38	7	22

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	1	1			1	1
Blood counts NEC		1		1		
Blood gas and acid base analyses	3	9	1	2	2	7
Carbohydrate tolerance analyses (incl diabetes)		2		2		
Coagulation and bleeding analyses	3	3	1	1	2	2
ECG investigations		2				2
Haematological analyses NEC	1	1			1	1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	8	20	3	13	5	7
Liver function analyses	1	4	1	4		
Metabolism tests NEC		1		1		
Mineral and electrolyte analyses		5		5		
Physical examination procedures and organ system status	2	9	1	6	1	3
Protein analyses NEC	5	18	2	6	3	12
Red blood cell analyses		3				3
Renal function analyses		3				3
Skeletal and cardiac muscle analyses	1	5		1	1	4
Tissue enzyme analyses NEC		1		1		
Vascular tests NEC (incl blood pressure)	3	18	1	7	2	11
Virus identification and serology		1				1
White blood cell analyses		1		1		
	28	108	10	51	18	57

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	9		4	1	5
Fluid intake decreased	1	3		1	1	2
Hyperglycaemic conditions NEC		1				1
Hypoglycaemic conditions NEC		2		1		1
Metabolic acidoses (excl diabetic acidoses)	1	2			1	2
Metabolic alkaloses		1		1		
Potassium imbalance		2				2
Total fluid volume decreased	1	2			1	2
	4	22		7	4	15

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1		1		
Bursal disorders		1				1
Joint related disorders NEC		3		2		1
Joint related signs and symptoms	7	61	1	36	6	25
Muscle pains	8	122	1	89	7	33
Muscle related signs and symptoms NEC	3	16	2	10	1	6
Muscle weakness conditions	3	12	2	4	1	8
Musculoskeletal and connective tissue conditions NEC	2	8	1	3	1	5
Musculoskeletal and connective tissue pain and discomfort	11	76	3	57	8	19
Myopathies		1				1
Rheumatoid arthropathies	1	1			1	1
Soft tissue disorders NEC	1	2	1	2		
Spondyloarthropathies		1				1
	36	305	11	204	25	101

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias acute NEC		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		1				1

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System Organ Class

**Nervous system disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		16	23
			1
		1	6
		2	2
		1	1
1	11	12	44
			1
		1	2
	1	5	7
		1	4
21	209	16	84
		1	1
		4	6
	2	4	5
1	4	1	3
1	1		1
	1	2	3
			1
9	86	8	84
			2
	2		
3	32	2	23
		8	14
			1
		3	8
1	13	2	8
	1		
	1	3	6
	1		
		1	2

Central nervous system haemorrhages and cerebrovascular accidents	16	23
Coma states		1
Coordination and balance disturbances	1	6
Cortical dysfunction NEC	2	2
Dementia (excl Alzheimer's type)	1	1
Disturbances in consciousness NEC	13	55
Dyskinesias and movement disorders NEC		1
Eye movement disorders	1	2
Facial cranial nerve disorders	5	8
Generalised tonic-clonic seizures	1	4
Headaches NEC	37	293
Increased intracranial pressure disorders	1	1
Memory loss (excl dementia)	4	6
Mental impairment (excl dementia and memory loss)	4	7
Migraine headaches	2	7
Muscle tone abnormal	1	2
Narcolepsy and hypersomnia	2	4
Nervous system disorders NEC		1
Neurological signs and symptoms NEC	17	170
Neurologic visual problems NEC		2
Olfactory nerve disorders		2
Paraesthesias and dysaesthesias	5	55
Paralysis and paresis (excl cranial nerve)	8	14
Parkinson's disease and parkinsonism		1
Seizures and seizure disorders NEC	3	8
Sensory abnormalities NEC	3	21
Sleep disturbances NEC		1
Speech and language abnormalities	3	7
Structural brain disorders NEC		1
Transient cerebrovascular events	1	2

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor (excl congenital)	4	20		7	4	13
	135	729	37	372	98	357

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	5		2	1	3
Behaviour and socialisation disturbances	1	2			1	2
Confusion and disorientation	5	13		1	5	12
Deliria	3	8			3	8
Delusional symptoms		1				1
Disturbances in initiating and maintaining sleep	1	6	1	6		
Eating disorders NEC		1		1		
Hallucinations (excl sleep-related)		1				1
Increased physical activity levels	1	10		7	1	3
Panic attacks and disorders		1				1
Perception disturbances NEC	1	5		4	1	1
Sleep disorders NEC	2	3	2	3		
Thinking disturbances		1				1

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\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	15	57	3	24	12	33

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	3			1	3
Glomerulonephritis and nephrotic syndrome	1	1			1	1
Renal failure and impairment	2	8			2	8
Urinary abnormalities	2	3	1	1	1	2
Urinary tract signs and symptoms NEC		2		1		1
	6	17	1	2	5	15

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		1		1		
Menopausal effects on the genitourinary tract		1				1
Vulvovaginal disorders NEC	1	2		1	1	1
Vulvovaginal signs and symptoms		3		3		
	1	7		5	1	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	31	121	3	29	28	92
Bronchospasm and obstruction	7	20		1	7	19
Conditions associated with abnormal gas exchange	2	5			2	5
Coughing and associated symptoms	8	30	1	15	7	15
Laryngeal spasm, oedema and obstruction		1				1
Lower respiratory tract inflammatory and immunologic conditions		2				2
Lower respiratory tract signs and symptoms	1	3	1	2		1
Nasal congestion and inflammations		5		5		
Nasal disorders NEC	2	7	1	2	1	5
Parenchymal lung disorders NEC	4	5			4	5
Pharyngeal disorders (excl infections and neoplasms)	1	15		5	1	10
Pneumothorax and pleural effusions NEC		2				2
Pulmonary hypertensions		1				1
Pulmonary oedemas	2	7			2	7
Pulmonary thrombotic and embolic conditions	18	23			18	23
Respiratory failures (excl neonatal)	4	15			4	15
Respiratory signs and symptoms NEC		2		2		
Respiratory tract disorders NEC	2	4		1	2	3
Tracheal disorders (excl infections and neoplasms)	1	1			1	1
Upper respiratory tract signs and symptoms	7	65	3	46	4	19
	90	334	9	108	81	226

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		7				7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	4	22		13	4	9
Dermal and epidermal conditions NEC		8		4		4
Dermatitis and eczema	1	4	1	2		2
Erythemas	2	39	1	24	1	15
Photosensitivity and photodermatosis conditions	1	1	1	1		
Pruritus NEC	3	45	3	32		13
Rashes, eruptions and exanthems NEC	8	76	4	52	4	24
Skin haemorrhages	1	1			1	1
Skin vasomotor conditions	1	2			1	2
Urticarias	8	40	4	25	4	15
	29	245	14	153	15	92

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC		1		1		
Circulatory collapse and shock		1				1
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis	9	11			9	11
Non-site specific necrosis and vascular insufficiency NEC	1	1			1	1
Non-site specific vascular disorders NEC	1	2			1	2
Peripheral embolism and thrombosis	9	10			9	10
Peripheral vascular disorders NEC	1	17	1	11		6
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	2			1	2
Phlebitis NEC	1	1			1	1
Site specific vascular disorders NEC	1	11		3	1	8
Vascular hypertensive disorders NEC	3	19	1	7	2	12

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular hypotensive disorders	3	11		1	3	10
Vasculitides NEC	1	1	1	1		
	31	89	3	25	28	64

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**ECUADOR**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	4	1	4
Nausea and vomiting symptoms		1		1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oral soft tissue swelling and oedema		1		1
	1	6	1	6

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	2	2	2		
Febrile disorders	5	6	5	6		
Feelings and sensations NEC	1	1	1	1		
Oedema NEC		1		1		
Pain and discomfort NEC	4	5	4	5		
Therapeutic and nontherapeutic responses	1	4			1	4
Vaccination site reactions	4	6	4	6		
	17	25	16	21	1	4

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	1	8		2	1	6
Upper respiratory tract infections		3		3		
	1	11		5	1	6

System Organ Class

**Investigations**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular tests NEC (incl blood pressure)	1	2	1	2
Virus identification and serology		1		1
	1	3	1	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Muscle pains	1	1	1	1
Musculoskeletal and connective tissue conditions NEC		1		1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	3	4	3	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Headaches NEC	1	1	1	1		
Neurological signs and symptoms NEC		2		2		
	2	4	1	3	1	1

System Organ Class

**Psychiatric disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Mood alterations with depressive symptoms		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coughing and associated symptoms	1	1	1	1
Parenchymal lung disorders NEC	1	1	1	1
Upper respiratory tract signs and symptoms		1		1
	2	3	2	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**EGYPT**

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Therapeutic and nontherapeutic responses	1	1	1	1
	1	1	1	1

*System Organ Class*

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**ESTONIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	5	1	5
	1	5	1	5

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac hypertensive complications	1	1			1	1
Cardiac signs and symptoms NEC		3		3		
Heart failures NEC	1	1			1	1
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	1	4	1	3		1
Supraventricular arrhythmias		1				1
Ventricular arrhythmias and cardiac arrest		1				1
	4	12	1	6	3	6

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	2	2	2		
Inner ear signs and symptoms	1	2	1	1		1
	3	4	3	3		1

\* I=Interval, C=Cumulative  
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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	1	1	1	1		
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Visual disorders NEC	3	4	3	4		
Visual impairment and blindness (excl colour blindness)	1	2			1	2
	6	8	4	5	2	3

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	3	1	3		
Dyspeptic signs and symptoms	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	2	3	2	2		1
Gastrointestinal signs and symptoms NEC	1	2		1	1	1
Nausea and vomiting symptoms	5	19	5	14		5
Oral soft tissue signs and symptoms		5		5		
Oral soft tissue swelling and oedema		2				2
	10	35	9	26	1	9

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	11	47	11	37		10
Body temperature altered	3	5			3	5
Death and sudden death	2	2			2	2

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders	13	38	13	36		2
Feelings and sensations NEC	9	25	9	24		1
General signs and symptoms NEC	4	5	4	4		1
Pain and discomfort NEC	5	10	5	7		3
Therapeutic and nontherapeutic responses	4	6			4	6
Vaccination site reactions	11	61	11	61		
	62	199	53	169	9	30

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	6		1	1	5
Allergies to foods, food additives, drugs and other chemicals		1				1
Immune and associated conditions NEC		1				1
	1	8		1	1	7

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	26	30		1	26	29
Herpes viral infections		2		2		
Infections NEC	1	1			1	1
Lower respiratory tract and lung infections		1				1
Upper respiratory tract infections	1	1	1	1		
	28	35	1	4	27	31

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	7	2	7		
Fractures and dislocations NEC		1				1
Medication errors, product use errors and issues NEC		1		1		
Non-site specific injuries NEC		5		3		2
Off label uses		1		1		
Skin injuries NEC		1				1
Spinal cord injuries NEC		1				1
Underdoses NEC		1		1		
Vaccination related complications	20	21			20	21
	22	39	2	13	20	26

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations		1				1
Physical examination procedures and organ system status	1	1	1	1		
Protein analyses NEC	1	1	1	1		
Skeletal and cardiac muscle analyses		1		1		
Vascular tests NEC (incl blood pressure)		1				1
	2	5	2	3		2

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	3				
Hypoglycaemic conditions NEC	1	1			1	1
	2	4	1	3	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		2		1		1
Joint related signs and symptoms	9	17	9	17		
Muscle pains	6	15	6	14		1
Muscle related signs and symptoms NEC		1		1		
Muscle weakness conditions	1	3	1	3		
Musculoskeletal and connective tissue conditions NEC		1				1
Musculoskeletal and connective tissue pain and discomfort	2	14	2	10		4
Tendon disorders	1	1	1	1		
	19	54	19	47		7

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	3			1	3
Coordination and balance disturbances	1	2	1	2		
Demyelinating disorders NEC		2				2
Disturbances in consciousness NEC	6	21	1	8	5	13

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye movement disorders	1	1			1	1
Facial cranial nerve disorders		2		1		1
Headaches NEC	9	38	9	34		4
Mental impairment (excl dementia and memory loss)		1		1		
Migraine headaches		1		1		
Myelitis (incl infective)		1				1
Neurological signs and symptoms NEC	6	15	6	10		5
Paraesthesias and dysaesthesias	2	22	2	19		3
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC	1	8	1	6		2
Speech and language abnormalities		1				1
Tremor (excl congenital)	1	2	1	2		
Trigeminal disorders	1	1			1	1
	29	123	21	84	8	39

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
		1		1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		12		9		3
Disturbances in initiating and maintaining sleep	4	5	4	5		
Increased physical activity levels		3		3		
Panic attacks and disorders		1		1		
	4	21	4	18		3

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		2		2
		2		2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	6	14	5	10	1	4
Bronchospasm and obstruction	1	1			1	1
Coughing and associated symptoms	2	4	2	4		
Laryngeal spasm, oedema and obstruction	1	2			1	2
Nasal congestion and inflammations		1		1		
Nasal disorders NEC		1		1		
Pharyngeal disorders (excl infections and neoplasms)		3		3		
Pulmonary oedemas	1	1			1	1
Pulmonary thrombotic and embolic conditions	1	2			1	2
Respiratory failures (excl neonatal)	3	3			3	3

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory signs and symptoms NEC		1		1		
Upper respiratory tract signs and symptoms	6	9	5	6	1	3
	21	42	12	26	9	16

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	3	4	3	3		1
Pruritus NEC	1	1	1	1		
Psoriatic conditions		1				1
	4	6	4	4		2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC		1		1		
Peripheral embolism and thrombosis	2	2	1	1	1	1
Peripheral vascular disorders NEC		1		1		
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC		4		3		1
Vascular hypotensive disorders		2				2
	2	11	1	6	1	5

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Country Where Event Occurred

**FINLAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bleeding tendencies	1	1			1	1
Lymphatic system disorders NEC	5	59	2	25	3	34
Neutropenias		1				1
Platelet disorders NEC	1	1			1	1
Thrombocytopenias	1	1			1	1
Thrombocytoses		1				1
	8	64	2	25	6	39

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	3	19		6	3	13
Cardiomyopathies		1				1
Coronary artery disorders NEC	1	1			1	1
Heart failures NEC	2	6			2	6
Ischaemic coronary artery disorders		3				3
Myocardial disorders NEC	1	1			1	1
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	7	37		4	7	33
Right ventricular failures	2	2			2	2
Supraventricular arrhythmias	4	8			4	8
Ventricular arrhythmias and cardiac arrest	2	2			2	2
	22	81		10	22	71

System Organ Class

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System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inborn errors of porphyrin metabolism	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	13		11	1	2
Hearing losses	5	8	2	3	3	5
Hyperacusia	1	1			1	1
Inner ear disorders NEC		1				1
Inner ear signs and symptoms	2	11		5	2	6
Tympanic membrane disorders (excl infections)		1		1		
	9	35	2	20	7	15

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival infections, irritations and inflammations	1	1			1	1
Corneal infections, oedemas and inflammations	1	2			1	2
Eyelid movement disorders		1				1
Glaucomas (excl congenital)	1	1			1	1
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders		1				1
Lid, lash and lacrimal infections, irritations and inflammations	1	11		1	1	10

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular bleeding and vascular disorders NEC	1	2			1	2
Ocular disorders NEC	1	11		4	1	7
Ocular infections, inflammations and associated manifestations		3		1		2
Ocular nerve and muscle disorders		4		1		3
Ocular sensation disorders		6		1		5
Pupil disorders		1		1		
Refractive and accommodative disorders		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)	5	5			5	5
Retinal, choroid and vitreous infections and inflammations	1	1			1	1
Retinal structural change, deposit and degeneration		1				1
Visual disorders NEC	3	8	2	3	1	5
Visual impairment and blindness (excl colour blindness)	4	8		1	4	7
	19	69	2	14	17	55

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal and rectal ulcers and perforation		1				1
Colitis (excl infective)		1				1
Dental pain and sensation disorders		2		2		
Diarrhoea (excl infective)	4	20		9	4	11
Dyspeptic signs and symptoms	1	1			1	1
Flatulence, bloating and distension	1	4		3	1	1
Gastrointestinal and abdominal pains (excl oral and throat)	3	22	1	6	2	16
Gastrointestinal disorders NEC		1		1		

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	1			1	1
Gastrointestinal signs and symptoms NEC		14		3		11
Gastrointestinal vascular occlusion and infarction	2	2			2	2
Gingival disorders, signs and symptoms NEC		1		1		
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	22	116	5	37	17	79
Non-site specific gastrointestinal haemorrhages		1				1
Oral dryness and saliva altered		4				4
Oral soft tissue disorders NEC		2		1		1
Oral soft tissue haemorrhages	1	1			1	1
Oral soft tissue signs and symptoms	2	42	2	20		22
Oral soft tissue swelling and oedema	3	8	2	4	1	4
Salivary gland enlargements		1				1
Salivary gland infections and inflammations		1				1
Tongue disorders		1				1
Tongue signs and symptoms	5	13		1	5	12
	46	261	10	88	36	173

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	37	234	3	65	34	169
Body temperature altered		4				4
Death and sudden death	1	15			1	15
Febrile disorders	18	155	1	45	17	110
Feelings and sensations NEC	16	111		34	16	77
Gait disturbances	1	12		2	1	10
General signs and symptoms NEC	14	62	1	10	13	52

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflamations	1	1			1	1
Mass conditions NEC	2	3	1	2	1	1
Oedema NEC	4	24	1	5	3	19
Pain and discomfort NEC	11	79		19	11	60
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	7	194	2	113	5	81
	113	895	9	295	104	600

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis		1		1
Cholestasis and jaundice		1		1
		2		2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	18		2	3	16
Allergies to foods, food additives, drugs and other chemicals		4				4
Anaphylactic and anaphylactoid responses	4	19			4	19
	7	41		2	7	39

System Organ Class

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	3			1	3
Bacterial infections NEC		1		1		
Borrelial infections		1				1
Central nervous system and spinal infections		2				2
Coronavirus infections	3	3			3	3
Dental and oral soft tissue infections		1				1
Eye and eyelid infections	2	2			2	2
Female reproductive tract infections		1				1
Herpes viral infections	4	17		8	4	9
Infections NEC	1	4			1	4
Influenza viral infections	2	3	1	1	1	2
Lower respiratory tract and lung infections	3	13			3	13
Pseudomonal infections	1	1			1	1
Skin structures and soft tissue infections		1				1
Streptococcal infections		2				2
Upper respiratory tract infections	2	11		1	2	10
Urinary tract infections	4	9	1	1	3	8
Viral infections NEC	1	4			1	4
	24	79	2	12	22	67

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC	1	1			1	1
Exposures associated with pregnancy, delivery and lactation		1		1		
Limb fractures and dislocations	1	1			1	1
Medication errors, product use errors and issues NEC		2		2		

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 \* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Muscle, tendon and ligament injuries		1				1	
Non-site specific injuries NEC	4	12		1	4	11	
Non-site specific procedural complications	1	1			1	1	
Off label uses	1	3	1	3			
Product administration errors and issues	2	24	2	24			
Product preparation errors and issues		12		12			
Site specific injuries NEC	2	4		1	2	3	
Skin injuries NEC	1	2		1	1	1	
Skull fractures, facial bone fractures and dislocations		1				1	
Vaccination related complications	2	2			2	2	
	15	67	3	45	12	22	

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Auditory function diagnostic procedures		2		2			
Bacteria identification and serology (excl mycobacteria)	2	3			2	3	
Blood gas and acid base analyses	1	4		1	1	3	
Bone marrow and immune tissue imaging procedures		1				1	
Carbohydrate tolerance analyses (incl diabetes)	1	2			1	2	
Cerebrospinal fluid tests (excl microbiology)	1	2			1	2	
Chemistry analyses NEC		1				1	
Coagulation and bleeding analyses	4	4	2	2	2	2	
ECG investigations	2	2			2	2	
Haematological analyses NEC		1				1	
Haem metabolism analyses	1	1			1	1	
Heart rate and pulse investigations	3	28		4	3	24	

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Liver function analyses		2					2
Metabolism tests NEC		1					1
Musculoskeletal and soft tissue histopathology procedures		1					1
Neurologic diagnostic procedures		2					2
Physical examination procedures and organ system status	1	11		3	1		8
Protein analyses NEC		13		2			11
Red blood cell analyses	1	2			1		2
Renal function analyses	1	2			1		2
Respiratory and pulmonary function diagnostic procedures		3					3
Respiratory tract and thoracic imaging procedures	1	1			1		1
Skeletal and cardiac muscle analyses	1	1			1		1
Tissue enzyme analyses NEC		1					1
Urinalysis NEC	4	4			4		4
Vascular tests NEC (incl blood pressure)	8	37		4	8		33
Virus identification and serology	2	4		1	2		3
White blood cell analyses	1	4			1		4
	35	140	2	19	33		121

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Appetite disorders	6	10	6	10
Fluid intake decreased		1		1
General nutritional disorders NEC		2		2
Metabolic acidoses (excl diabetic acidoses)	1	1	1	1
Potassium imbalance		5		5

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sodium imbalance	1	2	1	2
Total fluid volume decreased	1	1	1	1
	9	22	9	22

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	2	3			2	3
Bone related signs and symptoms		5		2		3
Connective tissue disorders NEC	1	2			1	2
Intervertebral disc disorders NEC		1		1		
Joint related signs and symptoms	12	74	2	28	10	46
Muscle pains	12	103	1	28	11	75
Muscle related signs and symptoms NEC	1	20		5	1	15
Muscle tone abnormalities	1	3	1	3		
Muscle weakness conditions	8	27	1	3	7	24
Musculoskeletal and connective tissue conditions NEC	7	21	2	10	5	11
Musculoskeletal and connective tissue pain and discomfort	20	130	9	48	11	82
Osteoarthropathies		1		1		
Rheumatoid arthropathies		1				1
Soft tissue disorders NEC		1				1
Spine and neck deformities		1				1
Spondyloarthropathies	1	3			1	3
Tendon disorders	1	2			1	2
	66	398	16	129	50	269

System Organ Class

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphomas unspecified NEC		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		2				2
Absence seizures	1	1			1	1
Alzheimer's disease (incl subtypes)		4				4
Central nervous system haemorrhages and cerebrovascular accidents	9	17			9	17
Central nervous system inflammatory disorders NEC	1	1			1	1
Central nervous system vascular disorders NEC	1	1			1	1
Coordination and balance disturbances	2	6	1	1	1	5
Cortical dysfunction NEC	1	2			1	2
Demyelinating disorders NEC	1	1			1	1
Disturbances in consciousness NEC	8	36		1	8	35
Dyskinesias and movement disorders NEC		4		3		1
Dystonias		1				1
Facial cranial nerve disorders	2	16			2	16
Headaches NEC	13	135	2	41	11	94
Memory loss (excl dementia)	1	3		1	1	2
Mental impairment (excl dementia and memory loss)	1	6		1	1	5
Migraine headaches	4	13		1	4	12
Muscle tone abnormal	1	3			1	3
Narcolepsy and hypersomnia	1	3		1	1	2
Neurological signs and symptoms NEC	17	83	2	20	15	63
Neuromuscular disorders NEC		2				2

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	19	112	3	29	16	83
Paralysis and paresis (excl cranial nerve)	7	11			7	11
Parkinson's disease and parkinsonism	1	1	1	1		
Peripheral neuropathies NEC	1	1			1	1
Seizures and seizure disorders NEC	1	8			1	8
Sensory abnormalities NEC	2	19	1	6	1	13
Sleep disturbances NEC	1	1			1	1
Speech and language abnormalities	8	15	1	1	7	14
Transient cerebrovascular events	2	4			2	4
Tremor (excl congenital)	2	15		2	2	13
Trigeminal disorders	1	1			1	1
	110	529	12	110	98	419

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issues NEC	1	1	1	1
	1	1	1	1

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*System Organ Class*

**Psychiatric disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	2			1	2
Confusion and disorientation	1	6		2	1	4
Deliria	1	1			1	1
Delusional symptoms		2		2		
Disturbances in initiating and maintaining sleep	3	19		6	3	13
Eating disorders NEC	1	1	1	1		
Emotional and mood disturbances NEC		2				2
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Hallucinations (excl sleep-related)		3				3
Perception disturbances NEC		1		1		
Psychiatric symptoms NEC		1		1		
Suicidal and self-injurious behaviour		1				1
Thinking disturbances		1				1
	7	41	1	14	6	27

*System Organ Class*

**Renal and urinary disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	3		1	1	2
Genital and urinary tract disorders NEC	1	1			1	1
Renal failure and impairment	3	3			3	3
Urinary abnormalities	1	1			1	1
	6	8		1	6	7

*System Organ Class*

**Reproductive system and breast disorders**

<i>Interval Total #</i>	<i>Cumulative Total #</i>	Spontaneous	
		Serious	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Benign and malignant breast neoplasms		1		1
Breast signs and symptoms		3		3
Menstruation and uterine bleeding NEC		1		1
Reproductive tract disorders NEC (excl neoplasms)		1		1
Vaginal and vulval infections and inflammations		1		1
		7		7

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	15	92		9	15	83
Bronchospasm and obstruction	1	8		1	1	7
Coughing and associated symptoms	5	25	1	3	4	22
Laryngeal spasm, oedema and obstruction		2				2
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms	2	9		1	2	8
Nasal congestion and inflammations	1	5		2	1	3
Nasal disorders NEC	1	7		2	1	5
Paranasal sinus disorders (excl infections and neoplasms)		1				1
Pharyngeal disorders (excl infections and neoplasms)	3	22		4	3	18
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	8	11			8	11
Respiratory signs and symptoms NEC	1	3			1	3
Respiratory tract disorders NEC	1	3			1	3
Upper respiratory tract signs and symptoms	4	60		18	4	42
	42	250	1	40	41	210

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	15		5	1	10
Bullous conditions	1	4		2	1	2
Dermal and epidermal conditions NEC	4	11	1	4	3	7
Dermatitis and eczema		2				2
Dermatitis ascribed to specific agent		2		2		
Erythemas	3	38	1	12	2	26
Photosensitivity and photodermatosis conditions		1				1
Pruritus NEC	2	15		9	2	6
Rashes, eruptions and exanthems NEC	6	25	2	9	4	16
Skin hypoplasias and atrophies	1	1			1	1
Urticarias	3	25		7	3	18
	21	139	4	50	17	89

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	5	19		1	5	18
	5	19		1	5	18

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Therapeutic procedures NEC	1	1	1	1
	1	1	1	1

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic infections and inflammations	1	1			1	1
Arterial infections and inflammations	1	1			1	1
Blood pressure disorders NEC		1				1
Circulatory collapse and shock	2	2			2	2
Haemorrhages NEC	1	3		2	1	1
Non-site specific embolism and thrombosis	5	6			5	6
Non-site specific vascular disorders NEC	1	1			1	1
Peripheral embolism and thrombosis	3	7			3	7
Peripheral vascular disorders NEC		11		2		9
Peripheral vasoconstriction, necrosis and vascular insufficiency		1				1
Site specific vascular disorders NEC		6		1		5
Vascular hypertensive disorders NEC	1	7		1	1	6
Vascular hypotensive disorders	2	3			2	3
	17	50		6	17	44

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Country Where Event Occurred

**FRANCE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia deficiencies		1				1
Anaemias haemolytic immune		1				1
Anaemias haemolytic NEC	2	2			2	2
Anaemias NEC	8	17	1	3	7	14
Bleeding tendencies	2	2			2	2
Coagulation factor deficiencies	2	2			2	2
Coagulopathies	1	1			1	1
Eosinophilic disorders	2	5			2	5
Leukocytoses NEC	11	27	3	6	8	21
Leukopenias NEC	13	23	6	8	7	15
Lymphatic system disorders NEC	28	141	13	68	15	73
Marrow depression and hypoplastic anaemias	2	5			2	5
Neutropenias	5	11			5	11
Spleen disorders	1	1			1	1
Thrombocytopenias	22	40	1	1	21	39
Thrombocytoses	1	1	1	1		
	100	280	25	87	75	193

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic valvular disorders	4	5			4	5
Cardiac conduction disorders	6	25	1	4	5	21
Cardiac disorders NEC	5	10	1	1	4	9
Cardiac signs and symptoms NEC	19	67	6	26	13	41

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System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiomyopathies	2	6			2	6
Coronary artery disorders NEC	6	9			6	9
Heart failure signs and symptoms	1	1	1	1		
Heart failures NEC	42	105			42	105
Ischaemic coronary artery disorders	24	81			24	81
Left ventricular failures	1	3			1	3
Mitral valvular disorders	4	8			4	8
Myocardial disorders NEC	6	11	1	2	5	9
Noninfectious myocarditis	1	8			1	8
Noninfectious pericarditis	10	25			10	25
Pericardial disorders NEC	7	10			7	10
Rate and rhythm disorders NEC	109	389	20	66	89	323
Supraventricular arrhythmias	60	154	3	5	57	149
Tricuspid valvular disorders		1				1
Ventricular arrhythmias and cardiac arrest	28	88	1	3	27	85
	335	1,006	34	108	301	898

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac septal defects congenital	1	2			1	2
Coagulation disorders congenital	1	1	1	1		
Congenital disorders NEC		1				1
Immune system abnormalities congenital		1				1
Inborn errors of amino acid metabolism		1				1
Lymphatic system disorders congenital		1				1
Tongue disorders congenital	1	3			1	3
	3	10	1	1	2	9

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\* AE=Adverse Event

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	14	30	6	13	8	17
Hearing disorders NEC		1				1
Hearing losses	13	33		2	13	31
Hyperacusia	1	1	1	1		
Inner ear disorders NEC	4	15	1	4	3	11
Inner ear signs and symptoms	47	176	17	49	30	127
	79	256	25	69	54	187

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	4			1	4
Adrenal cortical hypofunctions	1	2			1	2
Adrenal gland disorders NEC	1	1	1	1		
Posterior pituitary disorders		1				1
Thyroid disorders NEC		3		3		
Thyroid hyperfunction disorders	2	6			2	6
Thyroid hypofunction disorders	1	1			1	1
	6	18	1	4	5	14

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract conditions	1	1			1	1
Choroid and vitreous structural change, deposit and degeneration		1				1

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System Organ Class

Eye disorders

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		4	15
2	3		
	1	1	4
		1	1
			2
2	7		4
	1		
	5	4	14
		2	8
6	14	4	16
	2	4	8
1	1	1	3
2	4		10
		1	2
		1	1
1	3		4
			1
		8	12
		1	2
		1	1
			1
		1	1
		2	2
2	9	15	35

Conjunctival and corneal bleeding and vascular disorders	4	15
Conjunctival infections, irritations and inflammations	2	3
Eyelid movement disorders	1	5
Glaucomas (excl congenital)	1	1
Iris and uveal tract infections, irritations and inflammations		2
Lacrimation disorders	2	11
Lid bleeding and vascular disorders		1
Lid, lash and lacrimal infections, irritations and inflammations	4	19
Ocular bleeding and vascular disorders NEC	2	8
Ocular disorders NEC	10	30
Ocular infections, inflammations and associated manifestations	4	10
Ocular nerve and muscle disorders	2	4
Ocular sensation disorders	2	14
Optic nerve bleeding and vascular disorders	1	2
Orbital infections, inflammations and irritations	1	1
Pupil disorders	1	7
Refractive and accommodative disorders		1
Retinal bleeding and vascular disorders (excl retinopathy)	8	12
Retinal, choroid and vitreous infections and inflammations	1	2
Retinal structural change, deposit and degeneration	1	1
Scleral infections, irritations and inflammations		1
Scleral structural change, deposit and degeneration	1	1
Structural change, deposit and degeneration of eye NEC	2	2
Visual disorders NEC	17	44

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment and blindness (excl colour blindness)	11	37	1	4	10	33
	79	236	17	54	62	182

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal	1	2	1	2		
Acute and chronic pancreatitis	5	10			5	10
Colitis (excl infective)	5	7		1	5	6
Dental pain and sensation disorders		2		1		1
Diarrhoea (excl infective)	43	193	12	62	31	131
Diverticula	2	2	1	1	1	1
Dyspeptic signs and symptoms		11		1		10
Faecal abnormalities NEC	1	8		6	1	2
Flatulence, bloating and distension	5	11	3	6	2	5
Gastric and pyloric stenosis and obstruction		2				2
Gastritis (excl infective)		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	31	140	10	52	21	88
Gastrointestinal atonic and hypomotility disorders NEC	4	13	4	10		3
Gastrointestinal disorders NEC	4	16	2	4	2	12
Gastrointestinal dyskinetic disorders	1	3	1	2		1
Gastrointestinal inflammatory disorders NEC		1				1
Gastrointestinal signs and symptoms NEC	9	31	6	12	3	19
Gastrointestinal spastic and hypermotility disorders		2		1		1
Gastrointestinal stenosis and obstruction NEC		4				4
Gastrointestinal vascular occlusion and infarction	7	7			7	7

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gingival disorders, signs and symptoms NEC	1	4	1	2		1	2
Gingival haemorrhages	1	1			1		1
Haemorrhoids and gastrointestinal varices (excl oesophageal)		2					2
Intestinal haemorrhages	3	8			3		8
Nausea and vomiting symptoms	137	589	39	187	98		402
Non-site specific gastrointestinal haemorrhages	6	16			6		16
Oral dryness and saliva altered	2	12	1	6	1		6
Oral soft tissue disorders NEC		3		1			2
Oral soft tissue haemorrhages	4	5		1	4		4
Oral soft tissue signs and symptoms	10	50	4	23	6		27
Oral soft tissue swelling and oedema	3	30		4	3		26
Peptic ulcers and perforation		1					1
Peritoneal and retroperitoneal disorders		1					1
Rectal inflammations NEC	1	1	1	1			
Salivary gland disorders NEC		1		1			
Stomatitis and ulceration	3	11	2	6	1		5
Tongue disorders	1	5	1	3			2
Tongue signs and symptoms	4	21	2	6	2		15
	294	1,227	91	402	203		825

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Adverse effect absent	2	2	2	2			
Application and instillation site reactions		1		1			
Asthenic conditions	318	1,364	115	490	203		874
Body temperature altered	13	78	5	19	8		59
Death and sudden death	37	163			37		163

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\* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders	110	611	38	213	72	398
Feelings and sensations NEC	69	367	22	142	47	225
Gait disturbances	13	35	4	12	9	23
General signs and symptoms NEC	195	716	32	122	163	594
Inflamations	20	35	8	13	12	22
Injection site reactions	8	49	2	24	6	25
Interactions	2	2	1	1	1	1
Mass conditions NEC		1				1
Mucosal findings abnormal	2	4	1	3	1	1
Necrosis NEC	1	1			1	1
Oedema NEC	35	103	7	19	28	84
Pain and discomfort NEC	94	447	29	151	65	296
Therapeutic and nontherapeutic responses	59	212	3	4	56	208
Vaccination site reactions	112	713	46	385	66	328
Vascular complications associated with device	1	1			1	1
Withdrawal and rebound effects		1				1
	1,091	4,906	315	1601	776	3305

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis	1	3			1	3
Cholestasis and jaundice	6	16			6	16
Hepatic and hepatobiliary disorders NEC	1	2		1	1	1
Hepatic enzymes and function abnormalities	1	2	1	2		
Hepatic vascular disorders	2	3			2	3
Hepatobiliary signs and symptoms	1	3		1	1	2
Hepatocellular damage and hepatitis NEC	12	25	1	1	11	24
	24	54	2	5	22	49

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	13	79	1	25	12	54
Allergies to foods, food additives, drugs and other chemicals	2	8	1	3	1	5
Anaphylactic and anaphylactoid responses	14	54			14	54
Immune and associated conditions NEC	3	4			3	4
Immunodeficiency disorders NEC	2	2			2	2
Vasculitides		1				1
	34	148	2	28	32	120

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	5	11			5	11
Bacterial infections NEC	12	20			12	20
Blastocystis infections		1				1
Bone and joint infections		1				1
Borrelial infections	1	2			1	2
Breast infections		1				1
Candida infections	1	2			1	2
Central nervous system and spinal infections	2	7			2	7
Coronavirus infections	191	470	25	71	166	399
Coxsackie viral infections	1	1	1	1		
Cytomegaloviral infections	1	2			1	2
Dental and oral soft tissue infections	1	7		2	1	5
Ear infections	1	5	1	2		3
Enterococcal infections		1				1
Epstein-Barr viral infections		4				4
Escherichia infections	3	5			3	5
Eye and eyelid infections	2	7	1	3	1	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fungal infections NEC	1	1	1	1		
Hepatitis viral infections	1	1			1	1
Hepatobiliary and spleen infections		1				1
Herpes viral infections	54	151	2	41	52	110
Infections NEC	6	18	2	4	4	14
Influenza viral infections	13	55	6	14	7	41
Klebsiella infections		3				3
Lower respiratory tract and lung infections	13	47		2	13	45
Moraxella infections		2				2
Nematode infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	5	18			5	18
Skin structures and soft tissue infections	4	7			4	7
Staphylococcal infections	3	4			3	4
Streptococcal infections	5	12			5	12
Toxoplasma infections	1	1	1	1		
Upper respiratory tract infections	10	29	7	17	3	12
Urinary tract infections	7	14		1	7	13
Vascular infections	2	2			2	2
Viral infections NEC	3	16		3	3	13
	350	930	47	163	303	767

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC		1				1
Cardiac and vascular procedural complications	1	3			1	3
Cerebral injuries NEC	3	5			3	5
Chest and respiratory tract injuries NEC		1				1

\* I=Interval, C=Cumulative  
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System Organ Class

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Conditions caused by cold		4
Exposures associated with pregnancy, delivery and lactation	2	9
Exposures to agents or circumstances NEC		1
Eye injuries NEC	2	4
Fractures and dislocations NEC	2	2
Limb fractures and dislocations	2	6
Medication errors, product use errors and issues NEC	2	22
Muscle, tendon and ligament injuries	1	2
Nerve injuries NEC		1
Non-site specific injuries NEC	38	100
Occupational exposures		2
Off label uses	5	28
Overdoses NEC	2	11
Pathways and sources of exposure		1
Pelvic fractures and dislocations		1
Poisoning and toxicity	1	2
Product administration errors and issues	15	237
Product confusion errors and issues	1	1
Product preparation errors and issues	3	30
Product storage errors and issues in the product use system	1	1
Product transcribing errors and communication issues		1
Radiation injuries		1
Site specific injuries NEC	10	22
Skin injuries NEC	1	2
Skull fractures, facial bone fractures and dislocations	2	2
Spinal fractures and dislocations		2
Thermal burns	1	3
Thoracic cage fractures and dislocations	2	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3		1
	6	2	3
			1
	1	2	3
		2	2
		2	6
2	22		
		1	2
			1
9	18	29	82
	2		
4	27	1	1
2	11		
	1		
			1
		1	2
12	231	3	6
1	1		
3	30		
1	1		
	1		
			1
1	1	9	21
1	2		
		2	2
			2
		1	3
		2	4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdoses NEC	1	27	1	27		
Vaccination related complications	121	142		3	121	139
	219	681	37	388	182	293

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	1	2			1	2
Bacteria identification and serology (excl mycobacteria)	2	4	1	3	1	1
Blood gas and acid base analyses	27	117	5	12	22	105
Carbohydrate tolerance analyses (incl diabetes)	3	10	3	8		2
Cardiac auscultatory investigations		4		1		3
Cardiac function diagnostic procedures		2				2
Cell marker analyses		1				1
Central nervous system imaging procedures		1				1
Cholesterol analyses		1				1
Coagulation and bleeding analyses	11	23	1	2	10	21
Digestive enzymes		2		2		
ECG investigations	2	13		1	2	12
Endocrine analyses and imaging NEC	1	1			1	1
Gastrointestinal function diagnostic procedures	1	1	1	1		
Haematological analyses NEC		2		2		
Heart rate and pulse investigations	9	34	5	16	4	18
Immunoglobulin analyses	1	2	1	1		1
Investigations NEC		1				1
Liver function analyses	8	29	6	21	2	8
Metabolism tests NEC	5	10	2	4	3	6
Microbiology and serology tests NEC	3	3	2	2	1	1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mineral and electrolyte analyses	4	8	3	5	1	3
Neurologic diagnostic procedures	2	4	1	2	1	2
Parathyroid analyses	1	1	1	1		
Physical examination procedures and organ system status	16	39	4	8	12	31
Pituitary analyses anterior	4	6	2	4	2	2
Platelet analyses	2	5	1	2	1	3
Protein analyses NEC	19	52	9	27	10	25
Red blood cell analyses	5	10	2	5	3	5
Renal function analyses	2	10	2	3		7
Respiratory tract and thoracic imaging procedures	1	2			1	2
Skeletal and cardiac muscle analyses	5	17	2	4	3	13
Therapeutic drug monitoring analyses	2	2	1	1	1	1
Thyroid analyses	2	2	2	2		
Tissue enzyme analyses NEC	3	6	3	6		
Urinalysis NEC	1	3	1	2		1
Vascular auscultatory investigations		1		1		
Vascular tests NEC (incl blood pressure)	14	70	5	18	9	52
Virus identification and serology	25	57	11	32	14	25
Vitamin analyses	1	1			1	1
White blood cell analyses	7	21	4	11	3	10
	190	580	81	210	109	370

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	20	72	10	33	10	39
Calcium metabolism disorders	1	3	1	1		2

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cell metabolism disorders NEC	4	4			4	4
Chloride imbalance	1	1			1	1
Diabetes mellitus (incl subtypes)	15	25			15	25
Diabetic complications NEC	1	7			1	7
Disorders of purine metabolism	2	5	2	3		2
Elevated cholesterol		1		1		
Fat soluble vitamin deficiencies and disorders	1	2	1	1		1
Fluid intake increased		2		1		1
General nutritional disorders NEC	2	7		2	2	5
Hyperglycaemic conditions NEC	5	12	2	5	3	7
Hypervitaminoses NEC		1				1
Hypoglycaemic conditions NEC	2	11		1	2	10
Iron excess	1	1			1	1
Lipid metabolism and deposit disorders NEC		2		2		
Metabolic acidoses (excl diabetic acidoses)	1	4			1	4
Potassium imbalance	5	14			5	14
Protein metabolism disorders NEC	1	1			1	1
Sodium imbalance	4	8	2	4	2	4
Total fluid volume decreased	13	26	5	8	8	18
Total fluid volume increased		1				1
	79	210	23	62	56	148

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	7	17	1	3	6	14
Bone related signs and symptoms	8	23	2	6	6	17
Bursal disorders	1	6		2	1	4
Cartilage disorders	1	1			1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Connective tissue disorders NEC	5	5			5	5
Crystal arthropathic disorders	1	1			1	1
Intervertebral disc disorders NEC	2	3	2	2		1
Joint related disorders NEC		7		1		6
Joint related signs and symptoms	53	225	15	86	38	139
Lupus erythematosus (incl subtypes)		1				1
Muscle infections and inflammations	1	4		1	1	3
Muscle pains	61	342	18	132	43	210
Muscle related signs and symptoms NEC	7	29	2	14	5	15
Muscle tone abnormalities	1	7	1	5		2
Muscle weakness conditions	17	35	5	11	12	24
Musculoskeletal and connective tissue conditions NEC	28	119	7	33	21	86
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	2			1	2
Musculoskeletal and connective tissue pain and discomfort	71	241	27	101	44	140
Myopathies	5	6			5	6
Osteoarthropathies	3	5	3	4		1
Psoriatic arthropathies		1				1
Rheumatoid arthropathies	4	12			4	12
Soft tissue disorders NEC		1		1		
Spondyloarthropathies	4	10			4	10
Synovial disorders		2				2
Tendon disorders	1	13		5	1	8
	282	1,118	83	407	199	711

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
B-cell lymphomas NEC	1	1			1	1
Breast and nipple neoplasms benign		1		1		
Islet cell neoplasms and APUDoma NEC		1				1
Leukaemias acute myeloid	1	2			1	2
Metastases to specified sites		1				1
Myelodysplastic syndromes	1	1			1	1
Myeloproliferative disorders (excl leukaemias)		1				1
Neoplasms benign site unspecified NEC		1		1		
Neoplasms unspecified malignancy and site unspecified NEC		1				1
Nervous system neoplasms unspecified malignancy NEC	1	1			1	1
Oncologic complications and emergencies		1				1
Plasma cell neoplasms NEC	2	2			2	2
Soft tissue neoplasms benign NEC		2				2
	6	16		2	6	14

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		2		1		1
Absence seizures	3	9			3	9
Acute polyneuropathies	3	5			3	5
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	106	203			106	203
Central nervous system vascular disorders NEC	3	6			3	6
Cerebrovascular venous and sinus thrombosis	2	2			2	2
Cervical spinal cord and nerve root disorders	2	7		3	2	4
Coma states	7	17			7	17

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Coordination and balance disturbances	18	53
Cortical dysfunction NEC	11	30
Dementia (excl Alzheimer's type)	2	4
Demyelinating disorders NEC		1
Disturbances in consciousness NEC	64	215
Disturbances in sleep phase rhythm	1	1
Dyskinesias and movement disorders NEC	21	41
Encephalopathies NEC	3	7
Eye movement disorders	1	5
Facial cranial nerve disorders	49	119
Generalised tonic-clonic seizures	6	11
Headaches NEC	152	688
Hydrocephalic conditions	1	1
Hypoglossal nerve disorders	1	1
Increased intracranial pressure disorders		1
Lumbar spinal cord and nerve root disorders	1	3
Memory loss (excl dementia)	9	21
Mental impairment (excl dementia and memory loss)	6	18
Migraine headaches	7	35
Mononeuropathies	4	4
Muscle tone abnormal	5	11
Narcolepsy and hypersomnia	3	6
Nervous system disorders NEC	4	13
Neurological signs and symptoms NEC	68	256
Neurologic visual problems NEC	4	9
Neuromuscular disorders NEC	1	12
Neuromuscular junction dysfunction	4	4
Olfactory nerve disorders	3	10
Optic nerve disorders NEC	1	1
Paraesthesias and dysaesthesias	77	248
Paralysis and paresis (excl cranial nerve)	24	57

Spontaneous			
Nonserious		Serious	
I	C	I	C
8	14	10	39
1	6	10	24
		2	4
			1
6	21	58	194
1	1		
4	9	17	32
		3	7
		1	5
1	3	48	116
		6	11
47	250	105	438
		1	1
		1	1
			1
1	1		2
1	2	8	19
1	5	5	13
3	14	4	21
1	1	3	3
1	2	4	9
2	3	1	3
1	3	3	10
21	84	47	172
		4	9
1	3		9
		4	4
2	6	1	4
		1	1
22	85	55	163
	1	24	56

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parkinson's disease and parkinsonism	2	3			2	3
Partial complex seizures	2	3			2	3
Peripheral neuropathies NEC	8	14		2	8	12
Seizures and seizure disorders NEC	24	78			24	78
Sensory abnormalities NEC	29	103	9	41	20	62
Sleep disturbances NEC	1	2			1	2
Speech and language abnormalities	21	49	4	8	17	41
Spinal cord and nerve root disorders NEC	2	2			2	2
Structural brain disorders NEC	1	4			1	4
Transient cerebrovascular events	18	36			18	36
Tremor (excl congenital)	13	61	3	18	10	43
Trigeminal disorders	1	2			1	2
Vagus nerve disorders		1				1
	799	2,496	141	587	658	1909

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous	6	9			6	9
Gestational age and weight conditions	1	1			1	1
Maternal complications of pregnancy NEC		1		1		
	7	11		1	7	10

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	3	1	3
Product contamination and sterility issues		1		1
Product distribution and storage issues		164		164
Product packaging issues		1		1
Product physical issues		1		1
Product quality issues NEC	1	16	1	16
	2	186	2	186

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	7	14	2	3	5	11
Anxiety disorders NEC		2		1		1
Anxiety symptoms	11	52	2	21	9	31
Behaviour and socialisation disturbances	5	8	1	1	4	7
Bipolar disorders		1				1
Cognitive and attention disorders and disturbances NEC	2	3			2	3
Communications disorders	1	2	1	1		1
Confusion and disorientation	36	67	9	13	27	54
Deliria	1	8			1	8
Delusional symptoms	2	6		3	2	3
Dementia NEC		1				1
Depressive disorders	1	4		1	1	3
Disturbances in initiating and maintaining sleep	22	68	7	28	15	40
Eating disorders NEC		2		1		1
Emotional and mood disturbances NEC		3		2		1
Fear symptoms and phobic disorders (incl social phobia)	1	5	1	2		3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucinations (excl sleep-related)	15	32			15	32
Impulse control disorders	1	1	1	1		
Increased physical activity levels	2	11	1	5	1	6
Mood alterations with depressive symptoms		2				2
Mood disorders NEC	4	9	3	5	1	4
Panic attacks and disorders	1	2		1	1	1
Parasomnias	1	3		2	1	1
Perception disturbances NEC	2	4			2	4
Psychiatric elimination disorders		1				1
Sexual desire disorders	1	1	1	1		
Sleep disorders NEC	5	15	3	6	2	9
Speech and language usage disturbances		1				1
Speech articulation and rhythm disturbances		3				3
Stereotypies and automatisms		2				2
Suicidal and self-injurious behaviour		1				1
Thinking disturbances	1	2			1	2
	122	336	32	98	90	238

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	13	21	3	6	10	15
Bladder disorders NEC	1	1			1	1
Glomerulonephritis and nephrotic syndrome	1	2			1	2
Nephropathies and tubular disorders NEC	1	1			1	1
Renal failure and impairment	16	51		1	16	50
Renal neoplasms	1	2			1	2
Renal vascular and ischaemic conditions	1	2			1	2
Urinary abnormalities	7	19	4	7	3	12

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract signs and symptoms NEC	5	7	2	2	3	5
	46	106	9	16	37	90

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	1	1			1	1
Breast signs and symptoms	2	6	1	2	1	4
Erection and ejaculation conditions and disorders	1	4			1	4
Menstruation and uterine bleeding NEC		2				2
Menstruation with decreased bleeding	1	2			1	2
Menstruation with increased bleeding		1				1
Prostate and seminal vesicles infections and inflammations	3	4	2	2	1	2
Prostatic neoplasms and hypertrophy	2	2	1	1	1	1
Reproductive tract disorders NEC (excl neoplasms)	1	1			1	1
Reproductive tract signs and symptoms NEC	2	5			2	5
Testicular and epididymal disorders NEC	1	1	1	1		
Vulvovaginal disorders NEC		1				1
	14	30	5	6	9	24

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	77	300	14	42	63	258

\* I=Interval, C=Cumulative  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchial conditions NEC	1	2		1	1	1
Bronchospasm and obstruction	13	54	2	5	11	49
Conditions associated with abnormal gas exchange	7	30			7	30
Coughing and associated symptoms	34	104	14	36	20	68
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		4				4
Laryngeal spasm, oedema and obstruction	4	12			4	12
Lower respiratory tract inflammatory and immunologic conditions	7	32		1	7	31
Lower respiratory tract signs and symptoms	10	28	1	3	9	25
Nasal congestion and inflammations		4		3		1
Nasal disorders NEC	12	26	3	9	9	17
Paranasal sinus disorders (excl infections and neoplasms)		1				1
Parenchymal lung disorders NEC	4	9			4	9
Pharyngeal disorders (excl infections and neoplasms)		11		3		8
Pleural infections and inflammations	1	1			1	1
Pneumothorax and pleural effusions NEC	8	11	2	2	6	9
Pulmonary hypertensions	2	3			2	3
Pulmonary oedemas	16	55			16	55
Pulmonary thrombotic and embolic conditions	76	116			76	116
Respiratory failures (excl neonatal)	4	29			4	29
Respiratory signs and symptoms NEC		8		2		6
Respiratory tract disorders NEC	15	58	5	8	10	50
Upper respiratory tract signs and symptoms	19	86	6	39	13	47
Vascular pulmonary disorders NEC	1	1			1	1
	311	985	47	154	264	831

System Organ Class

**Skin and subcutaneous tissue disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	2	1	2		
Alopecias		1				1
Angioedemas	21	59		1	21	58
Apocrine and eccrine gland disorders	20	87	9	28	11	59
Bullous conditions	6	13			6	13
Connective tissue disorders	2	3			2	3
Dermal and epidermal conditions NEC	11	41	7	22	4	19
Dermatitis and eczema	2	8		4	2	4
Dermatitis ascribed to specific agent	3	4	1	1	2	3
Erythemas	19	96	4	42	15	54
Exfoliative conditions	1	4		1	1	3
Hyperpigmentation disorders	1	1			1	1
Panniculitides	2	3		1	2	2
Papulosquamous conditions		1				1
Photosensitivity and photodermatosis conditions		1		1		
Pilar disorders NEC		2		1		1
Pruritus NEC	13	80	3	32	10	48
Psoriatic conditions	2	3		1	2	2
Purpura and related conditions	13	27	4	11	9	16
Rashes, eruptions and exanthems NEC	29	124	5	49	24	75
Skin and subcutaneous conditions NEC		2		1		1
Skin and subcutaneous tissue ulcerations	1	2		1	1	1
Skin cysts and polyps		1				1
Skin injuries and mechanical dermatoses	2	3	1	1	1	2
Skin vasculitides	1	3			1	3
Skin vasomotor conditions	3	11	2	3	1	8
Urticarias	14	73	5	28	9	45
	167	655	42	231	125	424

System Organ Class

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	12	34	3	6	9	28
	12	34	3	6	9	28

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	1	1	1	1
	1	1	1	1

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematological therapeutic procedures NEC	1	1			1	1
Joint therapeutic procedures	1	1	1	1		
Skin and subcutaneous tissue therapeutic procedures NEC		1		1		
Therapeutic procedures NEC	1	1			1	1
	3	4	1	2	2	2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	52	152			52	152
Aneurysms and dissections non-site specific		1				1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Aortic aneurysms and dissections		2					2
Aortic necrosis and vascular insufficiency	1	2			1		2
Arterial infections and inflammations	6	8			6		8
Blood pressure disorders NEC	3	8	2	3	1		5
Circulatory collapse and shock	5	17		1	5		16
Haemorrhages NEC	8	17	1	3	7		14
Lymphoedemas	2	4	1	3	1		1
Non-site specific embolism and thrombosis	13	22			13		22
Non-site specific necrosis and vascular insufficiency NEC	6	10	1	1	5		9
Non-site specific vascular disorders NEC	3	6	1	3	2		3
Peripheral embolism and thrombosis	68	84	7	9	61		75
Peripheral vascular disorders NEC	15	75	5	30	10		45
Peripheral vasoconstriction, necrosis and vascular insufficiency	15	28	3	11	12		17
Phlebitis NEC	14	17	7	8	7		9
Site specific necrosis and vascular insufficiency NEC		1					1
Site specific vascular disorders NEC	5	26		2	5		24
Varicose veins NEC	2	2	1	1	1		1
Vascular hypertensive disorders NEC	162	474	12	57	150		417
Vascular hypotensive disorders	34	144	9	29	25		115
Vasculitides NEC		2		1			1
Vena caval embolism and thrombosis	2	2			2		2
	416	1,104	50	162	366		942

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Country Where Event Occurred

**FRENCH POLYNESIA**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart failures NEC		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenic conditions		2		2
Body temperature altered		1		1
		3		3

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Staphylococcal infections		1		1
		1		1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses		1		1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Joint related signs and symptoms		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coordination and balance disturbances		1		1
Dyskinesias and movement disorders NEC		1		1
Memory loss (excl dementia)		1		1
Paraesthesias and dysaesthesias		1		1
		4		4

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusion and disorientation		1		1
		1		1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities		1		1
Coughing and associated symptoms		1		1
Pulmonary oedemas		1		1
Pulmonary thrombotic and embolic conditions		1		1
		4		4

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bullous conditions		2		2
Dermal and epidermal conditions NEC		1		1
		3		3

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Country Where Event Occurred

**FRENCH SOUTHERN TERRITORIES**

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death and sudden death	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**GEORGIA**

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lower respiratory tract and lung infections	1	1	1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**GERMANY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Anaemias haemolytic immune		1							1
Anaemias haemolytic mechanical factor		1							1
Anaemias NEC	2	5				1	2		4
Coagulopathies	1	4					1		4
Eosinophilic disorders	1	1					1		1
Haematological disorders		1							1
Leukocytoses NEC		3							3
Leukopenias NEC	1	5				1	1		4
Lymphatic system disorders NEC	34	108		1	34	102			6
Marrow depression and hypoplastic anaemias	2	2					2		2
Neutropenias	1	3					1		3
Thrombocytopenias	6	17					6		17
	48	151		1	34	104	14		47

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Cardiac conduction disorders	3	8				1	3		7
Cardiac disorders NEC	9	47			6	26	3		21
Cardiac signs and symptoms NEC	16	64		4	10	41	6		23
Cardiomyopathies	1	3					1		3
Coronary artery disorders NEC	3	4					3		4
Heart failures NEC	10	52					10		52
Ischaemic coronary artery disorders	13	52					13		52
Left ventricular failures		1							1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Myocardial disorders NEC		1						1
Noninfectious myocarditis	3	12					3	12
Noninfectious pericarditis		1						1
Pericardial disorders NEC	1	1					1	1
Rate and rhythm disorders NEC	35	158		7	22	55	13	103
Right ventricular failures	1	2					1	2
Supraventricular arrhythmias	5	35			1	5	4	30
Ventricular arrhythmias and cardiac arrest	9	29			1	1	8	28
	109	470		11	40	129	69	341

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC		3		3
		3		3

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	11	2	9		2
Hearing losses	5	23		1	5	22
Hyperacusia	1	1	1	1		
Inner ear signs and symptoms	2	19	1	14	1	5
	10	54	4	25	6	29

System Organ Class

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 \* AE=Adverse Event  
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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis	2	3	2	3
Thyroid hyperfunction disorders	2	3	2	3
Thyroid hypofunction disorders	1	1	1	1
	5	7	5	7

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders		2				2
Conjunctival infections, irritations and inflammations	1	1			1	1
Corneal structural change, deposit and degeneration	1	1			1	1
Iris and uveal tract infections, irritations and inflammations	2	2			2	2
Lacrimation disorders	2	11	1	8	1	3
Lid, lash and lacrimal infections, irritations and inflammations	2	8	1	4	1	4
Ocular bleeding and vascular disorders NEC	4	8			4	8
Ocular disorders NEC	4	18	3	14	1	4
Ocular infections, inflammations and associated manifestations	3	19	2	12	1	7
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders		1		1		
Optic disc abnormalities NEC	1	1			1	1
Optic nerve bleeding and vascular disorders	1	1			1	1
Pupil disorders	1	2	1	1		1
Retinal bleeding and vascular disorders (excl retinopathy)	2	2			2	2

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal structural change, deposit and degeneration	1	3			1	3
Retinopathies NEC		1				1
Scleral infections, irritations and inflammations		1		1		
Visual disorders NEC	5	19	2	11	3	8
Visual impairment and blindness (excl colour blindness)	10	34	3	9	7	25
Visual pathway disorders		1				1
	40	137	13	61	27	76

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute and chronic pancreatitis	1	2					1	2
Anal and rectal disorders NEC	1	1					1	1
Benign neoplasms gastrointestinal (excl oral cavity)		1				1		
Colitis (excl infective)		4						4
Dental pain and sensation disorders		1				1		
Diarrhoea (excl infective)	45	123		11	40	100	5	23
Dyspeptic signs and symptoms	1	4			1	4		
Faecal abnormalities NEC	2	15			2	14		1
Flatulence, bloating and distension	2	6		1	1	5	1	1
Gastrointestinal and abdominal pains (excl oral and throat)	16	59		2	9	37	7	22
Gastrointestinal atonic and hypomotility disorders NEC		2				2		
Gastrointestinal disorders NEC	1	3			1	2		1
Gastrointestinal dyskinetic disorders		2				2		
Gastrointestinal inflammatory disorders NEC		2						2

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	3					1	3
Gastrointestinal signs and symptoms NEC	10	29			6	16	4	13
Gastrointestinal spastic and hypermotility disorders		1				1		
Gastrointestinal stenosis and obstruction NEC	2	5			1	1	1	4
Gastrointestinal vascular occlusion and infarction	3	8					3	8
Gingival disorders, signs and symptoms NEC		2				1		1
Gingival haemorrhages	1	2					1	2
Intestinal haemorrhages	1	2					1	2
Nausea and vomiting symptoms	90	316		43	78	235	12	81
Non-mechanical ileus		2						2
Non-site specific gastrointestinal haemorrhages	2	10					2	10
Oesophagitis (excl infective)		1						1
Oral dryness and saliva altered	4	11			2	6	2	5
Oral soft tissue haemorrhages	1	1			1	1		
Oral soft tissue signs and symptoms	14	42		1	14	34		8
Oral soft tissue swelling and oedema		18				4		14
Peritoneal and retroperitoneal disorders		1						1
Salivary gland enlargements		2				2		
Stomatitis and ulceration	2	5				1	2	4
Tongue disorders		2				2		
Tongue signs and symptoms	8	25			7	12	1	13
	208	713		58	163	484	45	229

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adverse effect absent		4				4		

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System Organ Class

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Application and instillation site reactions		1
Asthenic conditions	205	749
Body temperature altered	2	5
Death and sudden death	52	242
Febrile disorders	93	389
Feelings and sensations NEC	135	406
Gait disturbances	1	14
General signs and symptoms NEC	75	284
Healing abnormal NEC	1	1
Inflammations	2	5
Injection site reactions	3	14
Interactions	2	4
Mass conditions NEC		1
Mucosal findings abnormal		1
Necrosis NEC		1
Oedema NEC	2	9
Pain and discomfort NEC	40	127
Therapeutic and nontherapeutic responses	48	295
Vaccination site reactions	196	752
	857	3,304

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	105	185	657	20	92
				2	5
				52	242
	26	84	298	9	91
	27	119	343	16	63
			7	1	7
	4	53	173	22	111
				1	1
		1	1	1	4
		3	14		
			2	2	2
			1		
					1
					1
		2	4		5
	3	37	93	3	34
		7	13	41	282
	68	190	721	6	31
	233	681	2331	176	973

System Organ Class

**Hepatobiliary disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cholecystitis and cholelithiasis		1
Cholestasis and jaundice	1	5
Hepatic failure and associated disorders		4
Hepatic fibrosis and cirrhosis	1	1
Hepatobiliary signs and symptoms		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	2		3
			4
		1	1
	1		

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\* AE=Adverse Event  
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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	2	12	1	4	1	8

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic conditions NEC	24	98		4	17	40	7	58
Allergies to foods, food additives, drugs and other chemicals		6				3		3
Anaphylactic and anaphylactoid responses	10	107		1			10	107
Atopic disorders	1	1			1	1		
Autoimmune disorders NEC		1						1
	35	213		5	18	44	17	169

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	2	4		1			2	4
Bacterial infections NEC	2	11					2	11
Candida infections	1	1					1	1
Cardiac infections		2						2
Central nervous system and spinal infections	2	7					2	7
Coronavirus infections	109	491		1	56	130	53	361
Dental and oral soft tissue infections	2	3					2	3
Ear infections		1				1		
Epstein-Barr viral infections		3						3
Escherichia infections		1						1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Eye and eyelid infections	1	6			1	4		2
Female reproductive tract infections	1	1					1	1
Fungal infections NEC	1	2					1	2
Herpes viral infections	9	72			4	49	5	23
Infections NEC	4	21		1	1	4	3	17
Influenza viral infections	6	8			5	6	1	2
Lower respiratory tract and lung infections	6	45				2	6	43
Muscle and soft tissue infections	1	2					1	2
Prion-associated disorders	2	2					2	2
Sepsis, bacteraemia, viraemia and fungaemia NEC		9						9
Skin structures and soft tissue infections	4	9		1	3	6	1	3
Staphylococcal infections	1	3					1	3
Streptococcal infections	2	4					2	4
Upper respiratory tract infections	8	46		1	8	36		10
Urinary tract infections	1	4				2	1	2
Vascular infections		2						2
Viral infections NEC	4	6			3	4	1	2
	169	766		5	81	244	88	522

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accidental exposures to product		1				1		
Cerebral injuries NEC	1	2					1	2
Chemical injuries	1	1					1	1
Exposures associated with pregnancy, delivery and lactation	2	45			2	44		1
Fractures and dislocations NEC		1						1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Intentional product misuses	1	2			1	2		
Limb fractures and dislocations	1	3					1	3
Medication errors, product use errors and issues NEC	4	25			4	25		
Muscle, tendon and ligament injuries	1	1		1			1	1
Neurological and psychiatric procedural complications		1						1
Non-site specific injuries NEC	3	21				3	3	18
Occupational exposures		1				1		
Off label uses	8	34			8	34		
Overdoses NEC	1	2					1	2
Pelvic fractures and dislocations	1	1					1	1
Peripheral nerve injuries		1						1
Poisoning and toxicity	1	2					1	2
Product administration errors and issues	43	170			43	163		7
Product preparation errors and issues		12				12		
Product storage errors and issues in the product use system	2	3			2	3		
Site specific injuries NEC	2	3					2	3
Skin injuries NEC	2	8			1	3	1	5
Underdoses NEC		21				21		
Vaccination related complications	12	37					12	37
	86	398		1	61	312	25	86

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood counts NEC	1	1					1	1
Blood gas and acid base analyses	2	17				2	2	15
Carbohydrate tolerance analyses (incl diabetes)	3	10			1	8	2	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Chemistry analyses NEC		1						1
Cholesterol analyses		2				2		
Coagulation and bleeding analyses	2	6			2	5		1
Digestive enzymes	1	2			1	1		1
ECG investigations		3						3
Haematological analyses NEC	1	2			1	2		
Haem metabolism analyses		1				1		
Heart rate and pulse investigations	4	16			1	8	3	8
Immune response protein analyses NEC		1				1		
Immunoglobulin analyses		1				1		
Immunology analyses NEC		4				3		1
Investigations NEC	1	1			1	1		
Liver function analyses	5	14			3	5	2	9
Mineral and electrolyte analyses	2	9				4	2	5
Musculoskeletal and soft tissue tests NEC		1						1
Neurologic diagnostic procedures		4				3		1
Physical examination procedures and organ system status	21	78			18	57	3	21
Pituitary analyses anterior		1				1		
Platelet analyses		2						2
Protein analyses NEC	6	12			5	8	1	4
Red blood cell analyses	1	9				6	1	3
Renal function analyses		3				2		1
Respiratory tract and thoracic imaging procedures		1						1
Skeletal and cardiac muscle analyses		3				2		1
Tissue enzyme analyses NEC		2						2
Urinalysis NEC	1	3				1	1	2
Vascular tests NEC (incl blood pressure)	17	53		3	9	25	8	28
Virus identification and serology	18	115			17	94	1	21
White blood cell analyses	2	7			2	5		2
	88	385		3	61	248	27	137

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	11	36	8	20	3	16
Calcium metabolism disorders		3				3
Diabetes mellitus (incl subtypes)	1	5			1	5
Disorders of purine metabolism		1		1		
Electrolyte imbalance NEC		2		1		1
Fluid intake increased	1	1			1	1
General nutritional disorders NEC		1				1
Hyperglycaemic conditions NEC		2				2
Hypoglycaemic conditions NEC	1	2	1	2		
Lipid metabolism and deposit disorders NEC		1		1		
Metabolic acidoses (excl diabetic acidoses)		1				1
Metabolic disorders NEC		1				1
Mixed acid-base disorders		1				1
Potassium imbalance		1				1
Sodium imbalance		5		2		3
Total fluid volume decreased	1	6		1	1	5
Total fluid volume increased	1	1	1	1		
	16	70	10	29	6	41

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	1	4					1	4
Bone disorders NEC		1						1
Bone related signs and symptoms	10	28			9	24	1	4
Bursal disorders	2	2		1	1	1	1	1
Connective tissue disorders NEC	1	2					1	2
Joint related disorders NEC		1				1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Joint related signs and symptoms	46	126		22	45	108	1	18
Lupus erythematosus (incl subtypes)	1	1					1	1
Metabolic bone disorders	1	1			1	1		
Muscle infections and inflammations	1	2			1	1		1
Muscle pains	59	222		35	58	206	1	16
Muscle related signs and symptoms NEC	15	33		1	13	23	2	10
Muscle tone abnormalities	1	2			1	1		1
Muscle weakness conditions	2	18				11	2	7
Musculoskeletal and connective tissue conditions NEC	7	23			6	18	1	5
Musculoskeletal and connective tissue pain and discomfort	117	444			104	398	13	46
Myopathies		3						3
Rheumatoid arthropathies		2						2
Soft tissue disorders NEC		3				2		1
Spondyloarthropathies		1						1
Tendon disorders	1	3				1	1	2
	265	922		59	239	796	26	126

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias acute myeloid	1	1	1	1
Leukaemias NEC	1	1	1	1
Neoplasms unspecified malignancy and site unspecified NEC	1	1	1	1
Oncologic complications and emergencies	1	1	1	1
Skin melanomas (excl ocular)		1		1
	4	5	4	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Absence seizures		1						1
Acute polyneuropathies		2						2
Alzheimer's disease (incl subtypes)		1						1
Autonomic nervous system disorders	2	4			2	2		2
Central nervous system aneurysms and dissections		1						1
Central nervous system haemorrhages and cerebrovascular accidents	42	107					42	107
Central nervous system vascular disorders NEC		3						3
Cerebrovascular venous and sinus thrombosis	5	10					5	10
Chronic polyneuropathies		1						1
Coma states		2						2
Coordination and balance disturbances	2	16			1	3	1	13
Cortical dysfunction NEC	4	19				6	4	13
Cranial nerve disorders NEC		2				2		
Dementia (excl Alzheimer's type)	1	7					1	7
Disturbances in consciousness NEC	40	139		2	8	20	32	119
Dyskinesias and movement disorders NEC	4	19			2	8	2	11
Encephalitis NEC	1	1					1	1
Eye movement disorders	2	4					2	4
Facial cranial nerve disorders	19	74			5	18	14	56
Generalised tonic-clonic seizures		3						3
Headaches NEC	165	625		56	149	548	16	77
Increased intracranial pressure disorders	2	5					2	5
Memory loss (excl dementia)	4	17			1	5	3	12
Mental impairment (excl dementia and memory loss)	8	42			7	27	1	15
Migraine headaches	3	11			3	9		2
Motor neurone diseases		1						1
Multiple sclerosis acute and progressive	2	6					2	6
Muscle tone abnormal	9	18			6	11	3	7
Narcolepsy and hypersomnia	1	5			1	3		2

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 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Nervous system disorders NEC		5				1			4
Neurological signs and symptoms NEC	81	304		41	63	204	18		100
Neurologic visual problems NEC		3				1			2
Neuromuscular disorders NEC		2							2
Neuromuscular junction dysfunction		1							1
Olfactory nerve disorders	3	11			3	9			2
Optic nerve disorders NEC		2							2
Paraesthesias and dysaesthesias	55	180		5	41	115	14		65
Paralysis and paresis (excl cranial nerve)	14	44			2	4	12		40
Parkinson's disease and parkinsonism		4				1			3
Peripheral neuropathies NEC	4	16				4	4		12
Seizures and seizure disorders NEC	9	75					9		75
Sensory abnormalities NEC	27	74			24	63	3		11
Sleep disturbances NEC	1	8				5	1		3
Speech and language abnormalities	4	15			2	4	2		11
Spinal cord and nerve root disorders NEC	1	3				1	1		2
Structural brain disorders NEC		2							2
Transient cerebrovascular events	4	6					4		6
Tremor (excl congenital)	10	38			6	18	4		20
Trigeminal disorders	1	2			1	2			
	530	1,941		104	327	1094	203		847

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abortions not specified as induced or spontaneous		1				1	
Abortions spontaneous	1	4			1	4	
Normal pregnancy, labour and delivery		1		1			

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Unintended pregnancies	1	1			1	1
	2	7		1	2	6

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products		1		1		
Device issues NEC	1	1			1	1
Product distribution and storage issues	5	35	5	33		2
Product physical issues		1		1		
Product quality issues NEC	1	7	1	7		
Product supply and availability issues		2		2		
	7	47	6	44	1	3

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	17	2	10		7
Behaviour and socialisation disturbances	2	12		1	2	11
Communications disorders		1		1		
Confusion and disorientation	4	24	2	9	2	15
Deliria	1	6			1	6
Delusional symptoms		2				2
Depressive disorders	4	5	4	5		
Disturbances in initiating and maintaining sleep	4	17	4	16		1
Eating disorders NEC		2		2		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Emotional and mood disturbances NEC		1					1
Fear symptoms and phobic disorders (incl social phobia)		1					1
Hallucinations (excl sleep-related)	1	6			1		6
Increased physical activity levels	5	13	4	10	1		3
Mental disorders NEC	2	5	1	2	1		3
Mood alterations with depressive symptoms	1	2			1		2
Mood disorders NEC	3	12	3	7			5
Panic attacks and disorders	3	8	2	4	1		4
Sleep disorders NEC	1	12	1	11			1
Somatic symptom disorders		1					1
Stereotypies and automatisms		1					1
Stress disorders	1	1			1		1
	34	149	23	78	11		71

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bladder and urethral symptoms	5	11	4	7	1		4
Bladder infections and inflammations	1	1			1		1
Genitourinary tract infections and inflammations NEC		1					1
Glomerulonephritis and nephrotic syndrome		2					2
Myoneurogenic bladder disorders	1	1			1		1
Renal disorders NEC		2					2
Renal failure and impairment	4	32			4		32
Renal lithiasis	1	1			1		1
Urinary abnormalities	1	3	1	2			1
Urinary tract signs and symptoms NEC	1	5		2	1		3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	14	59	5	11	9	48

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breast signs and symptoms	2	2		1	2	2		
Cervix disorders NEC	1	1					1	1
Menstruation and uterine bleeding NEC		6				6		
Menstruation with increased bleeding		1				1		
Reproductive tract disorders NEC (excl neoplasms)	1	1					1	1
Reproductive tract signs and symptoms NEC		1				1		
Vulvovaginal signs and symptoms	3	3			1	1	2	2
	7	15		1	3	11	4	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	71	299		2	27	81	44	218
Bronchial conditions NEC		1				1		
Bronchospasm and obstruction	13	46			7	17	6	29
Conditions associated with abnormal gas exchange	2	3					2	3
Coughing and associated symptoms	17	62		1	14	45	3	17
Laryngeal spasm, oedema and obstruction	2	14					2	14
Lower respiratory tract inflammatory and immunologic conditions	1	5					1	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Lower respiratory tract signs and symptoms	2	8			1	3	1	5
Nasal congestion and inflammations	1	8			1	7		1
Nasal disorders NEC	3	7		1	2	5	1	2
Paranasal sinus disorders (excl infections and neoplasms)		2				2		
Parenchymal lung disorders NEC	1	3					1	3
Pharyngeal disorders (excl infections and neoplasms)	4	19		1	1	8	3	11
Pleural infections and inflammations		1						1
Pneumothorax and pleural effusions NEC		3						3
Pulmonary hypertensions	1	1					1	1
Pulmonary oedemas	2	9					2	9
Pulmonary thrombotic and embolic conditions	45	67					45	67
Respiratory failures (excl neonatal)	1	25					1	25
Respiratory signs and symptoms NEC	2	4			2	4		
Respiratory tract disorders NEC	1	8			1	2		6
Upper respiratory tract signs and symptoms	27	121		2	26	98	1	23
	196	716		7	82	273	114	443

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acnes		1				1		
Alopecias	1	4				2	1	2
Angioedemas	10	35			1	1	9	34
Apocrine and eccrine gland disorders	15	54		1	13	42	2	12
Bullous conditions	5	11			1	5	4	6
Dermal and epidermal conditions NEC	9	24			7	16	2	8
Dermatitis and eczema	9	29			8	24	1	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dermatitis ascribed to specific agent	1	2			1	1		1
Erythemas	18	71		2	16	52	2	19
Exfoliative conditions	1	3			1	3		
Nail and nail bed conditions (excl infections and infestations)		1				1		
Photosensitivity and photodermatosis conditions		1				1		
Pruritus NEC	27	75		2	20	48	7	27
Psoriatic conditions		2				1		1
Purpura and related conditions	5	13			3	5	2	8
Pustular conditions	1	1					1	1
Rashes, eruptions and exanthems NEC	35	121		4	27	77	8	44
Rosaceas		1						1
Skin and subcutaneous tissue ulcerations	1	1			1	1		
Skin haemorrhages		1						1
Skin vasculitides	3	6					3	6
Skin vasomotor conditions		1				1		
Urticarias	19	42		1	15	28	4	14
	160	500		10	114	310	46	190

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues		6		4		2
		6		4		2

System Organ Class

**Surgical and medical procedures**

Interval Total #	Cumulative Total #	Spontaneous	
		I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cranial nerve therapeutic procedures		1		1
Small intestine therapeutic procedures	1	1	1	1
Therapeutic procedures NEC		1		1
Vascular therapeutic procedures NEC	1	1	1	1
	2	4	2	4

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	4	20					4	20
Aortic aneurysms and dissections	2	5					2	5
Arterial infections and inflammations		1						1
Blood pressure disorders NEC	1	5			1	5		
Circulatory collapse and shock	18	61		1	4	4	14	57
Haemorrhages NEC	9	20			2	6	7	14
Lymphoedemas	1	2			1	2		
Non-site specific embolism and thrombosis	18	27					18	27
Non-site specific necrosis and vascular insufficiency NEC	4	9				1	4	8
Peripheral embolism and thrombosis	38	50			4	5	34	45
Peripheral vascular disorders NEC	24	97		1	20	46	4	51
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	6			2	5	1	1
Phlebitis NEC	1	1			1	1		
Site specific vascular disorders NEC	3	7			1	2	2	5
Varicose veins NEC	1	1			1	1		
Vascular hypertensive disorders NEC	16	73		3	9	27	7	46
Vascular hypotensive disorders	14	45			12	22	2	23
Vasculitides NEC	1	6				1	1	5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	158	436		5	58	128	100	308

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**GREECE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	2	2	1	1	1	1
Leukocytoses NEC	1	2	1	1		1
Leukopenias NEC		1		1		
Lymphatic system disorders NEC	20	67	10	30	10	37
	23	72	12	33	11	39

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	5	30		14	5	16
Cardiac valve disorders NEC		1				1
Coronary artery disorders NEC		1				1
Heart failures NEC	1	1			1	1
Ischaemic coronary artery disorders	3	7			3	7
Myocardial disorders NEC		1				1
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	17	81	5	33	12	48
Supraventricular arrhythmias	3	6			3	6
Ventricular arrhythmias and cardiac arrest	3	9			3	9
	32	138	5	47	27	91

System Organ Class

**Congenital, familial and genetic disorders**

Interval Total #	Cumulative Total #	Spontaneous
		Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac septal defects congenital		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		4		2		2
Hearing losses		4				4
Inner ear signs and symptoms	4	21	2	14	2	7
	4	29	2	16	2	13

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	3		1	1	2
Thyroid disorders NEC	1	1			1	1
Thyroid neoplasms		1				1
	2	5		1	2	4

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival infections, irritations and inflammations		2		2		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Eyelid movement disorders		3		1		2	
Iris and uveal tract infections, irritations and inflammations	5	6			5	6	
Lacrimation disorders	1	2	1	2			
Lid, lash and lacrimal infections, irritations and inflammations	2	7	2	5		2	
Ocular bleeding and vascular disorders NEC	2	2			2	2	
Ocular disorders NEC	5	9	4	5	1	4	
Ocular infections, inflammations and associated manifestations	3	8	1	4	2	4	
Ocular sensation disorders	1	1			1	1	
Optic disc abnormalities NEC		1				1	
Scleral infections, irritations and inflammations	1	2			1	2	
Visual disorders NEC		4		2		2	
Visual impairment and blindness (excl colour blindness)	2	2	1	1	1	1	
	22	49	9	22	13	27	

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute and chronic pancreatitis		2				2	
Dental disorders NEC		1				1	
Diarrhoea (excl infective)	3	27	3	17		10	
Dyspeptic signs and symptoms	2	11		6	2	5	
Flatulence, bloating and distension	1	3	1	1		2	
Gastrointestinal and abdominal pains (excl oral and throat)	1	19		12	1	7	
Gastrointestinal atonic and hypomotility disorders NEC	1	2		1	1	1	
Gastrointestinal disorders NEC	1	10		9	1	1	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal signs and symptoms NEC	4	26	1	8	3	18
Gastrointestinal spastic and hypermotility disorders		2				2
Nausea and vomiting symptoms	10	72	5	44	5	28
Non-site specific gastrointestinal haemorrhages	2	2			2	2
Oral dryness and saliva altered	2	8	2	6		2
Oral soft tissue disorders NEC	2	3			2	3
Oral soft tissue signs and symptoms	4	32	2	14	2	18
Oral soft tissue swelling and oedema	1	12		5	1	7
Salivary gland disorders NEC	1	2	1	2		
Salivary gland enlargements	2	3		1	2	2
Tongue disorders		1		1		
Tongue signs and symptoms	4	8			4	8
	41	246	15	127	26	119

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		10		10		
Asthenic conditions	34	180	23	106	11	74
Body temperature altered	1	2			1	2
Death and sudden death	3	12			3	12
Febrile disorders	38	174	28	105	10	69
Feelings and sensations NEC	12	101	9	50	3	51
Gait disturbances	4	10		4	4	6
General signs and symptoms NEC	10	27	4	10	6	17
Inflammations	1	4	1	1		3
Injection site reactions		3		3		
Interactions		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mucosal findings abnormal		1				1
Oedema NEC	3	16	1	7	2	9
Pain and discomfort NEC	10	63	3	28	7	35
Therapeutic and nontherapeutic responses	3	26		4	3	22
Vaccination site reactions	16	140	11	119	5	21
	135	770	80	447	55	323

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis		1		1
Hepatocellular damage and hepatitis NEC		1		1
		2		2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic sarcoidosis	1	1			1	1
Allergic conditions NEC	3	36		15	3	21
Allergies to foods, food additives, drugs and other chemicals		5		1		4
Anaphylactic and anaphylactoid responses	5	24			5	24
	9	66		16	9	50

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	2			1	2
Central nervous system and spinal infections	1	2			1	2
Coronavirus infections	8	42		11	8	31
Dental and oral soft tissue infections		1		1		
Eye and eyelid infections	1	2	1	2		
Herpes viral infections	5	27	3	13	2	14
Infections NEC	2	4	1	1	1	3
Lower respiratory tract and lung infections	1	3			1	3
Upper respiratory tract infections	2	4	2	4		
Urinary tract infections	1	3		1	1	2
Viral infections NEC		2		2		
	22	92	7	35	15	57

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC	1	1	1	1		
Cardiac and vascular procedural complications	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	3	5	3	5		
Limb fractures and dislocations	1	1			1	1
Medication errors, product use errors and issues NEC	1	8	1	8		
Muscle, tendon and ligament injuries		1		1		
Non-site specific injuries NEC	1	7		3	1	4
Occupational exposures	1	1	1	1		
Off label uses	1	5	1	5		
Overdoses NEC		1		1		
Product administration errors and issues	1	11	1	11		

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 \* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation errors and issues		1		1		
Site specific injuries NEC	1	2		1	1	1
Skin injuries NEC	1	1			1	1
Vaccination related complications	1	4			1	4
	14	50	8	38	6	12

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory function diagnostic procedures	1	1	1	1		
Blood gas and acid base analyses	6	10		1	6	9
Carbohydrate tolerance analyses (incl diabetes)		5		4		1
Cell marker analyses		2		1		1
Cerebrospinal fluid tests (excl microbiology)	1	1			1	1
Coagulation and bleeding analyses		3		2		1
ECG investigations	1	1			1	1
Heart rate and pulse investigations	8	34	2	17	6	17
Immunoglobulin analyses	1	1			1	1
Liver function analyses		4		3		1
Mineral and electrolyte analyses		3		3		
Neurologic diagnostic procedures	1	1	1	1		
Physical examination procedures and organ system status	1	3	1	3		
Platelet analyses		1		1		
Protein analyses NEC		3		3		
Red blood cell analyses	2	3	1	2	1	1
Renal function analyses		1		1		
Skeletal and cardiac muscle analyses		1		1		
Triglyceride analyses	1	1			1	1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)	21	73	3	32	18	41
Virus identification and serology	1	3	1	3		
White blood cell analyses		1		1		
	45	156	10	80	35	76

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	5	1	4	1	1
Diabetes mellitus (incl subtypes)	2	4			2	4
Fluid intake increased		1		1		
General nutritional disorders NEC	1	5	1	1		4
Hyperglycaemic conditions NEC		1				1
Hypoglycaemic conditions NEC	1	4		3	1	1
Potassium imbalance	2	2			2	2
Protein metabolism disorders NEC		1		1		
Sodium imbalance	2	3		1	2	2
Total fluid volume decreased	1	1			1	1
	11	27	2	11	9	16

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	3		1	1	2
Bone related signs and symptoms	3	10		2	3	8
Bursal disorders	1	2		1	1	1

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\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Connective tissue disorders NEC	1	1			1	1
Extremity deformities	1	1			1	1
Intervertebral disc disorders NEC	2	2	2	2		
Joint related disorders NEC	1	2	1	2		
Joint related signs and symptoms	10	72	6	34	4	38
Muscle pains	13	117	9	72	4	45
Muscle related signs and symptoms NEC	2	9		3	2	6
Muscle tone abnormalities		1		1		
Muscle weakness conditions	4	11		3	4	8
Musculoskeletal and connective tissue conditions NEC	2	3	2	2		1
Musculoskeletal and connective tissue pain and discomfort	21	61	17	49	4	12
Psoriatic arthropathies		1				1
Rheumatoid arthropathies		2				2
Soft tissue disorders NEC		2		1		1
Spondyloarthropathies	1	1			1	1
	63	301	37	173	26	128

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	2
			1
		3	6
1	1	1	4
		4	9
		1	1
			1
		1	1
	3	2	4
		1	1
2	18	5	30
1	5		2
3	3	9	15
14	86	5	50
			1
		1	2
			1
1	6		2
	3	1	3
8	61	10	43
	1	1	2
14	69	15	52
		5	11
		3	6
		1	2
1	10	5	18
	1		
1	3	3	6
			1
3	12	1	6

Abnormal reflexes	2	2
Absence seizures		1
Acute polyneuropathies	3	6
Autonomic nervous system disorders	2	5
Central nervous system haemorrhages and cerebrovascular accidents	4	9
Cerebrovascular venous and sinus thrombosis	1	1
Cervical spinal cord and nerve root disorders		1
Coma states	1	1
Coordination and balance disturbances	2	7
Cortical dysfunction NEC	1	1
Disturbances in consciousness NEC	7	48
Dyskinesias and movement disorders NEC	1	7
Facial cranial nerve disorders	12	18
Headaches NEC	19	136
Lumbar spinal cord and nerve root disorders		1
Memory loss (excl dementia)	1	2
Mental impairment (excl dementia and memory loss)		1
Migraine headaches	1	8
Muscle tone abnormal	1	6
Neurological signs and symptoms NEC	18	104
Olfactory nerve disorders	1	3
Paraesthesias and dysaesthesias	29	121
Paralysis and paresis (excl cranial nerve)	5	11
Peripheral neuropathies NEC	3	6
Seizures and seizure disorders NEC	1	2
Sensory abnormalities NEC	6	28
Sleep disturbances NEC		1
Speech and language abnormalities	4	9
Transient cerebrovascular events		1
Tremor (excl congenital)	4	18

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal disorders		1				1
	129	566	49	282	80	284

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues		1		1
Product physical issues		4		4
Product quality issues NEC		1		1
		6		6

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	7	1	5		2
Behaviour and socialisation disturbances		1				1
Communications disorders	1	1	1	1		

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	3	12	1	3	2	9
Depressive disorders		1		1		
Disturbances in initiating and maintaining sleep	2	7	1	5	1	2
Eating disorders NEC	2	2	1	1	1	1
Emotional and mood disturbances NEC	2	5		1	2	4
Increased physical activity levels		1		1		
Obsessive-compulsive disorders and symptoms		1				1
Panic attacks and disorders		1				1
	11	39	5	18	6	21

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	3	1	2		1
Renal failure and impairment	2	2			2	2
Urinary abnormalities		1				1
Urinary tract signs and symptoms NEC		1		1		
	3	7	1	3	2	4

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		1		1		
Cervix disorders NEC		1				1
Menstruation and uterine bleeding NEC	1	4	1	3		1
Menstruation with decreased bleeding		1		1		

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation with increased bleeding		3		2		1
	1	10	1	7		3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	11	48	1	16	10	32
Bronchospasm and obstruction	1	13		1	1	12
Coughing and associated symptoms	6	34	2	14	4	20
Laryngeal spasm, oedema and obstruction	1	11			1	11
Nasal congestion and inflammations	1	3	1	3		
Nasal disorders NEC	1	2	1	2		
Pharyngeal disorders (excl infections and neoplasms)		2		1		1
Pulmonary oedemas		2				2
Pulmonary thrombotic and embolic conditions	1	4			1	4
Respiratory failures (excl neonatal)	1	2			1	2
Respiratory tract disorders NEC	2	2			2	2
Upper respiratory tract signs and symptoms	13	61	5	26	8	35
	38	184	10	63	28	121

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	1	1	1		
Alopecias		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	3	16			3	16
Apocrine and eccrine gland disorders	7	27	2	12	5	15
Bullous conditions		4		4		
Connective tissue disorders	1	1			1	1
Dermal and epidermal conditions NEC	1	5		2	1	3
Dermatitis and eczema		5		2		3
Erythemas	8	65	4	43	4	22
Granulomatous and deep cutaneous inflammatory conditions	1	1	1	1		
Hyperkeratoses	1	1	1	1		
Nail and nail bed conditions (excl infections and infestations)		3		3		
Pruritus NEC	9	65	3	35	6	30
Psoriatic conditions		1		1		
Purpura and related conditions	2	3		1	2	2
Rashes, eruptions and exanthems NEC	16	94	8	44	8	50
Skin vasculitides	1	1			1	1
Skin vasomotor conditions		1		1		
Urticarias	1	7	1	5		2
	52	302	21	157	31	145

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	1	3		1	1	2
Non-occupational and unspecified environmental problems	1	1			1	1
	2	4		1	2	3

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nervous system therapeutic procedures NEC		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		16				16
Blood pressure disorders NEC		2		2		
Circulatory collapse and shock		1				1
Haemorrhages NEC		1				1
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	2	3			2	3
Non-site specific necrosis and vascular insufficiency NEC	1	2			1	2
Non-site specific vascular disorders NEC	1	2		1	1	1
Peripheral embolism and thrombosis	4	5			4	5
Peripheral vascular disorders NEC	4	35		15	4	20
Peripheral vasoconstriction, necrosis and vascular insufficiency	4	10	1	1	3	9
Site specific vascular disorders NEC	1	3		2	1	1
Vascular hypertensive disorders NEC	4	37		16	4	21
Vascular hypotensive disorders	1	22		7	1	15
Vasculitides NEC	1	1			1	1
	23	141	1	44	22	97

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Country Where Event Occurred

**GUINEA**

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headaches NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular hypertensive disorders NEC	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred  
**HOLY SEE (VATICAN CITY STATE)**

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Injection site reactions		1		1
Oedema NEC		2		2
Vaccination site reactions		2		2
		6		6

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue pain and discomfort		1		1
		1		1

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Country Where Event Occurred

**HONG KONG**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	2	2	2	2
	2	2	2	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	10	12	2	2	8	10
Coronary artery disorders NEC	1	2			1	2
Ischaemic coronary artery disorders		1				1
	11	15	2	2	9	13

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	2	2			2	2
Nausea and vomiting symptoms	5	5	2	2	3	3
	7	7	2	2	5	5

System Organ Class

**General disorders and administration site conditions**

Spontaneous
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\* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	3	6	2	5	1	1
Febrile disorders	2	2	1	1	1	1
Injection site reactions	1	1	1	1		
Pain and discomfort NEC	11	13	3	4	8	9
Vaccination site reactions	6	6	5	5	1	1
	23	28	12	16	11	12

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	3	1	1	1	2
Allergies to foods, food additives, drugs and other chemicals	3	3	2	2	1	1
Anaphylactic and anaphylactoid responses	1	2			1	2
	6	8	3	3	3	5

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal and gastrointestinal injuries NEC	1	1	1	1
Non-site specific injuries NEC	3	3	3	3
Skin injuries NEC	1	1	1	1
	5	5	5	5

System Organ Class

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)	4	5	2	3	2	2
	4	5	2	3	2	2

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	2	2	2	2		
Muscle related signs and symptoms NEC	1	1	1	1		
Muscle weakness conditions	1	1			1	1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	1	1			1	1
	6	6	4	4	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	2			1	2
Cortical dysfunction NEC	1	1	1	1		
Disturbances in consciousness NEC	18	19			18	19
Dyskinesias and movement disorders NEC	1	1	1	1		
Facial cranial nerve disorders	3	3			3	3
Headaches NEC	4	4	2	2	2	2
Migraine headaches	1	1	1	1		
Neurological signs and symptoms NEC	22	24	8	8	14	16
Paraesthesias and dysaesthesias	12	13	5	5	7	8
Paralysis and paresis (excl cranial nerve)	1	2			1	2
Seizures and seizure disorders NEC	6	6			6	6
Sensory abnormalities NEC		1		1		
Tremor (excl congenital)	1	1	1	1		
	71	78	19	20	52	58

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	4	7	1	2	3	5

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1		
	5	8	2	3	3	5

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	2	2	2	2		
Pruritus NEC	1	1	1	1		
Rashes, eruptions and exanthems NEC	12	14	7	7	5	7
Urticarias	1	1			1	1
	16	18	10	10	6	8

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular hypertensive disorders NEC	14	14	2	2	12	12
	14	14	2	2	12	12

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Country Where Event Occurred

**HUNGARY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	2	2	1	1	1	1
Leukocytoses NEC	1	1			1	1
Lymphatic system disorders NEC	4	51	2	43	2	8
Thrombocytopenias	1	1			1	1
	8	55	3	44	5	11

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	2	2			2	2
Cardiac signs and symptoms NEC	2	8	1	6	1	2
Heart failures NEC	2	6			2	6
Ischaemic coronary artery disorders	3	6			3	6
Left ventricular failures		1				1
Myocardial disorders NEC	2	2	1	1	1	1
Noninfectious pericarditis	1	1			1	1
Rate and rhythm disorders NEC		12		5		7
Supraventricular arrhythmias	2	4			2	4
Tricuspid valvular disorders	1	1			1	1
Ventricular arrhythmias and cardiac arrest		1				1
	15	44	2	12	13	32

System Organ Class

**Ear and labyrinth disorders**

Spontaneous
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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	11	1	9	2	2
Inner ear signs and symptoms	1	4	1	4		
	4	15	2	13	2	2

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	2		1	1	1
	1	2		1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders	1	1	1	1		
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders		5		5		
Lid, lash and lacrimal infections, irritations and inflammations	2	3	2	3		
Ocular bleeding and vascular disorders NEC		2				2
Ocular disorders NEC	2	5	1	2	1	3
Ocular infections, inflammations and associated manifestations	1	3		2	1	1
Ocular sensation disorders	1	1	1	1		
Retinal, choroid and vitreous infections and inflammations		1				1
Visual disorders NEC		3		3		

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment and blindness (excl colour blindness)		3		1		2
	7	28	5	18	2	10

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental disorders NEC		1				1
Dental pain and sensation disorders	1	1	1	1		
Diarrhoea (excl infective)	4	25	2	22	2	3
Flatulence, bloating and distension		3		3		
Gastric ulcers and perforation	1	1			1	1
Gastrointestinal and abdominal pains (excl oral and throat)		8		8		
Gastrointestinal atonic and hypomotility disorders NEC		1		1		
Gastrointestinal disorders NEC		1		1		
Gastrointestinal inflammatory disorders NEC	1	1			1	1
Gastrointestinal signs and symptoms NEC	2	16	1	6	1	10
Gastrointestinal spastic and hypermotility disorders		1		1		
Gingival disorders, signs and symptoms NEC		2		2		
Nausea and vomiting symptoms	11	61	11	54		7
Non-mechanical ileus		1				1
Non-site specific gastrointestinal haemorrhages	2	3			2	3
Oral dryness and saliva altered	1	3	1	2		1
Oral soft tissue signs and symptoms	4	9	3	7	1	2
Oral soft tissue swelling and oedema	1	5	1	1		4
Stomatitis and ulceration		1		1		
Tongue disorders		1		1		

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue signs and symptoms	1	2	1	2		
	29	147	21	113	8	34

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	27	159	23	139	4	20
Death and sudden death	2	6			2	6
Febrile disorders	20	103	17	94	3	9
Feelings and sensations NEC	15	88	14	77	1	11
Gait disturbances		3		3		
General signs and symptoms NEC	11	35	6	26	5	9
Inflamations	1	1	1	1		
Injection site reactions	1	5	1	5		
Interactions	2	2	2	2		
Mucosal findings abnormal	1	1			1	1
Oedema NEC	1	7	1	3		4
Pain and discomfort NEC	9	33	6	30	3	3
Therapeutic and nontherapeutic responses	13	28		1	13	27
Vaccination site reactions	32	148	32	147		1
	135	619	103	528	32	91

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis	1	1	1	1

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Structural and other bile duct disorders		1		1
	1	2	1	2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	12	1	8	2	4
Allergies to foods, food additives, drugs and other chemicals		3		2		1
Anaphylactic and anaphylactoid responses		4				4
	3	19	1	10	2	9

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1			1	1
Coronavirus infections	15	36	1	5	14	31
Dental and oral soft tissue infections		1		1		
Herpes viral infections		14		14		
Influenza viral infections		1		1		
Lower respiratory tract and lung infections	5	6	1	1	4	5
Streptococcal infections	1	1			1	1
Upper respiratory tract infections		5		5		
	22	65	2	27	20	38

System Organ Class

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bone and joint injuries NEC		1				1	
Exposures associated with pregnancy, delivery and lactation		9		8		1	
Heat injuries (excl thermal burns)		1		1			
Limb fractures and dislocations		2				2	
Medication errors, product use errors and issues NEC		3		3			
Muscle, tendon and ligament injuries		2		2			
Non-site specific injuries NEC	3	8	2	4	1	4	
Off label uses	1	3	1	3			
Overdoses NEC	1	1	1	1			
Product administration errors and issues	4	6	4	6			
Skull fractures, facial bone fractures and dislocations		1				1	
Vaccination related complications	2	5		1	2	4	
	11	42	8	29	3	13	

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood counts NEC	1	1			1	1
Blood gas and acid base analyses		3		2		1
Carbohydrate tolerance analyses (incl diabetes)	1	5	1	4		1
Coagulation and bleeding analyses	1	1			1	1
Haematological analyses NEC	1	2	1	2		
Heart rate and pulse investigations	3	12	3	10		2
Immunology analyses NEC	1	2	1	2		
Liver function analyses	4	4	4	4		
Mineral and electrolyte analyses		1		1		

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	1	3		2	1	1
Pituitary analyses anterior		1		1		
Protein analyses NEC	1	1	1	1		
Renal function analyses	1	1	1	1		
Thyroid analyses		3		3		
Urinalysis NEC	1	1			1	1
Vascular tests NEC (incl blood pressure)	7	29	1	16	6	13
Virus identification and serology	3	12		6	3	6
White blood cell analyses		2		2		
	26	84	13	57	13	27

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	8	3	7		1
General nutritional disorders NEC		2				2
Hypoglycaemic conditions NEC		1		1		
Metabolic acidoses (excl diabetic acidoses)		1				1
Total fluid volume decreased	1	1			1	1
	4	13	3	8	1	5

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		2				2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	2	1	2		
Bursal disorders		1		1		
Intervertebral disc disorders NEC		1		1		
Joint related disorders NEC		1		1		
Joint related signs and symptoms	5	21	3	17	2	4
Muscle pains	9	47	9	46		1
Muscle related signs and symptoms NEC	2	4	1	3	1	1
Muscle weakness conditions	1	7	1	7		
Musculoskeletal and connective tissue conditions NEC	1	5	1	4		1
Musculoskeletal and connective tissue pain and discomfort	12	76	12	74		2
Osteoarthropathies		1		1		
Soft tissue disorders NEC		1		1		
Spondyloarthropathies		1				1
	31	170	28	158	3	12

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasms unspecified malignancy and site unspecified NEC		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		2		2		
Acute polyneuropathies		1				1
Central nervous system haemorrhages and cerebrovascular accidents	1	6			1	6
Cervical spinal cord and nerve root disorders		1		1		
Coordination and balance disturbances	1	2	1	2		
Dementia (excl Alzheimer's type)	1	1			1	1
Disturbances in consciousness NEC	9	28	2	12	7	16
Dyskinesias and movement disorders NEC		1				1
Facial cranial nerve disorders		6		2		4
Headaches NEC	19	96	18	89	1	7
Lumbar spinal cord and nerve root disorders		1				1
Memory loss (excl dementia)	1	2		1	1	1
Mental impairment (excl dementia and memory loss)	2	2	1	1	1	1
Migraine headaches		5		4		1
Muscle tone abnormal	1	1			1	1
Neurological signs and symptoms NEC	9	46	7	40	2	6
Olfactory nerve disorders		4		4		
Paraesthesias and dysaesthesias	9	39	7	33	2	6
Paralysis and paresis (excl cranial nerve)		5				5
Peripheral neuropathies NEC		1				1
Sensory abnormalities NEC	2	14	2	12		2
Sleep disturbances NEC		1		1		
Speech and language abnormalities	1	1	1	1		
Spinal cord and nerve root disorders NEC		2		1		1
Structural brain disorders NEC		1		1		
Transient cerebrovascular events		1				1
Tremor (excl congenital)	2	10	1	7	1	3
	58	280	40	214	18	66

System Organ Class

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	2	3	2	3
	2	3	2	3

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues	1	1	1	1
Product quality issues NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	5	1	5		
Behaviour and socialisation disturbances	1	1			1	1
Confusion and disorientation	2	4	1	2	1	2
Depressive disorders		1		1		
Disturbances in initiating and maintaining sleep	2	8	2	8		
Emotional and mood disturbances NEC		3		3		
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Increased physical activity levels		1		1		
Mood alterations with depressive symptoms		2		2		
Mood disorders NEC		1				1
Panic attacks and disorders		1		1		
Psychiatric symptoms NEC	1	2			1	2

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorders NEC	1	2	1	2		
Speech articulation and rhythm disturbances	1	1			1	1
Thinking disturbances		1		1		
	9	34	5	27	4	7

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	2	5	1	4	1	1
Renal failure and impairment	2	2			2	2
Urinary abnormalities	1	4	1	3		1
Urinary tract signs and symptoms NEC		3		3		
	5	14	2	10	3	4

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	1	1			1	1
Breast signs and symptoms		1		1		
Lactation disorders	1	1	1	1		
Menstruation and uterine bleeding NEC		1		1		
Menstruation with decreased bleeding		1		1		
Pelvis and broad ligament disorders NEC		1		1		
Vulvovaginal signs and symptoms		1		1		
	2	7	1	6	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	4	23	2	11	2	12
Bronchospasm and obstruction	1	2		1	1	1
Conditions associated with abnormal gas exchange	1	4			1	4
Coughing and associated symptoms	8	16	5	13	3	3
Laryngeal spasm, oedema and obstruction		2				2
Nasal congestion and inflammations		2		2		
Nasal disorders NEC		1		1		
Parenchymal lung disorders NEC		1				1
Pharyngeal disorders (excl infections and neoplasms)	2	5	1	4	1	1
Pulmonary thrombotic and embolic conditions	1	1			1	1
Respiratory failures (excl neonatal)	2	3			2	3
Respiratory signs and symptoms NEC		1		1		
Respiratory tract disorders NEC	1	1	1	1		
Upper respiratory tract signs and symptoms	9	32	3	23	6	9
	29	94	12	57	17	37

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias		1		1		
Angioedemas		2				2
Apocrine and eccrine gland disorders	1	12	1	11		1
Bullous conditions	1	5		3	1	2
Dermal and epidermal conditions NEC	4	19	3	17	1	2
Dermatitis and eczema		2		2		
Erythemas	2	15	2	14		1
Papulosquamous conditions		1		1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus NEC	1	14	1	13		1
Purpura and related conditions	1	2		1	1	1
Rashes, eruptions and exanthems NEC	6	32	4	26	2	6
Skin and subcutaneous conditions NEC		1				1
Skin and subcutaneous tissue ulcerations	1	1			1	1
Skin cysts and polyps		1		1		
Skin haemorrhages	1	1			1	1
Skin hyperplasias and hypertrophies		1		1		
Skin injuries and mechanical dermatoses		1				1
Skin vasculitides		1		1		
Urticarias	2	10	1	8	1	2
	20	122	12	100	8	22

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Blood pressure disorders NEC	1	4	1	2		2
Circulatory collapse and shock	1	3			1	3
Haemorrhages NEC	2	6		1	2	5
Lymphoedemas		1		1		
Non-site specific necrosis and vascular insufficiency NEC	1	2			1	2
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	4	5	1	1	3	4
Peripheral vascular disorders NEC	3	10	2	7	1	3
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	3		2	1	1
Site specific vascular disorders NEC	1	5	1	4		1

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 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Varicose veins NEC		2		2		
Vascular hypertensive disorders NEC	1	4	1	3		1
Vascular hypotensive disorders		7		2		5
Vasculitides NEC		1		1		
	15	55	6	27	9	28

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**ICELAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	5	1	5
	1	5	1	5

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart failures NEC		2				2
Ischaemic coronary artery disorders	1	3			1	3
Rate and rhythm disorders NEC		3		1		2
Supraventricular arrhythmias		1				1
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	2	10		1	2	9

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral disorders congenital	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Spontaneous
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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		2		2
Visual impairment and blindness (excl colour blindness)	1	1	1	1
	1	3	1	3

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Gastrointestinal and abdominal pains (excl oral and throat)		1		1
Gastrointestinal signs and symptoms NEC		1		1
Nausea and vomiting symptoms	3	14	3	14
Oral dryness and saliva altered		1		1
Salivary gland enlargements		1		1
Salivary gland infections and inflammations		1		1
	3	19	3	19

System Organ Class

**General disorders and administration site conditions**

Spontaneous
-------------

\* I=Interval, C=Cumulative  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	51	1	45	1	6
Death and sudden death		8				8
Febrile disorders	2	43	2	39		4
Feelings and sensations NEC	2	20	2	20		
General signs and symptoms NEC	2	5	1	3	1	2
Injection site reactions		1		1		
Oedema NEC		1		1		
Pain and discomfort NEC	1	12	1	11		1
Vaccination site reactions	3	36	3	36		
	12	177	10	156	2	21

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract and lung infections		4				4
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Upper respiratory tract infections		5		5		
		10		5		5

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2		
Medication errors, product use errors and issues NEC		5		5		

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific injuries NEC	1	1	1	1		
Off label uses		4		4		
Skin injuries NEC		1				1
	3	13	3	12		1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		2				2
Coagulation and bleeding analyses	1	1			1	1
Heart rate and pulse investigations		2		2		
Liver function analyses		2		1		1
Physical examination procedures and organ system status		1				1
Vascular tests NEC (incl blood pressure)		2		1		1
	1	10		4	1	6

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders		4		4		
Total fluid volume increased		1				1
		5		4		1

System Organ Class

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1		1		
Bone related signs and symptoms		2		2		
Joint related signs and symptoms		8		8		
Muscle pains	1	26	1	26		
Muscle related signs and symptoms NEC		2		2		
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	4	12	2	10	2	2
	6	52	4	50	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances	1	1			1	1
Cortical dysfunction NEC		2		1		1
Disturbances in consciousness NEC	3	6			3	6
Dyskinesias and movement disorders NEC	1	1			1	1
Headaches NEC	2	36	2	36		
Memory loss (excl dementia)	1	1	1	1		
Migraine headaches		1		1		
Narcolepsy and hypersomnia		1		1		
Neurological signs and symptoms NEC	1	11	1	11		
Paraesthesias and dysaesthesias		5		5		
Sensory abnormalities NEC		2		2		
Sleep disturbances NEC		1		1		
Transient cerebrovascular events	1	2			1	2
Tremor (excl congenital)		1		1		

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 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	10	72	4	60	6	12

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Behaviour and socialisation disturbances		1				1
Confusion and disorientation	1	1			1	1
Deliria	2	3			2	3
Disturbances in initiating and maintaining sleep	1	2	1	2		
Sleep disorders NEC	1	1			1	1
	5	8	1	2	4	6

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		2		1		1
		2		1		1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast infections and inflammations		1		1
		1		1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		8		4		4
Bronchospasm and obstruction		2				2
Conditions associated with abnormal gas exchange		3				3
Coughing and associated symptoms		6		5		1
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms		1		1		
Parenchymal lung disorders NEC		1				1
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Pulmonary oedemas		1				1
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC		1		1		
Upper respiratory tract signs and symptoms		10		10		
		36		22		14

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		4		3		1
Dermal and epidermal conditions NEC		4		4		
Erythemas		5		5		
Pruritus NEC		6		6		
Rashes, eruptions and exanthems NEC		4		4		
		23		22		1

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Circulatory collapse and shock		1				1
Peripheral embolism and thrombosis	2	3			2	3
Peripheral vascular disorders NEC		1		1		
Site specific vascular disorders NEC		2		2		
Vascular hypertensive disorders NEC		1		1		
	2	9		4	2	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**INDIA**

*System Organ Class*

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms	1	1	1	1
	1	1	1	1

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Asthenic conditions	2	2	2	2
Pain and discomfort NEC	1	1	1	1
Therapeutic and nontherapeutic responses	1	1	1	1
Vaccination site reactions	1	1	1	1
	5	5	5	5

*System Organ Class*

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>Interval Total #</i>	<i>Cumulative Total #</i>	Spontaneous	
		Nonserious	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disturbances in consciousness NEC	1	1	1	1
Headaches NEC	1	1	1	1
Neurological signs and symptoms NEC	1	1	1	1
	3	3	3	3

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Counterfeit, falsified and substandard products		1		1
		1		1

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Country Where Event Occurred

**IRAQ**

*System Organ Class*

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms	1	1	1	1
	1	1	1	1

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	1	1	1	1
Febrile disorders	2	2	2	2
Vaccination site reactions	2	2	2	2
	5	5	5	5

*System Organ Class*

**Metabolism and nutrition disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	1	1	1
	1	1	1	1

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coughing and associated symptoms	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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Country Where Event Occurred

**IRELAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Lymphatic system disorders NEC		30		2		28
Neutropenias		1				1
		32		2		30

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC		1				1
Cardiac signs and symptoms NEC	1	17	1	2		15
Coronary artery disorders NEC	2	2			2	2
Heart failures NEC	1	2			1	2
Ischaemic coronary artery disorders	1	3			1	3
Noninfectious myocarditis	1	1			1	1
Rate and rhythm disorders NEC	1	22	1	1		21
Supraventricular arrhythmias	3	4			3	4
Ventricular arrhythmias and cardiac arrest	3	3			3	3
	13	55	2	3	11	52

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		3				3

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\* AE=Adverse Event  
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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	1	2			1	2
Inner ear signs and symptoms	3	8	2	4	1	4
	4	13	2	4	2	9

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		3				3
Eyelid movement disorders		2				2
Lacrimation disorders		4				4
Lid, lash and lacrimal infections, irritations and inflammations		3		1		2
Ocular disorders NEC	3	12	2	3	1	9
Ocular infections, inflammations and associated manifestations	1	4	1	1		3
Ocular nerve and muscle disorders		3				3
Ocular sensation disorders		2				2
Pupil disorders	2	2	2	2		
Visual disorders NEC	3	7	1	2	2	5
Visual impairment and blindness (excl colour blindness)		6		1		5
	9	48	6	10	3	38

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acute and chronic pancreatitis		1					1
Diarrhoea (excl infective)	3	21	1	4	2		17
Faecal abnormalities NEC		2					2
Flatulence, bloating and distension	1	5	1	2			3
Gastrointestinal and abdominal pains (excl oral and throat)	2	11	1	2	1		9
Gastrointestinal atonic and hypomotility disorders NEC		2					2
Gastrointestinal disorders NEC		1					1
Gastrointestinal signs and symptoms NEC	4	7	2	2	2		5
Gastrointestinal spastic and hypermotility disorders		1					1
Nausea and vomiting symptoms	20	141	9	28	11		113
Non-site specific gastrointestinal haemorrhages		4					4
Oral dryness and saliva altered	1	4	1	2			2
Oral soft tissue disorders NEC		1					1
Oral soft tissue signs and symptoms	5	23	5	6			17
Oral soft tissue swelling and oedema	2	11			2		11
Tongue disorders		1					1
Tongue signs and symptoms		8		1			7
	38	244	20	47	18		197

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Adverse effect absent	1	3	1	3			
Asthenic conditions	39	203	22	55	17		148
Complications associated with device NEC	1	2	1	2			
Death and sudden death	5	12			5		12
Febrile disorders	18	99	11	20	7		79

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feelings and sensations NEC	15	103	5	16	10	87
Gait disturbances	2	8	1	1	1	7
General signs and symptoms NEC	9	49	4	10	5	39
Inflammations		2				2
Injection site reactions	1	5	1	1		4
Mass conditions NEC		1				1
Pain and discomfort NEC	17	118	10	17	7	101
Therapeutic and nontherapeutic responses		5				5
Vaccination site reactions	19	74	17	30	2	44
	127	684	73	155	54	529

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholestasis and jaundice		1		1
		1		1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	9	1	1	1	8
Allergies to foods, food additives, drugs and other chemicals		2				2
Anaphylactic and anaphylactoid responses		10				10
	2	21	1	1	1	20

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2				2
Bacterial infections NEC	1	4			1	4
Breast infections	1	2			1	2
Central nervous system and spinal infections		1				1
Coronavirus infections	5	14		2	5	12
Ear infections		1				1
Eye and eyelid infections	1	2	1	1		1
Herpes viral infections	3	7	2	2	1	5
Infections NEC	2	4		1	2	3
Influenza viral infections		1				1
Lower respiratory tract and lung infections		3				3
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Staphylococcal infections		1				1
Upper respiratory tract infections	2	5	1	2	1	3
Urinary tract infections		1		1		
	15	49	4	9	11	40

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product	1	3	1	3		
Conditions caused by cold	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	4	18	3	15	1	3
Medication errors, product use errors and issues NEC	13	18	13	18		
Nerve injuries NEC		1				1
Non-site specific injuries NEC	1	4		1	1	3
Off label uses	1	10	1	10		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pathways and sources of exposure	1	2	1	2		
Product administration errors and issues	16	20	16	20		
Product preparation errors and issues	1	7	1	7		
Site specific injuries NEC		1				1
Skin injuries NEC	1	2	1	2		
Underdoses NEC		10		10		
Vaccination related complications	1	1			1	1
	41	98	37	88	4	10

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	3	12			3	12
Carbohydrate tolerance analyses (incl diabetes)		1				1
Heart rate and pulse investigations	4	17		1	4	16
Investigations NEC		1				1
Liver function analyses		3				3
Ophthalmic function diagnostic procedures	1	1			1	1
Physical examination procedures and organ system status	3	10	1	1	2	9
Platelet analyses		1				1
Protein analyses NEC		2				2
Red blood cell analyses		1				1
Respiratory and pulmonary function diagnostic procedures	1	1			1	1
Skeletal and cardiac muscle analyses		1				1
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	2	12		1	2	11
Virus identification and serology		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell analyses	1	2	1	1		1
	15	67	2	4	13	63

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	11	1	1	2	10
General nutritional disorders NEC		1				1
Hypoglycaemic conditions NEC		2				2
Metabolic acidoses (excl diabetic acidoses)		1				1
Total fluid volume decreased	1	2	1	1		1
	4	17	2	2	2	15

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	2	8		3	2	5
Joint related disorders NEC		1				1
Joint related signs and symptoms	14	52	10	14	4	38
Muscle pains	7	56	5	12	2	44
Muscle related signs and symptoms NEC	2	15	2	3		12
Muscle weakness conditions		6				6
Musculoskeletal and connective tissue conditions NEC	6	14	5	6	1	8
Musculoskeletal and connective tissue pain and discomfort	19	97	11	27	8	70
Soft tissue disorders NEC		2				2

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 \* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	50	251	33	65	17	186

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Skin neoplasms benign		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	4			2	4
Central nervous system vascular disorders NEC	1	1			1	1
Coordination and balance disturbances	1	4		1	1	3
Cortical dysfunction NEC	1	2			1	2
Cranial nerve disorders NEC		1				1
Disturbances in consciousness NEC	9	50		2	9	48
Dyskinesias and movement disorders NEC	1	3	1	1		2
Eye movement disorders		1				1
Facial cranial nerve disorders	2	18		1	2	17
Headaches NEC	19	151	11	31	8	120
Memory loss (excl dementia)	1	2			1	2
Mental impairment (excl dementia and memory loss)		4		2		2
Migraine headaches	2	8		2	2	6
Mononeuropathies		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle tone abnormal		2				2
Myelitis (incl infective)		1				1
Nervous system disorders NEC	1	1			1	1
Neurological signs and symptoms NEC	15	78	9	17	6	61
Neurologic visual problems NEC		1		1		
Olfactory nerve disorders		2		1		1
Paraesthesias and dysaesthesias	12	79	9	21	3	58
Paralysis and paresis (excl cranial nerve)	1	3			1	3
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC	1	4			1	4
Sensory abnormalities NEC	3	19	3	4		15
Sleep disturbances NEC	1	2		1	1	1
Speech and language abnormalities		5				5
Transient cerebrovascular events	2	3			2	3
Tremor (excl congenital)	1	9		1	1	8
Trigeminal disorders		3				3
	76	463	33	86	43	377

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	2	3	2	3
	2	3	2	3

System Organ Class

**Product issues**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	

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\* AE=Adverse Event  
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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	1	1	1	1
Product quality issues NEC		5		5
	1	6	1	6

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		9		2		7
Confusion and disorientation	3	11			3	11
Disturbances in initiating and maintaining sleep	2	17		2	2	15
Emotional and mood disturbances NEC	1	3			1	3
Fluctuating mood symptoms	1	1			1	1
Hallucinations (excl sleep-related)	1	1			1	1
Mood alterations with depressive symptoms	2	2			2	2
Panic attacks and disorders	1	3			1	3
Sleep disorders NEC		1				1
	11	48		4	11	44

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		4		1		3
Urinary abnormalities	2	4	2	2		2
	2	8	2	3		5

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	1	7	1	1		6
Menstruation and uterine bleeding NEC	2	5	1	1	1	4
Menstruation with decreased bleeding	1	2	1	1		1
Menstruation with increased bleeding	1	1	1	1		
Vulvovaginal disorders NEC		3				3
	5	18	4	4	1	14

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	4	32		1	4	31
Bronchospasm and obstruction		9				9
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	3	12	1	2	2	10
Laryngeal spasm, oedema and obstruction		3				3
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms		1				1
Nasal congestion and inflammations		3		1		2
Nasal disorders NEC	1	2			1	2
Paranasal sinus disorders (excl infections and neoplasms)	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)	3	9	3	4		5
Pulmonary thrombotic and embolic conditions		2				2
Respiratory failures (excl neonatal)	1	1			1	1
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	1	25	1	6		19
	14	103	5	14	9	89

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	2	4			2	4
Apocrine and eccrine gland disorders	1	28	1	4		24
Bullous conditions		1				1
Dermal and epidermal conditions NEC	1	7		1	1	6
Dermatitis and eczema	3	4	1	1	2	3
Erythemas	2	7	1	3	1	4
Exfoliative conditions		1				1
Pruritus NEC	1	19	1	5		14
Rashes, eruptions and exanthems NEC	7	40	4	9	3	31
Skin dystrophies		1				1
Urticarias	2	19	2	5		14
	19	131	10	28	9	103

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	3	29	1	4	2	25
	3	29	1	4	2	25

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections	1	1			1	1
Haemorrhages NEC		1				1
Non-site specific embolism and thrombosis		1				1
Peripheral embolism and thrombosis	4	6			4	6

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC		10		2		8
Site specific vascular disorders NEC	1	11	1	3		8
Vascular hypertensive disorders NEC	1	18		2	1	16
Vascular hypotensive disorders	4	11	3	3	1	8
	11	59	4	10	7	49

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Country Where Event Occurred

**ISRAEL**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic immune		1				1
Anaemias haemolytic NEC		1				1
Anaemias NEC	1	2		1	1	1
Coagulopathies	1	1			1	1
Leukocytoses NEC	3	8		1	3	7
Leukopenias NEC		2				2
Lymphatic system disorders NEC	4	20	1	16	3	4
Marrow depression and hypoplastic anaemias	1	1			1	1
Neutropenias	1	1			1	1
Thrombocytopenias	2	3			2	3
	13	40	1	18	12	22

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC		2				2
Cardiac signs and symptoms NEC	2	13		11	2	2
Heart failures NEC	6	9			6	9
Ischaemic coronary artery disorders	4	15			4	15
Myocardial disorders NEC		1		1		
Noninfectious myocarditis	53	70			53	70
Noninfectious pericarditis	28	43			28	43
Pericardial disorders NEC	2	3			2	3
Rate and rhythm disorders NEC		13		5		8
Supraventricular arrhythmias	3	10		1	3	9

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular arrhythmias and cardiac arrest		15				15
	98	194		18	98	176

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Musculoskeletal and connective tissue disorders of limbs congenital		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	11	1	9	2	2
Hearing losses	14	16	1	1	13	15
Inner ear signs and symptoms	12	19	4	8	8	11
	29	46	6	18	23	28

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hyperfunction disorders	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colour blindness (incl acquired)		1		1		
Conjunctival structural change, deposit and degeneration		1				1
Eyelid movement disorders		1		1		
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders		2		1		1
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular bleeding and vascular disorders NEC		1				1
Ocular disorders NEC		14		8		6
Ocular infections, inflammations and associated manifestations		3		2		1
Ocular sensation disorders		1		1		
Pupil disorders		1				1
Visual disorders NEC		6		6		
Visual impairment and blindness (excl colour blindness)	1	1			1	1
	1	34		21	1	13

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Anal and rectal signs and symptoms		1		1		
Dental pain and sensation disorders		3		3		
Diarrhoea (excl infective)	8	22	8	20		2
Dyspeptic signs and symptoms		7		7		
Gastric and oesophageal haemorrhages		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	13	1	12		1
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC		7		5		2
Gingival disorders, signs and symptoms NEC		1		1		
Gingival haemorrhages	1	1			1	1
Intestinal haemorrhages	1	2	1	2		
Nausea and vomiting symptoms	9	75	6	65	3	10
Non-site specific gastrointestinal haemorrhages		2				2
Oesophagitis (excl infective)		1		1		
Oral dryness and saliva altered		1		1		
Oral soft tissue disorders NEC	1	2	1	2		
Oral soft tissue signs and symptoms	3	38	3	33		5
Oral soft tissue swelling and oedema	1	4	1	2		2
Stomatitis and ulceration		1		1		
Tongue signs and symptoms		6		1		5
	25	190	21	157	4	33

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adverse effect absent	1	2			1	2		
Asthenic conditions	29	265			23	240	6	25
Body temperature altered		1						1
Death and sudden death	2	35					2	35
Febrile disorders	27	122			17	101	10	21
Feelings and sensations NEC	15	131			10	118	5	13
Gait disturbances	3	7			1	2	2	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
General signs and symptoms NEC	5	43			1	31	4	12
Inflamations	3	14			1	2	2	12
Injection site reactions		5				5		
Oedema NEC	1	3			1	1		2
Pain and discomfort NEC	35	96			20	72	15	24
Therapeutic and nontherapeutic responses	24	66		1	4	11	20	55
Vaccination site reactions	8	156			8	154		2
	153	946		1	87	739	66	207

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis		1		1		
Cholestasis and jaundice		2		1		1
Hepatic enzymes and function abnormalities	1	2			1	2
Hepatic failure and associated disorders	1	1			1	1
Hepatocellular damage and hepatitis NEC		4				4
	2	10		2	2	8

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	6	14	2	4	4	10
Allergies to foods, food additives, drugs and other chemicals		7		3		4
Anaphylactic and anaphylactoid responses	1	7			1	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	7	28	2	7	5	21

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections		1						1
Bacterial infections NEC		3				1		2
Bone and joint infections		1						1
Cardiac infections		1						1
Central nervous system and spinal infections	1	1					1	1
Coronavirus infections	30	76		1	2	10	28	66
Dental and oral soft tissue infections		2				2		
Ear infections		2				2		
Eye and eyelid infections		3				2		1
Herpes viral infections	13	37			10	29	3	8
Infections NEC	1	2				1	1	1
Influenza viral infections		3				3		
Lower respiratory tract and lung infections	1	5					1	5
Pseudomonal infections	1	1					1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	3					1	3
Streptococcal infections		1						1
Upper respiratory tract infections	1	6				5	1	1
Urinary tract infections		1				1		
Viral infections NEC		2				1		1
	49	151		1	12	57	37	94

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Abdominal and gastrointestinal injuries NEC		1				1			
Bone and joint injuries NEC		1							1
Exposures associated with pregnancy, delivery and lactation	3	20			1	17	2	3	
Exposures to agents or circumstances NEC				1					
Intentional product use issues		1				1			
Limb fractures and dislocations		1							1
Medication errors, product use errors and issues NEC	1	8			1	8			
Non-occupational environmental exposures	1	1			1	1			
Non-site specific injuries NEC	2	8			2	4			4
Off label uses		8				8			
Overdoses NEC		5				5			
Pelvic fractures and dislocations		1							1
Product administration errors and issues	5	55			5	55			
Product preparation errors and issues	1	6			1	6			
Site specific injuries NEC	1	3			1	1			2
Skin injuries NEC	1	2			1	1			1
Skin procedural complications	2	2			2	2			
Thoracic cage fractures and dislocations		1							1
Underdoses NEC		3				3			
Vaccination related complications	8	9					8	9	
	25	136		1	15	113	10	23	

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	2	2	1	1	1	1
Blood gas and acid base analyses		2		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Carbohydrate tolerance analyses (incl diabetes)		3		1			2
Chemistry analyses NEC		1					1
Coagulation and bleeding analyses	2	4		1	2		3
ECG investigations	2	3	1	1	1		2
Endocrine analyses and imaging NEC		1		1			
Foetal and neonatal diagnostic procedures		1					1
Heart rate and pulse investigations		11		9			2
Immunoglobulin analyses		1		1			
Liver function analyses	1	2		1	1		1
Mineral and electrolyte analyses	1	3		1	1		2
Physical examination procedures and organ system status		7		4			3
Platelet analyses		1		1			
Protein analyses NEC	1	4		2	1		2
Red blood cell analyses		6		5			1
Renal function analyses	1	2	1	1			1
Skeletal and cardiac muscle analyses	1	3			1		3
Tissue enzyme analyses NEC		1					1
Vascular tests NEC (incl blood pressure)	1	17		9	1		8
Virus identification and serology	1	6	1	3			3
Vitamin analyses	1	1			1		1
White blood cell analyses		3		2			1
	14	85	4	45	10		40

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Appetite disorders	2	13	2	11			2
Diabetic complications NEC		1					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1		1		
Sodium imbalance	1	1			1	1
	3	16	2	12	1	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	2	1	2		
Bone related signs and symptoms		10		10		
Joint related signs and symptoms	4	43	4	36		7
Muscle pains	7	84	6	78	1	6
Muscle related signs and symptoms NEC	2	4	2	4		
Muscle tone abnormalities		1		1		
Muscle weakness conditions	4	9	1	5	3	4
Musculoskeletal and connective tissue conditions NEC		7		5		2
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1		1		
Musculoskeletal and connective tissue pain and discomfort	11	93	9	89	2	4
Myopathies	1	1			1	1
Psoriatic arthropathies	1	1			1	1
Spondyloarthropathies		1				1
	31	257	23	231	8	26

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Interval Total #	Cumulative Total #	Spontaneous
		Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias chronic lymphocytic		1		1
Non-Hodgkin's lymphomas NEC		1		1
		2		2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	3	4			3	4
Central nervous system haemorrhages and cerebrovascular accidents	6	17			6	17
Chronic polyneuropathies		1				1
Coordination and balance disturbances	1	5	1	3		2
Cortical dysfunction NEC	2	2	1	1	1	1
Disturbances in consciousness NEC	8	28	1	4	7	24
Dyskinesias and movement disorders NEC	4	14	3	9	1	5
Eye movement disorders	2	2			2	2
Facial cranial nerve disorders	15	44		1	15	43
Headaches NEC	15	135	12	125	3	10
Increased intracranial pressure disorders		1				1
Migraine headaches		3		3		
Multiple sclerosis acute and progressive	2	7			2	7
Narcolepsy and hypersomnia		1		1		
Nervous system disorders NEC	1	1	1	1		
Neurological signs and symptoms NEC	7	59	3	47	4	12
Neuromuscular disorders NEC		4		4		
Neuromuscular junction dysfunction		2				2
Olfactory nerve disorders		7		7		
Paraesthesias and dysaesthesias	21	99	13	84	8	15
Paralysis and paresis (excl cranial nerve)	1	7			1	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Parkinson's disease and parkinsonism		1		1			
Peripheral neuropathies NEC	1	5		3	1	2	
Seizures and seizure disorders NEC	8	19			8	19	
Sensory abnormalities NEC	1	23		19	1	4	
Sleep disturbances NEC		2		2			
Speech and language abnormalities	2	10		4	2	6	
Structural brain disorders NEC		1				1	
Transient cerebrovascular events	6	6			6	6	
Tremor (excl congenital)	1	11		10	1	1	
	107	521	35	329	72	192	

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abortions spontaneous	1	2			1	2	
Labour onset and length abnormalities	1	1			1	1	
Maternal complications of labour NEC		1		1			
Multiple pregnancies		1		1			
Stillbirth and foetal death	2	4			2	4	
	4	9		2	4	7	

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product packaging issues		12		12
Product physical issues		21		21

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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issues NEC	2	3	2	3
	2	36	2	36

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	5	12	3	10	2	2
Behaviour and socialisation disturbances		1		1		
Confusion and disorientation	2	4	1	2	1	2
Depressive disorders		2		1		1
Disturbances in initiating and maintaining sleep		8		8		
Emotional and mood disturbances NEC		2		2		
Hallucinations (excl sleep-related)		2				2
Increased physical activity levels		2		1		1
Mental disorders NEC		2		2		
Mood alterations with depressive symptoms		5		4		1
Schizophrenia NEC		1				1
Sexual desire disorders		1		1		
Sleep disorders NEC	1	3	1	3		
Speech articulation and rhythm disturbances	1	1			1	1
Suicidal and self-injurious behaviour		1				1
Thinking disturbances		1		1		
Tic disorders		2		2		
	9	50	5	38	4	12

System Organ Class

**Renal and urinary disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment	1	2	1	2
Renal lithiasis	1	1	1	1
	2	3	2	3

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast infections and inflammations		1		1		
Breast signs and symptoms		1		1		
Menstruation and uterine bleeding NEC	1	8	1	8		
Menstruation with increased bleeding		3		3		
Pelvis and broad ligament disorders NEC		1		1		
Reproductive tract signs and symptoms NEC		1		1		
Testicular and epididymal disorders NEC	1	1	1	1		
Uterine disorders NEC		2		1		1
Vulvovaginal disorders NEC	4	10	1	5	3	5
	6	28	3	22	3	6

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	14	62	7	26	7	36
Bronchospasm and obstruction	2	7		2	2	5
Coughing and associated symptoms	5	15	2	12	3	3
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions	1	2			1	2
Lower respiratory tract signs and symptoms	1	2	1	1		1
Nasal disorders NEC	1	2			1	2
Parenchymal lung disorders NEC	1	2			1	2
Pharyngeal disorders (excl infections and neoplasms)	1	5		3	1	2
Pneumothorax and pleural effusions NEC	1	2			1	2
Pulmonary oedemas	1	3			1	3
Pulmonary thrombotic and embolic conditions	5	6			5	6
Respiratory failures (excl neonatal)	1	1			1	1
Respiratory signs and symptoms NEC	1	3			1	3
Respiratory tract disorders NEC	3	7	1	2	2	5
Tracheal disorders (excl infections and neoplasms)		1				1
Upper respiratory tract signs and symptoms	3	34	2	24	1	10
	41	155	13	71	28	84

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias		1		1		
Angioedemas	2	4			2	4
Apocrine and eccrine gland disorders	4	17	4	17		
Bullous conditions	1	1			1	1
Dermal and epidermal conditions NEC	4	9	4	9		
Erythemas	5	17	4	14	1	3
Exfoliative conditions	1	1	1	1		
Pruritus NEC	3	14	3	10		4
Purpura and related conditions	2	2	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rashes, eruptions and exanthems NEC	6	24	4	17	2	7
Urticarias	1	9		5	1	4
	29	99	21	75	8	24

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	1	2	1	2
Social issues NEC		1		1
	1	3	1	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	1			1	1
Circulatory collapse and shock		2				2
Haemorrhages NEC		2				2
Non-site specific embolism and thrombosis		5				5
Non-site specific vascular disorders NEC	1	1	1	1		
Peripheral embolism and thrombosis	3	3			3	3
Peripheral vascular disorders NEC		1		1		
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	6	1	4	2	2
Site specific vascular disorders NEC	1	2	1	2		
Vascular hypertensive disorders NEC		7		3		4
Vascular hypotensive disorders	2	5	1	2	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	11	35	4	13	7	22

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**ITALY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemias NEC	3	5				2	3	3
Coagulopathies		1						1
Haematological disorders	1	1					1	1
Leukocytoses NEC	3	6		1	1	4	2	2
Leukopenias NEC	3	8		1			3	8
Lymphatic system disorders NEC	100	1,041	15	19	76	831	24	210
Neutropenias		1		1				1
Spleen disorders		1						1
Thrombocytopenias	14	21	1	2			14	21
	124	1,085	16	24	77	837	47	248

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiac conduction disorders	1	3			1	1		2
Cardiac disorders NEC	1	3				1	1	2
Cardiac hypertensive complications	3	3					3	3
Cardiac signs and symptoms NEC	6	42			4	25	2	17
Coronary artery disorders NEC	3	5					3	5
Heart failures NEC	8	17					8	17
Ischaemic coronary artery disorders	11	30					11	30
Left ventricular failures		1						1
Mitral valvular disorders	3	4					3	4
Myocardial disorders NEC	4	4			2	2	2	2
Noninfectious myocarditis	2	6					2	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Noninfectious pericarditis	3	12					3	12
Pericardial disorders NEC	6	10					6	10
Rate and rhythm disorders NEC	53	433	1	7	21	225	32	208
Supraventricular arrhythmias	14	49	1	1	1	12	13	37
Tricuspid valvular disorders	2	2					2	2
Ventricular arrhythmias and cardiac arrest	21	41			1	6	20	35
	141	665	2	8	30	272	111	393

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac septal defects congenital		1		1
Corneal and scleral disorders congenital	1	1	1	1
Thyroid disorders congenital	1	1	1	1
Tongue disorders congenital		2		2
	2	5	2	5

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	7	60			5	40	2	20
Hearing disorders NEC		1						1
Hearing losses	7	21			2	2	5	19
Hyperacusia	1	2				1	1	1
Inner ear disorders NEC		1						1
Inner ear signs and symptoms	36	334	2	4	16	234	20	100

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	51	419	2	4	23	277	28	142

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	3	8	2	3	1	5
Adrenal gland disorders NEC	1	3	1	3		
Thyroid disorders NEC		5		2		3
Thyroid hyperfunction disorders		2				2
	4	18	3	8	1	10

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Choroid and vitreous haemorrhages and vascular disorders	1	1					1	1
Choroid and vitreous structural change, deposit and degeneration		7		1				7
Conjunctival and corneal bleeding and vascular disorders	1	10		2			1	10
Conjunctival infections, irritations and inflammations		10				5		5
Corneal structural change, deposit and degeneration	1	3					1	3
Eyelid movement disorders	3	16			1	7	2	9
Iris and ciliary body structural change, deposit and degeneration		1						1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Iris and uveal tract infections, irritations and inflammations		8						8
Lacrimation disorders	6	31			3	23	3	8
Lid, lash and lacrimal infections, irritations and inflammations	3	38		1	1	22	2	16
Lid, lash and lacrimal structural disorders	2	4			1	1	1	3
Ocular bleeding and vascular disorders NEC	1	4					1	4
Ocular disorders NEC	12	103		1	8	72	4	31
Ocular infections, inflammations and associated manifestations	7	94		1	3	68	4	26
Ocular nerve and muscle disorders	2	6				1	2	5
Ocular sensation disorders	2	45				36	2	9
Optic disc abnormalities NEC		2						2
Optic nerve bleeding and vascular disorders	1	1					1	1
Orbital structural change, deposit and degeneration		1						1
Pupil disorders	1	2				1	1	1
Refractive and accommodative disorders	1	2			1	1		1
Retinal bleeding and vascular disorders (excl retinopathy)	6	6		1			6	6
Retinal, choroid and vitreous infections and inflammations	1	2					1	2
Retinal structural change, deposit and degeneration	3	9					3	9
Retinopathies NEC	1	1					1	1
Scleral infections, irritations and inflammations		2				1		1
Scleral structural change, deposit and degeneration		1						1
Visual colour distortions		1						1
Visual disorders NEC	24	82			16	53	8	29
Visual impairment and blindness (excl colour blindness)	13	34		3	1	11	12	23
Visual pathway disorders		1						1
	92	528		10	35	302	57	226

\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

		Non Interventional Study		Spontaneous				
		Serious		Nonserious		Serious		
		I	C	I	C	I	C	
Abdominal findings abnormal	1	2			1	2		
Acute and chronic pancreatitis	3	6					3	6
Anal and rectal disorders NEC		1						1
Anal and rectal signs and symptoms		1						1
Colitis (excl infective)	1	3				2	1	1
Dental pain and sensation disorders	1	4			1	4		
Diarrhoea (excl infective)	36	463	2	3	25	356	11	107
Dyspeptic signs and symptoms	3	25			1	21	2	4
Faecal abnormalities NEC		3				2		1
Flatulence, bloating and distension	4	25			1	18	3	7
Gastritis (excl infective)		1				1		
Gastrointestinal and abdominal pains (excl oral and throat)	42	369	2	2	24	284	18	85
Gastrointestinal atonic and hypomotility disorders NEC		13				10		3
Gastrointestinal disorders NEC	11	36	1	1	10	30	1	6
Gastrointestinal dyskinetic disorders	1	2					1	2
Gastrointestinal inflammatory disorders NEC	1	3			1	2		1
Gastrointestinal signs and symptoms NEC	13	114		3	4	60	9	54
Gastrointestinal spastic and hypermotility disorders		8				5		3
Gastrointestinal stenosis and obstruction NEC		2						2
Gastrointestinal vascular occlusion and infarction	4	4					4	4
Gingival disorders, signs and symptoms NEC	2	8		1		4	2	4
Gingival haemorrhages	2	3				1	2	2
Intestinal haemorrhages	1	2					1	2
Nausea and vomiting symptoms	164	1,510	6	18	103	1082	61	428
Non-site specific gastrointestinal haemorrhages	1	6					1	6
Oesophageal disorders NEC		1						1
Oral dryness and saliva altered	10	89		1	6	61	4	28
Oral soft tissue disorders NEC	1	3				1	1	2
Oral soft tissue haemorrhages	1	2				1	1	1

\* I=Interval, C=Cumulative

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System Organ Class

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oral soft tissue infections		1
Oral soft tissue signs and symptoms	17	364
Oral soft tissue swelling and oedema	16	142
Peritoneal and retroperitoneal haemorrhages		1
Salivary gland enlargements		3
Stomatitis and ulceration		16
Tongue disorders	3	18
Tongue signs and symptoms	17	116
	356	3,370

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
3	5	9	238	8	126
2	3	9	83	7	59
					1
			2		1
1	1		12		4
			11	3	7
1	1	5	57	12	59
18	39	200	2351	156	1019

System Organ Class

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Administration site reactions NEC	2	74
Adverse effect absent	3	5
Application and instillation site reactions		2
Asthenic conditions	277	2,975
Body temperature altered	6	59
Death and sudden death	15	28
Febrile disorders	307	3,452
Feelings and sensations NEC	145	1,763
Gait disturbances	14	45
General signs and symptoms NEC	63	378
Inflamations	1	9
Infusion site reactions		3
Injection site reactions	14	1,334
Interactions	1	1
Mass conditions NEC		1
Mucosal findings abnormal		9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	72	1	2
		3	5		
			2		
8	17	168	2355	109	620
		1	30	5	29
	1			15	28
19	41	163	2401	144	1051
3	8	92	1374	53	389
		2	20	12	25
1	4	28	252	35	126
			6	1	3
			3		
	1	13	1330	1	4
				1	1
			1		
			4		5

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Oedema NEC	19	138	2	3	7	89	12	49
Pain and discomfort NEC	84	788	4	9	41	581	43	207
Therapeutic and nontherapeutic responses	22	110	1	1		2	22	108
Vaccination site reactions	261	2,270	4	9	211	1876	50	394
	1,234	13,444	42	94	730	10403	504	3041

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	1	2			1	2
Cholecystitis and cholelithiasis	1	1			1	1
Cholestasis and jaundice	2	5	1	1	1	4
Hepatic enzymes and function abnormalities		2				2
Hepatobiliary signs and symptoms		2		2		
Hepatocellular damage and hepatitis NEC		2				2
	4	14	1	3	3	11

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute and chronic sarcoidosis		1					1	
Allergic conditions NEC	13	76		3	5	26	8	50
Allergies to foods, food additives, drugs and other chemicals	3	19			1	4	2	15
Anaphylactic and anaphylactoid responses	3	84	1	4			3	84
Atopic disorders		1						1

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Immune and associated conditions NEC	19	183	1	7	6	32	13	151

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	14	182	5	6		3	14	179
Bacterial infections NEC	3	6					3	6
Bone and joint infections		2						2
Breast infections	2	7					2	7
Candida infections		3				3		
Central nervous system and spinal infections	1	2					1	2
Coronavirus infections	83	263	2	4	6	48	77	215
Coxiella infections	2	9					2	9
Dental and oral soft tissue infections		4				4		
Ear infections	3	17			1	10	2	7
Eye and eyelid infections	2	27			1	18	1	9
Female reproductive tract infections	1	2			1	2		
Herpes viral infections	21	125	1	1	7	66	14	59
Infections NEC	2	16			2	11		5
Influenza viral infections	3	31			3	28		3
Legionella infections		1						1
Listeria infections		1						1
Lower respiratory tract and lung infections	8	17					8	17
Male reproductive tract infections	1	1					1	1
Muscle and soft tissue infections		2						2
Retroviral infections		1						1
Sepsis, bacteraemia, viraemia and fungaemia NEC	4	8					4	8

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin structures and soft tissue infections	1	8			1	5		3
Staphylococcal infections		1				1		
Streptococcal infections	2	2	1	1			2	2
Upper respiratory tract infections	14	81	1	1	9	53	5	28
Urinary tract infections		5				4		1
Vascular infections	3	10					3	10
Viral infections NEC	4	7			1	2	3	5
	174	841	10	13	32	258	142	583

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Atmospheric pressure injuries		1				1		
Cerebral injuries NEC	1	1					1	1
Chest and respiratory tract injuries NEC		1						1
Conditions caused by cold	3	6			3	5		1
Exposures associated with pregnancy, delivery and lactation	11	30			7	25	4	5
Exposures to agents or circumstances NEC	1	3			1	3		
Fractures and dislocations NEC		2						2
Heat injuries (excl thermal burns)		3				2		1
Intentional product misuses	1	1			1	1		
Limb fractures and dislocations	1	1					1	1
Medication errors, product use errors and issues NEC	3	25			3	23		2
Muscle, tendon and ligament injuries		1				1		
Nerve injuries NEC	1	1			1	1		
Neurological and psychiatric procedural complications	1	1					1	1
Non-site specific injuries NEC	7	21			1	3	6	18

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Non-site specific procedural complications		1				1			
Occupational exposures		1				1			
Off label uses	7	30			6	28	1	2	
Overdoses NEC	9	48			7	44	2	4	
Product administration errors and issues	20	65			18	63	2	2	
Product confusion errors and issues		1				1			
Product preparation errors and issues		7				7			
Site specific injuries NEC	2	4					2	4	
Skin injuries NEC	6	10			3	6	3	4	
Skull fractures, facial bone fractures and dislocations		2							2
Spinal cord injuries NEC		1							1
Stoma complications		1							1
Thermal burns		3				1			2
Underdoses NEC		12				12			
Vaccination related complications	50	156	1	4		54	50	102	
	124	440	1	4	51	283	73	157	

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Autoimmunity analyses		1							1
Bacteria identification and serology (excl mycobacteria)		2							2
Blood counts NEC	1	1			1	1			
Blood gas and acid base analyses	15	60	1	2	1	9	14	51	
Carbohydrate tolerance analyses (incl diabetes)	1	5				3	1	2	
Coagulation and bleeding analyses	10	12			4	6	6	6	
Digestive enzymes		5				1			4

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
ECG investigations	2	4		1	1	1	1	3
Haematological analyses NEC	3	4				1	3	3
Haem metabolism analyses		1						1
Heart rate and pulse investigations	10	37			5	17	5	20
Immune response protein analyses NEC	1	1					1	1
Immunology analyses NEC		3				3		
Investigations NEC	1	6				2	1	4
Liver function analyses	3	7		1	1	3	2	4
Mineral and electrolyte analyses		2				2		
Neurologic diagnostic procedures		1						1
Physical examination procedures and organ system status	6	52	1	1	3	38	3	14
Pituitary analyses anterior	1	1			1	1		
Platelet analyses	2	2			1	1	1	1
Protein analyses NEC	5	12			2	7	3	5
Red blood cell analyses		11				8		3
Renal function analyses	1	1			1	1		
Respiratory and pulmonary function diagnostic procedures		1				1		
Skeletal and cardiac muscle analyses	4	6					4	6
Thyroid analyses		3				1		2
Tissue enzyme analyses NEC	1	2					1	2
Urinary tract function analyses NEC	1	2					1	2
Vascular tests NEC (incl blood pressure)	14	129		1	6	71	8	58
Virus identification and serology	14	47			2	25	12	22
White blood cell analyses	2	13			2	5		8
	98	434	2	6	31	208	67	226

System Organ Class

**Metabolism and nutrition disorders**

Interval Total #	Cumulative Total #	Non Interventional Study		Spontaneous	
		Serious	Nonserious	Serious	Nonserious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Appetite disorders	11	80	1	1	4	59	7	21
Calcium metabolism disorders	2	2			1	1	1	1
Diabetes mellitus (incl subtypes)	1	1					1	1
Electrolyte imbalance NEC		1						1
General nutritional disorders NEC		2				1		1
Hyperglycaemic conditions NEC	3	7			1	2	2	5
Hypoglycaemic conditions NEC	1	4			1	3		1
Iron excess		1				1		
Metabolic acidoses (excl diabetic acidoses)		1						1
Metabolic disorders NEC	1	1					1	1
Potassium imbalance	2	2					2	2
Sodium imbalance	1	1					1	1
Total fluid volume decreased		6						6
Total fluid volume increased		4				2		2
	22	113	1	1	7	69	15	44

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	2	8			1	3	1	5
Bone related signs and symptoms	15	161			11	119	4	42
Connective tissue disorders NEC	1	3					1	3
Extremity deformities		1				1		
Joint related disorders NEC		8				6		2
Joint related signs and symptoms	119	1,442	5	9	74	1124	45	318
Lupus erythematosus (incl subtypes)	1	2					1	2
Muscle infections and inflammations		4		1		1		3
Muscle pains	138	1,672	7	12	87	1356	51	316
Muscle related signs and symptoms NEC	8	70	1	1	3	47	5	23

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\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Muscle tone abnormalities	5	42			3	29	2	13
Muscle weakness conditions	11	72			6	49	5	23
Musculoskeletal and connective tissue conditions NEC	9	55	1	1	6	33	3	22
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1					1	1
Musculoskeletal and connective tissue infections and inflammations NEC	1	2				1	1	1
Musculoskeletal and connective tissue pain and discomfort	144	1,381	3	8	91	1098	53	283
Myopathies	1	1					1	1
Osteoarthropathies	1	1			1	1		
Psoriatic arthropathies	3	3					3	3
Rheumatoid arthropathies	2	5					2	5
Soft tissue disorders NEC	1	5	2	2	1	5		
Spondyloarthropathies				1				
Tendon disorders	4	7			1	3	3	4
	467	4,946	19	35	285	3876	182	1070

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias NEC	1	1	1	1
Lymphomas unspecified NEC	1	1	1	1
Nervous system neoplasms unspecified malignancy NEC		1		1
Reproductive neoplasms male unspecified malignancy	1	1	1	1
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		1		1
Soft tissue neoplasms benign NEC		1		1

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
	3	6	3	6

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	1	3					1	3
Absence seizures	1	2					1	2
Acute polyneuropathies	3	6					3	6
Alzheimer's disease (incl subtypes)		1						1
Central nervous system aneurysms and dissections	1	2					1	2
Central nervous system haemorrhages and cerebrovascular accidents	48	71	1	1			48	71
Cerebrovascular venous and sinus thrombosis	1	2					1	2
Cervical spinal cord and nerve root disorders		9				6		3
Chronic polyneuropathies		2						2
Coma states	1	4					1	4
Coordination and balance disturbances	9	39	3	3	1	15	8	24
Cortical dysfunction NEC	16	26	1	1		3	16	23
Cranial nerve disorders NEC		6				3		3
Demyelinating disorders NEC		1						1
Disturbances in consciousness NEC	71	475	2	7	11	151	60	324
Dyskinesias and movement disorders NEC	15	57			2	28	13	29
Encephalopathies NEC		2						2
Eye movement disorders	4	6			1	1	3	5
Facial cranial nerve disorders	16	115	2	2	3	22	13	93
Generalised tonic-clonic seizures		4						4
Headaches NEC	217	2,720	9	21	136	2166	81	554
Hydrocephalic conditions	1	1					1	1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoglossal nerve disorders		2
Increased intracranial pressure disorders	1	1
Lumbar spinal cord and nerve root disorders		6
Memory loss (excl dementia)	1	17
Mental impairment (excl dementia and memory loss)	4	27
Migraine headaches	11	169
Mononeuropathies	1	2
Multiple sclerosis acute and progressive		8
Muscle tone abnormal	1	12
Narcolepsy and hypersomnia	2	8
Nervous system disorders NEC	4	8
Neurological signs and symptoms NEC	73	536
Neurologic visual problems NEC	2	7
Neuromuscular disorders NEC	1	10
Neuromuscular junction dysfunction	1	5
Olfactory nerve disorders	10	40
Optic nerve disorders NEC	1	6
Paraesthesias and dysaesthesias	88	883
Paralysis and paresis (excl cranial nerve)	19	71
Parkinson's disease and parkinsonism		1
Partial complex seizures	1	1
Peripheral neuropathies NEC	5	29
Seizures and seizure disorders NEC	8	45
Sensory abnormalities NEC	19	208
Sleep disturbances NEC		3
Speech and language abnormalities	16	31
Spinal cord and nerve root disorders NEC		7
Transient cerebrovascular events	4	5
Tremor (excl congenital)	18	133
Trigeminal disorders	2	16
Vagus nerve disorders		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
			5		1
		1	7		10
2	2	1	13	3	14
2	2	7	132	4	37
		1	2		
			4		4
		1	8		4
		1	5	1	3
			1	4	7
	5	36	330	37	206
			3	2	4
			6	1	4
				1	5
2	2	5	26	5	14
				1	6
2	5	48	596	40	287
			8	19	63
					1
				1	1
	1	1	9	4	20
			7	8	38
5	6	13	150	6	58
			1		2
2	2	1	8	15	23
			6		1
				4	5
	2	8	70	10	63
		1	8	1	8
					2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	698	5,853	33	62	279	3800	419	2053

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	2	1	2
Abortions spontaneous	1	6	1	6
Foetal growth complications		1		1
Maternal complications of pregnancy NEC		1		1
	2	10	2	10

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Device malfunction events NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour NEC		1			1			
Affect alterations NEC		1					1	
Anxiety disorders NEC		1			1			

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anxiety symptoms	3	66		1	1	44	2	22
Behaviour and socialisation disturbances		1				1		
Confusion and disorientation	26	131	4	8	9	70	17	61
Deliria		1						1
Delusional symptoms	1	2				1	1	1
Dissociative states		2				2		
Disturbances in initiating and maintaining sleep	19	180			9	149	10	31
Emotional and mood disturbances NEC	1	15			1	11		4
Hallucinations (excl sleep-related)	3	21					3	21
Increased physical activity levels		8				4		4
Mental disorders due to a general medical condition NEC		1						1
Mental disorders NEC		2				1		1
Mood alterations with depressive symptoms		2				2		
Mood disorders NEC		2						2
Obsessive-compulsive disorders and symptoms		1						1
Panic attacks and disorders		9				6		3
Parasomnias		1				1		
Psychotic disorder NEC	1	1					1	1
Sexual desire disorders	1	1			1	1		
Sleep disorders NEC	9	23	1	2	4	14	5	9
Speech and language usage disturbances	1	1					1	1
Speech articulation and rhythm disturbances	1	1					1	1
Substance related and addictive disorders	1	1					1	1
Thinking disturbances	1	2					1	2
	68	478	5	11	25	309	43	169

System Organ Class

**Renal and urinary disorders**

Interval Total #      Cumulative Total #

Non Interventional Study		Spontaneous	
Serious		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bladder and urethral symptoms	9	28			1	8	8	20
Bladder disorders NEC		1						1
Bladder infections and inflammations	1	5					1	5
Glomerulonephritis and nephrotic syndrome		1						1
Myoneurogenic bladder disorders	1	2					1	2
Renal failure and impairment	4	16		1			4	16
Renal failure complications		1						1
Urinary abnormalities	2	11				6	2	5
Urinary tract signs and symptoms NEC	1	13				10	1	3
	18	78		1	1	24	17	54

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Benign and malignant breast neoplasms		1		1			
Breast disorders NEC		1		1			
Breast signs and symptoms	3	25		15	3	10	
Erection and ejaculation conditions and disorders	2	4			2	4	
Menstruation and uterine bleeding NEC	1	11	1	8		3	
Menstruation with decreased bleeding		2		2			
Menstruation with increased bleeding	3	6		2	3	4	
Reproductive tract signs and symptoms NEC	1	8	1	7		1	
Scrotal disorders NEC	1	1			1	1	
Sexual function and fertility disorders NEC	1	1	1	1			
Uterine disorders NEC	1	1			1	1	
Vulvovaginal disorders NEC		2		1		1	
Vulvovaginal signs and symptoms		1		1			
	13	64	3	39	10	25	

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	58	402	3	9	11	124	47	278
Bronchial conditions NEC		2						2
Bronchospasm and obstruction	8	88	2	4		25	8	63
Conditions associated with abnormal gas exchange	3	10					3	10
Coughing and associated symptoms	23	191		1	8	94	15	97
Diaphragmatic disorders		2				1		1
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1	7				1	1	6
Laryngeal spasm, oedema and obstruction	15	97				4	15	93
Lower respiratory tract inflammatory and immunologic conditions	2	5					2	5
Lower respiratory tract signs and symptoms	2	9			1	4	1	5
Nasal congestion and inflammations	4	15			2	11	2	4
Nasal disorders NEC	1	23			1	17		6
Parenchymal lung disorders NEC	3	7					3	7
Pharyngeal disorders (excl infections and neoplasms)	9	79		1	3	34	6	45
Pleural infections and inflammations		1						1
Pneumothorax and pleural effusions NEC	9	10			1	1	8	9
Pulmonary hypertensions	1	1					1	1
Pulmonary oedemas	4	7					4	7
Pulmonary thrombotic and embolic conditions	15	25	2	2			15	25
Respiratory failures (excl neonatal)	14	30					14	30
Respiratory signs and symptoms NEC	2	15			1	7	1	8
Respiratory tract disorders NEC	3	21				3	3	18
Tracheal disorders (excl infections and neoplasms)		2				1		1
Upper respiratory tract signs and symptoms	40	398		4	17	221	23	177
Vascular pulmonary disorders NEC		1						1
	217	1,448	7	21	45	548	172	900

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Acnes		3				3			
Alopecias	2	5			1	1	1	4	
Angioedemas	10	63			1	6	9	57	
Apocrine and eccrine gland disorders	14	223		1	4	153	10	70	
Bullous conditions	6	33	1	1	2	11	4	22	
Connective tissue disorders		1				1			
Dermal and epidermal conditions NEC	10	76			4	42	6	34	
Dermatitis and eczema	1	28			1	22		6	
Dermatitis ascribed to specific agent	1	3				1	1	2	
Erythemas	31	349	1	2	15	232	16	117	
Exfoliative conditions	1	6			1	3		3	
Lipodystrophies		1						1	
Panniculitides	3	5			2	2	1	3	
Papulosquamous conditions	1	3				2	1	1	
Photosensitivity and photodermatosis conditions		3				1		2	
Pilar disorders NEC		1						1	
Pruritus NEC	28	376	1	2	18	281	10	95	
Psoriatic conditions	2	4			1	1	1	3	
Purpura and related conditions	10	18		2	4	10	6	8	
Rashes, eruptions and exanthems NEC	38	380		4	19	245	19	135	
Rosaceas		2				1		1	
Skin and subcutaneous conditions NEC	1	3			1	3			
Skin cysts and polyps	1	2			1	2			
Skin haemorrhages	1	2					1	2	
Skin hypoplasias and atrophies	1	1			1	1			
Skin vascular conditions NEC		1				1			
Skin vasculitides	2	4				1	2	3	
Skin vasomotor conditions		1		1		1			
Urticarias	48	315		2	33	212	15	103	
	212	1,912	3	15	109	1239	103	673	

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	3	9	3	6		3
Social issues NEC	2	4	2	3		1
	5	13	5	9		4

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Immunisations		2		2
Joint therapeutic procedures		1		1
Limb therapeutic procedures		1		1
Therapeutic procedures NEC		1		1
		5		5

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	16	86		2			16	86
Aneurysms and dissections non-site specific		1						1
Aortic aneurysms and dissections	1	1					1	1
Blood pressure disorders NEC	1	4				1	1	3
Circulatory collapse and shock	2	7					2	7
Haemorrhages NEC	6	16			1	8	5	8
Lymphoedemas		8				6		2
Non-site specific embolism and thrombosis	10	16					10	16
Non-site specific necrosis and vascular insufficiency NEC	2	8				1	2	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Non-site specific vascular disorders NEC	3	15			1	7	2	8
Peripheral embolism and thrombosis	28	35	2	3	5	5	23	30
Peripheral vascular disorders NEC	19	190			11	143	8	47
Peripheral vasoconstriction, necrosis and vascular insufficiency	7	32		1	4	21	3	11
Phlebitis NEC	7	9			6	6	1	3
Site specific vascular disorders NEC	4	26		1	2	17	2	9
Varicose veins NEC		1				1		
Vascular hypertensive disorders NEC	19	124			5	53	14	71
Vascular hypotensive disorders	19	147	1	3	5	70	14	77
Vascular malformations and acquired anomalies	1	1					1	1
Vasculitides NEC	11	12			7	7	4	5
	156	739	3	10	47	346	109	393

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Country Where Event Occurred

**JAPAN**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	4	5	4	4		1
Coagulopathies	1	1			1	1
Leukopenias NEC	1	1			1	1
Lymphatic system disorders NEC	14	15	11	12	3	3
Thrombocytopenias	1	1			1	1
	21	23	15	16	6	7

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		1		1		
Cardiac disorders NEC	3	3	3	3		
Cardiac signs and symptoms NEC	108	148	68	85	40	63
Heart failures NEC	4	5			4	5
Ischaemic coronary artery disorders	3	7			3	7
Myocardial disorders NEC	1	1			1	1
Noninfectious myocarditis	5	7			5	7
Noninfectious pericarditis	2	2			2	2
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	39	57	14	17	25	40
Supraventricular arrhythmias	5	7	3	3	2	4
Ventricular arrhythmias and cardiac arrest	10	11	2	2	8	9
	181	250	90	111	91	139

System Organ Class

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System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders congenital NEC		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	7	10	4	4	3	6
Hearing disorders NEC	1	1	1	1		
Hearing losses	10	15	1	1	9	14
Inner ear signs and symptoms	13	19	7	7	6	12
	31	45	13	13	18	32

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hypofunction disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration	1	1	1	1		

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	1	2			1	2
Conjunctival infections, irritations and inflammations	13	18	8	10	5	8
Eyelid movement disorders	6	7			6	7
Lacrimation disorders	4	6	2	4	2	2
Lid, lash and lacrimal infections, irritations and inflammations	20	37	12	18	8	19
Ocular bleeding and vascular disorders NEC	1	1			1	1
Ocular disorders NEC	11	20	4	8	7	12
Ocular infections, inflammations and associated manifestations	23	30	15	19	8	11
Ocular nerve and muscle disorders	4	5			4	5
Ocular sensation disorders	6	7	3	3	3	4
Optic disc abnormalities NEC	1	1			1	1
Pupil disorders	2	2	2	2		
Retinal bleeding and vascular disorders (excl retinopathy)	2	2			2	2
Scleral infections, irritations and inflammations	1	1			1	1
Visual colour distortions	1	1			1	1
Visual disorders NEC	9	11	7	8	2	3
Visual impairment and blindness (excl colour blindness)	3	7	2	4	1	3
	109	159	56	77	53	82

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal and rectal signs and symptoms	1	1			1	1
Colitis (excl infective)	2	3			2	3
Dental pain and sensation disorders	1	1	1	1		

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\* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	45	64	29	39	16	25
Diverticula	1	1			1	1
Dyspeptic signs and symptoms	6	7	3	4	3	3
Faecal abnormalities NEC	3	5	2	4	1	1
Flatulence, bloating and distension	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	45	60	24	30	21	30
Gastrointestinal disorders NEC	3	4			3	4
Gastrointestinal dyskinetic disorders	1	1	1	1		
Gastrointestinal inflammatory disorders NEC	3	5			3	5
Gastrointestinal mucosal dystrophies and secretion disorders	1	1			1	1
Gastrointestinal signs and symptoms NEC	23	33	11	15	12	18
Gastrointestinal spastic and hypermotility disorders	2	4	1	1	1	3
Nausea and vomiting symptoms	255	361	142	183	113	178
Non-mechanical ileus	1	1			1	1
Non-site specific gastrointestinal haemorrhages	5	9			5	9
Oral dryness and saliva altered	3	4	1	1	2	3
Oral soft tissue disorders NEC	1	1	1	1		
Oral soft tissue haemorrhages	1	1	1	1		
Oral soft tissue signs and symptoms	36	53	27	34	9	19
Oral soft tissue swelling and oedema	12	21	8	13	4	8
Peritoneal and retroperitoneal disorders	1	1			1	1
Salivary gland enlargements	1	1	1	1		
Stomatitis and ulceration	2	3	2	3		
Tongue disorders		1				1
Tongue signs and symptoms	2	2	2	2		
	458	650	258	335	200	315

System Organ Class

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	2	2	2	2		
Asthenic conditions	231	305	172	211	59	94
Body temperature altered	6	6	2	2	4	4
Death and sudden death	4	4			4	4
Febrile disorders	266	338	199	251	67	87
Feelings and sensations NEC	277	377	169	210	108	167
Gait disturbances	8	12	1	2	7	10
General signs and symptoms NEC	46	66	26	37	20	29
Inflammations		2		1		1
Injection site reactions	11	16	9	14	2	2
Mucosal findings abnormal	2	3	1	2	1	1
Oedema NEC	10	17	3	5	7	12
Pain and discomfort NEC	81	106	53	65	28	41
Therapeutic and nontherapeutic responses	6	7			6	7
Vaccination site reactions	220	303	182	248	38	55
	1,170	1,564	819	1050	351	514

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic and hepatobiliary disorders NEC	1	1			1	1
Hepatic enzymes and function abnormalities	7	7	2	2	5	5
	8	8	2	2	6	6

System Organ Class

**Immune system disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	42	63	23	28	19	35
Allergies to foods, food additives, drugs and other chemicals	10	17	6	9	4	8
Anaphylactic and anaphylactoid responses	485	759	2	2	483	757
Atopic disorders	1	1	1	1		
	538	840	32	40	506	800

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	5	5	1	1	4	4
Bacterial infections NEC	7	8			7	8
Bone and joint infections	1	1			1	1
Cardiac infections	1	1			1	1
Central nervous system and spinal infections	7	11			7	11
Coronavirus infections	9	11	1	2	8	9
Dental and oral soft tissue infections	2	3	1	2	1	1
Herpes viral infections	5	5			5	5
Infections NEC	1	1	1	1		
Lower respiratory tract and lung infections	3	5			3	5
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Streptococcal infections	1	1			1	1
Upper respiratory tract infections	2	2	2	2		
Viral infections NEC	3	4			3	4
	48	59	6	8	42	51

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular injuries	1	1	1	1		
Chest and respiratory tract injuries NEC	1	4			1	4
Exposures associated with pregnancy, delivery and lactation	2	2	2	2		
Fractures and dislocations NEC	1	1	1	1		
Medication errors, product use errors and issues NEC	1	1			1	1
Muscle, tendon and ligament injuries	1	1	1	1		
Non-site specific injuries NEC	8	13	4	7	4	6
Off label uses	1	1	1	1		
Overdoses NEC		1		1		
Product administration errors and issues	9	11	9	11		
Product preparation errors and issues		2		2		
Radiation injuries	1	1	1	1		
Site specific injuries NEC	1	2	1	1		1
Skin injuries NEC	1	1			1	1
Underdoses NEC	1	5	1	5		
Vaccination related complications	3	3	1	1	2	2
	32	50	23	35	9	15

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	14	19	5	6	9	13
Carbohydrate tolerance analyses (incl diabetes)		1				1
Cerebrospinal fluid tests (excl microbiology)	1	1			1	1
Coagulation and bleeding analyses	1	1			1	1
Heart rate and pulse investigations	30	44	16	24	14	20
Neurologic diagnostic procedures		1				1

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 \* AE=Adverse Event  
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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	18	25	13	17	5	8
Platelet analyses	3	3			3	3
Protein analyses NEC	1	2		1	1	1
Renal function analyses		1		1		
Skeletal and cardiac muscle analyses		1		1		
Urinalysis NEC	1	1	1	1		
Vascular tests NEC (incl blood pressure)	128	182	67	90	61	92
Virus identification and serology	1	2	1	2		
White blood cell analyses	2	5	1	3	1	2
	200	289	104	146	96	143

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	12	18	3	7	9	11
Calcium metabolism disorders	1	1			1	1
General nutritional disorders NEC	5	6	1	1	4	5
Mixed acid-base disorders		1				1
Potassium imbalance	1	3			1	3
Total fluid volume decreased	3	4	1	1	2	3
	22	33	5	9	17	24

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	4	4	1	1	3	3
Joint related signs and symptoms	68	80	48	54	20	26
Muscle infections and inflammations		2		1		1
Muscle pains	76	98	67	86	9	12
Muscle related signs and symptoms NEC	10	15	6	8	4	7
Muscle weakness conditions	24	32	9	12	15	20
Musculoskeletal and connective tissue conditions NEC	9	12	5	8	4	4
Musculoskeletal and connective tissue pain and discomfort	69	91	53	69	16	22
Soft tissue disorders NEC	2	2			2	2
Spondyloarthropathies	1	1			1	1
	263	337	189	239	74	98

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast and nipple neoplasms malignant	1	1	1	1
Leukaemias acute lymphocytic	1	1	1	1
Lymphomas unspecified NEC	1	1	1	1
Nervous system neoplasms unspecified malignancy NEC		1		1
Neuromas	1	1	1	1
	4	5	4	5

System Organ Class

**Nervous system disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	2
		7	7
		4	5
		3	3
		18	22
		1	1
		1	1
	1	1	3
		1	2
8	10	50	83
2	3	5	5
		1	1
		1	2
		13	15
145	189	66	97
			1
		2	3
		1	1
	1	1	1
		1	1
1	1	1	1
107	142	50	83
1	1		
1	2		
63	86	43	50
		5	6
		1	1
2	2	21	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizures and seizure disorders NEC	19	23			19	23
Sensory abnormalities NEC	11	16	7	9	4	7
Sleep disturbances NEC	1	1	1	1		
Speech and language abnormalities	3	3	2	2	1	1
Tremor (excl congenital)	16	27	7	10	9	17
Trigeminal disorders	3	4	1	1	2	3
Vagus nerve disorders		1				1
	682	938	348	462	334	476

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	2	2	2	2
Product physical issues	1	2	1	2
	3	4	3	4

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	12	13	6	7	6	6
Cognitive and attention disorders and disturbances NEC	1	2	1	1		1
Communications disorders	1	1	1	1		
Confusion and disorientation	1	1	1	1		
Deliria	1	1			1	1
Disturbances in initiating and maintaining sleep	2	2	2	2		

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorders NEC	2	2			2	2
Emotional and mood disturbances NEC	5	8	3	4	2	4
Hallucinations (excl sleep-related)	1	1			1	1
Mood disorders NEC	2	4	2	4		
Panic attacks and disorders		1				1
Perception disturbances NEC		1				1
Psychiatric symptoms NEC	1	1	1	1		
Sleep disorders NEC	1	2			1	2
Somatic symptom disorders	1	2	1	2		
Thinking disturbances	1	1			1	1
	32	43	18	23	14	20

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	5			1	5
Glomerulonephritis and nephrotic syndrome	1	2			1	2
Urinary abnormalities	2	2			2	2
Urinary tract lithiasis (excl renal)		1		1		
	4	10		1	4	9

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostate and seminal vesicles infections and inflammations	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostatic signs, symptoms and disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	147	236	63	82	84	154
Bronchial conditions NEC	1	1			1	1
Bronchospasm and obstruction	56	94	13	26	43	68
Conditions associated with abnormal gas exchange	2	3	1	1	1	2
Coughing and associated symptoms	141	216	60	81	81	135
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	3	4	1	1	2	3
Laryngeal spasm, oedema and obstruction	8	13	1	2	7	11
Nasal congestion and inflammations	2	4			2	4
Nasal disorders NEC	1	4			1	4
Parenchymal lung disorders NEC	1	3			1	3
Pharyngeal disorders (excl infections and neoplasms)	15	17	7	8	8	9
Pneumothorax and pleural effusions NEC	2	2			2	2
Pulmonary oedemas	3	3			3	3
Pulmonary thrombotic and embolic conditions	2	2			2	2
Respiratory signs and symptoms NEC	4	8	1	2	3	6
Respiratory tract disorders NEC	9	10	3	3	6	7
Tracheal disorders (excl infections and neoplasms)	2	2			2	2
Upper respiratory tract signs and symptoms	228	356	131	176	97	180
	627	978	281	382	346	596

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	2	3			2	3
Apocrine and eccrine gland disorders	62	89	33	43	29	46
Bullous conditions	10	11			10	11
Dermal and epidermal conditions NEC	5	8	4	6	1	2
Dermatitis and eczema	10	19	10	14		5
Dermatitis ascribed to specific agent	8	12	3	6	5	6
Erythemas	178	252	123	156	55	96
Pigmentation changes NEC		1		1		
Pilar disorders NEC	1	2			1	2
Pruritus NEC	210	306	136	189	74	117
Purpura and related conditions	3	3	3	3		
Rashes, eruptions and exanthems NEC	137	201	89	124	48	77
Skin and subcutaneous conditions NEC	1	5	1	3		2
Skin haemorrhages	8	8			8	8
Skin vasculitides	1	1	1	1		
Skin vasomotor conditions	1	1	1	1		
Urticarias	149	218	105	145	44	73
	786	1,140	509	692	277	448

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	1	2	1	1		1
	1	2	1	1		1

System Organ Class

**Vascular disorders**

Spontaneous			

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 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	2	3			2	3
Aneurysms and dissections non-site specific	1	1			1	1
Aortic aneurysms and dissections	2	2			2	2
Blood pressure disorders NEC	1	2	1	1		1
Circulatory collapse and shock	7	10			7	10
Haemorrhages NEC	15	15			15	15
Lymphoedemas	1	1			1	1
Non-site specific embolism and thrombosis	5	5			5	5
Non-site specific necrosis and vascular insufficiency NEC	1	1			1	1
Non-site specific vascular disorders NEC	3	3	2	2	1	1
Peripheral embolism and thrombosis	3	3	1	1	2	2
Peripheral vascular disorders NEC	54	85	34	47	20	38
Peripheral vasoconstriction, necrosis and vascular insufficiency	26	29	19	19	7	10
Phlebitis NEC	1	1	1	1		
Site specific vascular disorders NEC	17	24	6	9	11	15
Vascular hypertensive disorders NEC	18	26	6	6	12	20
Vascular hypotensive disorders		1				1
Vasculitides NEC	1	1	1	1		
	158	213	71	87	87	126

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**JORDAN**

*System Organ Class*

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		1				1
Gastrointestinal vascular occlusion and infarction		1				1
Non-site specific gastrointestinal haemorrhages		1				1
Tongue disorders		1		1		
		4		1		3

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	4		3	1	1
Febrile disorders		1		1		
Feelings and sensations NEC		1		1		
General signs and symptoms NEC		4		2		2
Injection site reactions		1		1		
Pain and discomfort NEC		2		2		
Vaccination site reactions		2		2		
	1	15		12	1	3

*System Organ Class*

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		1				1

\* I=Interval, C=Cumulative  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections		4		1		3
Influenza viral infections		1		1		
Lower respiratory tract and lung infections		1				1
		7		2		5

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vaccination related complications		1		1
		1		1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status		1		1		
Vascular tests NEC (incl blood pressure)		1				1
		2		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains		3		3
Muscle related signs and symptoms NEC		1		1

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\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue pain and discomfort		3		3
		7		7

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	2			2	2
Disturbances in consciousness NEC		3				3
Headaches NEC		1		1		
Neurological signs and symptoms NEC		1		1		
Olfactory nerve disorders		1		1		
Sensory abnormalities NEC		1		1		
	2	9		4	2	5

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusion and disorientation	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		2				2
Bronchospasm and obstruction		2		1		1
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms		2		1		1
Lower respiratory tract signs and symptoms		1				1
Respiratory failures (excl neonatal)		1				1
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms		1				1
		11		2		9

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erythemas		1		1
		1		1

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Country Where Event Occurred  
**KOREA, REPUBLIC OF (SOUTH KOREA)**

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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Country Where Event Occurred

**KUWAIT**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC		1		1
Spleen disorders		1		1
		2		2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		2		2
Febrile disorders		2		2
General signs and symptoms NEC		2		2
Mucosal findings abnormal		1		1
Pain and discomfort NEC	1	3	1	3
Vaccination site reactions		2		2
	1	12	1	12

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections	1	2	1	2
	1	2	1	2

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Red blood cell analyses		1		1
White blood cell analyses		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains		1		1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort		2		2
	1	4	1	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	1	2	1	2
	1	2	1	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bronchospasm and obstruction		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**LATVIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC		30		22		8
		30		22		8

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		1				1
Cardiac signs and symptoms NEC		3				3
Ischaemic coronary artery disorders		1				1
Rate and rhythm disorders NEC		11		1		10
Supraventricular arrhythmias		1				1
		17		1		16

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		3		1		2
Hearing losses		2		1		1
Inner ear signs and symptoms	1	4	1	4		
	1	9	1	6		3

System Organ Class

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hypofunction disorders		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders		1				1
Lacrimation disorders	1	2	1	1		1
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular disorders NEC		12		12		
Ocular sensation disorders		4		3		1
Visual disorders NEC		2				2
	1	22	1	17		5

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)		6		6		
Gastrointestinal and abdominal pains (excl oral and throat)		8		6		2
Nausea and vomiting symptoms		32		30		2
Oral dryness and saliva altered		2		1		1
Oral soft tissue signs and symptoms		3		1		2
Oral soft tissue swelling and oedema		1		1		

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis and ulceration		1				1
Tongue signs and symptoms		1				1
		55		46		9

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	98		86	1	12
Febrile disorders		81		66		15
Feelings and sensations NEC		58		57		1
Gait disturbances		2		2		
General signs and symptoms NEC	1	8	1	5		3
Mucosal findings abnormal	1	1			1	1
Oedema NEC		3				3
Pain and discomfort NEC	2	7	1	5	1	2
Therapeutic and nontherapeutic responses		3				3
Vaccination site reactions	2	114	2	98		16
	7	375	4	319	3	56

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic and anaphylactoid responses		1				1
Immune and associated conditions NEC		1		1		
		2		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	3	9		3	3	6
Herpes viral infections		1				1
Upper respiratory tract infections		1		1		
	3	11		4	3	7

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		2		1		1
Medication errors, product use errors and issues NEC		1		1		
Off label uses		2		2		
Product administration errors and issues		1		1		
Vaccination related complications	3	3			3	3
	3	9		5	3	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations		3		2		1
Physical examination procedures and organ system status	2	50	2	49		1
Protein analyses NEC		3		3		
Renal function analyses		1		1		
Skeletal and cardiac muscle analyses		1		1		
Vascular tests NEC (incl blood pressure)		4		2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Virus identification and serology		1				1
White blood cell analyses		1		1		
	2	64	2	59		5

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		8		8
		8		8

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		2		2		
Joint related signs and symptoms		54		49		5
Muscle pains	1	58	1	54		4
Muscle related signs and symptoms NEC		2		1		1
Muscle weakness conditions		5		2		3
Musculoskeletal and connective tissue conditions NEC		3		1		2
Musculoskeletal and connective tissue pain and discomfort		15		12		3
Myopathies		1				1
	1	140	1	121		19

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Coordination and balance disturbances		1		1		
Disturbances in consciousness NEC		11		7		4
Facial cranial nerve disorders		3				3
Generalised tonic-clonic seizures		1				1
Headaches NEC		79		70		9
Mental impairment (excl dementia and memory loss)		9		5		4
Migraine headaches		2		1		1
Neurological signs and symptoms NEC	1	23		18	1	5
Neurologic visual problems NEC		1				1
Olfactory nerve disorders	1	1			1	1
Paraesthesias and dysaesthesias		19		6		13
Peripheral neuropathies NEC		1				1
Sensory abnormalities NEC		9		3		6
Transient cerebrovascular events	1	1			1	1
	4	162		111	4	51

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

Spontaneous

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		2				2
Confusion and disorientation		1		1		
Depressive disorders		1		1		
Disturbances in initiating and maintaining sleep		5		4		1
Mood alterations with depressive symptoms		1		1		
Sleep disorders NEC		3		3		
Thinking disturbances		1		1		
		14		11		3

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary tract signs and symptoms NEC		1		1
		1		1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation with increased bleeding		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		9		5		4
Bronchospasm and obstruction		2		1		1
Coughing and associated symptoms	1	8	1	8		
Nasal congestion and inflammations		2		2		
Nasal disorders NEC		2		1		1
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Upper respiratory tract signs and symptoms	1	15		13	1	2
	2	39	1	31	1	8

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		10		9		1
Dermal and epidermal conditions NEC		3		1		2
Erythemas		2		1		1
Pruritus NEC		3		1		2
Purpura and related conditions		2				2
Rashes, eruptions and exanths NEC	1	8	1	7		1
Skin vasculitides	1	1	1	1		
Urticarias	1	1	1	1		
	3	30	3	21		9

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		2				2
Peripheral vascular disorders NEC		3		2		1
Peripheral vasoconstriction, necrosis and vascular insufficiency		2		1		1
Vascular hypertensive disorders NEC		3		2		1
Vascular hypotensive disorders		1		1		
		11		6		5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**LEBANON**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rate and rhythm disorders NEC	2	3	2	2		1
	2	3	2	2		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Visual disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
Gastrointestinal and abdominal pains (excl oral and throat)		1		1
Gastrointestinal spastic and hypermotility disorders		1		1
	1	3	1	3

System Organ Class

**General disorders and administration site conditions**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	3	1	3		
Death and sudden death	10	11			10	11
Febrile disorders	2	6	2	5		1
Feelings and sensations NEC	4	7	4	6		1
Pain and discomfort NEC		2		2		
Therapeutic and nontherapeutic responses	2	4			2	4
Vaccination site reactions		1		1		
	19	34	7	17	12	17

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1				1
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1		
Anaphylactic and anaphylactoid responses		1				1
	1	3	1	1		2

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	7	14	1	4	6	10
Influenza viral infections		1		1		
Urinary tract infections	1	1			1	1
	8	16	1	5	7	11

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administration errors and issues		2		2		
Vaccination related complications	4	4			4	4
	4	6		2	4	4

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
Total fluid volume decreased	1	1	1	1
	1	2	1	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Muscle pains		2		2
Muscle related signs and symptoms NEC		1		1
Musculoskeletal and connective tissue pain and discomfort		5		5
	1	9	1	9

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Central nervous system haemorrhages and cerebrovascular accidents		1				1	
Disturbances in consciousness NEC	1	1			1	1	
Facial cranial nerve disorders	1	2			1	2	
Headaches NEC	1	4	1	4			
Lumbar spinal cord and nerve root disorders		1		1			
Neurological signs and symptoms NEC		1		1			
Paraesthesias and dysaesthesias	1	5	1	5			
Speech and language abnormalities		1		1			
	4	16	2	12	2	4	

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep	1	1	1	1
Emotional and mood disturbances NEC	1	1	1	1
Panic attacks and disorders	1	1	1	1
	3	3	3	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	2	1	2		
Respiratory tract disorders NEC	1	2			1	2
Upper respiratory tract signs and symptoms	5	8	4	6	1	2
	7	12	5	8	2	4

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\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1	1	1		
Dermatitis and eczema		1		1		
Erythemas	1	1			1	1
Pruritus NEC	1	1			1	1
Rashes, eruptions and exanthems NEC		2				2
Urticarias		1		1		
	3	7	1	3	2	4

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC	1	1	1	1		
Vascular hypertensive disorders NEC	3	5	2	3	1	2
Vascular hypotensive disorders	1	1	1	1		
	5	7	4	5	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LIECHTENSTEIN**

*System Organ Class*

**Injury, poisoning and procedural complications**

*High Level Term*

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**LITHUANIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC		1				1
Lymphatic system disorders NEC	1	7	1	5		2
	1	8	1	5		3

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart failures NEC		1				1
Ischaemic coronary artery disorders	2	4			2	4
Rate and rhythm disorders NEC	1	3		1	1	2
	3	8		1	3	7

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	2	1	2		
Hearing losses		1		1		
Inner ear signs and symptoms		2		1		1
	1	5	1	4		1

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1				1
Lacrimation disorders	2	4	2	3		1
Ocular disorders NEC	4	6	4	6		
Ocular infections, inflammations and associated manifestations		1		1		
Visual impairment and blindness (excl colour blindness)	1	1	1	1		
	7	13	7	11		2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)		6		4		2
Diverticula		1		1		
Dyspeptic signs and symptoms		1		1		
Flatulence, bloating and distension		1		1		
Gastritis (excl infective)		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)		4		3		1
Gastrointestinal signs and symptoms NEC		1				1
Nausea and vomiting symptoms	5	19	4	11	1	8
Oral soft tissue signs and symptoms		1				1
Oral soft tissue swelling and oedema		1		1		
	5	36	4	23	1	13

System Organ Class

**General disorders and administration site conditions**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	11	34	10	25	1	9
Death and sudden death		3				3
Febrile disorders	8	26	8	25		1
Feelings and sensations NEC	5	23	5	19		4
Gait disturbances	1	1			1	1
General signs and symptoms NEC		8		4		4
Injection site reactions	1	1	1	1		
Mucosal findings abnormal	1	1	1	1		
Pain and discomfort NEC	4	10	4	7		3
Vaccination site reactions	14	45	14	41		4
	45	152	43	123	2	29

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC		1		1
Anaphylactic and anaphylactoid responses		3		3
		4		4

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1				1
Coronavirus infections	1	2	1	1		1
Herpes viral infections		1		1		
Infections NEC	9	9			9	9

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract and lung infections	1	1			1	1
Upper respiratory tract infections	5	5	4	4	1	1
	16	19	5	6	11	13

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Medication errors, product use errors and issues NEC		1		1		
Off label uses		1		1		
Overdoses NEC		1		1		
Product administration errors and issues		1				1
Product preparation errors and issues		1				1
Underdoses NEC		1		1		
Vaccination related complications		2		1		1
		9		6		3

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	1	9	1	5		4
Physical examination procedures and organ system status	2	5	2	3		2
Vascular tests NEC (incl blood pressure)	2	11	2	3		8
	5	25	5	11		14

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	2	1	2
	1	2	1	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	3	5	3	5		
Joint related signs and symptoms	4	14	4	13		1
Muscle infections and inflammations		2		1		1
Muscle pains	4	19	4	17		2
Muscle related signs and symptoms NEC		2		2		
Muscle weakness conditions		2		2		
Musculoskeletal and connective tissue conditions NEC	2	2	2	2		
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	8	20	7	19	1	1
Tendon disorders		1		1		
	21	68	20	62	1	6

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination and balance disturbances		2		1		1
Disturbances in consciousness NEC	2	15	1	4	1	11
Facial cranial nerve disorders	2	6	1	1	1	5

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	7	26	6	19	1	7
Memory loss (excl dementia)		1		1		
Mental impairment (excl dementia and memory loss)		1				1
Neurological signs and symptoms NEC	4	15	3	11	1	4
Paraesthesias and dysaesthesias	2	12	2	10		2
Paralysis and paresis (excl cranial nerve)		1				1
Seizures and seizure disorders NEC		7				7
Sensory abnormalities NEC		3		1		2
Tremor (excl congenital)		5		3		2
	17	94	13	51	4	43

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	2		1	1	1
Confusion and disorientation		3		1		2
Disturbances in initiating and maintaining sleep	1	1	1	1		
Emotional and mood disturbances NEC		1				1
Mood disorders NEC		1		1		
	2	8	1	4	1	4

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		5		2		3
Coughing and associated symptoms	3	4	3	4		
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1		
Pulmonary oedemas		1				1
Upper respiratory tract signs and symptoms	1	2	1	2		
	5	13	5	9		4

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	3	1	3		
Dermal and epidermal conditions NEC	1	2	1	2		
Erythemas	2	3	2	2		1
Pruritus NEC		2		2		
Rashes, eruptions and exanthems NEC	2	3	2	2		1
Skin and subcutaneous conditions NEC		1				1
	6	14	6	11		3

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Blood pressure disorders NEC		2		1		1
Non-site specific embolism and thrombosis	1	1			1	1
Peripheral embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	1	1	1	1		
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1		
Site specific vascular disorders NEC	1	1			1	1
Vascular hypertensive disorders NEC		2		1		1
Vascular hypotensive disorders		1				1
	4	11	1	4	3	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**LUXEMBOURG**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	3	5	3	4		1
	3	5	3	4		1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac signs and symptoms NEC		3		3
Ischaemic coronary artery disorders	1	1	1	1
Rate and rhythm disorders NEC	2	6	2	6
	3	10	3	10

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inner ear signs and symptoms	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal infections, irritations and inflammations	2	2	1	1	1	1
Ocular disorders NEC	1	1			1	1
Ocular nerve and muscle disorders		1				1
Visual disorders NEC		1				1
	3	5	1	1	2	4

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	7	1	1		6
Flatulence, bloating and distension		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	1	2			1	2
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	3	15	1	1	2	14
Oral dryness and saliva altered		2				2
Oral soft tissue signs and symptoms	1	1	1	1		
Tongue disorders		1				1
	6	30	3	3	3	27

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	7	43	3	7	4	36
Body temperature altered	1	2	1	1		1
Febrile disorders	4	18	2	2	2	16

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feelings and sensations NEC	3	18	3	3		15
General signs and symptoms NEC	2	7	1	3	1	4
Injection site reactions	1	2	1	1		1
Oedema NEC	1	2			1	2
Pain and discomfort NEC	1	6		1	1	5
Therapeutic and nontherapeutic responses	1	2	1	1		1
Vaccination site reactions	16	26	16	16		10
	37	126	28	35	9	91

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	4	1	1		3
	1	4	1	1		3

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	1	2			1	2
Eye and eyelid infections		1				1
Herpes viral infections		2		2		
Influenza viral infections	1	6		2	1	4
Lower respiratory tract and lung infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Upper respiratory tract infections		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infections	1	1	1	1		
	4	15	1	6	3	9

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conditions caused by cold	1	1	1	1		
Non-site specific injuries NEC	1	2			1	2
Vaccination related complications		4				4
	2	7	1	1	1	6

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses		1		1
Heart rate and pulse investigations		2		2
Red blood cell analyses		1		1
Vascular tests NEC (incl blood pressure)		1		1
Virus identification and serology		1		1
		6		6

System Organ Class

**Metabolism and nutrition disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Appetite disorders		1				1	
Calcium metabolism disorders	1	1	1	1			
General nutritional disorders NEC		1				1	
Sodium imbalance		1				1	
Water soluble vitamin deficiencies		1				1	
	1	5	1	1		4	

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	5	16	4	4	1	12
Muscle pains	5	26	4	6	1	20
Muscle weakness conditions		1				1
Musculoskeletal and connective tissue conditions NEC	1	2			1	2
Musculoskeletal and connective tissue pain and discomfort	4	9	2	4	2	5
	15	54	10	14	5	40

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Disturbances in consciousness NEC		4				4
Eye movement disorders	1	1			1	1
Headaches NEC	9	36	6	6	3	30

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine headaches		1				1
Narcolepsy and hypersomnia		1		1		
Neurological signs and symptoms NEC	2	7			2	7
Paraesthesias and dysaesthesias	1	7			1	7
Paralysis and paresis (excl cranial nerve)	1	1			1	1
Seizures and seizure disorders NEC	2	3			2	3
Sensory abnormalities NEC		1				1
Tremor (excl congenital)	2	3	1	1	1	2
	19	66	7	8	12	58

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	2	1	1		1
Disturbances in initiating and maintaining sleep		1				1
Thinking disturbances		1				1
	1	4	1	1		3

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1
Renal failure and impairment		1		1
		2		2

System Organ Class

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities		6		6
Bronchospasm and obstruction		3		3
Conditions associated with abnormal gas exchange		1		1
Coughing and associated symptoms		2		2
Lower respiratory tract signs and symptoms		1		1
Nasal disorders NEC		1		1
Pulmonary thrombotic and embolic conditions	3	3	3	3
Respiratory failures (excl neonatal)		1		1
Respiratory tract disorders NEC		1		1
Upper respiratory tract signs and symptoms	2	5	2	5
	5	24	5	24

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		2				2
Bullous conditions		1				1
Dermal and epidermal conditions NEC		1				1
Dermatitis and eczema		1				1
Panniculitides		1				1
Pruritus NEC	1	6	1	1		5
Rashes, eruptions and exanthems NEC		3				3
Skin haemorrhages		1				1
Urticarias	1	1	1	1		
	2	17	2	2		15

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC	1	1	1	1		
Peripheral embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	1	1			1	1
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1			1	1
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC	3	7	1	1	2	6
Vascular hypotensive disorders	1	5		1	1	4
	8	17	2	3	6	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**MACAO**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders		1		1
		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF**

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oral soft tissue swelling and oedema		1		1
		1		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Administration site reactions NEC		1		1
Asthenic conditions		5		5
Febrile disorders		4		4
Vaccination site reactions	1	1	1	1
	1	11	1	11

System Organ Class

**Immune system disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC		1		1
		1		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Upper respiratory tract infections		1		1
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Physical examination procedures and organ system status		3		3
		3		3

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Muscle pains	1	3	1	3
	2	4	2	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	2	4	2	4		
	3	5	2	4	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Upper respiratory tract signs and symptoms		1		1
		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rashes, eruptions and exanthems NEC		1		1
		1		1

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Country Where Event Occurred

**MALAYSIA**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		1		1		
Asthenic conditions	2	3	2	3		
Death and sudden death		1				1
Febrile disorders	1	1	1	1		
Vaccination site reactions	1	2	1	2		
	4	8	4	7		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections		1		1
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	2	2	2	2		
Neurological signs and symptoms NEC		1		1		
Paraesthesias and dysaesthesias	1	1	1	1		
Peripheral neuropathies NEC		2				2
Seizures and seizure disorders NEC		1				1
	3	7	3	4		3

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermal and epidermal conditions NEC	1	1			1	1
Pilar disorders NEC	1	1	1	1		
Rashes, eruptions and exanthems NEC	2	2	2	2		
Urticarias		1		1		
	4	5	3	4	1	1

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**MALTA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1		1		
Lymphatic system disorders NEC	1	3	1	3		
Red blood cell abnormal findings NEC		1		1		
Thrombocytopenias		1				1
	1	6	1	5		1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	3	5		1	3	4
Rate and rhythm disorders NEC		2				2
Supraventricular arrhythmias		2				2
	3	9		1	3	8

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		1		1
		1		1

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thyroid disorders NEC		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	1	2		1	1	1
Ocular infections, inflammations and associated manifestations		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Visual disorders NEC	2	2			2	2
	4	6		2	4	4

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders	1	1	1	1		
Diarrhoea (excl infective)		3		2		1
Gastrointestinal and abdominal pains (excl oral and throat)		2		2		
Gastrointestinal signs and symptoms NEC		2		1		1
Gastrointestinal spastic and hypermotility disorders		1		1		
Nausea and vomiting symptoms		7		5		2
Oral soft tissue swelling and oedema	1	2		1	1	1
Tongue signs and symptoms	1	1			1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	3	19	1	13	2	6

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	4	23	4	21		2
Body temperature altered		1				1
Febrile disorders	5	23	5	21		2
Feelings and sensations NEC	3	12	2	11	1	1
Gait disturbances		2		2		
General signs and symptoms NEC	4	8	2	4	2	4
Injection site reactions		1		1		
Pain and discomfort NEC	6	14	3	11	3	3
Therapeutic and nontherapeutic responses		6				6
Vaccination site reactions	6	21	6	20		1
	28	111	22	91	6	20

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	4	7	1	3	3	4
Anaphylactic and anaphylactoid responses	3	7			3	7
	7	14	1	3	6	11

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint infections	1	1			1	1
Coronavirus infections	1	11		1	1	10
Sepsis, bacteraemia, viraemia and fungaemia NEC		2				2
	2	14		1	2	13

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Medication errors, product use errors and issues NEC		1		1		
Off label uses	1	2	1	2		
Overdoses NEC		1		1		
Product administration errors and issues		1		1		
Vaccination related complications	1	2			1	2
	2	7	1	5	1	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood gas and acid base analyses		1		1
Carbohydrate tolerance analyses (incl diabetes)		1		1
Coagulation and bleeding analyses		2		2
Heart rate and pulse investigations	1	1	1	1
Liver function analyses		1		1
Mineral and electrolyte analyses		2		2
Platelet analyses		2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Protein analyses NEC		2		2
Red blood cell analyses		9		9
Renal function analyses		3		3
Tissue enzyme analyses NEC		1		1
Water and electrolyte analyses NEC		1		1
White blood cell analyses		10		10
	1	36	1	36

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
Total fluid volume decreased		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	2	1	2		
Joint related signs and symptoms	2	4	2	4		
Muscle pains	3	9	3	9		
Muscle related signs and symptoms NEC	1	2	1	2		
Musculoskeletal and connective tissue conditions NEC		3		3		
Musculoskeletal and connective tissue pain and discomfort	4	14	3	10	1	4
	11	34	10	30	1	4

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Disturbances in consciousness NEC	5	18	4	14	1	4
Facial cranial nerve disorders	2	5			2	5
Generalised tonic-clonic seizures		1				1
Headaches NEC	4	6	3	5	1	1
Migraine headaches		1		1		
Neurological signs and symptoms NEC		4		4		
Olfactory nerve disorders		1		1		
Paraesthesias and dysaesthesias	2	11	1	9	1	2
Sensory abnormalities NEC	1	3	1	2		1
Structural brain disorders NEC		3				3
Tremor (excl congenital)	1	1			1	1
	16	55	9	36	7	19

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep		1		1
Fear symptoms and phobic disorders (incl social phobia)		1		1
Increased physical activity levels		1		1
Panic attacks and disorders		1		1
		4		4

System Organ Class

**Renal and urinary disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Serious	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	8			1	8
Bronchospasm and obstruction		5				5
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms		3		2		1
Pulmonary thrombotic and embolic conditions	1	1			1	1
Upper respiratory tract signs and symptoms	2	5		1	2	4
	4	24		3	4	21

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		4		4		
Erythemas	3	8	2	5	1	3
Pruritus NEC	3	8	1	4	2	4
Rashes, eruptions and exanthems NEC	2	10	1	4	1	6
Urticarias	1	3	1	2		1
	9	33	5	19	4	14

System Organ Class

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System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Therapeutic procedures NEC		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism and thrombosis		1				1
Peripheral vascular disorders NEC	2	4	2	4		
Peripheral vasoconstriction, necrosis and vascular insufficiency		2		2		
Vascular hypertensive disorders NEC	1	3	1	1		2
	3	10	3	7		3

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Country Where Event Occurred

**MEXICO**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	1	1			1	1
Bleeding tendencies	9	10			9	10
Leukopenias NEC		5		1		4
Lymphatic system disorders NEC	37	94	34	85	3	9
Spleen disorders	1	1	1	1		
Thrombocytopenias	3	5	1	2	2	3
	51	116	36	89	15	27

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1	1	1		
Cardiac signs and symptoms NEC	7	24	6	20	1	4
Ischaemic coronary artery disorders	2	5			2	5
Pericardial disorders NEC	1	1	1	1		
Rate and rhythm disorders NEC	117	484	73	355	44	129
Supraventricular arrhythmias	2	6	1	2	1	4
Ventricular arrhythmias and cardiac arrest	2	2			2	2
	132	523	82	379	50	144

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	15	3	14		1
External ear disorders NEC		1		1		
External ear infections and inflammations		1		1		
Hearing losses		6		3		3
Inner ear signs and symptoms	15	48	12	39	3	9
Tympanic membrane disorders (excl infections)		1		1		
	18	72	15	59	3	13

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	3	5			3	5
Conjunctival infections, irritations and inflammations	1	4		3	1	1
Corneal structural change, deposit and degeneration	1	1			1	1
Eyelid movement disorders	3	6	3	6		
Lacrimation disorders	3	13	3	13		
Lid, lash and lacrimal infections, irritations and inflammations	4	10	2	8	2	2
Ocular disorders NEC	9	32	8	30	1	2
Ocular infections, inflammations and associated manifestations	10	30	9	29	1	1
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders	1	7	1	7		
Visual disorders NEC	11	40	9	33	2	7
Visual impairment and blindness (excl colour blindness)		3		1		2
	46	152	35	130	11	22

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis (excl infective)	1	2	1	2		
Dental pain and sensation disorders		2		2		
Diarrhoea (excl infective)	68	232	47	193	21	39
Diverticula	1	1			1	1
Dyspeptic signs and symptoms	1	3	1	3		
Faecal abnormalities NEC	2	7	1	5	1	2
Flatulence, bloating and distension		2		2		
Gastritis (excl infective)	2	4	2	4		
Gastrointestinal and abdominal pains (excl oral and throat)	49	186	38	162	11	24
Gastrointestinal atonic and hypomotility disorders NEC	2	2	2	2		
Gastrointestinal disorders NEC		1				1
Gastrointestinal dyskinetic disorders	2	4	2	4		
Gastrointestinal signs and symptoms NEC	5	22	4	17	1	5
Gastrointestinal spastic and hypermotility disorders	1	2	1	2		
Gastrointestinal stenosis and obstruction NEC	9	13			9	13
Gingival disorders, signs and symptoms NEC	3	3	3	3		
Gingival haemorrhages	1	1	1	1		
Nausea and vomiting symptoms	267	802	193	662	74	140
Non-site specific gastrointestinal haemorrhages	11	21			11	21
Oral dryness and saliva altered	8	24	6	16	2	8
Oral soft tissue disorders NEC	2	4	1	3	1	1
Oral soft tissue haemorrhages		1				1
Oral soft tissue signs and symptoms	39	113	27	89	12	24
Oral soft tissue swelling and oedema	4	8	3	7	1	1
Salivary gland enlargements		1		1		
Stomatitis and ulceration	3	3	3	3		
Tongue signs and symptoms	3	6	3	5		1
	484	1,470	339	1188	145	282

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\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		1		1		
Application and instillation site reactions		1		1		
Asthenic conditions	501	1,583	407	1392	94	191
Body temperature altered	11	34	6	16	5	18
Death and sudden death	2	4			2	4
Febrile disorders	146	543	124	482	22	61
Feelings and sensations NEC	162	614	121	516	41	98
Fibrosis NEC	1	1	1	1		
Gait disturbances	2	6	2	6		
General signs and symptoms NEC	106	301	93	271	13	30
Inflammations	42	149	36	134	6	15
Injection site reactions	1	2	1	2		
Mass conditions NEC	66	185	59	168	7	17
Mucosal findings abnormal	2	2	2	2		
Oedema NEC	68	251	53	213	15	38
Pain and discomfort NEC	267	909	212	789	55	120
Therapeutic and nontherapeutic responses	5	30			5	30
Trophic disorders	1	1	1	1		
Vaccination site reactions	190	583	179	548	11	35
	1,573	5,200	1297	4543	276	657

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholestasis and jaundice	1	4			1	4
Hepatic enzymes and function abnormalities	1	1	1	1		
Hepatobiliary signs and symptoms		1		1		
	2	6	1	2	1	4

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 \* AE=Adverse Event  
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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	7	42	5	32	2	10
Allergies to foods, food additives, drugs and other chemicals	2	10		6	2	4
Anaphylactic and anaphylactoid responses	24	73			24	73
Immune and associated conditions NEC		2		2		
	33	127	5	40	28	87

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	2		1	1	1
Bacterial infections NEC	27	68	7	14	20	54
Candida infections	1	2	1	2		
Central nervous system and spinal infections		3				3
Coronavirus infections	23	76	15	36	8	40
Dental and oral soft tissue infections		2		2		
Ear infections	2	6	2	6		
Eye and eyelid infections	4	12	4	12		
Herpes viral infections	2	3	2	3		
Infections NEC	8	10	7	9	1	1
Influenza viral infections	2	5	2	5		
Lower respiratory tract and lung infections	5	25			5	25
Rubeola viral infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2			2	2
Tuberculous infections	7	12			7	12
Upper respiratory tract infections	4	12	2	8	2	4
Urinary tract infections	2	4	2	3		1
Vascular infections		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral infections NEC		3		1		2
	91	249	44	102	47	147

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC		1		1		
Bone and joint injuries NEC		1		1		
Chest and respiratory tract injuries NEC		3		2		1
Exposures associated with pregnancy, delivery and lactation	6	18	6	18		
Exposures to agents or circumstances NEC		1		1		
Eye injuries NEC	3	19	1	14	2	5
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC	8	14	8	14		
Non-site specific injuries NEC	5	7	3	4	2	3
Off label uses	4	12	4	12		
Overdoses NEC	1	1	1	1		
Peripheral nerve injuries		1				1
Poisoning and toxicity	1	1			1	1
Product administration errors and issues	14	21	14	21		
Skin injuries NEC	3	4	3	4		
Thermal burns	3	4			3	4
Vaccination related complications	2	2	1	1	1	1
	50	111	41	94	9	17

System Organ Class

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System Organ Class

**Investigations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	9	50	6	30	3	20
Carbohydrate tolerance analyses (incl diabetes)	2	4	2	3		1
Coagulation and bleeding analyses		1				1
Heart rate and pulse investigations	4	18	4	16		2
Immunology analyses NEC	4	6	4	6		
Liver function analyses	2	4	1	1	1	3
Physical examination procedures and organ system status	57	168	49	148	8	20
Platelet analyses	5	5	4	4	1	1
Protein analyses NEC		1		1		
Red blood cell analyses	3	3	3	3		
Vascular tests NEC (incl blood pressure)	24	57	14	36	10	21
Virus identification and serology	1	5	1	3		2
White blood cell analyses	3	4	3	3		1
	114	326	91	254	23	72

System Organ Class

**Metabolism and nutrition disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	28	93	27	83	1	10
Diabetes mellitus (incl subtypes)	1	1			1	1
Diabetic complications NEC		1				1
Electrolyte imbalance NEC		1				1
Hyperglycaemic conditions NEC	3	4	2	2	1	2
Hypoglycaemic conditions NEC		1				1
Lipid metabolism and deposit disorders NEC	1	1	1	1		
Sodium imbalance		1				1
Total fluid volume decreased	1	5	1	3		2
	34	108	31	89	3	19

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	2	1	1		1
Bone related signs and symptoms		4		2		2
Joint related signs and symptoms	164	619	136	550	28	69
Lupus erythematosus (incl subtypes)		1				1
Muscle pains	189	721	155	641	34	80
Muscle related signs and symptoms NEC	6	17	6	16		1
Muscle tone abnormalities		1		1		
Muscle weakness conditions	10	26	3	15	7	11
Musculoskeletal and connective tissue conditions NEC	3	20	3	20		
Musculoskeletal and connective tissue pain and discomfort	64	148	60	139	4	9
Myopathies	1	1	1	1		
Soft tissue disorders NEC	1	2	1	2		
Synovial disorders	2	2	2	2		
	441	1,564	368	1390	73	174

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diffuse large B-cell lymphomas	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
			1
		7	9
		1	1
		6	12
		1	1
2	6	1	4
	2		
			3
5	22	23	110
4	15	2	4
		2	2
			1
2	6	8	29
		3	8
282	1035	73	159
		1	1
			1
			1
		1	1
1	2		
1	1		
			3
2	3		
			1
1	2	1	1
		1	3
144	591	55	132
	3	1	3

Abnormal reflexes	2	3
Absence seizures		1
Acute polyneuropathies	7	9
Central nervous system aneurysms and dissections	1	1
Central nervous system haemorrhages and cerebrovascular accidents	6	12
Chronic polyneuropathies	1	1
Coordination and balance disturbances	3	10
Cortical dysfunction NEC		2
Demyelinating disorders NEC		3
Disturbances in consciousness NEC	28	132
Dyskinesias and movement disorders NEC	6	19
Dystonias	2	2
Encephalitis NEC		1
Facial cranial nerve disorders	10	35
Generalised tonic-clonic seizures	3	8
Headaches NEC	355	1,194
Hypoglossal nerve disorders	1	1
Increased intracranial pressure disorders		1
Lumbar spinal cord and nerve root disorders		1
Memory loss (excl dementia)	1	1
Mental impairment (excl dementia and memory loss)	1	2
Migraine headaches	1	1
Mononeuropathies		3
Muscle tone abnormal	2	3
Myelitis (incl infective)		1
Narcolepsy and hypersomnia	2	3
Nervous system disorders NEC	1	3
Neurological signs and symptoms NEC	199	723
Neuromuscular disorders NEC	1	6

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Olfactory nerve disorders	10	30	9	27	1	3
Paraesthesias and dysaesthesias	62	201	40	143	22	58
Paralysis and paresis (excl cranial nerve)	14	48	3	3	11	45
Peripheral neuropathies NEC	2	9	2	3		6
Seizures and seizure disorders NEC	30	104	8	22	22	82
Sensory abnormalities NEC	15	45	14	38	1	7
Speech and language abnormalities	4	7	3	6	1	1
Spinal cord and nerve root disorders NEC	1	3	1	1		2
Tremor (excl congenital)	11	25	8	22	3	3
	782	2,654	534	1956	248	698

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Counterfeit, falsified and substandard products	4	4	4	4
Product physical issues	1	1	1	1
Product quality issues NEC	1	1	1	1
Product supply and availability issues		1		1
	6	7	6	7

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect alterations NEC		1		1		
Anxiety symptoms	18	51	11	37	7	14
Behaviour and socialisation disturbances	2	2	2	2		

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	1	12		9	1	3
Deliria	1	1			1	1
Depressive disorders		1		1		
Disturbances in initiating and maintaining sleep	2	5	1	4	1	1
Eating disorders NEC	1	1	1	1		
Emotional and mood disturbances NEC	39	112	26	91	13	21
Hallucinations (excl sleep-related)	1	3			1	3
Increased physical activity levels		1		1		
Mood alterations with depressive symptoms	1	3	1	3		
Mood disorders NEC	1	1	1	1		
Panic attacks and disorders	1	1	1	1		
Parasomnias		1				1
Perception disturbances NEC		1				1
Sleep disorders NEC	1	1			1	1
Somatic symptom disorders	1	2	1	2		
	70	200	45	154	25	46

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		2		2		
Renal failure and impairment	1	1			1	1
Urinary abnormalities	1	2			1	2
	2	5		2	2	3

System Organ Class

**Reproductive system and breast disorders**

Spontaneous			

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		1		1		
Menstruation and uterine bleeding NEC		3		3		
Reproductive tract disorders NEC (excl neoplasms)	1	1	1	1		
Reproductive tract infections and inflammations NEC		1		1		
Reproductive tract signs and symptoms NEC	1	3		2	1	1
Vulvovaginal disorders NEC		1		1		
	2	10	1	9	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	227	1,246	80	477	147	769
Bronchial conditions NEC		2		2		
Bronchospasm and obstruction	32	84	15	42	17	42
Conditions associated with abnormal gas exchange	1	1			1	1
Coughing and associated symptoms	83	321	62	271	21	50
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		2				2
Laryngeal spasm, oedema and obstruction	5	16	1	2	4	14
Lower respiratory tract inflammatory and immunologic conditions		1		1		
Lower respiratory tract signs and symptoms	1	2	1	2		
Nasal congestion and inflammations	3	17	3	17		
Nasal disorders NEC	4	11	2	8	2	3
Pharyngeal disorders (excl infections and neoplasms)	5	18	4	7	1	11
Pneumothorax and pleural effusions NEC		1		1		
Pulmonary oedemas		1				1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failures (excl neonatal)	2	3			2	3
Respiratory signs and symptoms NEC		5		4		1
Respiratory tract disorders NEC	3	4	2	3	1	1
Upper respiratory tract signs and symptoms	155	665	131	595	24	70
	521	2,400	301	1432	220	968

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	2	2	2	2		
Angioedemas	2	10			2	10
Apocrine and eccrine gland disorders	14	50	5	34	9	16
Bullous conditions	6	11	1	2	5	9
Dermal and epidermal conditions NEC	211	595	173	523	38	72
Dermatitis and eczema	3	5	3	5		
Erythemas	60	193	46	166	14	27
Exfoliative conditions		1		1		
Nail and nail bed conditions (excl infections and infestations)		1		1		
Photosensitivity and photodermatosis conditions		1		1		
Pigmentation changes NEC		1		1		
Pruritus NEC	67	187	50	150	17	37
Purpura and related conditions	4	11	2	6	2	5
Rashes, eruptions and exanthems NEC	53	183	40	138	13	45
Skin and subcutaneous conditions NEC	1	1	1	1		
Skin haemorrhages		1		1		
Skin vasomotor conditions	2	3	2	3		
Urticarias	9	16	7	14	2	2
	434	1,272	332	1049	102	223

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 \* AE=Adverse Event  
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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dietary and nutritional issues	1	1	1	1		
Disability issues		2		1		1
	1	3	1	2		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	12	71			12	71
Circulatory collapse and shock	21	35			21	35
Haemorrhages NEC	24	28	2	2	22	26
Non-site specific embolism and thrombosis	5	5			5	5
Non-site specific vascular disorders NEC	3	8	3	7		1
Peripheral vascular disorders NEC	5	20	2	16	3	4
Peripheral vasoconstriction, necrosis and vascular insufficiency	4	10	3	9	1	1
Site specific vascular disorders NEC	1	9	1	7		2
Vascular hypertensive disorders NEC	27	104	12	60	15	44
Vascular hypotensive disorders	9	25	4	13	5	12
	111	315	27	114	84	201

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Country Where Event Occurred

**MONACO**

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Therapeutic and nontherapeutic responses		1		1
		1		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Speech and language abnormalities		1		1
		1		1

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Country Where Event Occurred

**NETHERLANDS**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	1	1			1	1
Anaemias NEC	1	1	1	1		
Bleeding tendencies		1		1		
Coagulopathies	1	1	1	1		
Leukopenias NEC		1				1
Lymphatic system disorders NEC	40	85	39	84	1	1
Marrow depression and hypoplastic anaemias	1	1			1	1
Spleen disorders	1	1			1	1
Thrombocytopenias	4	5			4	5
	49	97	41	87	8	10

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic valvular disorders	1	3					1	3
Cardiac conduction disorders	1	2				1	1	1
Cardiac disorders NEC	4	7			1	1	3	6
Cardiac signs and symptoms NEC	12	34			10	26	2	8
Coronary artery disorders NEC	1	1					1	1
Heart failure signs and symptoms	5	6					5	6
Heart failures NEC	11	38					11	38
Ischaemic coronary artery disorders	20	37					20	37
Left ventricular failures	1	1					1	1
Myocardial disorders NEC	1	3					1	3
Noninfectious pericarditis	1	3					1	3

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rate and rhythm disorders NEC	12	34			2	9	10	25
Right ventricular failures	1	2					1	2
Supraventricular arrhythmias	9	32	1	1	1	5	8	27
Ventricular arrhythmias and cardiac arrest	8	19					8	19
	88	222	1	1	14	42	74	180

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coagulation disorders congenital		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	2	7			2	7		
External ear disorders NEC		1				1		
Hearing losses	7	15				2	7	13
Hyperacusia		1				1		
Inner ear disorders NEC	1	5					1	5
Inner ear signs and symptoms	6	24	1	1	4	21	2	3
	16	53	1	1	6	32	10	21

System Organ Class

**Endocrine disorders**

Spontaneous
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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal cortical hypofunctions	1	1	1	1
Adrenal gland disorders NEC		1		1
Hypothalamic and pituitary disorders NEC		1		1
	1	3	1	3

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Conjunctival and corneal bleeding and vascular disorders		2							2
Conjunctival infections, irritations and inflammations		1							1
Eyelid movement disorders	1	1			1	1			
Iris and uveal tract infections, irritations and inflammations	1	1					1	1	
Lacrimation disorders	2	4			2	4			
Lid, lash and lacrimal infections, irritations and inflammations	2	5			2	4			1
Ocular bleeding and vascular disorders NEC	4	4					4	4	
Ocular disorders NEC	9	16			7	13	2	3	
Ocular infections, inflammations and associated manifestations	1	5			1	4			1
Ocular nerve and muscle disorders	2	3			1	1	1	2	
Ocular sensation disorders	1	1			1	1			
Optic nerve bleeding and vascular disorders	1	1					1	1	
Pupil disorders		1				1			
Refractive and accommodative disorders		1				1			
Retinal bleeding and vascular disorders (excl retinopathy)	3	3					3	3	
Retinal structural change, deposit and degeneration	1	2					1	2	

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Structural change, deposit and degeneration of eye NEC	1	1					1	1
Visual disorders NEC	13	20			12	18	1	2
Visual impairment and blindness (excl colour blindness)	15	25	1	1	5	7	10	18
	57	97	1	1	32	55	25	42

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal and rectal disorders NEC		2		1		1
Colitis (excl infective)	1	1			1	1
Dental pain and sensation disorders		2		2		
Diaphragmatic hernias		1				1
Diarrhoea (excl infective)	18	42	16	39	2	3
Duodenal and small intestinal stenosis and obstruction		1				1
Dyspeptic signs and symptoms	1	2	1	2		
Faecal abnormalities NEC	1	3	1	2		1
Gastric and oesophageal haemorrhages	1	1			1	1
Gastrointestinal and abdominal pains (excl oral and throat)	15	27	13	25	2	2
Gastrointestinal atonic and hypomotility disorders NEC		3		2		1
Gastrointestinal disorders NEC		1		1		
Gastrointestinal inflammatory disorders NEC		1				1
Gastrointestinal signs and symptoms NEC	7	32	4	15	3	17
Gastrointestinal stenosis and obstruction NEC	1	2			1	2
Gastrointestinal vascular occlusion and infarction	1	4			1	4
Gingival disorders, signs and symptoms NEC	1	1	1	1		

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 \* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhoids and gastrointestinal varices (excl oesophageal)		1		1		
Intestinal haemorrhages	3	5			3	5
Nausea and vomiting symptoms	200	493	182	432	18	61
Non-site specific gastrointestinal haemorrhages	2	9			2	9
Oral dryness and saliva altered		3		2		1
Oral soft tissue disorders NEC		2		2		
Oral soft tissue signs and symptoms	10	28	7	22	3	6
Oral soft tissue swelling and oedema	4	7	2	3	2	4
Salivary gland disorders NEC		1		1		
Stomatitis and ulceration	1	2	1	2		
Tongue disorders		4		2		2
Tongue signs and symptoms	2	13	2	6		7
	269	694	230	563	39	131

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		1		1		
Asthenic conditions	731	1,640	667	1477	64	163
Body temperature altered	2	4			2	4
Death and sudden death	15	56			15	56
Febrile disorders	238	505	181	364	57	141
Feelings and sensations NEC	232	574	222	543	10	31
Gait disturbances	10	16	5	10	5	6
General signs and symptoms NEC	32	81	11	39	21	42
Inflammations	4	5	2	3	2	2
Injection site reactions	27	67	27	67		
Mucosal findings abnormal	1	1	1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema NEC	7	11	2	5	5	6
Pain and discomfort NEC	63	119	50	96	13	23
Therapeutic and nontherapeutic responses	6	11			6	11
Vaccination site reactions	993	2,436	987	2428	6	8
Vascular complications associated with device	1	1			1	1
	2,362	5,528	2155	5034	207	494

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis		1				1
Cholestasis and jaundice	2	5	1	1	1	4
Hepatic failure and associated disorders	1	2			1	2
Hepatocellular damage and hepatitis NEC	2	2			2	2
	5	10	1	1	4	9

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic conditions NEC	6	20			4	10	2	10
Allergies to foods, food additives, drugs and other chemicals	1	4		1	1	2		2
Anaphylactic and anaphylactoid responses	4	19					4	19
Immune and associated conditions NEC	2	4					2	4
	13	47		1	5	12	8	35

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	2			1	2
Bacterial infections NEC	2	3			2	3
Bone and joint infections	1	1			1	1
Candida infections		1				1
Cardiac infections		1				1
Coronavirus infections	10	32	2	9	8	23
Dental and oral soft tissue infections		2				2
Enteroviral infections NEC		1				1
Escherichia infections	1	1			1	1
Eye and eyelid infections	1	1			1	1
Female reproductive tract infections	1	1			1	1
Hepatitis viral infections		1				1
Herpes viral infections	6	16	2	8	4	8
Infections NEC	3	10			3	10
Lower respiratory tract and lung infections	15	29			15	29
Muscle and soft tissue infections		1				1
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	6			2	6
Streptococcal infections		4				4
Tinea infections		1		1		
Upper respiratory tract infections	5	19	5	18		1
Urinary tract infections	9	17	3	7	6	10
Vascular infections		2				2
Viral infections NEC	2	4			2	4
	59	156	12	43	47	113

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cerebral injuries NEC	2	3					2	3
Chest and respiratory tract injuries NEC	2	2					2	2
Conditions caused by cold	3	3			3	3		
Exposures associated with pregnancy, delivery and lactation	3	6			1	4	2	2
Exposures to agents or circumstances NEC		1				1		
Fractures and dislocations NEC		1						1
Intentional product use issues	1	1			1	1		
Limb fractures and dislocations	1	5					1	5
Medication errors, product use errors and issues NEC		1				1		
Muscle, tendon and ligament injuries	3	6			2	5	1	1
Non-site specific injuries NEC	14	30	1	1	5	13	9	17
Occupational exposures		1				1		
Off label uses	6	8			6	8		
Pelvic fractures and dislocations	1	1					1	1
Product administration errors and issues	7	12			7	12		
Product confusion errors and issues		1				1		
Product preparation errors and issues	1	2			1	2		
Product storage errors and issues in the product use system	1	1			1	1		
Reproductive system and breast injuries		1				1		
Site specific injuries NEC	3	4				1	3	3
Skin injuries NEC	5	5			3	3	2	2
Skull fractures, facial bone fractures and dislocations	1	1					1	1
Vaccination related complications	1	2					1	2
	55	98	1	1	30	58	25	40

System Organ Class

**Investigations**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteria identification and serology (excl mycobacteria)	1	1			1	1
Blood gas and acid base analyses	6	24	2	3	4	21
Carbohydrate tolerance analyses (incl diabetes)	3	10	3	9		1
Chemistry analyses NEC		1				1
Cholesterol analyses	2	3	2	3		
Coagulation and bleeding analyses	6	7	2	3	4	4
Digestive enzymes	1	1	1	1		
ECG investigations		1				1
Heart rate and pulse investigations	8	20	7	12	1	8
Liver function analyses	7	11	7	11		
Metabolism tests NEC		1		1		
Mineral and electrolyte analyses	7	8	6	7	1	1
Physical examination procedures and organ system status	12	76	9	64	3	12
Platelet analyses	5	6	4	5	1	1
Protein analyses NEC	7	11	6	8	1	3
Red blood cell analyses	17	19	14	16	3	3
Renal function analyses	5	10	5	10		
Skeletal and cardiac muscle analyses	2	3	1	2	1	1
Tissue enzyme analyses NEC	3	3	3	3		
Toxicology laboratory analyses	1	1	1	1		
Urinary tract function analyses NEC		1		1		
Vascular tests NEC (incl blood pressure)	10	21	5	10	5	11
Virus identification and serology	1	4		1	1	3
White blood cell analyses	10	11	8	9	2	2
	114	254	86	180	28	74

System Organ Class

**Metabolism and nutrition disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	5	27	3	16	2	11
Diabetes mellitus (incl subtypes)	2	3			2	3
Electrolyte imbalance NEC		1				1
Elevated triglycerides	1	1			1	1
Fluid intake decreased	1	3		1	1	2
General nutritional disorders NEC	4	8	2	4	2	4
Hyperglycaemic conditions NEC		2		1		1
Hypoglycaemic conditions NEC		3		1		2
Metabolic acidoses (excl diabetic acidoses)		1		1		
Potassium imbalance	1	2			1	2
Sodium imbalance		3		1		2
Total fluid volume decreased	2	5		1	2	4
Total fluid volume increased	1	3		1	1	2
	17	62	5	27	12	35

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	3	4	1	1	2	3
Bone related signs and symptoms	4	5	3	4	1	1
Extremity deformities		1				1
Joint related signs and symptoms	162	376	156	363	6	13
Muscle pains	375	816	365	794	10	22
Muscle related signs and symptoms NEC	5	14	4	12	1	2
Muscle tone abnormalities	1	2	1	2		
Muscle weakness conditions	6	12	3	7	3	5
Musculoskeletal and connective tissue conditions NEC	7	13	6	11	1	2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal and connective tissue pain and discomfort	57	106	49	95	8	11
Osteoarthropathies	1	1	1	1		
Rheumatoid arthropathies	1	2			1	2
Soft tissue disorders NEC	1	1			1	1
	623	1,353	589	1290	34	63

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Myelodysplastic syndromes		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute polyneuropathies	1	1					1	1
Alzheimer's disease (incl subtypes)		1						1
Autonomic nervous system disorders		2						2
Central nervous system haemorrhages and cerebrovascular accidents	58	102	1	1			58	102
Central nervous system vascular disorders NEC	2	3					2	3
Cerebrovascular venous and sinus thrombosis	1	1					1	1
Cervical spinal cord and nerve root disorders	1	1			1	1		
Choreiform movements		1						1
Coma states		1						1
Coordination and balance disturbances	7	19			3	11	4	8

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Nervous system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cortical dysfunction NEC	10	18
Dementia (excl Alzheimer's type)		1
Disturbances in consciousness NEC	68	150
Dyskinesias and movement disorders NEC	6	6
Encephalitis NEC	1	1
Encephalopathies NEC	1	1
Eye movement disorders	1	1
Facial cranial nerve disorders	13	18
Generalised tonic-clonic seizures	1	6
Headaches NEC	389	851
Increased intracranial pressure disorders	1	1
Lumbar spinal cord and nerve root disorders		1
Memory loss (excl dementia)	2	5
Mental impairment (excl dementia and memory loss)	3	9
Migraine headaches	3	5
Mononeuropathies		2
Multiple sclerosis acute and progressive	1	2
Muscle tone abnormal	1	1
Narcolepsy and hypersomnia		3
Nervous system cysts and polyps	1	1
Neurological signs and symptoms NEC	44	144
Neuromuscular disorders NEC	1	1
Olfactory nerve disorders	1	6
Optic nerve disorders NEC		1
Paraesthesias and dysaesthesias	16	50
Paralysis and paresis (excl cranial nerve)	13	22
Parkinson's disease and parkinsonism	3	3
Peripheral neuropathies NEC	5	6
Seizures and seizure disorders NEC	26	49
Sensory abnormalities NEC	8	24
Sleep disturbances NEC		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	8	14
					1
1	1		8	68	142
		4	4	2	2
				1	1
				1	1
		1	2	12	16
				1	6
		378	825	11	26
				1	1
					1
			3	2	2
			4	3	5
		3	4		1
			1		1
				1	2
				1	1
			3		
				1	1
		33	118	11	26
		1	1		
		1	6		
					1
		14	45	2	5
				13	22
				3	3
				5	6
		2	2	24	47
		8	24		
			1		

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Speech and language abnormalities	11	19			2	6	9	13
Spinal cord and nerve root disorders NEC	2	2					2	2
Transient cerebrovascular events	39	49	1	1			39	49
Tremor (excl congenital)	6	15			3	12	3	3
Trigeminal disorders	1	1			1	1		
	748	1,608	3	3	457	1086	291	522

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion related conditions and complications	2	2	2	2
Abortions not specified as induced or spontaneous	2	2	2	2
Abortions spontaneous	9	11	9	11
	13	15	13	15

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product packaging issues		1		1
		1		1

System Organ Class

**Psychiatric disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	1			1	1
Affect alterations NEC	1	1	1	1		
Anxiety symptoms	7	10	7	9		1
Behaviour and socialisation disturbances		1		1		
Communications disorders	1	2			1	2
Confusion and disorientation	16	24	5	10	11	14
Decreased physical activity levels		2		1		1
Deliria	12	24			12	24
Delusional symptoms		1		1		
Depressive disorders	1	6		4	1	2
Dissociative states		1		1		
Disturbances in initiating and maintaining sleep	2	2	2	2		
Emotional and mood disturbances NEC	4	5	2	3	2	2
Fear symptoms and phobic disorders (incl social phobia)	1	2		1	1	1
Hallucinations (excl sleep-related)	3	5			3	5
Increased physical activity levels	1	6		5	1	1
Mood alterations with depressive symptoms	2	4	2	4		
Mood disorders NEC	3	6	3	5		1
Panic attacks and disorders	1	1	1	1		
Parasomnias		4		4		
Perception disturbances NEC	1	2		1	1	1
Personality disorders NEC		1		1		
Psychotic disorder NEC		2				2
Sleep disorders NEC	1	1	1	1		
Somatic symptom disorders		1				1
Speech and language usage disturbances		1		1		
Suicidal and self-injurious behaviour		1				1
Thinking disturbances	2	4	2	3		1
	60	121	26	60	34	61

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	5	12	2	3	3	9
Bladder infections and inflammations	1	1			1	1
Glomerulonephritis and nephrotic syndrome		3				3
Renal disorders NEC	1	2	1	2		
Renal failure and impairment	3	8		1	3	7
Renal failure complications		2				2
Renal lithiasis	2	3			2	3
Renal vascular and ischaemic conditions	1	1			1	1
Urinary tract signs and symptoms NEC		1		1		
	13	33	3	7	10	26

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1		1		
Erection and ejaculation conditions and disorders		1				1
Menopausal effects on the genitourinary tract	1	2			1	2
Reproductive tract disorders NEC (excl neoplasms)		1		1		
Reproductive tract signs and symptoms NEC	2	2	2	2		
Vulvovaginal signs and symptoms	1	1	1	1		
	4	8	3	5	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	47	130		1	19	59	28	71
Bronchospasm and obstruction	1	9			1	2		7
Conditions associated with abnormal gas exchange	6	14					6	14
Coughing and associated symptoms	5	23			3	18	2	5
Laryngeal spasm, oedema and obstruction	2	3					2	3
Lower respiratory tract inflammatory and immunologic conditions	2	10					2	10
Lower respiratory tract signs and symptoms	1	4			1	3		1
Nasal congestion and inflammations	2	3			1	2	1	1
Nasal disorders NEC	9	11			3	4	6	7
Parenchymal lung disorders NEC		1						1
Pharyngeal disorders (excl infections and neoplasms)	8	17			3	4	5	13
Pneumothorax and pleural effusions NEC	2	3					2	3
Pulmonary hypertensions	1	1					1	1
Pulmonary oedemas	1	2					1	2
Pulmonary thrombotic and embolic conditions	33	38					33	38
Respiratory failures (excl neonatal)	4	10					4	10
Respiratory signs and symptoms NEC	1	3			1	3		
Respiratory tract disorders NEC	4	14			3	6	1	8
Upper respiratory tract signs and symptoms	15	51			11	36	4	15
	144	347		1	46	137	98	210

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acnes	1	1			1	1		
Angioedemas	7	14					7	14
Apocrine and eccrine gland disorders	10	34			8	27	2	7

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bullous conditions	2	5				1	2	4
Dermal and epidermal conditions NEC	10	19			8	17	2	2
Dermatitis and eczema	3	3			3	3		
Dermatitis ascribed to specific agent	1	1					1	1
Erythemas	10	34			8	27	2	7
Nail and nail bed conditions (excl infections and infestations)		1				1		
Panniculitides	2	2					2	2
Pilar disorders NEC	1	2			1	2		
Pruritus NEC	5	22		1	4	19	1	3
Purpura and related conditions	5	6			4	4	1	2
Rashes, eruptions and exanthems NEC	9	35		1	7	29	2	6
Scaly conditions		1				1		
Skin vasculitides	2	2					2	2
Skin vasomotor conditions		1						1
Urticarias	5	20			4	15	1	5
	73	203		2	48	147	25	56

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues		5		3		2
		5		3		2

System Organ Class

**Vascular disorders**

Interval Total #	Cumulative Total #	Non Interventional Study		Spontaneous	
		Serious	Nonserious	Serious	Nonserious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	1	2					1	2
Aneurysms and dissections non-site specific		1						1
Aortic aneurysms and dissections	1	1					1	1
Arterial infections and inflammations	1	2					1	2
Circulatory collapse and shock	1	8					1	8
Haemorrhages NEC	3	4			1	1	2	3
Non-site specific embolism and thrombosis	17	23					17	23
Non-site specific necrosis and vascular insufficiency NEC	1	1					1	1
Non-site specific vascular disorders NEC	1	1					1	1
Peripheral embolism and thrombosis	26	34			3	4	23	30
Peripheral vascular disorders NEC	2	11			1	8	1	3
Peripheral vasoconstriction, necrosis and vascular insufficiency		9				7		2
Site specific vascular disorders NEC	2	14			1	7	1	7
Vascular hypertensive disorders NEC	15	31			7	15	8	16
Vascular hypotensive disorders	8	19	1	1	3	7	5	12
Vasculitides NEC	3	3			3	3		
	82	164	1	1	19	52	63	112

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**NEW ZEALAND**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
General signs and symptoms NEC	1	1	1	1
Therapeutic and nontherapeutic responses	1	2	1	2
	2	3	2	3

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC	5	5	5	5
	5	5	5	5

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections		1		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Exposures to agents or circumstances NEC		1		1
		1		1

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemic conditions NEC	1	3	1	3
	1	3	1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Feelings and sensations NEC		1		1
Pain and discomfort NEC		1		1
		3		3

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		2		2
		2		2

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
Musculoskeletal and connective tissue pain and discomfort		1		1
		2		2

*System Organ Class*

**Nervous system disorders**

Spontaneous
-------------

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
Neurological signs and symptoms NEC		1		1
Sleep disturbances NEC		1		1
		3		3

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**NORWAY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bleeding tendencies	1	1			1	1
Eosinophilic disorders	1	1			1	1
Leukocytoses NEC		2		1		1
Lymphatic system disorders NEC	2	6	1	4	1	2
Marrow depression and hypoplastic anaemias	1	1			1	1
Neutropenias		1				1
Thrombocytopenias	5	6			5	6
	10	18	1	5	9	13

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		1				1
Cardiac disorders NEC		2				2
Cardiac signs and symptoms NEC	3	6	2	3	1	3
Coronary artery disorders NEC		2				2
Heart failures NEC		4				4
Ischaemic coronary artery disorders	1	10			1	10
Left ventricular failures		1				1
Noninfectious pericarditis	4	6			4	6
Pericardial disorders NEC		3				3
Rate and rhythm disorders NEC	5	18	2	5	3	13
Supraventricular arrhythmias	1	6			1	6
Ventricular arrhythmias and cardiac arrest	1	5			1	5
	15	64	4	8	11	56

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	6	1	6		
Hearing disorders NEC	1	1	1	1		
Inner ear signs and symptoms	2	4		1	2	3
	4	11	2	8	2	3

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hyperfunction disorders		2		2
		2		2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1		1		
Iris and uveal tract infections, irritations and inflammations	2	2			2	2
Lid, lash and lacrimal infections, irritations and inflammations	1	2	1	1		1
Ocular bleeding and vascular disorders NEC		2				2
Ocular disorders NEC		1		1		
Ocular infections, inflammations and associated manifestations		2		1		1
Ocular sensation disorders		3		2		1
Orbital structural change, deposit and degeneration		1				1
Pupil disorders		2				2

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Refractive and accommodative disorders	1	1			1	1
Visual disorders NEC	3	6		1	3	5
Visual impairment and blindness (excl colour blindness)	3	5	1	2	2	3
	10	28	2	9	8	19

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal wall conditions NEC		1				1
Diarrhoea (excl infective)	4	31	1	18	3	13
Faecal abnormalities NEC		2		1		1
Flatulence, bloating and distension		1		1		
Gastric and oesophageal haemorrhages	1	1			1	1
Gastritis (excl infective)		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	6	28		12	6	16
Gastrointestinal atonic and hypomotility disorders NEC		2		1		1
Gastrointestinal disorders NEC		1				1
Gastrointestinal dyskinetic disorders		1				1
Gastrointestinal inflammatory disorders NEC		1				1
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC	1	10	1	4		6
Gastrointestinal vascular occlusion and infarction		2				2
Intestinal haemorrhages	1	2			1	2
Nausea and vomiting symptoms	20	129	10	71	10	58
Non-site specific gastrointestinal haemorrhages	1	5			1	5
Oral dryness and saliva altered		6		5		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral soft tissue haemorrhages	1	1	1	1		
Oral soft tissue signs and symptoms	3	10	1	4	2	6
Oral soft tissue swelling and oedema		1				1
	38	237	14	119	24	118

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	32	168	21	118	11	50
Body temperature altered		1				1
Death and sudden death	2	38			2	38
Febrile disorders	22	108	12	61	10	47
Feelings and sensations NEC	9	54	5	36	4	18
Gait disturbances	1	2	1	1		1
General signs and symptoms NEC	29	114	11	33	18	81
Inflammations		1				1
Injection site reactions		2		2		
Interactions	3	4	3	3		1
Oedema NEC		6		2		4
Pain and discomfort NEC	17	52	10	28	7	24
Therapeutic and nontherapeutic responses	3	5	1	3	2	2
Vaccination site reactions	4	65	2	50	2	15
	122	620	66	337	56	283

System Organ Class

**Hepatobiliary disorders**

Interval Total #	Cumulative Total #	Spontaneous
		Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis		1		1
Hepatic and hepatobiliary disorders NEC	1	1	1	1
	1	2	1	2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	7		2	1	5
Allergies to foods, food additives, drugs and other chemicals		2				2
Anaphylactic and anaphylactoid responses	5	13			5	13
Immune and associated conditions NEC	1	1			1	1
	7	23		2	7	21

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	2	4			2	4
Bacterial infections NEC	1	3			1	3
Borrelial infections		1				1
Coronavirus infections	5	5	1	1	4	4
Eye and eyelid infections		1		1		
Herpes viral infections	2	3	1	1	1	2
Infections NEC	1	10		1	1	9
Influenza viral infections		2		2		
Lower respiratory tract and lung infections	5	28		1	5	27

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	5			1	5
Staphylococcal infections	1	1			1	1
Streptococcal infections	2	3			2	3
Upper respiratory tract infections		2		1		1
Urinary tract infections		7		5		2
Vascular infections	1	1			1	1
	21	76	2	13	19	63

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC		1				1
Cardiac and vascular procedural complications	2	2			2	2
Cerebral injuries NEC	3	4			3	4
Conditions caused by cold		1				1
Exposures associated with pregnancy, delivery and lactation		3		3		
Fractures and dislocations NEC		2				2
Intentional product use issues	1	1	1	1		
Limb fractures and dislocations		3				3
Medication errors, product use errors and issues NEC		1		1		
Non-site specific injuries NEC	5	23	1	5	4	18
Off label uses	2	2	2	2		
Product administration errors and issues	2	19	2	19		
Product preparation errors and issues		11		11		
Site specific injuries NEC		2				2
Skin injuries NEC	1	2			1	2
Transfusion related complications	1	1	1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination related complications	2	2			2	2
	19	80	7	43	12	37

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	1	1	1	1		
Bacteria identification and serology (excl mycobacteria)	1	2		1	1	1
Blood gas and acid base analyses	3	19	1	2	2	17
Carbohydrate tolerance analyses (incl diabetes)	1	6	1	6		
Chemistry analyses NEC	1	1			1	1
Coagulation and bleeding analyses		2				2
Haematological analyses NEC	1	1	1	1		
Heart rate and pulse investigations	3	17		5	3	12
Metabolism tests NEC	1	2			1	2
Physical examination procedures and organ system status	4	20	1	9	3	11
Protein analyses NEC	10	30	3	8	7	22
Red blood cell analyses	1	3			1	3
Skeletal and cardiac muscle analyses		1				1
Thyroid analyses	1	1	1	1		
Vascular tests NEC (incl blood pressure)	5	18		4	5	14
White blood cell analyses	2	3	2	2		1
	35	127	11	40	24	87

System Organ Class

**Metabolism and nutrition disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	20	1	7	1	13
Diabetes mellitus (incl subtypes)	1	1			1	1
Electrolyte imbalance NEC	1	1			1	1
General nutritional disorders NEC		1				1
Hyperglycaemic conditions NEC	1	2	1	1		1
Potassium imbalance		1				1
Sodium imbalance	2	3			2	3
Total fluid volume decreased	1	3		1	1	2
	8	32	2	9	6	23

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		2		1		1
Bone related signs and symptoms	1	2	1	1		1
Joint related signs and symptoms	11	25	9	21	2	4
Muscle pains	10	44	6	33	4	11
Muscle related signs and symptoms NEC	1	6		2	1	4
Muscle tone abnormalities		1				1
Muscle weakness conditions	4	6	1	1	3	5
Musculoskeletal and connective tissue conditions NEC	1	9		6	1	3
Musculoskeletal and connective tissue pain and discomfort	9	39	6	27	3	12
Soft tissue disorders NEC		1				1
Spondyloarthropathies		1				1
Tendon disorders		1		1		
	37	137	23	93	14	44

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastases to specified sites		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	1			1	1
Alzheimer's disease (incl subtypes)		1				1
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	22	54			22	54
Central nervous system vascular disorders NEC		2		1		1
Chronic polyneuropathies	1	1			1	1
Coma states		1				1
Coordination and balance disturbances	4	11	1	3	3	8
Cortical dysfunction NEC	3	5			3	5
Dementia (excl Alzheimer's type)		2				2
Disturbances in consciousness NEC	17	86		13	17	73
Dyskinesias and movement disorders NEC		6		3		3
Eye movement disorders	1	1			1	1
Facial cranial nerve disorders	3	13	1	3	2	10
Generalised tonic-clonic seizures		1				1
Headaches NEC	24	91	12	67	12	24
Memory loss (excl dementia)	2	5	2	4		1
Mental impairment (excl dementia and memory loss)	1	6		3	1	3
Migraine headaches	1	4	1	2		2
Narcolepsy and hypersomnia		1		1		
Neurological signs and symptoms NEC	23	69	7	30	16	39

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neurologic visual problems NEC	1	1			1	1
Neuromuscular disorders NEC	2	2	1	1	1	1
Olfactory nerve disorders	2	2	2	2		
Paraesthesias and dysaesthesias	3	19	2	10	1	9
Paralysis and paresis (excl cranial nerve)	6	13	1	1	5	12
Peripheral neuropathies NEC		2				2
Seizures and seizure disorders NEC		7				7
Sensory abnormalities NEC	1	5	1	4		1
Speech and language abnormalities	3	12	2	4	1	8
Transient cerebrovascular events	3	5			3	5
Tremor (excl congenital)	2	8	1	3	1	5
	126	438	34	155	92	283

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	1	7	1	7
	1	7	1	7

System Organ Class

\* I=Interval, C=Cumulative  
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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abnormal behaviour NEC		1					1
Anxiety symptoms		4		1			3
Behaviour and socialisation disturbances	1	2	1	1			1
Communications disorders		1		1			
Confusion and disorientation	6	32	1	10	5		22
Deliria	2	5			2		5
Disturbances in initiating and maintaining sleep	1	2	1	2			
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1			
Hallucinations (excl sleep-related)	1	10			1		10
Increased physical activity levels	1	13		5	1		8
Mood alterations with depressive symptoms		1		1			
Mood alterations with manic symptoms		1					1
Mood disorders NEC		3		1			2
Panic attacks and disorders	1	1	1	1			
Parasomnias	1	2	1	2			
Perception disturbances NEC	1	1	1	1			
Sleep disorders NEC	1	2		1	1		1
	17	82	7	28	10		54

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bladder and urethral symptoms	1	5		1	1		4
Glomerulonephritis and nephrotic syndrome		2					2
Nephritis NEC		1					1
Renal disorders NEC		1					1
Renal failure and impairment	3	6			3		6
Renal lithiasis	1	1			1		1

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\* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	5	16		1	5	15

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast disorders NEC		1		1
Breast signs and symptoms		1		1
		2		2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	18	87	6	23	12	64
Bronchospasm and obstruction	3	12			3	12
Conditions associated with abnormal gas exchange	2	7			2	7
Coughing and associated symptoms	4	26	1	12	3	14
Laryngeal spasm, oedema and obstruction	1	2			1	2
Lower respiratory tract inflammatory and immunologic conditions	2	5			2	5
Lower respiratory tract signs and symptoms	2	10		3	2	7
Mediastinal disorders		1				1
Nasal congestion and inflammations		4		4		
Nasal disorders NEC		4		3		1
Parenchymal lung disorders NEC	1	6		2	1	4
Pharyngeal disorders (excl infections and neoplasms)	3	5		1	3	4

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural infections and inflammations		1				1
Pneumothorax and pleural effusions NEC		3				3
Pulmonary oedemas	1	2			1	2
Pulmonary thrombotic and embolic conditions	7	14			7	14
Respiratory failures (excl neonatal)	4	10			4	10
Respiratory tract disorders NEC		3				3
Upper respiratory tract signs and symptoms	5	31	2	21	3	10
	53	233	9	69	44	164

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		3				3
Apocrine and eccrine gland disorders	1	20	1	11		9
Dermal and epidermal conditions NEC	1	3	1	2		1
Dermatitis and eczema		2				2
Dermatitis ascribed to specific agent	1	1			1	1
Erythemas	2	11	1	7	1	4
Exfoliative conditions	1	1			1	1
Pruritus NEC	3	15		4	3	11
Purpura and related conditions	3	5	1	1	2	4
Rashes, eruptions and exanthems NEC	4	19		11	4	8
Skin haemorrhages	2	4	1	2	1	2
Skin injuries and mechanical dermatoses		1		1		
Skin vasomotor conditions		1		1		
Urticarias	2	9		1	2	8
	20	95	5	41	15	54

System Organ Class

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	3	10	1	2	2	8
	3	10	1	2	2	8

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		2				2
Aortic necrosis and vascular insufficiency		2		1		1
Arterial infections and inflammations	1	1			1	1
Circulatory collapse and shock	2	5			2	5
Haemorrhages NEC		6				6
Non-site specific embolism and thrombosis		1				1
Peripheral embolism and thrombosis	11	12	3	3	8	9
Peripheral vascular disorders NEC	2	7	1	4	1	3
Peripheral vasoconstriction, necrosis and vascular insufficiency		3		2		1
Site specific necrosis and vascular insufficiency NEC	1	1			1	1
Site specific vascular disorders NEC		11		3		8
Vascular hypertensive disorders NEC	1	6		4	1	2
Vascular hypotensive disorders	3	19	1	2	2	17
	21	76	5	19	16	57

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Country Where Event Occurred

**OMAN**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1
Gastritis (excl infective)		1		1
		2		2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Febrile disorders		1		1
Pain and discomfort NEC		1		1
Therapeutic and nontherapeutic responses		1		1
		4		4

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

System Organ Class

**Nervous system disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
		1		1

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues		1		1
		1		1

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Country Where Event Occurred

**PANAMA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence, bloating and distension		1		1		
Gastrointestinal signs and symptoms NEC	1	1	1	1		
Oral dryness and saliva altered	1	1	1	1		
Oral soft tissue signs and symptoms	1	1			1	1
	3	4	2	3	1	1

System Organ Class

**General disorders and administration site conditions**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	5	1	5		
Febrile disorders	1	1			1	1
Feelings and sensations NEC		1		1		
Gait disturbances	1	1			1	1
General signs and symptoms NEC	1	2	1	2		
Vaccination site reactions	3	5	2	4	1	1
	7	15	4	12	3	3

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	2	1	2		
Allergies to foods, food additives, drugs and other chemicals	2	2	2	2		
Anaphylactic and anaphylactoid responses		1				1
	3	5	3	4		1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Overdoses NEC		1		1
Product administration errors and issues		1		1
		2		2

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC		3				3
Headaches NEC	1	1	1	1		
Muscle tone abnormal		1		1		
Neuromuscular disorders NEC		2		1		1
Paraesthesias and dysaesthesias	1	1			1	1
Paralysis and paresis (excl cranial nerve)	1	1			1	1
	3	9	1	3	2	6

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation	1	1	1	1
Emotional and mood disturbances NEC		1		1
	1	2	1	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	1			1	1
Lower respiratory tract signs and symptoms	1	1			1	1
Upper respiratory tract signs and symptoms	1	1	1	1		
	3	3	1	1	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas		1		1		
Rashes, eruptions and exanthems NEC		8				8
		9		1		8

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Site specific vascular disorders NEC		1		1
		1		1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**PERU**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
Gastrointestinal signs and symptoms NEC	1	1	1	1
	2	2	2	2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	1	1	1		
Febrile disorders	7	7	7	7		
Pain and discomfort NEC	4	4	4	4		
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	1	2	1	2		
	14	15	13	14	1	1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2
Medication errors, product use errors and issues NEC	2	2	2	2
Off label uses	2	2	2	2
	6	6	6	6

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heart rate and pulse investigations	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	3	3	3	3
	4	4	4	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	4	5	4	5
	4	5	4	5

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coughing and associated symptoms	1	1	1	1		
Nasal disorders NEC	2	2	1	1	1	1
Upper respiratory tract signs and symptoms	1	1	1	1		
	4	4	3	3	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Apocrine and eccrine gland disorders	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**POLAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Bleeding tendencies	1	1			1	1
Coagulopathies		2		1		1
Lymphatic system disorders NEC	14	101	4	35	10	66
Thrombocytopenias	1	1			1	1
	16	106	4	36	12	70

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	3	1	1		2
Cardiac signs and symptoms NEC	1	8		2	1	6
Coronary artery disorders NEC		1				1
Heart failures NEC		2				2
Ischaemic coronary artery disorders	1	5			1	5
Myocardial disorders NEC		2				2
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	7	43	1	4	6	39
Supraventricular arrhythmias	3	6			3	6
Ventricular arrhythmias and cardiac arrest	5	12			5	12
	18	83	2	7	16	76

System Organ Class

**Ear and labyrinth disorders**

Spontaneous
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 \* AE=Adverse Event  
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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		2		1		1
Hearing losses		3				3
Hyperacusia		1		1		
Inner ear signs and symptoms	2	12	1	6	1	6
	2	18	1	8	1	10

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
Thyroid disorders NEC		2		2
		3		3

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders		1			1	
Conjunctival infections, irritations and inflammations		3		1	2	
Iris and uveal tract infections, irritations and inflammations		1		1		
Lacrimation disorders		7			7	
Lid, lash and lacrimal infections, irritations and inflammations		1			1	
Lid, lash and lacrimal structural disorders	1	1	1	1		
Ocular disorders NEC	1	13		3	1	10

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 \* AE=Adverse Event  
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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular infections, inflammations and associated manifestations		2				2
Ocular sensation disorders		5		2		3
Visual disorders NEC		1		1		
Visual impairment and blindness (excl colour blindness)	1	6	1	2		4
	3	41	2	11	1	30

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	2			1	2
Dental pain and sensation disorders		3		2		1
Diarrhoea (excl infective)	11	35	8	20	3	15
Dyspeptic signs and symptoms	1	1			1	1
Faecal abnormalities NEC	1	1			1	1
Flatulence, bloating and distension	2	3		1	2	2
Gastrointestinal and abdominal pains (excl oral and throat)	4	24	1	12	3	12
Gastrointestinal disorders NEC	1	2	1	1		1
Gastrointestinal signs and symptoms NEC	2	7		1	2	6
Gastrointestinal spastic and hypermotility disorders		1		1		
Gingival disorders, signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	11	98	5	53	6	45
Non-site specific gastrointestinal haemorrhages		4				4
Oral dryness and saliva altered	1	3	1	2		1
Oral soft tissue disorders NEC		1				1
Oral soft tissue signs and symptoms	1	11	1	3		8
Oral soft tissue swelling and oedema		3		1		2

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis and ulceration		1		1		
Tongue signs and symptoms		5		1		4
	37	206	18	100	19	106

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	39	251	21	163	18	88
Body temperature altered		1				1
Death and sudden death	6	21			6	21
Febrile disorders	37	232	19	118	18	114
Feelings and sensations NEC	17	143	9	92	8	51
Gait disturbances	1	5		3	1	2
General signs and symptoms NEC	9	34	5	20	4	14
Inflamations		4		3		1
Injection site reactions	1	9	1	9		
Oedema NEC	2	12	1	3	1	9
Pain and discomfort NEC	1	35	1	23		12
Therapeutic and nontherapeutic responses	20	58	2	4	18	54
Vaccination site reactions	19	259	14	181	5	78
	152	1,064	73	619	79	445

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		25		3		22

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergies to foods, food additives, drugs and other chemicals	1	7		3	1	4
Anaphylactic and anaphylactoid responses	1	25			1	25
	2	57		6	2	51

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Candida infections		1		1		
Coronavirus infections	32	89	1	11	31	78
Dental and oral soft tissue infections		2		2		
Ear infections	1	2			1	2
Herpes viral infections	1	6	1	6		
Infections NEC		5		3		2
Influenza viral infections		1		1		
Lower respiratory tract and lung infections	2	8			2	8
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Streptococcal infections	1	1			1	1
Upper respiratory tract infections	1	7	1	4		3
Urinary tract infections		1		1		
Viral infections NEC	3	4	1	2	2	2
	41	128	4	31	37	97

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Bone and joint injuries NEC		1				1	
Exposures associated with pregnancy, delivery and lactation	2	14	2	14			
Medication errors, product use errors and issues NEC	1	12	1	11		1	
Muscle, tendon and ligament injuries		1					1
Non-site specific injuries NEC	3	5			3		5
Off label uses	2	15	2	14			1
Peripheral nerve injuries		1					1
Product administration errors and issues	3	18	3	18			
Product confusion errors and issues		2		2			
Product preparation errors and issues		1		1			
Site specific injuries NEC	1	1			1		1
Skin injuries NEC	1	7	1	1			6
Vaccination related complications	7	15		2	7		13
	20	93	9	63	11		30

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Blood gas and acid base analyses	4	15	1	3	3		12
Carbohydrate tolerance analyses (incl diabetes)	1	2			1		2
Cell marker analyses		1					1
Coagulation and bleeding analyses	1	2	1	1			1
Heart rate and pulse investigations	4	13	2	6	2		7
Histopathology procedures NEC		1		1			
Immunology analyses NEC		10		10			
Liver function analyses		5					5
Musculoskeletal and soft tissue imaging procedures	1	1	1	1			

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	1	14		8	1	6
Pituitary analyses anterior		1				1
Protein analyses NEC	1	4	1	2		2
Skeletal and cardiac muscle analyses		3		1		2
Urinalysis NEC		3		3		
Vascular tests NEC (incl blood pressure)	12	53	4	10	8	43
Virus identification and serology	1	4	1	2		2
White blood cell analyses		6		5		1
	26	138	11	53	15	85

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	13		6	2	7
Diabetes mellitus (incl subtypes)	1	1			1	1
Electrolyte imbalance NEC		1		1		
Metabolic acidoses (excl diabetic acidoses)		1				1
	3	16		7	3	9

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		3		3		
Bone related signs and symptoms	2	22		13	2	9
Bursal disorders		1		1		

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intervertebral disc disorders NEC		1				1
Joint related signs and symptoms	7	89	4	54	3	35
Lupus erythematosus (incl subtypes)		1				1
Muscle pains	18	127	12	78	6	49
Muscle related signs and symptoms NEC		4		4		
Muscle weakness conditions		6		2		4
Musculoskeletal and connective tissue conditions NEC	1	6		5	1	1
Musculoskeletal and connective tissue pain and discomfort	14	108	11	82	3	26
Myopathies		1				1
Psoriatic arthropathies	1	1			1	1
Soft tissue disorders NEC		1		1		
Spine and neck deformities		1				1
Synovial disorders		1		1		
	43	373	27	244	16	129

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder neoplasms malignant		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		1				1

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System Organ Class

**Nervous system disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		4	11
	1		
			1
	3	1	1
	1	1	2
			1
	9	12	67
1	2		1
			2
		3	12
			1
9	92	5	50
			1
	1	1	1
1	3	1	1
1	6		2
	2		
	1		
			1
			3
			1
2	27	4	30
	2		
	4	2	21
2	11		4
			1
7	28	2	31
	1		8
		1	1
		3	32

Central nervous system haemorrhages and cerebrovascular accidents	4	11
Choreiform movements		1
Coma states		1
Coordination and balance disturbances	1	4
Cortical dysfunction NEC	1	3
Cranial nerve disorders NEC		1
Disturbances in consciousness NEC	12	76
Dyskinesias and movement disorders NEC	1	3
Encephalopathies NEC		2
Facial cranial nerve disorders	3	12
Generalised tonic-clonic seizures		1
Headaches NEC	14	142
Increased intracranial pressure disorders		1
Lumbar spinal cord and nerve root disorders	1	2
Memory loss (excl dementia)	2	4
Mental impairment (excl dementia and memory loss)	1	8
Migraine headaches		2
Mononeuropathies		1
Multiple sclerosis acute and progressive		1
Muscle tone abnormal		3
Nervous system disorders NEC		1
Neurological signs and symptoms NEC	6	57
Neurologic visual problems NEC		2
Neuromuscular disorders NEC	2	25
Olfactory nerve disorders	2	15
Optic nerve disorders NEC		1
Paraesthesias and dysaesthesias	9	59
Paralysis and paresis (excl cranial nerve)		9
Peripheral neuropathies NEC	1	1
Seizures and seizure disorders NEC	3	32

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory abnormalities NEC		24		13		11
Sleep disturbances NEC		1		1		
Speech and language abnormalities	3	11		3	3	8
Spinal cord and nerve root disorders NEC		3		2		1
Transient cerebrovascular events		1				1
Tremor (excl congenital)	1	7	1	4		3
Trigeminal disorders		4		2		2
	67	533	24	219	43	314

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
Product contamination and sterility issues		1		1
Product distribution and storage issues		1		1
		3		3

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	10		5	1	5
Cognitive and attention disorders and disturbances NEC		1		1		
Communications disorders		1		1		
Confusion and disorientation	2	9		3	2	6
Deliria	1	2			1	2

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in initiating and maintaining sleep		12		12		
Eating disorders NEC		1		1		
Emotional and mood disturbances NEC		1		1		
Hallucinations (excl sleep-related)	1	1			1	1
Increased physical activity levels		1				1
Mental disorders NEC		1		1		
Parasomnias		1		1		
Psychiatric symptoms NEC		1				1
Sleep disorders NEC	1	1			1	1
	6	43		26	6	17

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	3			1	3
Bladder disorders NEC		1		1		
Genitourinary tract infections and inflammations NEC		1				1
Renal failure and impairment	2	10		1	2	9
Renal obstructive disorders		1				1
Urinary abnormalities	2	4		1	2	3
Urinary tract signs and symptoms NEC		1		1		
	5	21		4	5	17

System Organ Class

**Reproductive system and breast disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1		1		
Breast signs and symptoms		2		1		1
Lactation disorders		2		1		1
Pelvis and broad ligament disorders NEC		1		1		
Prostate and seminal vesicles infections and inflammations		1				1
		7		4		3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	13	55	3	11	10	44
Bronchospasm and obstruction		10				10
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	7	19	3	8	4	11
Laryngeal spasm, oedema and obstruction		9				9
Lower respiratory tract signs and symptoms	2	2	1	1	1	1
Nasal congestion and inflammations		2		1		1
Nasal disorders NEC		2		2		
Parenchymal lung disorders NEC	2	2	2	2		
Pharyngeal disorders (excl infections and neoplasms)		5		2		3
Pneumothorax and pleural effusions NEC		1		1		
Pulmonary oedemas	1	4			1	4
Respiratory failures (excl neonatal)	2	5			2	5
Respiratory signs and symptoms NEC		3		1		2
Respiratory tract disorders NEC	3	6	2	3	1	3
Tracheal disorders (excl infections and neoplasms)		1				1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper respiratory tract signs and symptoms	1	25	1	18		7
	31	153	12	50	19	103

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	12			1	12
Apocrine and eccrine gland disorders	3	25	1	15	2	10
Bullous conditions		4				4
Dermal and epidermal conditions NEC	2	6		2	2	4
Dermatitis and eczema		1				1
Erythemas	2	12		3	2	9
Exfoliative conditions		1				1
Pruritus NEC	2	9		4	2	5
Purpura and related conditions		5		1		4
Rashes, eruptions and exanthems NEC	6	28	1	8	5	20
Skin and subcutaneous conditions NEC		1		1		
Skin haemorrhages		1				1
Skin hyperplasias and hypertrophies		1		1		
Skin vasomotor conditions		4				4
Urticarias	2	12	1	3	1	9
	18	122	3	38	15	84

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues		2		1		1
Educational issues		1				1
		3		1		2

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Blood pressure disorders NEC		2				2
Circulatory collapse and shock	2	3			2	3
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis	4	9			4	9
Non-site specific necrosis and vascular insufficiency NEC	1	2	1	1		1
Non-site specific vascular disorders NEC		2		1		1
Peripheral embolism and thrombosis	1	2	1	1		1
Peripheral vascular disorders NEC		11		5		6
Peripheral vasoconstriction, necrosis and vascular insufficiency		3		2		1
Phlebitis NEC	1	1	1	1		
Site specific vascular disorders NEC	1	10		1	1	9

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Varicose veins NEC	1	1			1	1
Vascular hypertensive disorders NEC	4	8	1	2	3	6
Vascular hypotensive disorders		5		1		4
	15	61	4	16	11	45

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**PORTUGAL**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1		1		
Coagulopathies		1				1
Leukocytoses NEC	2	3			2	3
Lymphatic system disorders NEC	67	255	19	46	48	209
Marrow depression and hypoplastic anaemias		2				2
Thrombocytopenias		1				1
	69	263	19	47	50	216

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		2				2
Cardiac disorders NEC		1				1
Cardiac signs and symptoms NEC	7	21	2	5	5	16
Heart failures NEC		1				1
Ischaemic coronary artery disorders	2	6			2	6
Noninfectious myocarditis		2				2
Noninfectious pericarditis		1				1
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	12	85	4	14	8	71
Supraventricular arrhythmias	2	4			2	4
Ventricular arrhythmias and cardiac arrest	2	5			2	5
	26	129	6	19	20	110

System Organ Class

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	5	1	1		4
Hearing disorders NEC		1				1
Hearing losses	2	10			2	10
Inner ear signs and symptoms	5	26	1	4	4	22
	8	42	2	5	6	37

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid disorders NEC	1	1	1	1
Thyroid hypofunction disorders		1		1
	1	2	1	2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration	1	1			1	1
Conjunctival and corneal bleeding and vascular disorders		1				1
Conjunctival infections, irritations and inflammations		1				1
Corneal structural change, deposit and degeneration		2				2
Eyelid movement disorders		1				1
Lacrimation disorders		2		1		1
Lid, lash and lacrimal infections, irritations and inflammations		4				4

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC		8		6		2
Ocular infections, inflammations and associated manifestations	1	8	1	4		4
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders		9		3		6
Retinal bleeding and vascular disorders (excl retinopathy)		1				1
Retinal, choroid and vitreous infections and inflammations		1				1
Scleral infections, irritations and inflammations		1				1
Structural change, deposit and degeneration of eye NEC		1				1
Visual disorders NEC	4	9	3	5	1	4
Visual impairment and blindness (excl colour blindness)	3	7		1	3	6
	9	58	4	20	5	38

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Colitis (excl infective)		2				2
Diarrhoea (excl infective)	28	90	8	17	20	73
Dyspeptic signs and symptoms	3	7	1	3	2	4
Faecal abnormalities NEC		2				2
Flatulence, bloating and distension		4		1		3
Gastrointestinal and abdominal pains (excl oral and throat)	12	46	4	9	8	37
Gastrointestinal atonic and hypomotility disorders NEC	1	1			1	1
Gastrointestinal disorders NEC		4				4

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal signs and symptoms NEC	3	20	2	4	1	16
Nausea and vomiting symptoms	95	335	33	63	62	272
Non-site specific gastrointestinal haemorrhages	1	1			1	1
Oesophageal disorders NEC		1				1
Oral dryness and saliva altered	2	11	2	5		6
Oral soft tissue disorders NEC	2	3	1	1	1	2
Oral soft tissue signs and symptoms	9	59	7	16	2	43
Oral soft tissue swelling and oedema	1	19	1	1		18
Stomatitis and ulceration	1	7	1	3		4
Tongue disorders	1	3		2	1	1
Tongue signs and symptoms	8	30	6	7	2	23
	167	646	66	132	101	514

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		2		1		1
Asthenic conditions	106	494	30	93	76	401
Body temperature altered	2	17		4	2	13
Death and sudden death	4	9			4	9
Febrile disorders	83	502	18	87	65	415
Feelings and sensations NEC	64	271	23	53	41	218
Gait disturbances	1	6		3	1	3
General signs and symptoms NEC	8	35	4	9	4	26
Inflammations	1	5			1	5
Injection site reactions	1	8	1	7		1
Interactions	1	2			1	2
Mass conditions NEC	1	1	1	1		
Mucosal findings abnormal		1				1

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema NEC	16	56	4	11	12	45
Pain and discomfort NEC	42	156	16	36	26	120
Therapeutic and nontherapeutic responses	15	72			15	72
Vaccination site reactions	274	828	130	314	144	514
	619	2,465	227	619	392	1846

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bile duct infections and inflammations	1	1	1	1
Cholestasis and jaundice	2	2	2	2
Hepatocellular damage and hepatitis NEC	2	2	2	2
	5	5	5	5

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		13		4		9
Allergies to foods, food additives, drugs and other chemicals		4				4
Anaphylactic and anaphylactoid responses	5	26			5	26
	5	43		4	5	39

System Organ Class

**Infections and infestations**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		3				3
Breast infections	1	2			1	2
Candida infections	1	2			1	2
Central nervous system and spinal infections		1				1
Coronavirus infections	37	182	6	34	31	148
Dental and oral soft tissue infections	1	1	1	1		
Escherichia infections	1	1			1	1
Herpes viral infections		5				5
Infections NEC	1	2		1	1	1
Influenza viral infections	2	6			2	6
Lower respiratory tract and lung infections	1	2			1	2
Neisseria infections		1				1
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Skin structures and soft tissue infections	1	1			1	1
Treponema infections	1	2			1	2
Upper respiratory tract infections		7		3		4
Urinary tract infections	1	7			1	7
Viral infections NEC	1	1			1	1
	50	227	7	39	43	188

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conditions caused by cold		1		1		
Exposures associated with pregnancy, delivery and lactation	5	22	4	21	1	1
Exposures to agents or circumstances NEC		1				1
Gastrointestinal and hepatobiliary procedural complications		1				1

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb fractures and dislocations	1	1			1	1
Medication errors, product use errors and issues NEC	2	12	2	12		
Non-site specific injuries NEC	1	5		3	1	2
Non-site specific procedural complications		1				1
Occupational exposures		1		1		
Off label uses	2	14	2	14		
Overdoses NEC	8	23	8	22		1
Product administration errors and issues	5	32	5	31		1
Site specific injuries NEC		1				1
Skin injuries NEC	1	2		1	1	1
Vaccination related complications	16	61		1	16	60
	41	178	21	107	20	71

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	5	13			5	13
Carbohydrate tolerance analyses (incl diabetes)		2		1		1
Central nervous system imaging procedures		1		1		
Coagulation and bleeding analyses	4	4	3	3	1	1
Digestive enzymes		2				2
Heart rate and pulse investigations		6		1		5
Liver function analyses		1				1
Physical examination procedures and organ system status		11		3		8
Pituitary analyses anterior		1				1
Platelet analyses	1	1	1	1		
Respiratory and pulmonary function diagnostic procedures		2				2

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract and thoracic imaging procedures		1		1		
Thyroid analyses		1		1		
Vascular tests NEC (incl blood pressure)	4	14		3	4	11
Virus identification and serology		11		1		10
White blood cell analyses	1	1	1	1		
	15	72	5	17	10	55

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	8	35	1	4	7	31
Fluid intake increased	1	5			1	5
Hyperglycaemic conditions NEC		5		1		4
Hypoglycaemic conditions NEC		3				3
Metabolic acidoses (excl diabetic acidoses)	1	1			1	1
Mixed acid-base disorders	1	1			1	1
Potassium imbalance		3				3
	11	53	1	5	10	48

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1				1
Bone disorders NEC		1				1
Bone related signs and symptoms	1	4		1	1	3

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	52	201	8	19	44	182
Muscle pains	137	710	38	140	99	570
Muscle related signs and symptoms NEC	2	10	1	3	1	7
Muscle tone abnormalities		2				2
Muscle weakness conditions	3	15	1	2	2	13
Musculoskeletal and connective tissue conditions NEC	8	17	3	5	5	12
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	30	104	12	24	18	80
Myopathies		1				1
Soft tissue disorders NEC		4		2		2
Spondyloarthropathies		1				1
Synovial disorders	2	9			2	9
Tendon disorders		1		1		
	235	1,082	63	197	172	885

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Autonomic nervous system disorders		2					2
Central nervous system haemorrhages and cerebrovascular accidents	12	16			12		16
Cerebrovascular venous and sinus thrombosis	1	2			1		2
Coordination and balance disturbances		10					10
Cortical dysfunction NEC	1	2			1		2
Disturbances in consciousness NEC	32	104	11	28	21		76
Dyskinesias and movement disorders NEC	4	10	2	2	2		8
Facial cranial nerve disorders	2	15		1	2		14
Generalised tonic-clonic seizures		3					3
Headaches NEC	131	616	50	137	81		479
Hydrocephalic conditions	1	1			1		1
Lumbar spinal cord and nerve root disorders		1					1
Memory loss (excl dementia)		1		1			
Mental impairment (excl dementia and memory loss)	1	1			1		1
Migraine headaches	2	9	1	3	1		6
Neurological signs and symptoms NEC	44	190	24	43	20		147
Neuromuscular disorders NEC	1	4	1	1			3
Olfactory nerve disorders		7		3			4
Paraesthesias and dysaesthesias	37	122	20	37	17		85
Paralysis and paresis (excl cranial nerve)	2	4			2		4
Peripheral neuropathies NEC	1	2			1		2
Seizures and seizure disorders NEC	3	11			3		11
Sensory abnormalities NEC	13	50	11	21	2		29
Sleep disturbances NEC		2					2
Speech and language abnormalities	2	8		2	2		6
Spinal cord and nerve root disorders NEC	1	1			1		1
Transient cerebrovascular events	1	1			1		1
Tremor (excl congenital)	3	46	2	9	1		37
Trigeminal disorders		1					1
	295	1,242	122	288	173		954

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	5	16	4	7	1	9
Cognitive and attention disorders and disturbances NEC	1	1			1	1
Confusion and disorientation	3	5	1	1	2	4
Disturbances in initiating and maintaining sleep	5	26	3	8	2	18
Emotional and mood disturbances NEC		1				1
Fear symptoms and phobic disorders (incl social phobia)		1				1
Hallucinations (excl sleep-related)		1				1
Increased physical activity levels	1	1	1	1		
Mood alterations with depressive symptoms		1				1
Mood disorders NEC	1	1			1	1
Sexual desire disorders		1		1		
Sleep disorders NEC	1	5			1	5
Thinking disturbances		2				2
	17	62	9	18	8	44

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	1			1	1
Bladder disorders NEC	1	1			1	1
Renal failure and impairment	5	5	1	1	4	4
Renal vascular and ischaemic conditions		1				1
Urinary abnormalities	1	3		2	1	1
Urinary tract signs and symptoms NEC		1				1
	8	12	1	3	7	9

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	2	2	1	1	1	1
Breast signs and symptoms	2	8		3	2	5
Lactation disorders		1		1		
Menstruation and uterine bleeding NEC	1	2	1	1		1
Menstruation with decreased bleeding	1	1	1	1		
Reproductive tract signs and symptoms NEC		1				1
Vulvovaginal disorders NEC	1	2			1	2
Vulvovaginal signs and symptoms	1	3	1	1		2
	8	20	4	8	4	12

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	24	63		7	24	56
Bronchospasm and obstruction	4	12		1	4	11

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coughing and associated symptoms	13	58	2	10	11	48
Laryngeal spasm, oedema and obstruction		13				13
Lower respiratory tract inflammatory and immunologic conditions	1	2			1	2
Lower respiratory tract signs and symptoms		2				2
Nasal congestion and inflammations	1	6		1	1	5
Nasal disorders NEC	4	10	3	6	1	4
Parenchymal lung disorders NEC	1	2		1	1	1
Pharyngeal disorders (excl infections and neoplasms)	7	19	2	4	5	15
Pulmonary oedemas	1	1			1	1
Pulmonary thrombotic and embolic conditions	4	4			4	4
Respiratory failures (excl neonatal)	1	1			1	1
Respiratory signs and symptoms NEC		1				1
Respiratory tract disorders NEC		2				2
Upper respiratory tract signs and symptoms	24	102	11	35	13	67
	85	298	18	65	67	233

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		1				1
Angioedemas	1	12			1	12
Apocrine and eccrine gland disorders	6	36	3	5	3	31
Dermal and epidermal conditions NEC	4	17		2	4	15
Dermatitis and eczema		3				3
Dermatitis ascribed to specific agent		1				1
Erythemas	2	33	1	9	1	24
Exfoliative conditions	3	4			3	4

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Panniculitides	1	1			1	1
Papulosquamous conditions		2				2
Pilar disorders NEC		4				4
Pruritus NEC	5	47	3	9	2	38
Purpura and related conditions	2	7			2	7
Rashes, eruptions and exanthems NEC	27	113	8	30	19	83
Skin vasculitides		1				1
Urticarias	2	21	1	5	1	16
	53	303	16	60	37	243

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	9		2	2	7
Pregnancy related circumstances		1				1
	2	10		2	2	8

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast therapeutic procedures NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		5				5
Arterial infections and inflammations		1				1
Blood pressure disorders NEC	1	1			1	1
Circulatory collapse and shock	1	2			1	2
Haemorrhages NEC	1	4		1	1	3
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	4	5			4	5
Non-site specific necrosis and vascular insufficiency NEC	1	1	1	1		
Non-site specific vascular disorders NEC		1				1
Peripheral embolism and thrombosis	5	6			5	6
Peripheral vascular disorders NEC	6	24	3	5	3	19
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	7			3	7
Phlebitis NEC		1				1
Site specific vascular disorders NEC		13		2		11
Vascular hypertensive disorders NEC	10	40	4	4	6	36
Vascular hypotensive disorders	3	26		1	3	25
Vasculitides NEC	1	2			1	2
	36	140	8	14	28	126

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**PUERTO RICO**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	7	1	7
	1	7	1	7

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		1		1		
Rate and rhythm disorders NEC		3		3		
Supraventricular arrhythmias		1				1
		5		4		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular sensation disorders		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

\* I=Interval, C=Cumulative  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		3		3
Dyspeptic signs and symptoms		1		1
Flatulence, bloating and distension		1		1
Gastrointestinal and abdominal pains (excl oral and throat)		2		2
Gastrointestinal signs and symptoms NEC		4		4
Gingival haemorrhages		1		1
Nausea and vomiting symptoms		6		6
Oral dryness and saliva altered		1		1
Oral soft tissue signs and symptoms		1		1
		20		20

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	17	1	17		
Death and sudden death	1	1			1	1
Febrile disorders	1	16	1	16		
Feelings and sensations NEC	1	9		8	1	1
Gait disturbances		1		1		
General signs and symptoms NEC		4		3		1
Inflammations		1		1		
Injection site reactions		4		4		
Mass conditions NEC		1		1		
Pain and discomfort NEC		11		11		
Vaccination site reactions	2	16	2	16		
	6	81	4	78	2	3

System Organ Class

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections		1		1		
Lower respiratory tract and lung infections		1				1
Urinary tract infections		1				1
		3		1		2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Off label uses	1	2	1	2		
Product administration errors and issues	1	14	1	14		
	2	17	2	17		

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1		1		
Haematological analyses NEC		1		1		
Heart rate and pulse investigations		2		1		1
Immunology analyses NEC		1		1		
Investigations NEC		1		1		
Vascular tests NEC (incl blood pressure)		1		1		
		7		6		1

System Organ Class

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
Total fluid volume decreased		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone disorders NEC		1		1
Bone related signs and symptoms		1		1
Joint related signs and symptoms		10		10
Muscle pains		10		10
Muscle related signs and symptoms NEC		3		3
Musculoskeletal and connective tissue conditions NEC		1		1
Musculoskeletal and connective tissue pain and discomfort	1	11	1	11
	1	37	1	37

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1			1	
Coordination and balance disturbances		1	1			
Disturbances in consciousness NEC		1	1			
Dyskinesias and movement disorders NEC		2	1		1	
Facial cranial nerve disorders	1	3			1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	1	22	1	22		
Migraine headaches		1				1
Neurological signs and symptoms NEC		4		4		
Paraesthesias and dysaesthesias	1	12	1	12		
Sensory abnormalities NEC		4		4		
Speech and language abnormalities		1		1		
	3	52	2	46	1	6

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms		1		1
Depressive disorders		1		1
Disturbances in initiating and maintaining sleep	1	1	1	1
	1	3	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		2		1		1
Coughing and associated symptoms		1		1		
Upper respiratory tract signs and symptoms		2		2		
		5		4		1

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	2			1	2
Erythemas		1		1		
Pruritus NEC	1	2	1	2		
Rashes, eruptions and exanthems NEC	2	4	2	4		
	4	9	3	7	1	2

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis	1	1			1	1
Peripheral embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC		2		2		
Vascular hypertensive disorders NEC	1	3		2	1	1
	3	8		5	3	3

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Country Where Event Occurred

**QATAR**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rate and rhythm disorders NEC	1	2	1	1		1
	1	2	1	1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ocular infections, inflammations and associated manifestations		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspeptic signs and symptoms		2		2		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms		1				1
		3		2		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	2		1	1	1
Febrile disorders	1	2	1	1		1
Feelings and sensations NEC		2		1		1
Gait disturbances	1	1	1	1		
Therapeutic and nontherapeutic responses	1	1			1	1
	4	8	2	4	2	4

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses		1		1
		1		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	2	3		1	2	2

\* I=Interval, C=Cumulative  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections		2		2		
Rhinoviral infections		1				1
	2	6	3	2	2	3

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Medication errors, product use errors and issues NEC	1	1	1	1		
Overdoses NEC		1		1		
Product preparation errors and issues		1		1		
Vaccination related complications	1	1			1	1
	3	5	2	4	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chemistry analyses NEC		1				1
Haematological analyses NEC		1				1
Heart rate and pulse investigations	1	2	1	2		
Platelet analyses		1				1
Protein analyses NEC		1				1
Vascular tests NEC (incl blood pressure)		1		1		
White blood cell analyses		2				2
	1	9	1	3		6

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
General nutritional disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle pains		1		1		
Musculoskeletal and connective tissue pain and discomfort	3	3			3	3
	3	4		1	3	3

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC		1				1
Facial cranial nerve disorders		1				1
Headaches NEC	1	2	1	2		
Mental impairment (excl dementia and memory loss)	1	1	1	1		
Neurological signs and symptoms NEC		3				3
Neuromuscular disorders NEC	1	1			1	1
Sensory abnormalities NEC		2		2		
	3	11	2	5	1	6

System Organ Class

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation	1	1	1	1
Disturbances in initiating and maintaining sleep	1	1	1	1
Emotional and mood disturbances NEC		1		1
Mood alterations with depressive symptoms	1	1	1	1
Sleep disorders NEC	1	1	1	1
	4	5	4	5

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities		1		1
Coughing and associated symptoms		1		1
		2		2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1			1	
Erythemas	1	2	1	1	1	
Rashes, eruptions and exanthems NEC		1			1	
	1	4	1	1	3	

System Organ Class

**Vascular disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1
Vascular hypertensive disorders NEC	1	1	1	1
Vascular hypotensive disorders	1	1	1	1
	2	3	2	3

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Country Where Event Occurred

**ROMANIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenias NEC		1				1
Lymphatic system disorders NEC	15	46	7	25	8	21
	15	47	7	25	8	22

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		1				1
Cardiac signs and symptoms NEC	7	12	1	1	6	11
Ischaemic coronary artery disorders	1	6			1	6
Noninfectious pericarditis		1				1
Rate and rhythm disorders NEC	8	35	1	9	7	26
Supraventricular arrhythmias	1	5			1	5
Ventricular arrhythmias and cardiac arrest		3		1		2
	17	63	2	11	15	52

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		4		3		1
Hearing losses	4	4			4	4
Inner ear disorders NEC		1		1		
Inner ear signs and symptoms	12	30	2	7	10	23

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	16	39	2	11	14	28

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis		1		1		
Thyroid disorders NEC		1				1
Thyroid hypofunction disorders		1				1
		3		1		2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract conditions	1	1			1	1
Eyelid movement disorders		2		1		1
Glaucomas (excl congenital)		1				1
Lid, lash and lacrimal infections, irritations and inflammations		3		1		2
Ocular bleeding and vascular disorders NEC	2	2			2	2
Ocular disorders NEC	4	5	2	2	2	3
Ocular infections, inflammations and associated manifestations		2		2		
Ocular sensation disorders	1	2			1	2
Visual disorders NEC	5	8	1	1	4	7
Visual impairment and blindness (excl colour blindness)	3	6	1	1	2	5
	16	32	4	8	12	24

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Dental disorders NEC	1	1			1	1
Diarrhoea (excl infective)	5	16	3	6	2	10
Dyspeptic signs and symptoms		1				1
Faecal abnormalities NEC		1				1
Flatulence, bloating and distension	1	1			1	1
Gastrointestinal and abdominal pains (excl oral and throat)	4	11	1	4	3	7
Gastrointestinal signs and symptoms NEC	2	5		1	2	4
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	28	94	11	39	17	55
Oral dryness and saliva altered	2	4			2	4
Oral soft tissue signs and symptoms	3	7	1	3	2	4
Oral soft tissue swelling and oedema	1	8		2	1	6
Stomatitis and ulceration	2	2			2	2
Tongue disorders		1		1		
Tongue signs and symptoms	1	3			1	3
	50	157	16	56	34	101

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	7	8	7	7		1
Adverse effect absent		2		2		
Asthenic conditions	61	162	36	107	25	55
Body temperature altered		1		1		
Death and sudden death	6	9			6	9
Febrile disorders	48	149	23	82	25	67
Feelings and sensations NEC	53	138	22	67	31	71

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\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbances	1	2			1	2
General signs and symptoms NEC	9	26	6	17	3	9
Inflamations		3		2		1
Injection site reactions		4		4		
Mucosal findings abnormal		1				1
Oedema NEC	2	9	1	2	1	7
Pain and discomfort NEC	15	46	4	26	11	20
Therapeutic and nontherapeutic responses	32	92		2	32	90
Vaccination site reactions	76	245	63	199	13	46
	310	897	162	518	148	379

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatocellular damage and hepatitis NEC		2		2
		2		2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	19	24	17	20	2	4
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses	7	16			7	16
Autoimmune disorders NEC	1	1			1	1
	27	42	17	21	10	21

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	121	190	4	11	117	179
Dental and oral soft tissue infections	1	1			1	1
Herpes viral infections		2		1		1
Influenza viral infections		1		1		
Lower respiratory tract and lung infections	1	2			1	2
Nematode infections	1	1			1	1
Upper respiratory tract infections		2		1		1
Viral infections NEC	2	2			2	2
	126	201	4	14	122	187

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	6	2	6		
Exposures to agents or circumstances NEC	1	1	1	1		
Medication errors, product use errors and issues NEC	3	26	3	26		
Off label uses	1	4	1	4		
Overdoses NEC		1		1		
Product administration errors and issues	3	13	3	10		3
Product preparation errors and issues	4	22	4	22		
Site specific injuries NEC		1				1
Skin injuries NEC		1		1		
Thermal burns		1				1
Underdoses NEC	2	3	2	3		
Vaccination related complications	7	15			7	15
	23	94	16	74	7	20

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteria identification and serology (excl mycobacteria)	1	1	1	1		
Blood gas and acid base analyses	3	6		1	3	5
Carbohydrate tolerance analyses (incl diabetes)	2	2			2	2
Cholesterol analyses	1	1	1	1		
Coagulation and bleeding analyses	1	1	1	1		
Digestive enzymes		1		1		
Gastrointestinal function diagnostic procedures		1		1		
Heart rate and pulse investigations	10	28	2	7	8	21
Investigations NEC	1	2	1	2		
Liver function analyses		1		1		
Metabolism tests NEC	2	2	2	2		
Parasite identification and serology	1	1	1	1		
Physical examination procedures and organ system status	2	10	1	7	1	3
Red blood cell analyses		1		1		
Urinalysis NEC	4	4	4	4		
Vascular tests NEC (incl blood pressure)	4	18	2	7	2	11
Virus identification and serology	3	26	3	20		6
	35	106	19	58	16	48

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	6	10	3	4	3	6
Calcium metabolism disorders		1				1
Diabetes mellitus (incl subtypes)	2	2			2	2
Hyperglycaemic conditions NEC		3		1		2
Metabolic acidoses (excl diabetic acidoses)		1				1

\* I=Interval, C=Cumulative  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Potassium imbalance		2				2
Total fluid volume decreased		1				1
	8	20	3	5	5	15

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC		1				1
Bone related signs and symptoms	5	13		5	5	8
Joint related disorders NEC		1				1
Joint related signs and symptoms	14	58	9	34	5	24
Muscle pains	47	137	25	74	22	63
Muscle related signs and symptoms NEC		2		1		1
Muscle tone abnormalities	1	1			1	1
Muscle weakness conditions	2	6	2	5		1
Musculoskeletal and connective tissue conditions NEC	3	6		3	3	3
Musculoskeletal and connective tissue pain and discomfort	21	61	6	42	15	19
Tendon disorders	1	1			1	1
	94	287	42	164	52	123

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neuromas	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	1			1	1
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	3	5			3	5
Central nervous system vascular disorders NEC		1				1
Coma states		2				2
Coordination and balance disturbances	3	6	1	2	2	4
Dementia (excl Alzheimer's type)	1	1			1	1
Disturbances in consciousness NEC	35	81	6	20	29	61
Dyskinesias and movement disorders NEC		2		1		1
Encephalopathies NEC		1				1
Facial cranial nerve disorders	5	15	2	2	3	13
Headaches NEC	65	172	33	98	32	74
Increased intracranial pressure disorders		1				1
Memory loss (excl dementia)		1				1
Mental impairment (excl dementia and memory loss)	1	4		1	1	3
Migraine headaches		3		1		2
Muscle tone abnormal		1				1
Nervous system disorders NEC		3		3		
Neurological signs and symptoms NEC	27	73	7	30	20	43
Neurologic visual problems NEC		1				1
Neuromuscular disorders NEC		2		1		1
Olfactory nerve disorders	3	7		3	3	4
Optic nerve disorders NEC	1	1			1	1
Paraesthesias and dysaesthesias	25	64	3	22	22	42
Paralysis and paresis (excl cranial nerve)	2	5			2	5
Parkinson's disease and parkinsonism	1	1			1	1
Peripheral neuropathies NEC	2	3			2	3
Seizures and seizure disorders NEC		3				3
Sensory abnormalities NEC	4	13	2	7	2	6
Speech and language abnormalities		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor (excl congenital)	3	8		2	3	6
Trigeminal disorders		1				1
	182	484	54	193	128	291

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
Product quality issues NEC		1		1
		2		2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		15		5		10
Confusion and disorientation	1	2		1	1	1
Disturbances in initiating and maintaining sleep	2	7		2	2	5

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Emotional and mood disturbances NEC		1		1		
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Mental disorders NEC	1	1			1	1
Panic attacks and disorders	1	3	1	3		
Sleep disorders NEC	1	1			1	1
	6	31	1	13	5	18

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	2	2	2	2
Nephropathies and tubular disorders NEC		1		1
Urinary tract signs and symptoms NEC	2	6	2	6
	4	9	4	9

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast infections and inflammations	2	2			2	2
Breast signs and symptoms	1	4		1	1	3
Lactation disorders		1		1		
Menstruation and uterine bleeding NEC	1	2			1	2
Menstruation with decreased bleeding	1	1	1	1		
Pelvis and broad ligament disorders NEC		1				1
Reproductive tract signs and symptoms NEC	1	1			1	1

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	6	12	1	3	5	9

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	12	29	1	3	11	26
Bronchospasm and obstruction	2	11	1	3	1	8
Conditions associated with abnormal gas exchange	1	2			1	2
Coughing and associated symptoms	2	13	1	6	1	7
Laryngeal spasm, oedema and obstruction		5		1		4
Lower respiratory tract signs and symptoms		1				1
Nasal congestion and inflammations	1	1			1	1
Nasal disorders NEC	1	5		2	1	3
Pleural infections and inflammations		1				1
Pulmonary oedemas		2				2
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC	2	5	1	2	1	3
Respiratory tract disorders NEC		3		2		1
Upper respiratory tract signs and symptoms	8	18	3	10	5	8
	29	97	7	29	22	68

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	6			1	6

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	7	26	1	10	6	16
Bullous conditions		1				1
Dermal and epidermal conditions NEC	4	7	1	3	3	4
Dermatitis and eczema	2	7	1	1	1	6
Dermatitis ascribed to specific agent		2				2
Erythemas		22		13		9
Panniculitides		2		1		1
Photosensitivity and photodermatosis conditions	1	1			1	1
Pruritus NEC	1	12	1	6		6
Purpura and related conditions	1	1			1	1
Rashes, eruptions and exanthems NEC	2	24	1	12	1	12
Skin hyperplasias and hypertrophies	1	1			1	1
Skin vasomotor conditions	1	1			1	1
Urticarias	3	17	1	7	2	10
	24	130	6	53	18	77

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	6	1	3	1	3
	2	6	1	3	1	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	2			1	2

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	3			1	3
Circulatory collapse and shock		1				1
Non-site specific embolism and thrombosis	1	1			1	1
Non-site specific necrosis and vascular insufficiency NEC		1				1
Non-site specific vascular disorders NEC		1				1
Peripheral embolism and thrombosis	2	3			2	3
Peripheral vascular disorders NEC		5		3		2
Peripheral vasoconstriction, necrosis and vascular insufficiency		4		1		3
Site specific vascular disorders NEC	2	4		1	2	3
Vascular hypertensive disorders NEC	23	49	4	8	19	41
Vascular hypotensive disorders	1	7		1	1	6
	31	81	4	14	27	67

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Country Where Event Occurred

**SAUDI ARABIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulation factor deficiencies		1				1
Lymphatic system disorders NEC		4		4		
		5		4		1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ventricular arrhythmias and cardiac arrest		1		1
		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		2		1		1
Nausea and vomiting symptoms		4		1		3
Stomatitis and ulceration		1		1		
		7		3		4

System Organ Class

**General disorders and administration site conditions**

Spontaneous
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	11	1	10		1
Febrile disorders	1	7	1	6		1
Feelings and sensations NEC	2	4	2	4		
Gait disturbances		3		1		2
Pain and discomfort NEC	2	7	2	6		1
Vaccination site reactions	1	9	1	9		
	7	41	7	36		5

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses		1		1
		1		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections	1	3	1	3
Female reproductive tract infections		1		1
Herpes viral infections		1		1
Upper respiratory tract infections		1		1
	1	6	1	6

System Organ Class

**Injury, poisoning and procedural complications**

Spontaneous
-------------

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\* AE=Adverse Event  
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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		2		2
Product preparation errors and issues		1		1
		3		3

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematological analyses NEC		1		1		
Heart rate and pulse investigations		1				1
Protein analyses NEC		1		1		
		3		2		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		1		1		
Joint related signs and symptoms		3		3		
Muscle pains	1	7	1	6		1
Musculoskeletal and connective tissue conditions NEC		6		5		1
Musculoskeletal and connective tissue pain and discomfort		4		2		2
	1	21	1	17		4

System Organ Class

\* I=Interval, C=Cumulative  
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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphomas unspecified NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system vascular disorders NEC		1				1
Coordination and balance disturbances		1				1
Disturbances in consciousness NEC		4		1		3
Dyskinesias and movement disorders NEC		1		1		
Headaches NEC	1	6	1	6		
Lumbar spinal cord and nerve root disorders		2		2		
Neurological signs and symptoms NEC		2		1		1
Seizures and seizure disorders NEC	1	2			1	2
Tremor (excl congenital)	1	1	1	1		
	3	20	2	12	1	8

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sleep disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Renal and urinary disorders**

Spontaneous
-------------

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\* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms		1		1
		1		1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation and uterine bleeding NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary thrombotic and embolic conditions	1	1			1	1
Upper respiratory tract signs and symptoms		2		2		
	1	3		2	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	5	1	4		1
Dermal and epidermal conditions NEC		1		1		
	1	6	1	5		1

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues		1		1
		1		1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC	1	1	1	1		
Peripheral vasoconstriction, necrosis and vascular insufficiency		2		2		
Vascular hypotensive disorders		1				1
	1	4	1	3		1

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 \* AE=Adverse Event  
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Country Where Event Occurred

**SERBIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC		4		2		2
		4		2		2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		1		1		
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC		2				2
	1	4		1	1	3

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses		2				2
Inner ear signs and symptoms		2		2		
		4		2		2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		2				2
Lacrimation disorders		1		1		
Lid, lash and lacrimal infections, irritations and inflammations		2		2		
Ocular disorders NEC	1	1	1	1		
Visual disorders NEC		2		1		1
	1	8	1	5		3

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Diarrhoea (excl infective)		2		2		
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1		
Nausea and vomiting symptoms	3	23	3	19		4
Non-site specific gastrointestinal haemorrhages		1				1
Oral dryness and saliva altered		1		1		
Oral soft tissue disorders NEC	1	1	1	1		
Oral soft tissue signs and symptoms		4		3		1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral soft tissue swelling and oedema		2		2		
Tongue signs and symptoms		2		1		1
	5	38	5	30		8

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		3		3		
Asthenic conditions	9	39	8	34	1	5
Febrile disorders	3	38	2	33	1	5
Feelings and sensations NEC	2	16	2	14		2
General signs and symptoms NEC	1	6	1	4		2
Mucosal findings abnormal		1				1
Oedema NEC	1	4	1	3		1
Pain and discomfort NEC		9		5		4
Therapeutic and nontherapeutic responses	1	3			1	3
Vaccination site reactions		27		26		1
	17	146	14	122	3	24

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		3		2		1
Anaphylactic and anaphylactoid responses		1				1
		4		2		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	4	11	4	8		3
Eye and eyelid infections		1		1		
Herpes viral infections		1		1		
Infections NEC		1				1
Lower respiratory tract and lung infections		1		1		
Upper respiratory tract infections		1		1		
	4	16	4	12		4

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		2		2		
Non-site specific injuries NEC		2		1		1
Off label uses	1	1	1	1		
Overdoses NEC	1	1			1	1
Product administration errors and issues	1	3	1	3		
Vaccination related complications		6		5		1
	3	15	2	12	1	3

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1				1
Chemistry analyses NEC		1		1		
Coagulation and bleeding analyses	1	1	1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematological analyses NEC		1				1
Heart rate and pulse investigations	1	1	1	1		
Ophthalmic function diagnostic procedures		1				1
Physical examination procedures and organ system status	3	14	3	13		1
Protein analyses NEC	1	2	1	1		1
Red blood cell analyses	1	1	1	1		
Tissue enzyme analyses NEC		1				1
Vascular tests NEC (incl blood pressure)		2		1		1
Virus identification and serology		4		2		2
White blood cell analyses		1		1		
	7	31	7	22		9

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		3		3		
Joint related signs and symptoms		14		12		2
Muscle infections and inflammations		1				1
Muscle pains	2	15	2	14		1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle weakness conditions		2		2		
Musculoskeletal and connective tissue conditions NEC		1		1		
Musculoskeletal and connective tissue pain and discomfort	4	15	3	13	1	2
	6	51	5	45	1	6

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances		1				1
Disturbances in consciousness NEC	3	8	1	2	2	6
Dyskinesias and movement disorders NEC		1		1		
Facial cranial nerve disorders		2				2
Headaches NEC	5	24	4	21	1	3
Neurological signs and symptoms NEC	2	6	2	5		1
Olfactory nerve disorders	1	2	1	2		
Paraesthesias and dysaesthesias	2	5	2	5		
Sensory abnormalities NEC	1	4	1	2		2
Tremor (excl congenital)	1	2	1	2		
	15	56	12	40	3	16

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues		1		1
		1		1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		3		2		1
Confusion and disorientation		1		1		
Disturbances in initiating and maintaining sleep	1	2	1	1		1
Fear symptoms and phobic disorders (incl social phobia)	1	2		1	1	1
Sleep disorders NEC		1		1		
	2	9	1	6	1	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		4				4
Bronchospasm and obstruction		3		1		2
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	1	3	1	1		2
Lower respiratory tract signs and symptoms		2		1		1
Nasal congestion and inflammations		2		1		1
Upper respiratory tract signs and symptoms	1	4	1	2		2
	2	20	2	6		14

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	4	1	3		1
Dermal and epidermal conditions NEC	1	3	1	1		2
Erythemas		8		7		1
Pruritus NEC	1	2	1	2		
Rashes, eruptions and exanthems NEC	1	5	1	2		3
Urticarias		4		4		
	4	26	4	19		7

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis	1	1			1	1
Non-site specific vascular disorders NEC	1	1	1	1		
Peripheral embolism and thrombosis	1	1			1	1
Phlebitis NEC		1				1
Site specific vascular disorders NEC		2		2		
Vascular hypertensive disorders NEC	1	8		2	1	6
	4	15	1	6	3	9

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Country Where Event Occurred

**SINGAPORE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilic disorders	1	1			1	1
Lymphatic system disorders NEC	1	1	1	1		
Marrow depression and hypoplastic anaemias	1	1			1	1
	3	3	1	1	2	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	8	10	1	1	7	9
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	6	6			6	6
Supraventricular arrhythmias	1	1			1	1
	16	18	1	1	15	17

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing disorders NEC		1		1		
Hearing losses	1	1			1	1
Inner ear signs and symptoms	1	1	1	1		
	2	3	1	2	1	1

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\* AE=Adverse Event  
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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hyperfunction disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders	1	1	1	1		
Lacrimation disorders	2	2			2	2
Lid, lash and lacrimal infections, irritations and inflammations	1	1			1	1
Ocular disorders NEC	7	9	1	2	6	7
Ocular infections, inflammations and associated manifestations	2	2	1	1	1	1
Ocular nerve and muscle disorders	3	3			3	3
Visual disorders NEC	3	3			3	3
Visual impairment and blindness (excl colour blindness)	1	1			1	1
	20	22	3	4	17	18

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	3	5		1	3	4
Gastrointestinal and abdominal pains (excl oral and throat)	5	6			5	6
Gastrointestinal atonic and hypomotility disorders NEC	1	1			1	1
Gastrointestinal signs and symptoms NEC	2	2			2	2

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 \* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms	18	20	7	7	11	13
Oral dryness and saliva altered	1	1	1	1		
Oral soft tissue disorders NEC	2	4			2	4
Oral soft tissue signs and symptoms	1	1			1	1
Oral soft tissue swelling and oedema	4	6	1	1	3	5
Tongue signs and symptoms	1	1			1	1
	38	47	9	10	29	37

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	8	9	5	5	3	4
Febrile disorders	9	10	3	4	6	6
Feelings and sensations NEC	11	13	1	3	10	10
Gait disturbances	1	1			1	1
General signs and symptoms NEC	6	6	3	3	3	3
Injection site reactions	1	2	1	2		
Oedema NEC	1	1	1	1		
Pain and discomfort NEC	16	17	3	3	13	14
Vaccination site reactions	8	13	2	7	6	6
	61	72	19	28	42	44

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatocellular damage and hepatitis NEC	1	1	1	1

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
	1	1	1	1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	3		1	2	2
Allergies to foods, food additives, drugs and other chemicals	1	1			1	1
Anaphylactic and anaphylactoid responses	15	22			15	22
	18	26		1	18	25

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1			1	1
Hepatitis viral infections		1		1		
Infections NEC	1	1			1	1
Viral infections NEC	1	1			1	1
	3	4		1	3	3

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Limb fractures and dislocations	1	1			1	1
Nerve injuries NEC	1	1			1	1
Non-site specific injuries NEC	2	2			2	2
Product administration errors and issues	1	3	1	3		
Skin injuries NEC	1	1			1	1
Vaccination related complications	1	1			1	1
	7	10	1	4	6	6

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses	2	2	2	2
Heart rate and pulse investigations	2	3	2	3
Immune response protein analyses NEC	1	1	1	1
Liver function analyses	5	5	5	5
Ophthalmic function diagnostic procedures	1	1	1	1
Physical examination procedures and organ system status	4	4	4	4
Red blood cell analyses	2	2	2	2
Skeletal and cardiac muscle analyses	1	1	1	1
Tissue enzyme analyses NEC	1	1	1	1
Vascular tests NEC (incl blood pressure)	7	7	7	7
	26	27	26	27

System Organ Class

**Metabolism and nutrition disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Appetite disorders	1	1	1	1
General nutritional disorders NEC	1	1	1	1
Total fluid volume decreased	1	1	1	1
	3	3	3	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1			1	1
Joint related signs and symptoms	2	2			2	2
Muscle pains	3	3	2	2	1	1
Muscle weakness conditions	2	2			2	2
Musculoskeletal and connective tissue conditions NEC	1	1			1	1
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	5	5	3	3	2	2
Rheumatoid arthropathies	1	1			1	1
Tendon disorders	1	1			1	1
	17	17	5	5	12	12

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Neoplasms benign site unspecified NEC		1		1
		1		1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Absence seizures	1	1			1	1
Coordination and balance disturbances	1	1			1	1
Disturbances in consciousness NEC	7	7			7	7
Dyskinesias and movement disorders NEC	4	4			4	4
Eye movement disorders	1	1			1	1
Facial cranial nerve disorders	3	3			3	3
Generalised tonic-clonic seizures	2	2			2	2
Headaches NEC	6	7	4	5	2	2
Migraine headaches	1	1			1	1
Neurological signs and symptoms NEC	24	26	5	6	19	20
Olfactory nerve disorders	2	2	2	2		
Optic nerve disorders NEC	1	1			1	1
Paraesthesias and dysaesthesias	6	6	1	1	5	5
Peripheral neuropathies NEC	1	1			1	1
Seizures and seizure disorders NEC	7	7			7	7
Sensory abnormalities NEC	1	2		1	1	1
Spinal cord and nerve root disorders NEC	1	1			1	1
	69	73	12	15	57	58

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusion and disorientation	2	2	2	2
Mental disorders NEC	1	1	1	1
Psychotic disorder NEC	1	1	1	1
Tic disorders	1	1	1	1
	5	5	5	5

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment	2	2	2	2
Urinary abnormalities	2	2	2	2
	4	4	4	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	22	24	2	2	20	22
Bronchospasm and obstruction	6	6	1	1	5	5
Coughing and associated symptoms	2	4			2	4
Laryngeal spasm, oedema and obstruction	1	1			1	1
Lower respiratory tract inflammatory and immunologic conditions	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)	3	3	1	1	2	2
Pulmonary thrombotic and embolic conditions	1	1			1	1
Upper respiratory tract signs and symptoms	23	26	5	5	18	21
	59	66	9	9	50	57

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		1		1		
Angioedemas	4	7			4	7
Apocrine and eccrine gland disorders	3	3	1	1	2	2
Bullous conditions	2	2			2	2
Dermal and epidermal conditions NEC		1		1		

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis and eczema	1	1	1	1		
Dermatitis ascribed to specific agent	1	1			1	1
Erythemas	2	2			2	2
Pruritus NEC	4	5			4	5
Pustular conditions	1	1			1	1
Rashes, eruptions and exanthems NEC	19	25	4	8	15	17
Urticarias	10	13	1	2	9	11
	47	62	7	14	40	48

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	3	3			3	3
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1		
Site specific vascular disorders NEC	1	1			1	1
Vascular hypertensive disorders NEC	4	5			4	5
Vascular hypotensive disorders	6	6			6	6
	16	17	1	1	15	16

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Country Where Event Occurred

**SLOVAKIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	7	15	7	15
	7	15	7	15

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	2	8	2	8		
Heart failures NEC		1				1
Ischaemic coronary artery disorders		2				2
Rate and rhythm disorders NEC	4	12	4	7		5
Supraventricular arrhythmias		3				3
	6	26	6	15		11

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	3	3			3	3
Inner ear signs and symptoms	9	19	8	18	1	1
	12	22	8	18	4	4

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	1	1	1	1		
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular disorders NEC	1	6	1	4		2
Ocular infections, inflammations and associated manifestations	3	7	3	7		
Ocular sensation disorders		2		2		
Pupil disorders		1		1		
Visual disorders NEC	3	4	3	4		
Visual impairment and blindness (excl colour blindness)	1	1			1	1
	9	23	8	20	1	3

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Diarrhoea (excl infective)	3	8	2	6	1	2
Flatulence, bloating and distension		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	2	4	2	3		1
Gastrointestinal signs and symptoms NEC	2	3	2	2		1
Nausea and vomiting symptoms	17	41	16	35	1	6
Oral dryness and saliva altered	1	3	1	2		1
Oral soft tissue disorders NEC	1	1	1	1		
Oral soft tissue signs and symptoms		4		3		1
Oral soft tissue swelling and oedema		1		1		
Tongue signs and symptoms	2	2	1	1	1	1
	29	69	25	55	4	14

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		1		1		
Asthenic conditions	40	101	38	94	2	7
Febrile disorders	24	62	24	59		3
Feelings and sensations NEC	32	91	32	85		6
Gait disturbances		1		1		
General signs and symptoms NEC	3	6	3	6		
Inflamations		1		1		
Oedema NEC	1	5	1	4		1
Pain and discomfort NEC	6	18	5	17	1	1
Therapeutic and nontherapeutic responses	5	7			5	7
Vaccination site reactions	43	105	43	103		2
	154	398	146	371	8	27

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		2		1		1
Anaphylactic and anaphylactoid responses		2				2
		4		1		3

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	6	14		3	6	11
Eye and eyelid infections		2		1		1
Skin structures and soft tissue infections		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Streptococcal infections		1				1
Upper respiratory tract infections		2		2		
Vascular infections	1	1			1	1
Viral infections NEC	1	1			1	1
	8	22		7	8	15

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation		2		2		
Medication errors, product use errors and issues NEC		1		1		
Non-site specific injuries NEC	1	2	1	1		1
Peripheral nerve injuries	1	1			1	1
Product administration errors and issues	1	4		3	1	1
Vaccination related complications	1	2			1	2
	4	13	1	7	3	6

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carbohydrate tolerance analyses (incl diabetes)	2	2	2	2		
Heart rate and pulse investigations	2	5	2	5		
Immunology analyses NEC		1		1		

\* I=Interval, C=Cumulative  
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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	21	34	19	30	2	4
Vascular tests NEC (incl blood pressure)	11	28	3	9	8	19
Virus identification and serology		3		1		2
	36	73	26	48	10	25

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	5	3	5		
Hyperglycaemic conditions NEC		1				1
Total fluid volume decreased	2	2	1	1	1	1
	5	8	4	6	1	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	2	2	2	2		
Joint related signs and symptoms	15	33	15	32		1
Muscle pains	16	46	16	46		
Muscle weakness conditions	1	2		1	1	1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	25	58	25	58		
Synovial disorders		1		1		
Tendon disorders	1	1	1	1		

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	61	144	60	142	1	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Cervical spinal cord and nerve root disorders	1	1			1	1
Coordination and balance disturbances	1	1	1	1		
Cortical dysfunction NEC	2	2	1	1	1	1
Disturbances in consciousness NEC	7	21	1	4	6	17
Dyskinesias and movement disorders NEC	2	3	2	3		
Facial cranial nerve disorders		1				1
Headaches NEC	24	69	24	68		1
Memory loss (excl dementia)	1	1			1	1
Migraine headaches		1		1		
Neurological signs and symptoms NEC	11	30	10	23	1	7
Paraesthesias and dysaesthesias	7	24	7	19		5
Seizures and seizure disorders NEC	1	2			1	2
Speech and language abnormalities	2	2	1	1	1	1
Tremor (excl congenital)		1				1
	60	160	47	121	13	39

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	1	1	1	1		
Disturbances in initiating and maintaining sleep	1	3	1	3		
Increased physical activity levels		2				2
Parasomnias		1		1		
	2	7	2	5		2

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	10	2	6	1	4
Bronchospasm and obstruction	1	1			1	1
Conditions associated with abnormal gas exchange	1	1			1	1
Coughing and associated symptoms	2	8	2	8		
Upper respiratory tract signs and symptoms	2	7	2	7		
	9	27	6	21	3	6

System Organ Class

**Skin and subcutaneous tissue disorders**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		2				2
Apocrine and eccrine gland disorders	2	10	2	7		3
Dermal and epidermal conditions NEC		1		1		
Dermatitis and eczema		1		1		
Erythemas	1	6	1	5		1
Pruritus NEC	1	4	1	3		1
Purpura and related conditions		1		1		
Rashes, eruptions and exanthems NEC	3	9	3	9		
Skin vasculitides		1		1		
Urticarias		1				1
	7	36	7	28		8

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Non-site specific embolism and thrombosis	1	2			1	2
Peripheral embolism and thrombosis	1	4			1	4
Peripheral vascular disorders NEC	4	9	3	6	1	3
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	4		3	1	1
Site specific vascular disorders NEC	1	3	1	2		1
Vascular hypertensive disorders NEC		4		3		1
	8	27	4	14	4	13

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**SLOVENIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC		6		6		
Neutropenias		1				1
Thrombocytopenias		2				2
		9		6		3

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart failures NEC	3	4			3	4
Ischaemic coronary artery disorders	1	5			1	5
Myocardial disorders NEC		1				1
Pericardial disorders NEC		1				1
Rate and rhythm disorders NEC	6	8		2	6	6
Supraventricular arrhythmias	1	5			1	5
Ventricular arrhythmias and cardiac arrest	1	3		1	1	2
	12	27		3	12	24

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		1				1
Inner ear signs and symptoms	4	11	2	5	2	6
	4	12	2	5	2	7

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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular disorders NEC		1		1		
Ocular infections, inflammations and associated manifestations		1		1		
Pupil disorders		1				1
Visual impairment and blindness (excl colour blindness)		1				1
		5		3		2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	2	7	1	6	1	1
Gastrointestinal and abdominal pains (excl oral and throat)	1	5	1	5		
Gastrointestinal signs and symptoms NEC		1		1		
Nausea and vomiting symptoms	1	12	1	7		5
Non-site specific gastrointestinal haemorrhages	1	1			1	1
Oral soft tissue signs and symptoms	1	3		1	1	2
Oral soft tissue swelling and oedema	1	2		1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue signs and symptoms		5		5		
	7	36	3	26	4	10

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	4	48	2	35	2	13
Death and sudden death	2	5			2	5
Febrile disorders		11		9		2
Feelings and sensations NEC	4	13	2	10	2	3
Gait disturbances	1	2			1	2
General signs and symptoms NEC		2				2
Oedema NEC	1	2			1	2
Pain and discomfort NEC	5	14	1	6	4	8
Therapeutic and nontherapeutic responses	1	2			1	2
Vaccination site reactions	9	71	6	65	3	6
	27	170	11	125	16	45

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Anaphylactic and anaphylactoid responses		1				1
		2		1		1

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		1				1
Coronavirus infections	1	6			1	6
Herpes viral infections		1				1
Infections NEC		1				1
Lower respiratory tract and lung infections	1	3			1	3
Upper respiratory tract infections		3		3		
	2	15		3	2	12

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Non-site specific injuries NEC	2	3	1	1	1	2
Off label uses	1	3	1	3		
Product administration errors and issues	1	3	1	3		
Site specific injuries NEC	1	1	1	1		
Vaccination related complications		2				2
	6	13	5	9	1	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		3				3
Physical examination procedures and organ system status	1	12		10	1	2
Protein analyses NEC		1		1		

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory and pulmonary function diagnostic procedures	1	1			1	1
Vascular tests NEC (incl blood pressure)		1		1		
White blood cell analyses		1		1		
	2	19		13	2	6

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diabetes mellitus (incl subtypes)	1	1	1	1
Potassium imbalance		1		1
	1	2	1	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		1		1		
Joint related signs and symptoms		6		6		
Muscle pains		12		10		2
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort		3		2		1
	1	23	1	20		3

System Organ Class

\* I=Interval, C=Cumulative  
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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
B-cell lymphomas NEC		1		1
Leukaemias acute lymphocytic		1		1
		2		2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		2				2
Central nervous system haemorrhages and cerebrovascular accidents	2	7			2	7
Coordination and balance disturbances		1				1
Cortical dysfunction NEC	1	2			1	2
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	4	24		5	4	19
Facial cranial nerve disorders		1				1
Headaches NEC	2	24	1	20	1	4
Migraine headaches		3		1		2
Neurological signs and symptoms NEC	3	12	1	5	2	7
Olfactory nerve disorders		2		2		
Paraesthesias and dysaesthesias		9		5		4
Paralysis and paresis (excl cranial nerve)	1	3			1	3
Seizures and seizure disorders NEC	1	4			1	4
Sensory abnormalities NEC		5		4		1
Speech and language abnormalities	1	3		1	1	2
Transient cerebrovascular events		1				1
	15	104	2	43	13	61

System Organ Class

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 \* AE=Adverse Event  
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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Behaviour and socialisation disturbances	1	1	1	1		
Confusion and disorientation	1	2	1	1		1
Disturbances in initiating and maintaining sleep		3		3		
Emotional and mood disturbances NEC	2	2			2	2
Increased physical activity levels		1		1		
Parasomnias		1		1		
Thinking disturbances		1		1		
	4	11	2	8	2	3

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Uterine tone disorders		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	8		1	2	7
Bronchial conditions NEC		1				1
Bronchospasm and obstruction		1				1
Coughing and associated symptoms		1				1
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Pneumothorax and pleural effusions NEC	1	1			1	1
Pulmonary oedemas	1	1			1	1

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary thrombotic and embolic conditions	1	3			1	3
Respiratory signs and symptoms NEC		1				1
Upper respiratory tract signs and symptoms		2		2		
	5	20		4	5	16

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		1				1
Apocrine and eccrine gland disorders		1				1
Dermal and epidermal conditions NEC		2		1		1
Erythemas		2		1		1
Papulosquamous conditions		1		1		
Rashes, eruptions and exanthems NEC	1	4	1	4		
Urticarias		1				1
	1	12	1	7		5

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues	1	2	1	2
	1	2	1	2

System Organ Class

**Vascular disorders**

Spontaneous

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock	2	3			2	3
Non-site specific vascular disorders NEC	1	1			1	1
Peripheral embolism and thrombosis	2	3			2	3
Peripheral vascular disorders NEC	1	1			1	1
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1		
Vascular hypertensive disorders NEC	1	5			1	5
Vascular hypotensive disorders		1				1
	7	15		1	7	14

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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Country Where Event Occurred

**SPAIN**

*System Organ Class*

**Blood and lymphatic system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic immune	2	2			2	2
Anaemias haemolytic mechanical factor	1	1			1	1
Anaemias NEC	2	3		1	2	2
Bleeding tendencies		2				2
Coagulopathies		2				2
Leukocytoses NEC	3	5	2	3	1	2
Leukopenias NEC		4		3		1
Lymphatic system disorders NEC	34	157	13	56	21	101
Marrow depression and hypoplastic anaemias	1	2			1	2
Neutropenias		1				1
Thrombocytopenias	11	15			11	15
	54	194	15	63	39	131

*System Organ Class*

**Cardiac disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic valvular disorders	1	1			1	1
Cardiac conduction disorders	2	3		1	2	2
Cardiac disorders NEC	1	2	1	1		1
Cardiac signs and symptoms NEC	6	25	2	5	4	20
Heart failures NEC	12	26			12	26
Ischaemic coronary artery disorders	7	14			7	14
Myocardial disorders NEC	7	7			7	7
Noninfectious myocarditis		3				3
Noninfectious pericarditis	3	10			3	10

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericardial disorders NEC	1	2			1	2
Rate and rhythm disorders NEC	18	91	6	16	12	75
Supraventricular arrhythmias	12	24		2	12	22
Tricuspid valvular disorders	1	1			1	1
Ventricular arrhythmias and cardiac arrest	5	18			5	18
	76	227	9	25	67	202

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC		2		2
Tongue disorders congenital	1	1	1	1
	1	3	1	3

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	9	1	2	1	7
Hearing losses		11				11
Hyperacusia		1				1
Inner ear disorders NEC	1	1			1	1
Inner ear signs and symptoms	6	36	1	10	5	26
	9	58	2	12	7	46

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	1			1	1
Adrenal gland disorders NEC		1		1		
Thyroid disorders NEC		1		1		
Thyroid hyperfunction disorders		1				1
Thyroid hypofunction disorders	1	2			1	2
	2	6		2	2	4

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		4				4
Colour blindness (incl acquired)	1	1			1	1
Conjunctival and corneal bleeding and vascular disorders	3	8			3	8
Conjunctival infections, irritations and inflammations	2	3			2	3
Corneal infections, oedemas and inflammations	2	2			2	2
Eyelid movement disorders	1	2		1	1	1
Iris and uveal tract infections, irritations and inflammations	1	1			1	1
Lacrimation disorders	1	7		2	1	5
Lid, lash and lacrimal infections, irritations and inflammations	2	8	1	3	1	5
Lid, lash and lacrimal structural disorders		1				1
Ocular bleeding and vascular disorders NEC	1	1			1	1
Ocular disorders NEC	2	12		4	2	8
Ocular infections, inflammations and associated manifestations	2	8		2	2	6
Ocular nerve and muscle disorders	1	2	1	1		1
Ocular sensation disorders	4	14	2	5	2	9

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Pupil disorders		1				1	
Refractive and accommodative disorders	1	1	1	1			
Retinal bleeding and vascular disorders (excl retinopathy)	3	4			3	4	
Retinal, choroid and vitreous infections and inflammations		1				1	
Scleral infections, irritations and inflammations		2				2	
Visual disorders NEC	7	26	3	7	4	19	
Visual impairment and blindness (excl colour blindness)	5	9			5	9	
	39	118	8	26	31	92	

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal findings abnormal	1	1	1	1			
Acute and chronic pancreatitis	1	1			1	1	
Anal and rectal disorders NEC		3				3	
Anal and rectal pains		1		1			
Anal and rectal signs and symptoms		2				2	
Colitis (excl infective)	2	4	1	1	1	3	
Dental and periodontal infections and inflammations		1		1			
Diaphragmatic hernias	2	3		1	2	2	
Diarrhoea (excl infective)	44	138	36	75	8	63	
Duodenal ulcers and perforation		1				1	
Dyspeptic signs and symptoms	2	4	1	1	1	3	
Faecal abnormalities NEC	1	4	1	3		1	
Flatulence, bloating and distension	3	7	3	6		1	
Gastritis (excl infective)	2	2	1	1	1	1	

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	14	46	12	26	2	20
Gastrointestinal atonic and hypomotility disorders NEC	5	10	3	6	2	4
Gastrointestinal disorders NEC	3	4	3	3		1
Gastrointestinal signs and symptoms NEC	8	27	3	11	5	16
Gastrointestinal stenosis and obstruction NEC	1	4			1	4
Gastrointestinal vascular occlusion and infarction		2				2
Gingival disorders, signs and symptoms NEC	1	3		1	1	2
Gingival haemorrhages	2	3	1	1	1	2
Intestinal haemorrhages	2	6			2	6
Nausea and vomiting symptoms	94	304	82	169	12	135
Non-mechanical ileus	1	2			1	2
Non-site specific gastrointestinal haemorrhages	4	8			4	8
Oral dryness and saliva altered	3	9		1	3	8
Oral soft tissue disorders NEC	1	8		1	1	7
Oral soft tissue infections		1		1		
Oral soft tissue signs and symptoms	9	64	7	20	2	44
Oral soft tissue swelling and oedema	7	41	2	5	5	36
Rectal inflammations NEC		1				1
Salivary gland enlargements	2	2	2	2		
Stomatitis and ulceration	1	13	1	8		5
Tongue disorders	1	7	1	2		5
Tongue signs and symptoms	3	32	1	6	2	26
	220	769	162	354	58	415

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	1	1	1	1		
Asthenic conditions	152	484	115	264	37	220
Body temperature altered	8	37	3	14	5	23
Death and sudden death	6	26			6	26
Febrile disorders	201	576	170	330	31	246
Feelings and sensations NEC	39	169	34	93	5	76
Gait disturbances	5	22		5	5	17
General signs and symptoms NEC	21	80	10	24	11	56
Inflamations	4	12	3	6	1	6
Injection site reactions		6		6		
Interactions		2		1		1
Mass conditions NEC		3		1		2
Mucosal findings abnormal		1				1
Necrosis NEC		1				1
Oedema NEC	9	42	2	8	7	34
Pain and discomfort NEC	32	137	20	57	12	80
Therapeutic and nontherapeutic responses	7	53			7	53
Vaccination site reactions	148	391	127	248	21	143
	633	2,043	485	1058	148	985

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations		2				2
Cholestasis and jaundice	2	2			2	2
Gal bladder disorders NEC		1				1
Hepatic and hepatobiliary disorders NEC	1	2	1	2		
Hepatic enzymes and function abnormalities		4		1		3
Hepatic failure and associated disorders	1	2			1	2

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic vascular disorders	1	1			1	1
Hepatobiliary signs and symptoms		1				1
Hepatocellular damage and hepatitis NEC	5	11			5	11
Structural and other bile duct disorders	1	1	1	1		
	11	27	2	4	9	23

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	5	32	2	4	3	28
Allergies to foods, food additives, drugs and other chemicals	1	14		1	1	13
Anaphylactic and anaphylactoid responses	5	55			5	55
Immune and associated conditions NEC		4		2		2
	11	105	2	7	9	98

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	6	10			3	4	3	6
Bacterial infections NEC	3	16					3	16
Bordetella infections		2						2
Candida infections	2	5			1	3	1	2
Central nervous system and spinal infections	1	6					1	6
Clostridia infections		1						1
Coronavirus infections	37	136			17	32	20	104

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dental and oral soft tissue infections	1	5				2	1	3
Ear infections		2						2
Enterococcal infections	1	1					1	1
Epstein-Barr viral infections		2						2
Escherichia infections	1	2					1	2
Eye and eyelid infections		1						1
Fungal infections NEC		1						1
Herpes viral infections	27	86	1	1	6	16	21	70
Infections NEC	4	10			1	1	3	9
Infectious disorders carrier		1						1
Influenza viral infections	1	6			1	2		4
Lower respiratory tract and lung infections	5	17					5	17
Pseudomonal infections	1	1					1	1
Retroviral infections	1	1					1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	5	7					5	7
Skin structures and soft tissue infections		2						2
Staphylococcal infections	2	3					2	3
Tuberculous infections		1						1
Upper respiratory tract infections	7	19			6	10	1	9
Urinary tract infections	4	15				3	4	12
Vascular infections		3						3
Viral infections NEC	2	4					2	4
	111	366	1	1	35	73	76	293

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC		2		1		1

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC	1	2			1	2
Cardiac and vascular procedural complications	1	1			1	1
Cerebral injuries NEC	2	6			2	6
Chest and respiratory tract injuries NEC		2				2
Exposures associated with pregnancy, delivery and lactation	3	15	3	11		4
Eye injuries NEC		2		1		1
Fractures and dislocations NEC		1				1
Limb fractures and dislocations	3	4		1	3	3
Medication errors, product use errors and issues NEC	1	11	1	11		
Muscle, tendon and ligament injuries		1		1		
Non-site specific injuries NEC	7	22	1	8	6	14
Off label uses	2	13	2	13		
Overdoses NEC	4	9	4	9		
Peripheral nerve injuries		1				1
Poisoning and toxicity		2				2
Product administration errors and issues	13	26	13	26		
Product preparation errors and issues	5	9	5	9		
Site specific injuries NEC	2	5		1	2	4
Skin injuries NEC	3	6		2	3	4
Skull fractures, facial bone fractures and dislocations	1	3			1	3
Spinal cord injuries NEC		1				1
Thoracic cage fractures and dislocations	1	1			1	1
Underdoses NEC		5		5		
Vaccination related complications	11	28		1	11	27
	60	178	29	100	31	78

System Organ Class

**Investigations**

Spontaneous
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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

Investigations

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
6	7	5	16
	1		2
		1	1
5	7	7	10
1	1		
		2	8
			1
	2		
	2	3	7
		2	2
	1		
	1	2	3
		1	1
	1		
2	7	1	1
			1
	3	2	3
	1		
	1	1	1
1	4		
3	6		1
2	2	1	1
		2	3
			1
	1		
1	1	1	1
	2		
	1		

Autoimmunity analyses		1
Bacteria identification and serology (excl mycobacteria)	1	1
Blood gas and acid base analyses	11	23
Carbohydrate tolerance analyses (incl diabetes)		3
Cardiac imaging procedures	1	1
Coagulation and bleeding analyses	12	17
Digestive enzymes	1	1
ECG investigations	2	8
Foetal and neonatal diagnostic procedures		1
Haematological analyses NEC		2
Heart rate and pulse investigations	3	9
Imaging procedures NEC	2	2
Immunology analyses NEC		1
Liver function analyses	2	4
Metabolism tests NEC	1	1
Microbiology and serology tests NEC		1
Mineral and electrolyte analyses	3	8
Ophthalmic function diagnostic procedures		1
Physical examination procedures and organ system status	2	6
Pituitary analyses anterior		1
Platelet analyses	1	2
Protein analyses NEC	1	4
Red blood cell analyses	3	7
Renal function analyses	3	3
Skeletal and cardiac muscle analyses	2	3
Therapeutic drug monitoring analyses		1
Thyroid analyses		1
Tissue enzyme analyses NEC	2	2
Urinalysis NEC		2
Urinary tract function analyses NEC		1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular auscultatory investigations		2				2
Vascular tests NEC (incl blood pressure)	6	24	3	14	3	10
Virus identification and serology	5	16	3	12	2	4
Vitamin analyses		2		2		
White blood cell analyses	4	11	4	10		1
	68	173	31	90	37	83

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	4	14	2	4	2	10
Calcium metabolism disorders	1	2		1	1	1
Cell metabolism disorders NEC	1	1			1	1
Diabetes mellitus (incl subtypes)	1	4			1	4
Diabetic complications NEC		3				3
Electrolyte imbalance NEC		1				1
Elevated cholesterol	1	1	1	1		
Fat soluble vitamin deficiencies and disorders		1		1		
General nutritional disorders NEC		2		1		1
Hyperglycaemic conditions NEC	4	10		2	4	8
Hypoglycaemic conditions NEC	1	6		1	1	5
Iron deficiencies		1		1		
Phosphorus metabolism disorders		1		1		
Potassium imbalance	1	2			1	2
Sodium imbalance	2	6		1	2	5
Total fluid volume decreased		3		2		1
Total fluid volume increased	1	1			1	1
Water soluble vitamin deficiencies		1		1		
	17	60	3	17	14	43

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	5			1	5
Bone disorders NEC		1		1		
Bone related signs and symptoms		3		1		2
Bursal disorders		2				2
Cartilage disorders		1				1
Joint related disorders NEC	2	6		2	2	4
Joint related signs and symptoms	47	133	38	78	9	55
Lupus erythematosus (incl subtypes)		1				1
Muscle infections and inflammations	1	4			1	4
Muscle pains	92	259	77	154	15	105
Muscle related signs and symptoms NEC	4	16	1	7	3	9
Muscle tone abnormalities	1	6			1	6
Muscle weakness conditions	1	15	1	7		8
Musculoskeletal and connective tissue conditions NEC	5	27	2	11	3	16
Musculoskeletal and connective tissue pain and discomfort	32	148	20	70	12	78
Osteoarthropathies	2	2	1	1	1	1
Psoriatic arthropathies		1				1
Soft tissue disorders NEC		2		1		1
Spine and neck deformities	1	1			1	1
Spondyloarthropathies	1	2			1	2
Tendon disorders	1	4	1	1		3
	191	639	141	334	50	305

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Kaposi's sarcomas		1				1

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Leukaemias acute NEC		1					1
Leukaemias chronic lymphocytic	1	1			1		1
Neoplasms unspecified malignancy and site unspecified NEC	1	2	1	2			
Soft tissue neoplasms benign NEC	1	1	1	1			
	3	6	2	3	1		3

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abnormal reflexes		3		2			1
Absence seizures		6					6
Acute polyneuropathies	4	6			4		6
Auditory nerve disorders		1					1
Central nervous system haemorrhages and cerebrovascular accidents	35	53			35		53
Central nervous system vascular disorders NEC	1	1			1		1
Cerebrovascular venous and sinus thrombosis	3	4			3		4
Cervical spinal cord and nerve root disorders	1	2	1	1			1
Coordination and balance disturbances	7	21	2	8	5		13
Cortical dysfunction NEC	3	9		1	3		8
Demyelinating disorders NEC	1	3			1		3
Disturbances in consciousness NEC	26	149	3	14	23		135
Disturbances in sleep phase rhythm	1	1			1		1
Dyskinesias and movement disorders NEC	2	14	1	4	1		10
Dystonias		2		1			1
Encephalopathies NEC	2	4			2		4
Facial cranial nerve disorders	14	53		1	14		52
Generalised tonic-clonic seizures	2	7			2		7

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 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	145	442	118	240	27	202
Increased intracranial pressure disorders		1				1
Memory loss (excl dementia)	1	10		4	1	6
Mental impairment (excl dementia and memory loss)	4	17		2	4	15
Migraine headaches	4	14	1	3	3	11
Mononeuropathies		1				1
Multiple sclerosis acute and progressive		1				1
Muscle tone abnormal		1		1		
Narcolepsy and hypersomnia		1				1
Nervous system disorders NEC	1	3			1	3
Neurological signs and symptoms NEC	55	207	36	88	19	119
Neurologic visual problems NEC		1				1
Neuromuscular disorders NEC	1	5	1	3		2
Olfactory nerve disorders	5	10	3	3	2	7
Optic nerve disorders NEC		1				1
Paraesthesias and dysaesthesias	35	173	11	42	24	131
Paralysis and paresis (excl cranial nerve)	6	17		1	6	16
Peripheral neuropathies NEC	7	10	1	1	6	9
Seizures and seizure disorders NEC	9	28			9	28
Sensory abnormalities NEC	10	40	5	15	5	25
Sleep disturbances NEC		1				1
Speech and language abnormalities	5	16	1	5	4	11
Spinal cord and nerve root disorders NEC	1	1			1	1
Structural brain disorders NEC	2	2	1	1	1	1
Transient cerebrovascular events	4	8			4	8
Tremor (excl congenital)	1	16	1	4		12
Trigeminal disorders	1	3	1	1		2
	399	1,369	187	446	212	923

System Organ Class

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	2	1	2
Abortions spontaneous		3		3
Neonatal disorders due to birth trauma (excl intracranial haemorrhages)	1	1	1	1
	2	6	2	6

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	9	21	2	11	7	10
Confusion and disorientation	9	28	2	9	7	19
Deliria	3	4			3	4
Delusional symptoms	1	1			1	1
Depressive disorders		1				1
Disturbances in initiating and maintaining sleep	4	10	3	6	1	4
Eating disorders NEC		1		1		
Emotional and mood disturbances NEC		4		1		3
Fear symptoms and phobic disorders (incl social phobia)		1				1
Hallucinations (excl sleep-related)	6	8			6	8
Increased physical activity levels	2	5		2	2	3
Mental disorders NEC		1				1
Mood alterations with depressive symptoms	1	3	1	3		
Mood disorders NEC	1	1			1	1
Panic attacks and disorders		1				1
Psychotic disorder NEC	2	2	1	1	1	1
Sexual desire disorders		1				1
Somatic symptom disorders	1	1	1	1		
Speech and language usage disturbances		1				1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stereotypies and automatisms		1		1		
Suicidal and self-injurious behaviour		1				1
Thinking disturbances	3	8	2	4	1	4
Tic disorders		3				3
	42	108	12	40	30	68

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	6	14	3	4	3	10
Myoneurogenic bladder disorders		2				2
Renal failure and impairment	9	18			9	18
Renal neoplasms	1	2	1	2		
Urinary abnormalities	2	4		2	2	2
Urinary tract signs and symptoms NEC	1	1			1	1
	19	41	4	8	15	33

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1		1		
Breast signs and symptoms	1	2			1	2
Lactation disorders		1				1
Menstruation and uterine bleeding NEC	1	9		1	1	8
Menstruation with decreased bleeding	1	3			1	3
Menstruation with increased bleeding	1	3	1	1		2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ovarian and fallopian tube cysts and neoplasms		1				1
Pelvis and broad ligament disorders NEC	1	1	1	1		
Penile disorders NEC (excl erection and ejaculation)		1		1		
Reproductive tract disorders NEC (excl neoplasms)		2		1		1
Reproductive tract signs and symptoms NEC		1		1		
Testicular and epididymal disorders NEC	1	1	1	1		
Uterine disorders NEC		2				2
Vulvovaginal disorders NEC		3		1		2
Vulvovaginal signs and symptoms		1		1		
	6	32	3	10	3	22

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	33	165	9	19	24	146
Bronchial conditions NEC		1				1
Bronchospasm and obstruction	7	36	3	4	4	32
Conditions associated with abnormal gas exchange	2	18			2	18
Coughing and associated symptoms	12	54	9	23	3	31
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		3				3
Laryngeal spasm, oedema and obstruction	2	17		1	2	16
Lower respiratory tract inflammatory and immunologic conditions	3	6			3	6
Lower respiratory tract signs and symptoms	3	6	1	1	2	5
Nasal congestion and inflammations	5	14	5	9		5
Nasal disorders NEC	4	7	3	3	1	4

\* I=Interval, C=Cumulative

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parenchymal lung disorders NEC	1	8	1	3		5
Pharyngeal disorders (excl infections and neoplasms)	5	18	2	2	3	16
Pneumothorax and pleural effusions NEC	2	6		1	2	5
Pulmonary hypertensions	1	1			1	1
Pulmonary oedemas	1	2			1	2
Pulmonary thrombotic and embolic conditions	33	45			33	45
Respiratory failures (excl neonatal)	9	25			9	25
Respiratory signs and symptoms NEC	1	3			1	3
Respiratory tract disorders NEC	2	7	1	1	1	6
Upper respiratory tract signs and symptoms	22	89	14	34	8	55
	148	531	48	101	100	430

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	2	2			2	2
Angioedemas	5	37		1	5	36
Apocrine and eccrine gland disorders	6	26	4	9	2	17
Bullous conditions	1	7	1	1		6
Dermal and epidermal conditions NEC	4	20	2	7	2	13
Dermatitis and eczema	4	11		1	4	10
Dermatitis ascribed to specific agent	2	3	1	1	1	2
Erythemas	12	59	10	25	2	34
Exfoliative conditions		2				2
Panniculitides		2				2
Papulosquamous conditions	1	5			1	5
Pigmentation changes NEC		1		1		
Pruritus NEC	21	85	13	26	8	59

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Psoriatic conditions		1				1
Purpura and related conditions	3	10	1	3	2	7
Pustular conditions		1				1
Rashes, eruptions and exanthems NEC	26	96	12	25	14	71
Skin and subcutaneous tissue ulcerations	2	4	2	3		1
Skin vasculitides	2	2			2	2
Skin vasomotor conditions		1				1
Urticarias	25	64	19	25	6	39
	116	439	65	128	51	311

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	4		1	2	3
	2	4		1	2	3

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Induced abortions		1		1
Limb therapeutic procedures		1		1
		2		2

System Organ Class

**Vascular disorders**

Spontaneous
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	6	31			6	31
Aortic aneurysms and dissections		1				1
Arterial infections and inflammations	1	1			1	1
Circulatory collapse and shock	1	4			1	4
Haemorrhages NEC	5	12	3	5	2	7
Non-site specific embolism and thrombosis	3	4			3	4
Non-site specific necrosis and vascular insufficiency NEC	2	2			2	2
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	26	34	2	2	24	32
Peripheral vascular disorders NEC	1	13	1	5		8
Peripheral vasoconstriction, necrosis and vascular insufficiency	5	15	5	5		10
Phlebitis NEC	2	4	1	2	1	2
Site specific vascular disorders NEC		7		2		5
Vascular hypertensive disorders NEC	14	55	5	13	9	42
Vascular hypotensive disorders	8	34	1	8	7	26
Vasculitides NEC	2	3			2	3
	76	221	18	43	58	178

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Country Where Event Occurred

**SWAZILAND**

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death and sudden death		1				1
Febrile disorders		1		1		
General signs and symptoms NEC		1		1		
		3		2		1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses		1		1
		1		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Upper respiratory tract infections		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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\* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities		1		1
		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		1				1
Dermal and epidermal conditions NEC		1		1		
Dermatitis and eczema		1		1		
		3		2		1

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Country Where Event Occurred

**SWEDEN**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	1	2			1	2
Anaemias NEC	1	1			1	1
Bleeding tendencies	1	1			1	1
Coagulopathies	1	1			1	1
Leukocytoses NEC		1				1
Leukopenias NEC	2	2			2	2
Lymphatic system disorders NEC	3	35	1	22	2	13
Marrow depression and hypoplastic anaemias	2	3			2	3
Spleen disorders	1	1			1	1
Thrombocytopenias	16	17			16	17
	28	64	1	22	27	42

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	5	1	1		4
Cardiac disorders NEC	2	6			2	6
Cardiac signs and symptoms NEC	7	35		7	7	28
Coronary artery disorders NEC	1	3			1	3
Heart failures NEC	6	21			6	21
Ischaemic coronary artery disorders	9	28			9	28
Left ventricular failures		1				1
Myocardial disorders NEC	1	4			1	4
Noninfectious myocarditis	3	4			3	4
Noninfectious pericarditis		1				1

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\* AE=Adverse Event

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System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericardial disorders NEC		4				4
Rate and rhythm disorders NEC	4	28		5	4	23
Right ventricular failures		1				1
Supraventricular arrhythmias	6	15			6	15
Ventricular arrhythmias and cardiac arrest	12	23			12	23
	52	179	1	13	51	166

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac septal defects congenital		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	7			2	7
Hearing losses		10				10
Hyperacusia		1				1
Inner ear signs and symptoms	4	22		3	4	19
	6	40		3	6	37

System Organ Class

**Endocrine disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal cortical hypofunctions		1				1
Hyperparathyroid disorders		1		1		
Thyroid disorders NEC	1	2			1	2
Thyroid hyperfunction disorders		1				1
	1	5		1	1	4

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1				1
Lacrimation disorders		1				1
Ocular bleeding and vascular disorders NEC	2	2			2	2
Ocular disorders NEC		25		4		21
Ocular infections, inflammations and associated manifestations		6				6
Ocular sensation disorders		9				9
Refractive and accommodative disorders		1				1
Retinal bleeding and vascular disorders (excl retinopathy)	3	3			3	3
Visual disorders NEC	2	9	1	2	1	7
Visual impairment and blindness (excl colour blindness)	5	15		1	5	14
	12	72	1	7	11	65

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal wall conditions NEC	1	1			1	1
Dental disorders NEC	1	1			1	1
Diarrhoea (excl infective)	7	49	3	27	4	22
Diverticula		1		1		
Dyspeptic signs and symptoms		1		1		
Flatulence, bloating and distension	1	4	1	2		2
Gastric and oesophageal haemorrhages	1	1			1	1
Gastritis (excl infective)		2		1		1
Gastrointestinal and abdominal pains (excl oral and throat)	6	33	3	14	3	19
Gastrointestinal atonic and hypomotility disorders NEC		3		3		
Gastrointestinal disorders NEC	1	2		1	1	1
Gastrointestinal signs and symptoms NEC	7	21	2	6	5	15
Gastrointestinal vascular occlusion and infarction	1	5			1	5
Intestinal haemorrhages	1	3			1	3
Nausea and vomiting symptoms	33	178	9	69	24	109
Non-site specific gastrointestinal haemorrhages	3	7			3	7
Oesophageal ulcers and perforation	1	1			1	1
Oral dryness and saliva altered	1	3			1	3
Oral soft tissue signs and symptoms	4	41	1	14	3	27
Oral soft tissue swelling and oedema		10		2		8
Peritoneal and retroperitoneal disorders		1				1
Peritoneal and retroperitoneal haemorrhages	1	1			1	1
Stomatitis and ulceration	2	3	2	2		1
Tongue signs and symptoms	3	20		3	3	17
	75	392	21	146	54	246

System Organ Class

**General disorders and administration site conditions**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	53	314	18	159	35	155
Body temperature altered		4		1		3
Death and sudden death	6	49			6	49
Febrile disorders	41	275	13	135	28	140
Feelings and sensations NEC	23	170	7	85	16	85
Gait disturbances	1	5		1	1	4
General signs and symptoms NEC	43	147	9	43	34	104
Implant and catheter site reactions		1		1		
Inflamations	1	4			1	4
Injection site reactions		1		1		
Mass conditions NEC		2		1		1
Oedema NEC	1	4	1	1		3
Pain and discomfort NEC	38	161	11	67	27	94
Therapeutic and nontherapeutic responses	1	10			1	10
Vaccination site reactions	26	265	21	196	5	69
	234	1,412	80	691	154	721

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bile duct infections and inflammations	1	1	1	1
Cholecystitis and cholelithiasis		1		1
Cholestasis and jaundice		1		1
Gal bladder disorders NEC		2		2
Hepatic and hepatobiliary disorders NEC		2		2
Hepatocellular damage and hepatitis NEC		1		1
Structural and other bile duct disorders	1	2	1	2
	2	10	2	10

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	38		4	3	34
Allergies to foods, food additives, drugs and other chemicals		3		1		2
Anaphylactic and anaphylactoid responses	8	30			8	30
Immune and associated conditions NEC		2				2
Transplant rejections		1				1
	11	74		5	11	69

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	2	3			2	3
Bacterial infections NEC		1				1
Central nervous system and spinal infections	1	5			1	5
Clostridia infections	1	1			1	1
Coronavirus infections	10	49	3	24	7	25
Escherichia infections		3				3
Herpes viral infections	7	21		5	7	16
Infections NEC	4	14		1	4	13
Lower respiratory tract and lung infections	3	16			3	16
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	12			2	12
Staphylococcal infections		1				1
Streptococcal infections	4	9			4	9
Upper respiratory tract infections	6	19	2	8	4	11
Urinary tract infections	3	10	1	5	2	5
Viral infections NEC		2		1		1
	43	166	6	44	37	122

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	4	4	1	1	3	3
Heat injuries (excl thermal burns)		1				1
Limb fractures and dislocations	1	3			1	3
Medication errors, product use errors and issues NEC		30		30		
Non-site specific injuries NEC	9	19	2	4	7	15
Non-site specific procedural complications		1				1
Off label uses	3	4	3	4		
Overdoses NEC		2		2		
Product administration errors and issues	6	51	6	51		
Product preparation errors and issues		4		4		
Product storage errors and issues in the product use system		1		1		
Respiratory tract and thoracic cavity procedural complications		1				1
Site specific injuries NEC	3	6	1	2	2	4
Skin injuries NEC	3	3			3	3
Thoracic cage fractures and dislocations	1	1			1	1
Underdoses NEC		5		5		
Vaccination related complications	5	7			5	7
	35	143	13	104	22	39

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	3	24		5	3	19
Carbohydrate tolerance analyses (incl diabetes)		4		1		3
Cardiac auscultatory investigations	1	1			1	1
Central nervous system imaging procedures		1				1
Coagulation and bleeding analyses	2	2			2	2

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\* AE=Adverse Event  
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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
ECG investigations	2	3			2	3
Haematological analyses NEC		1				1
Heart rate and pulse investigations	2	32		12	2	20
Liver function analyses	1	4			1	4
Mineral and electrolyte analyses	1	2		1	1	1
Physical examination procedures and organ system status	2	19	1	5	1	14
Platelet analyses	1	1			1	1
Protein analyses NEC	7	15	2	7	5	8
Red blood cell analyses		2				2
Renal function analyses	5	6	2	3	3	3
Skeletal and cardiac muscle analyses	1	1	1	1		
Tissue enzyme analyses NEC	1	2			1	2
Urinalysis NEC		1		1		
Urinary tract function analyses NEC		2				2
Vascular tests NEC (incl blood pressure)	4	26	1	7	3	19
White blood cell analyses	1	2	1	2		
	34	151	8	45	26	106

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	20	1	7	2	13
Calcium metabolism disorders		1				1
Disorders of purine metabolism		1				1
Fluid intake decreased		1				1
General nutritional disorders NEC	2	3	1	1	1	2
Hyperglycaemic conditions NEC		1				1
Hypoglycaemic conditions NEC		4				4

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metabolic acidoses (excl diabetic acidoses)	1	2			1	2
Metabolic disorders NEC	1	2	1	1		1
Potassium imbalance	1	2			1	2
Protein metabolism disorders NEC		1		1		
Sodium imbalance		1				1
Total fluid volume decreased	3	7	1	2	2	5
Total fluid volume increased	1	2			1	2
	12	48	4	12	8	36

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	2	7		2	2	5
Bone disorders NEC		2		1		1
Bone related signs and symptoms		4		2		2
Bursal disorders	1	1			1	1
Connective tissue disorders NEC		1				1
Joint related disorders NEC	1	2			1	2
Joint related signs and symptoms	7	59	1	29	6	30
Lupus erythematosus (incl subtypes)	1	1			1	1
Muscle pains	14	101	3	48	11	53
Muscle related signs and symptoms NEC	5	21	3	5	2	16
Muscle weakness conditions	8	27		4	8	23
Musculoskeletal and connective tissue conditions NEC	2	27		9	2	18
Musculoskeletal and connective tissue pain and discomfort	27	170	10	103	17	67
Tendon disorders		1				1
	68	424	17	203	51	221

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastases to unknown and unspecified sites	1	1	1	1
Neoplasms unspecified malignancy and site unspecified NEC		1		1
	1	2	1	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Abnormal sleep-related events	1	2	1	1		1
Absence seizures		2				2
Acute polyneuropathies		1				1
Alzheimer's disease (incl subtypes)		1				1
Autonomic nervous system disorders	1	2			1	2
Central nervous system haemorrhages and cerebrovascular accidents	30	53			30	53
Central nervous system vascular disorders NEC	1	2			1	2
Coordination and balance disturbances	8	19	1	1	7	18
Cortical dysfunction NEC	1	3			1	3
Cranial nerve disorders NEC		1				1
Dementia (excl Alzheimer's type)		2				2
Disturbances in consciousness NEC	21	77	2	5	19	72
Dyskinesias and movement disorders NEC		4				4
Dystonias	1	1			1	1
Encephalopathies NEC		1				1
Facial cranial nerve disorders	6	32			6	32
Generalised tonic-clonic seizures	1	1			1	1
Headaches NEC	29	229	11	131	18	98
Lumbar spinal cord and nerve root disorders		2		1		1

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Memory loss (excl dementia)	3	12		2	3	10
Mental impairment (excl dementia and memory loss)	3	9		2	3	7
Migraine headaches	3	12		5	3	7
Multiple sclerosis acute and progressive	1	3			1	3
Muscle tone abnormal		1				1
Narcolepsy and hypersomnia	1	3		1	1	2
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC	27	132	3	38	24	94
Neurologic visual problems NEC	1	4			1	4
Neuromuscular disorders NEC		1				1
Olfactory nerve disorders	1	10		3	1	7
Paraesthesias and dysaesthesias	14	126	5	35	9	91
Paralysis and paresis (excl cranial nerve)	4	12			4	12
Parkinson's disease and parkinsonism	1	2			1	2
Peripheral neuropathies NEC	1	5			1	5
Seizures and seizure disorders NEC	9	20			9	20
Sensory abnormalities NEC	2	26	1	9	1	17
Sleep disturbances NEC	1	2	1	1		1
Speech and language abnormalities	3	12	1	3	2	9
Structural brain disorders NEC		2				2
Transient cerebrovascular events	6	9			6	9
Tremor (excl congenital)	1	14	1	2		12
Trigeminal disorders	1	2			1	2
	183	856	27	240	156	616

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues		36		36
		36		36

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC		3		1		2
Anxiety symptoms	4	20	1	8	3	12
Behaviour and socialisation disturbances		1				1
Cognitive and attention disorders and disturbances NEC	1	8		1	1	7
Confusion and disorientation	3	19	1	1	2	18
Deliria	1	1			1	1
Delusional disorders		1				1
Depressive disorders	1	2		1	1	1
Dissociative states		1				1
Disturbances in initiating and maintaining sleep	1	10		4	1	6
Eating disorders NEC	1	1			1	1
Fear symptoms and phobic disorders (incl social phobia)	1	1			1	1
Hallucinations (excl sleep-related)	1	8			1	8

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Learning disorders		1				1
Mood alterations with depressive symptoms		5		1		4
Mood disorders NEC	1	3		1	1	2
Panic attacks and disorders		4				4
Parasomnias	2	6	2	2		4
Perception disturbances NEC		1				1
Psychiatric symptoms NEC	1	1			1	1
Psychotic disorder NEC	2	3			2	3
Sleep disorders NEC	2	6			2	6
Speech and language usage disturbances		1				1
	22	107	4	20	18	87

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		3		1		2
Renal disorders NEC	1	1			1	1
Renal failure and impairment	3	8			3	8
Renal lithiasis	1	1			1	1
Renal vascular and ischaemic conditions	1	2			1	2
Urinary abnormalities	1	1			1	1
Urinary tract signs and symptoms NEC		3		2		1
	7	19		3	7	16

System Organ Class

**Reproductive system and breast disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	1	1			1	1
Menstruation and uterine bleeding NEC		1				1
Menstruation with decreased bleeding		1		1		
Penile disorders NEC (excl erection and ejaculation)	1	1			1	1
Uterine infections and inflammations (excl cervix)		1		1		
Vulvovaginal disorders NEC		1				1
	2	6		2	2	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	28	148	2	23	26	125
Bronchial conditions NEC		1				1
Bronchospasm and obstruction	4	20	1	3	3	17
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	10	41	2	16	8	25
Laryngeal spasm, oedema and obstruction		1				1
Lower respiratory tract inflammatory and immunologic conditions	2	3			2	3
Lower respiratory tract signs and symptoms		4		1		3
Nasal congestion and inflammations	1	12	1	5		7
Nasal disorders NEC	4	7		3	4	4
Paranasal sinus disorders (excl infections and neoplasms)		2		2		
Parenchymal lung disorders NEC	1	3			1	3
Pharyngeal disorders (excl infections and neoplasms)	5	27		5	5	22
Pleural infections and inflammations		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumothorax and pleural effusions NEC	1	6		1	1	5
Pulmonary hypertensions	1	1			1	1
Pulmonary oedemas	1	9			1	9
Pulmonary thrombotic and embolic conditions	36	53			36	53
Respiratory failures (excl neonatal)	2	4			2	4
Respiratory signs and symptoms NEC	1	2	1	2		
Respiratory tract disorders NEC	3	4			3	4
Upper respiratory tract signs and symptoms	12	77	1	45	11	32
	112	427	8	106	104	321

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		1		1		
Angioedemas	1	6			1	6
Apocrine and eccrine gland disorders	3	27	1	10	2	17
Bullous conditions		6		1		5
Dermal and epidermal conditions NEC	4	15		7	4	8
Dermatitis and eczema		4		2		2
Dermatitis ascribed to specific agent		2		1		1
Erythemas	7	34	4	18	3	16
Nail and nail bed conditions (excl infections and infestations)		1				1
Photosensitivity and photodermatosis conditions	1	1			1	1
Pruritus NEC	7	33	2	11	5	22
Psoriatic conditions		1		1		
Purpura and related conditions	4	6	1	1	3	5
Rashes, eruptions and exanthems NEC	5	34	2	13	3	21
Skin and subcutaneous tissue ulcerations	1	4			1	4

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin haemorrhages	1	1			1	1
Skin injuries and mechanical dermatoses		1		1		
Skin vasomotor conditions		1		1		
Urticarias	6	39	1	14	5	25
	40	217	11	82	29	135

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	5		3	2	2
	2	5		3	2	2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Aortic necrosis and vascular insufficiency	1	2		1	1	1
Blood pressure disorders NEC		1				1
Circulatory collapse and shock	2	7			2	7
Haemorrhages NEC	6	11			6	11
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	10	18			10	18
Non-site specific necrosis and vascular insufficiency NEC		2				2
Non-site specific vascular disorders NEC	1	1	1	1		
Peripheral embolism and thrombosis	22	30	1	1	21	29

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 \* AE=Adverse Event  
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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC	1	10	1	3		7
Peripheral vasoconstriction, necrosis and vascular insufficiency		4		1		3
Phlebitis NEC	1	1			1	1
Site specific vascular disorders NEC	1	8	1	4		4
Vascular hypertensive disorders NEC	5	17	1	4	4	13
Vascular hypotensive disorders	7	24	1	4	6	20
Vasculitides NEC		1				1
	57	139	6	19	51	120

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Country Where Event Occurred

**SWITZERLAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Eosinophilic disorders		1		1		
Leukocytoses NEC		2		1		1
Leukopenias NEC		1				1
Lymphatic system disorders NEC	4	5		1	4	4
Sickle cell trait and disorders	1	1			1	1
Thrombocytopenias	1	3			1	3
	6	14		3	6	11

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	2	2			2	2
Cardiac signs and symptoms NEC	2	4			2	4
Cardiomyopathies	1	1			1	1
Coronary artery disorders NEC		1				1
Heart failures NEC	6	9			6	9
Ischaemic coronary artery disorders	2	4			2	4
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	10	20	1	2	9	18
Supraventricular arrhythmias	5	5			5	5
Ventricular arrhythmias and cardiac arrest	1	4			1	4
	30	51	1	2	29	49

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	2			1	2
Hearing losses		2				2
Inner ear disorders NEC	1	1			1	1
Inner ear signs and symptoms	2	6	1	1	1	5
	4	11	1	1	3	10

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal infections, irritations and inflammations	1	3			1	3
Ocular bleeding and vascular disorders NEC	1	1			1	1
Ocular disorders NEC	1	2	1	2		
Ocular sensation disorders	1	1			1	1
Visual disorders NEC	1	1			1	1
Visual impairment and blindness (excl colour blindness)	2	4			2	4
	7	12	1	2	6	10

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Diarrhoea (excl infective)	7	12	1	3	6	9
Gastritis (excl infective)	1	1			1	1
Gastrointestinal and abdominal pains (excl oral and throat)	3	7		1	3	6

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\* AE=Adverse Event  
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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal atonic and hypomotility disorders NEC	2	2			2	2
Gastrointestinal disorders NEC	2	4	2	2		2
Gastrointestinal signs and symptoms NEC	2	2	1	1	1	1
Intestinal haemorrhages		1		1		
Nausea and vomiting symptoms	18	43	3	9	15	34
Non-site specific gastrointestinal haemorrhages	1	1			1	1
Oesophageal ulcers and perforation		1				1
Oral dryness and saliva altered		1				1
Oral soft tissue disorders NEC		1		1		
Oral soft tissue signs and symptoms	4	6	2	2	2	4
Oral soft tissue swelling and oedema	1	2			1	2
Peritoneal and retroperitoneal disorders		1				1
Stomatitis and ulceration	1	1			1	1
Tongue signs and symptoms		2				2
	42	89	9	20	33	69

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	38	61	10	18	28	43
Body temperature altered		1		1		
Death and sudden death	3	10			3	10
Febrile disorders	24	49	7	12	17	37
Feelings and sensations NEC	12	29	2	8	10	21
Gait disturbances		4		1		3
General signs and symptoms NEC	12	21	5	7	7	14
Inflammations		3				3
Interactions		1		1		

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 \* AE=Adverse Event  
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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema NEC	1	3		1	1	2
Pain and discomfort NEC	13	19	2	4	11	15
Therapeutic and nontherapeutic responses	3	9		2	3	7
Trophic disorders		1				1
Vaccination site reactions	11	34	3	15	8	19
	117	245	29	70	88	175

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis	1	1	1	1
Cholestasis and jaundice	1	2	1	2
Hepatic and hepatobiliary disorders NEC	1	1	1	1
Hepatic fibrosis and cirrhosis		1		1
Hepatocellular damage and hepatitis NEC	1	2	1	2
	4	7	4	7

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	12	24	3	4	9	20
Anaphylactic and anaphylactoid responses	3	15			3	15
Immune and associated conditions NEC	1	1			1	1
	16	40	3	4	13	36

System Organ Class

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\* AE=Adverse Event  
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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2				2
Bacterial infections NEC		3				3
Central nervous system and spinal infections	1	2			1	2
Coronavirus infections	10	22	1	2	9	20
Dental and oral soft tissue infections	1	1			1	1
Herpes viral infections	18	23			18	23
Infections NEC		2		1		1
Influenza viral infections	1	1			1	1
Lower respiratory tract and lung infections	2	4			2	4
Sepsis, bacteraemia, viraemia and fungaemia NEC		3				3
Skin structures and soft tissue infections		2				2
Streptococcal infections	2	3			2	3
Upper respiratory tract infections	1	2		1	1	1
Urinary tract infections	2	3			2	3
Viral infections NEC	1	1	1	1		
	39	74	2	5	37	69

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	2	2			2	2
Exposures associated with pregnancy, delivery and lactation	1	1			1	1
Fractures and dislocations NEC	1	1			1	1
Medication errors, product use errors and issues NEC		1		1		
Muscle, tendon and ligament injuries	1	1			1	1
Non-site specific injuries NEC	5	7	1	1	4	6
Off label uses	1	1	1	1		

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administration errors and issues	5	9	5	8		1
Skin injuries NEC	1	2	1	2		
Skull fractures, facial bone fractures and dislocations	1	1			1	1
Underdoses NEC		2		2		
Vaccination related complications	4	4			4	4
	22	32	8	15	14	17

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1				1
Blood gas and acid base analyses	1	3			1	3
Carbohydrate tolerance analyses (incl diabetes)		1		1		
Cell marker analyses	2	2	2	2		
Cerebrospinal fluid tests (excl microbiology)		1				1
Heart rate and pulse investigations		2				2
Liver function analyses		1		1		
Neurologic diagnostic procedures	1	1			1	1
Physical examination procedures and organ system status	1	2	1	2		
Platelet analyses		1		1		
Protein analyses NEC	1	4	1	1		3
Respiratory and pulmonary function diagnostic procedures	1	1			1	1
Tissue enzyme analyses NEC		1		1		
Vascular tests NEC (incl blood pressure)	2	7		2	2	5
Virus identification and serology		1		1		
	9	29	4	12	5	17

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	3		1	1	2
Diabetic complications NEC		2				2
Disorders of purine metabolism		1				1
General nutritional disorders NEC	1	2	1	1		1
Hyperglycaemic conditions NEC		2				2
Total fluid volume decreased	1	2			1	2
Total fluid volume increased	1	1			1	1
	4	13	1	2	3	11

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC		1		1		
Bone related signs and symptoms	1	1	1	1		
Joint related signs and symptoms	7	13	3	3	4	10
Muscle pains	11	20	4	7	7	13
Muscle related signs and symptoms NEC		4				4
Muscle weakness conditions	1	2			1	2
Musculoskeletal and connective tissue conditions NEC	1	2	1	1		1
Musculoskeletal and connective tissue pain and discomfort	11	16	4	8	7	8
Rheumatoid arthropathies		2				2
Tendon disorders	1	1	1	1		
	33	62	14	22	19	40

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Spontaneous
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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nervous system neoplasms unspecified malignancy NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	10			2	10
Central nervous system vascular disorders NEC		2				2
Coma states		3				3
Cortical dysfunction NEC		4				4
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	9	18		1	9	17
Encephalopathies NEC		1				1
Facial cranial nerve disorders	4	6			4	6
Generalised tonic-clonic seizures		2				2
Headaches NEC	16	33	4	12	12	21
Memory loss (excl dementia)	1	2	1	2		
Mental impairment (excl dementia and memory loss)	2	4		1	2	3
Migraine headaches	1	1	1	1		
Nervous system disorders NEC		2				2
Neurological signs and symptoms NEC	13	31	1	5	12	26
Paraesthesias and dysaesthesias	4	9	1	2	3	7
Paralysis and paresis (excl cranial nerve)	1	2			1	2
Peripheral neuropathies NEC	2	3			2	3
Seizures and seizure disorders NEC	1	7			1	7
Sensory abnormalities NEC	5	9		3	5	6
Speech and language abnormalities	1	3			1	3

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal cord and nerve root disorders NEC	1	1			1	1
Structural brain disorders NEC		1		1		
Transient cerebrovascular events		2				2
Tremor (excl congenital)		3				3
Trigeminal disorders	1	1			1	1
	64	161	8	28	56	133

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	3			2	3
Behaviour and socialisation disturbances		1				1
Confusion and disorientation	1	5			1	5
Deliria	2	4			2	4
Dissociative states		1				1
Disturbances in initiating and maintaining sleep	1	3	1	3		
Hallucinations (excl sleep-related)	1	1			1	1
Mood alterations with depressive symptoms	1	1	1	1		
Perception disturbances NEC		1		1		
Psychiatric elimination disorders	1	1			1	1
Sleep disorders NEC		1		1		
Stress disorders		2				2
	9	24	2	6	7	18

System Organ Class

**Renal and urinary disorders**

Interval Total #	Cumulative Total #	Spontaneous
		Serious

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1
Genital and urinary tract disorders NEC		1		1
Glomerulonephritis and nephrotic syndrome		1		1
Renal failure and impairment	3	6	3	6
	3	9	3	9

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast signs and symptoms	2	2	2	2
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	14	29	2	4	12	25
Bronchospasm and obstruction		6				6
Coughing and associated symptoms	3	7		2	3	5
Nasal disorders NEC		1		1		
Parenchymal lung disorders NEC	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)	2	2			2	2
Pneumothorax and pleural effusions NEC	1	2		1	1	1
Pulmonary oedemas	2	3			2	3
Pulmonary thrombotic and embolic conditions	5	5			5	5
Respiratory failures (excl neonatal)	1	4			1	4

\* I=Interval, C=Cumulative  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	2	6		2	2	4
	32	67	2	10	30	57

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	1			1	1
Angioedemas	4	9			4	9
Apocrine and eccrine gland disorders	2	5			2	5
Bullous conditions		1		1		
Dermal and epidermal conditions NEC	2	3			2	3
Dermatitis and eczema		1		1		
Dermatitis ascribed to specific agent	1	1			1	1
Erythemas	3	8	1	2	2	6
Papulosquamous conditions	1	1			1	1
Pilar disorders NEC		1		1		
Pruritus NEC	4	15		4	4	11
Purpura and related conditions	1	1			1	1
Rashes, eruptions and exanthems NEC	8	18	4	7	4	11
Urticarias	2	6		1	2	5
	29	71	5	17	24	54

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	1	1	1	1
	1	1	1	1

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast therapeutic procedures NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		3				3
Circulatory collapse and shock	3	3			3	3
Lymphangiopathies	1	1			1	1
Non-site specific embolism and thrombosis		1				1
Non-site specific necrosis and vascular insufficiency NEC		1				1
Peripheral embolism and thrombosis	2	3			2	3
Peripheral vascular disorders NEC		3				3
Peripheral vasoconstriction, necrosis and vascular insufficiency		2				2
Site specific vascular disorders NEC	1	2			1	2
Vascular hypertensive disorders NEC	8	18		2	8	16
Vascular hypotensive disorders	5	7		1	5	6
	20	44		3	20	41

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Country Where Event Occurred

**TUNISIA**

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	4	4	4	4
Febrile disorders	1	1	1	1
Feelings and sensations NEC	1	1	1	1
General signs and symptoms NEC	1	1	1	1
Injection site reactions	1	1	1	1
Vaccination site reactions	2	2	2	2
	10	10	10	10

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Muscle pains	2	2	2	2
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
	4	4	4	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	1	1	1	1
Neurological signs and symptoms NEC	2	2	2	2
Paraesthesias and dysaesthesias	1	1	1	1
Sensory abnormalities NEC	1	1	1	1
	5	5	5	5

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coughing and associated symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular hypertensive disorders NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**TURKEY**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dental pain and sensation disorders	2	2	2	2
Nausea and vomiting symptoms	2	2	2	2
	4	4	4	4

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	5	5	5	5		
Febrile disorders	3	3	3	3		
Feelings and sensations NEC	1	1	1	1		
General signs and symptoms NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	4	4	4	4		
	15	15	14	14	1	1

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	1	1	1	1
	1	1	1	1

System Organ Class

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system and spinal infections	1	1			1	1
Coronavirus infections	4	4	3	3	1	1
Herpes viral infections	1	1	1	1		
	6	6	4	4	2	2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Off label uses	1	1	1	1
Overdoses NEC	1	1	1	1
Product administration errors and issues	3	3	3	3
Product preparation errors and issues	2	2	2	2
	8	8	8	8

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	2	2	2	2
	3	3	3	3

System Organ Class

\* I=Interval, C=Cumulative  
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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast and nipple neoplasms malignant	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	5	5	5	5
Neurological signs and symptoms NEC	2	2	2	2
	7	7	7	7

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities	1	1	1	1
Coughing and associated symptoms	1	1	1	1
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1
Upper respiratory tract signs and symptoms	1	1	1	1
	4	4	4	4

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dermal and epidermal conditions NEC	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythemas	2	2	2	2
Pruritus NEC	1	1	1	1
Urticarias	1	1	1	1
	5	5	5	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**TURKS AND CAICOS ISLANDS**

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Mass conditions NEC		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains		1		1
		1		1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1	1	1
Generalised tonic-clonic seizures		1		1
Seizures and seizure disorders NEC		1		1
	1	3	1	3

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Country Where Event Occurred  
**UKRAINE**

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Paraesthesias and dysaesthesias	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED ARAB EMIRATES**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	2	3	2	3		
Red blood cell abnormal findings NEC		1				1
	2	4	2	3		1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hearing losses		1		1
		1		1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular bleeding and vascular disorders NEC	1	1			1	1
Visual disorders NEC		2		2		
Visual impairment and blindness (excl colour blindness)	1	1			1	1
	2	4		2	2	2

System Organ Class

**Gastrointestinal disorders**

Spontaneous			

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	4	1	4		
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	1	8	1	7		1
	2	13	2	11		2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	4	8	4	8		
Death and sudden death		2				2
Febrile disorders	4	11	4	11		
Feelings and sensations NEC	2	5	2	5		
Gait disturbances		1		1		
General signs and symptoms NEC		1				1
Injection site reactions		2		2		
Pain and discomfort NEC	2	6	1	4	1	2
Therapeutic and nontherapeutic responses	1	7			1	7
Vaccination site reactions	3	7	3	7		
	16	50	14	38	2	12

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Babesia infections		1				1
Borrelial infections		1				1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	4	11	2	2	2	9
Herpes viral infections	1	1			1	1
Lower respiratory tract and lung infections	1	1			1	1
Upper respiratory tract infections		1		1		
	6	16	2	3	4	13

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Medication errors, product use errors and issues NEC		1		1		
Off label uses		1		1		
Product administration errors and issues	1	1	1	1		
Site specific injuries NEC	1	1			1	1
Vaccination related complications	1	1			1	1
	3	6	1	4	2	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)		1				1
Virus identification and serology		3		3		
		4		3		1

System Organ Class

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone related signs and symptoms	1	1	1	1
Joint related signs and symptoms		2		2
Muscle pains	2	3	2	3
Muscle related signs and symptoms NEC		1		1
Musculoskeletal and connective tissue pain and discomfort	2	4	2	4
	5	11	5	11

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	3		1	1	2
Facial cranial nerve disorders	1	2			1	2
Headaches NEC	3	7	3	6		1
Lumbar spinal cord and nerve root disorders		2		2		
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC		4		3		1
Paraesthesias and dysaesthesias		2		1		1
Sensory abnormalities NEC	2	3	2	3		
Sleep disturbances NEC		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor (excl congenital)	1	1	1	1		
	8	26	6	18	2	8

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Mood alterations with depressive symptoms		1		1
		1		1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erection and ejaculation conditions and disorders		1		1
		1		1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		3		2		1
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms		1		1		
Respiratory tract disorders NEC		1		1		

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
		6	4		2	

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1	1	1		
Dermatitis and eczema		1		1		
Pruritus NEC		1		1		
Rashes, eruptions and exanthems NEC	1	3	1	2		1
Urticarias		1				1
	2	7	2	5		2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific embolism and thrombosis	2	2			2	2
Vascular hypertensive disorders NEC		2		1		1
	2	4		1	2	3

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**UNITED KINGDOM**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia deficiencies	3	6			3	3		3
Anaemias haemolytic immune	3	4					3	4
Anaemias haemolytic NEC		1						1
Anaemias NEC	10	24				2	10	22
Bleeding tendencies	3	10				4	3	6
Coagulation factor deficiencies		1						1
Coagulopathies	7	13				1	7	12
Eosinophilic disorders		1				1		
Haematological disorders		5						5
Haemolyses NEC	1	3					1	3
Leukocytoses NEC	2	5				1	2	4
Leukopenias NEC	3	6				2	3	4
Lymphatic system disorders NEC	1,147	2,856	1	5	364	951	783	1905
Marrow depression and hypoplastic anaemias	1	4					1	4
Neutropenias	9	25					9	25
Platelet disorders NEC	1	2					1	2
Red blood cell abnormal findings NEC	1	4					1	4
Spleen disorders	1	4					1	4
Thrombocytopenias	63	106					63	106
Thrombocytoses		2				1		1
White blood cell abnormal findings NEC	2	2					2	2
	1,257	3,084	1	5	367	966	890	2118

System Organ Class

**Cardiac disorders**

Interval Total #	Cumulative Total #	Non Interventional Study		Spontaneous	
		Serious		Nonserious	
		I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiac conduction disorders	6	9				1	6	8
Cardiac disorders NEC	3	16			1	2	2	14
Cardiac hypertensive complications		3						3
Cardiac signs and symptoms NEC	190	699		1	58	182	132	517
Cardiac valve disorders NEC		1						1
Cardiomyopathies	2	4					2	4
Coronary artery disorders NEC	3	10					3	10
Heart failures NEC	10	30					10	30
Ischaemic coronary artery disorders	61	163					61	163
Left ventricular failures		2						2
Mitral valvular disorders	1	2					1	2
Myocardial disorders NEC	3	11				2	3	9
Noninfectious myocarditis	4	15					4	15
Noninfectious pericarditis	3	15					3	15
Pericardial disorders NEC	3	8					3	8
Rate and rhythm disorders NEC	102	496	1	1	28	110	74	386
Right ventricular failures		2						2
Supraventricular arrhythmias	43	173	1	1	3	17	40	156
Ventricular arrhythmias and cardiac arrest	12	88				1	12	87
	446	1,747	2	3	90	315	356	1432

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac disorders congenital NEC		2		2
Cardiac septal defects congenital		1		1
Coagulation disorders congenital		1		1
Congenital disorders NEC	1	1	1	1
Connective tissue disorders congenital		1		1

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 \* AE=Adverse Event  
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System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Gastrointestinal tract disorders congenital NEC	1	1	1	1
Haematological disorders congenital NEC		1		1
Musculoskeletal disorders congenital NEC	1	2	1	2
Neurological disorders congenital NEC		2		2
Peripheral nervous system disorders congenital NEC	1	1	1	1
Pulmonary and bronchial disorders congenital		1		1
Retinal disorders congenital		1		1
	4	15	4	15

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	113	374			33	110	80	264
Eustachian tube disorders		3						3
External ear disorders NEC	3	10			1	3	2	7
External ear infections and inflammations		1						1
Hearing disorders NEC	2	6				1	2	5
Hearing losses	73	155			9	17	64	138
Hyperacusia	11	30			3	9	8	21
Inner ear disorders NEC	7	16				2	7	14
Inner ear infections and inflammations		1						1
Inner ear signs and symptoms	322	788		1	65	148	257	640
Middle ear disorders NEC		1						1
Middle ear infections and inflammations		1						1
Tympanic membrane disorders (excl infections)	1	1					1	1
	532	1,387		1	111	290	421	1097

System Organ Class

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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis		1		1		
Adrenal cortical hypofunctions	3	9			3	9
Endocrine abnormalities of puberty	1	1	1	1		
Female gonadal function disorders		1				1
Thyroid disorders NEC	4	7	1	2	3	5
Thyroid hyperfunction disorders	6	9			6	9
Thyroid hypofunction disorders	6	10			6	10
	20	38	2	4	18	34

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amblyopic vision impairment	1	2				1	1	1
Cataract conditions	1	1					1	1
Choroid and vitreous haemorrhages and vascular disorders	2	5					2	5
Choroid and vitreous structural change, deposit and degeneration	10	27				6	10	21
Colour blindness (incl acquired)	1	1			1	1		
Conjunctival and corneal bleeding and vascular disorders	6	17					6	17
Conjunctival infections, irritations and inflammations	2	4					2	4
Corneal disorders NEC		1						1
Corneal infections, oedemas and inflammations		8				3		5
Corneal structural change, deposit and degeneration		1						1
Eyelid movement disorders	12	36			5	13	7	23
Glaucomas (excl congenital)	2	5					2	5
Iris and ciliary body structural change, deposit and degeneration		1						1

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Iris and uveal tract infections, irritations and inflammations	2	20
Lacrimation disorders	19	112
Lid bleeding and vascular disorders	1	1
Lid, lash and lacrimal infections, irritations and inflammations	27	81
Lid, lash and lacrimal structural disorders	1	3
Ocular bleeding and vascular disorders NEC	5	13
Ocular disorders NEC	184	667
Ocular infections, inflammations and associated manifestations	76	245
Ocular nerve and muscle disorders	7	19
Ocular sensation disorders	66	256
Optic disc abnormalities NEC		2
Optic nerve bleeding and vascular disorders	1	1
Orbital infections, inflammations and irritations	1	1
Orbital structural change, deposit and degeneration	1	1
Pupil disorders	5	13
Retinal bleeding and vascular disorders (excl retinopathy)	8	15
Retinal, choroid and vitreous infections and inflammations	2	3
Retinal structural change, deposit and degeneration	6	10
Retinopathies NEC	3	3
Scleral infections, irritations and inflammations	2	6
Scleral structural change, deposit and degeneration		4
Structural change, deposit and degeneration of eye NEC		1
Visual colour distortions	1	4
Visual disorders NEC	141	437
Visual impairment and blindness (excl colour blindness)	83	208

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	19
		6	33	13	79
				1	1
		9	28	18	53
		1	1		2
				5	13
	2	68	185	116	482
	2	38	81	38	164
		1	2	6	17
		22	69	44	187
					2
				1	1
				1	1
				1	1
		2	2	3	11
				8	15
				2	3
				6	10
				3	3
			1	2	5
			2		2
					1
		1	2		2
		41	120	100	317
		19	46	64	162

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Visual pathway disorders		2							2
	679	2,237		4	214	597	465	1640	

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	5	14			2	3	3	11
Abdominal hernias NEC	1	1					1	1
Acute and chronic pancreatitis	3	10					3	10
Anal and rectal disorders NEC		2						2
Anal and rectal pains	2	6			1	3	1	3
Anal and rectal signs and symptoms	2	7			1	4	1	3
Benign oral cavity neoplasms	2	4				2	2	2
Colitis (excl infective)	24	52	1	1	1	1	23	51
Dental and periodontal infections and inflammations	1	1					1	1
Dental disorders NEC	1	5			1	4		1
Dental pain and sensation disorders	19	49			6	14	13	35
Diarrhoea (excl infective)	443	1,722	2	7	182	477	261	1245
Diverticula	1	2				1	1	1
Duodenal and small intestinal stenosis and obstruction	1	2					1	2
Duodenal ulcers and perforation	1	2					1	2
Dyspeptic signs and symptoms	35	125			11	34	24	91
Faecal abnormalities NEC	11	40			2	15	9	25
Flatulence, bloating and distension	59	179			22	57	37	122
Gastric and oesophageal haemorrhages		6						6
Gastric ulcers and perforation	1	2					1	2
Gastritis (excl infective)	6	20				4	6	16

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System Organ Class

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gastrointestinal and abdominal pains (excl oral and throat)	332	1,188
Gastrointestinal atonic and hypomotility disorders NEC	39	127
Gastrointestinal disorders NEC	14	34
Gastrointestinal dyskinetic disorders	3	9
Gastrointestinal inflammatory disorders NEC	2	5
Gastrointestinal mucosal dystrophies and secretion disorders		6
Gastrointestinal signs and symptoms NEC	109	388
Gastrointestinal spastic and hypermotility disorders	10	60
Gastrointestinal stenosis and obstruction NEC	3	6
Gastrointestinal vascular malformations	1	2
Gastrointestinal vascular occlusion and infarction	5	7
Gingival disorders, signs and symptoms NEC	17	63
Gingival haemorrhages	6	11
Haemorrhoids and gastrointestinal varices (excl oesophageal)	2	10
Intestinal haemorrhages	12	40
Intestinal ulcers and perforation NEC	1	2
Malabsorption syndromes	2	7
Nausea and vomiting symptoms	1,700	6,525
Non-mechanical ileus	1	1
Non-site specific gastrointestinal haemorrhages	10	52
Oesophageal stenosis and obstruction		1
Oesophagitis (excl infective)	1	1
Oral dryness and saliva altered	51	230
Oral soft tissue disorders NEC	17	55
Oral soft tissue haemorrhages	7	14
Oral soft tissue infections	1	1
Oral soft tissue signs and symptoms	212	859
Oral soft tissue swelling and oedema	78	323

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	3	110	325	222	863
		12	22	27	105
		2	11	12	23
		2	5	1	4
			1	2	4
			1		5
1	4	43	118	66	270
		3	9	7	51
				3	6
				1	2
				5	7
		5	15	12	48
		3	4	3	7
				2	10
				12	40
				1	2
		1	1	1	6
1	26	736	2102	964	4423
				1	1
				10	52
					1
		1	1		
	1	25	85	26	145
		7	21	10	34
		3	6	4	8
				1	1
	1	134	399	78	460
	1	38	100	40	223

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Pancreatic disorders NEC		1							1
Peptic ulcers and perforation	1	2					1		2
Peritoneal and retroperitoneal disorders		3							3
Peritoneal and retroperitoneal fibrosis and adhesions	1	2					1		2
Peritoneal and retroperitoneal haemorrhages	1	2					1		2
Rectal inflammations NEC	1	2			1	1			1
Salivary gland disorders NEC	2	6					2		6
Salivary gland enlargements	4	9			1	3	3		6
Salivary gland infections and inflammations	1	1					1		1
Salivary gland stenosis and obstruction		1							1
Stomatitis and ulceration	53	161		1	21	54	32		107
Tongue disorders	12	49			5	17	7		32
Tongue signs and symptoms	106	405		1	47	136	59		269
	3,436	12,922	5	46	1429	4056	2007		8866

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Administration site reactions NEC	3	7			2	2	1		5
Adverse effect absent	3	8			3	8			
Application and instillation site reactions	1	1					1		1
Asthenic conditions	3,136	11,701	19	94	1275	3760	1861		7941
Body temperature altered	7	37			1	4	6		33
Complications associated with device NEC		1				1			
Death and sudden death	18	127					18		127
Eye complications associated with device		1							1
Febrile disorders	1,355	5,552	4	22	645	1974	710		3578
Feelings and sensations NEC	1,720	6,455	6	28	749	2313	971		4142

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\* AE=Adverse Event

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gait disturbances	107	330		2	16	58	91	272
General signs and symptoms NEC	1,489	4,474	4	12	518	1384	971	3090
Healing abnormal NEC	1	2					1	2
Implant and catheter site reactions		1						1
Inflamations	40	112			17	37	23	75
Injection site reactions	62	121			46	79	16	42
Interactions	5	13				3	5	10
Mass conditions NEC	15	33			4	9	11	24
Mucosal findings abnormal	1	3					1	3
Oedema NEC	27	73			11	24	16	49
Pain and discomfort NEC	1,799	5,463	2	18	681	1882	1118	3581
Therapeutic and nontherapeutic responses	144	659	2	3	16	42	128	617
Ulcers NEC	1	5				1	1	4
Vaccination site reactions	1,611	5,994	1	10	958	2974	653	3020
Vascular complications associated with device	1	1					1	1
Withdrawal and rebound effects	1	4			1	2		2
	11,547	41,178	38	189	4943	14557	6604	26621

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	1	2			1	2
Cholecystitis and cholelithiasis	2	3			2	3
Cholestasis and jaundice	4	8		1	4	7
Gal bladder disorders NEC	1	1			1	1
Hepatic and hepatobiliary disorders NEC		1				1
Hepatic enzymes and function abnormalities		1				1
Hepatic failure and associated disorders		1				1
Hepatic fibrosis and cirrhosis		2				2

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic vascular disorders	1	3			1	3
Hepatobiliary signs and symptoms	4	11	1	1	3	10
Hepatocellular damage and hepatitis NEC	7	14			7	14
Obstructive bile duct disorders (excl neoplasms)		1				1
	20	48	1	2	19	46

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic sarcoidosis	3	9			3	9
Allergic conditions NEC	72	302	25	77	47	225
Allergies to foods, food additives, drugs and other chemicals	14	88	4	29	10	59
Anaphylactic and anaphylactoid responses	41	304			41	304
Atopic disorders	6	13	3	5	3	8
Autoimmune disorders NEC	4	15			4	15
Immune and associated conditions NEC	11	32	1	5	10	27
Immunodeficiency disorders NEC		3				3
Primary immunodeficiency syndromes	1	1			1	1
Transplant rejections	1	1			1	1
	153	768	33	116	120	652

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	11	34			1	2	10	32

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System Organ Class

**Infections and infestations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Aspergillus infections		1
Bacterial infections NEC	38	142
Bone and joint infections		1
Borrelial infections	1	1
Breast infections	8	18
Caliciviral infections	1	1
Candida infections	10	31
Central nervous system and spinal infections	9	17
Clostridia infections		2
Coronavirus infections	233	1,036
Coxiella infections	1	7
Cytomegaloviral infections		1
Dental and oral soft tissue infections	4	17
Ear infections	30	67
Ectoparasitic infestations	1	1
Epstein-Barr viral infections	1	5
Eye and eyelid infections	9	37
Female reproductive tract infections		1
Fungal infections NEC	1	3
Hepatitis viral infections	1	1
Hepatobiliary and spleen infections		2
Herpes viral infections	104	470
Infections NEC	73	160
Infectious transmissions	1	1
Influenza viral infections	175	530
Lower respiratory tract and lung infections	41	152
Male reproductive tract infections	1	6
Mumps viral infections	1	3
Muscle and soft tissue infections	1	3
Neisseria infections		1
Parainfluenzae viral infections	1	1
Prion-associated disorders	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	7	37	135
					1
				1	1
				8	18
				1	1
		2	8	8	23
				9	17
					2
2	3	81	267	152	769
				1	7
					1
		1	5	3	12
		6	13	24	54
				1	1
				1	5
		4	7	5	30
					1
				1	3
				1	1
					2
	1	18	139	86	331
		16	37	57	123
				1	1
1	4	59	143	116	387
			1	41	151
				1	6
				1	3
				1	3
					1
				1	1
				1	3

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rotaviral infections	1	1					1	1
Rubeola viral infections	2	2					2	2
Sepsis, bacteraemia, viraemia and fungaemia NEC	12	38					12	38
Skin structures and soft tissue infections	10	33			4	12	6	21
Staphylococcal infections	6	18			1	3	5	15
Streptococcal infections	2	6					2	6
Trypanosomal infections	1	2					1	2
Tuberculous infections	1	1					1	1
Upper respiratory tract infections	130	387	1	2	51	133	79	254
Urinary tract infections	32	107	1	1	6	15	26	92
Vascular infections	2	4					2	4
Viral infections NEC	46	154	1	1	3	17	43	137
	1,003	3,509	6	12	254	809	749	2700

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal injuries NEC	6	9					6	9
Accidental exposures to product		3				2		1
Anaesthetic and allied procedural complications	3	3			1	1	2	2
Bone and joint injuries NEC	3	9			1	5	2	4
Cardiovascular injuries	6	13					6	13
Cerebral injuries NEC	2	5				1	2	4
Chest and respiratory tract injuries NEC	4	6					4	6
Conditions caused by cold	24	29			20	21	4	8
Cranial nerve injuries		1						1
Exposures associated with pregnancy, delivery and lactation	91	248	4	4	54	175	37	73

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Exposures to agents or circumstances NEC		3
Eye injuries NEC	4	19
Fractures and dislocations NEC		2
Gastrointestinal and hepatobiliary procedural complications	1	5
Heat injuries (excl thermal burns)	1	7
Intentional product misuses		1
Intentional product use issues		1
Limb fractures and dislocations	6	21
Medication errors, product use errors and issues NEC	59	496
Muscle, tendon and ligament injuries	11	35
Musculoskeletal procedural complications		1
Nerve injuries NEC	7	19
Neurological and psychiatric procedural complications	2	5
Non-occupational environmental exposures	1	1
Non-site specific injuries NEC	61	185
Non-site specific procedural complications	7	29
Occupational exposures		3
Off label uses	443	947
Overdoses NEC	6	24
Peripheral nerve injuries	1	5
Poisoning and toxicity	2	6
Product administration errors and issues	425	731
Product confusion errors and issues		1
Product preparation errors and issues	3	13
Product prescribing errors and issues	1	1
Product storage errors and issues in the product use system	1	8
Radiation injuries	1	3
Reproductive tract and breast procedural complications	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
	1	2	5	2	14
					2
		1	1		4
			2	1	5
			1		
			1		
				6	21
		50	462	9	34
		2	4	9	31
					1
		3	6	4	13
		1	1	1	4
				1	1
		16	51	45	134
		1	5	6	24
			3		
1	1	421	901	22	46
		6	23		1
				1	5
	1			2	6
1	1	407	701	18	30
			1		
		3	13		
		1	1		
		1	8		
		1	1		2
				2	2

\* I=Interval, C=Cumulative  
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System Organ Class

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Site specific injuries NEC	22	65
Skin injuries NEC	114	260
Skull fractures, facial bone fractures and dislocations		2
Spinal fractures and dislocations	2	2
Stoma complications		4
Thermal burns	7	20
Thoracic cage fractures and dislocations		1
Underdoses NEC	1	12
Vaccination related complications	12	33
	1,342	3,299

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	17	19	48
	2	44	100	70	160
					2
				2	2
			1		3
		3	5	4	15
					1
		1	12		
		5	10	7	23
6	10	1048	2542	294	757

System Organ Class

**Investigations**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Adrenal cortex tests		2
Adrenal medulla tests		1
Autoimmunity analyses		1
Bacteria identification and serology (excl mycobacteria)	1	1
Blood counts NEC	3	5
Blood gas and acid base analyses	10	73
Bone marrow and immune tissue imaging procedures		1
Carbohydrate tolerance analyses (incl diabetes)	23	108
Cardiac auscultatory investigations	4	7
Cardiac function diagnostic procedures	1	1
Cell marker analyses		1
Central nervous system imaging procedures	2	2
Chemistry analyses NEC		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
				1	1
				3	5
		4	12	6	61
					1
		2	30	21	78
			1	4	6
		1	1		
			1		
				2	2
			2		6

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cholesterol analyses	2	4
Coagulation and bleeding analyses	31	79
Digestive enzymes	1	1
ECG investigations	3	11
Endocrine analyses and imaging NEC		2
Faecal analyses NEC	1	2
Gastrointestinal and abdominal imaging procedures	1	1
Haematological analyses NEC	4	9
Haem metabolism analyses		1
Heart rate and pulse investigations	132	500
Imaging procedures NEC	1	2
Immunoglobulin analyses	2	4
Immunology analyses NEC	1	2
Investigations NEC	8	15
Liver function analyses	16	44
Metabolism tests NEC	1	3
Microbiology and serology tests NEC		1
Mineral and electrolyte analyses	11	24
Musculoskeletal and soft tissue tests NEC		1
Neurologic diagnostic procedures		4
Ophthalmic function diagnostic procedures	2	4
Physical examination procedures and organ system status	180	545
Pituitary analyses anterior	1	6
Platelet analyses	35	44
Protein analyses NEC	12	29
Psychiatric investigations		1
Red blood cell analyses	3	15
Renal function analyses		4
Reproductive hormone analyses	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
		4	14	27	65
		1	1		
		1	2	2	9
					2
				1	2
				1	1
			1	4	8
					1
	1	44	138	88	362
				1	2
			2	2	2
		1	2		
		1	3	7	12
		2	11	14	33
				1	3
					1
		6	9	5	15
					1
					4
			1	2	3
	2	86	206	94	339
		1	5		1
		8	9	27	35
		1	6	11	23
					1
			4	3	11
			2		2
		1	2		1

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Respiratory and pulmonary function diagnostic procedures	4	9					4	9
Respiratory tract and thoracic histopathology procedures		2						2
Respiratory tract and thoracic imaging procedures		1				1		
Skeletal and cardiac muscle analyses	4	13				1	4	12
Therapeutic drug monitoring analyses	2	5					2	5
Thyroid analyses	3	8				2	3	6
Tissue enzyme analyses NEC	1	5				1	1	4
Toxicology laboratory analyses		1				1		
Urinalysis NEC	7	26			2	6	5	20
Urinary tract function analyses NEC	3	11			2	4	1	7
Vascular tests NEC (incl blood pressure)	66	266			23	98	43	168
Virus identification and serology	16	73			5	27	11	46
Vitamin analyses	3	3			1	1	2	2
Water and electrolyte analyses NEC		1				1		
White blood cell analyses	18	37			3	10	15	27
	620	2,033		3	200	618	420	1415

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Appetite disorders	181	741		4	64	215	117	526
Calcium metabolism disorders	1	5				1	1	4
Diabetes mellitus (incl subtypes)	16	44					16	44
Diabetic complications NEC	2	10					2	10
Disorders of purine metabolism	8	28					8	28
Electrolyte imbalance NEC	2	2			1	1	1	1
Fat soluble vitamin deficiencies and disorders	1	3					1	3

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Fluid intake decreased		2							2
Fluid intake increased	1	3				1		1	2
Food malabsorption and intolerance syndromes (excl sugar intolerance)	6	7			1	1		5	6
General nutritional disorders NEC	13	70			2	25		11	45
Hyperglycaemic conditions NEC	11	45			2	7		9	38
Hypoglycaemic conditions NEC	6	39			2	7		4	32
Iron deficiencies	2	3						2	3
Lipid metabolism and deposit disorders NEC	1	1			1	1			
Metabolic acidoses (excl diabetic acidoses)		5							5
Mixed acid-base disorders	1	3				1		1	2
Potassium imbalance		5							5
Sodium imbalance	2	7						2	7
Sugar intolerance (excl glucose intolerance)		1				1			
Total fluid volume decreased	21	78			8	24		13	54
Total fluid volume increased	4	12			1	2		3	10
Vitamin deficiencies NEC	2	3			1	1		1	2
	281	1,117		4	83	288		198	829

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Arthropathies NEC	43	121			6	16		37	105
Bone disorders NEC	7	10				1		7	9
Bone related signs and symptoms	104	364	2	3	33	107		71	257
Bursal disorders	7	14			1	1		6	13
Cartilage disorders	8	22			1	2		7	20
Connective tissue disorders NEC	13	31						13	31
Crystal arthropathic disorders	1	2						1	2

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\* AE=Adverse Event

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Epiphyseal disorders		1							1
Extremity deformities	3	4			1	1	2	3	
Intervertebral disc disorders NEC	2	3			1	1	1	2	
Joint related disorders NEC	18	47		1	1	7	17	40	
Joint related signs and symptoms	1,198	3,982	3	24	426	1162	772	2820	
Ligament disorders	2	3					2	3	
Lupus erythematosus (incl subtypes)	5	12		1			5	12	
Metabolic bone disorders		1						1	
Muscle infections and inflammations	5	12			1	4	4	8	
Muscle pains	1,208	4,346	8	28	574	1554	634	2792	
Muscle related signs and symptoms NEC	164	568	1	1	52	160	112	408	
Muscle tone abnormalities	5	23		1	1	2	4	21	
Muscle weakness conditions	121	425			37	111	84	314	
Musculoskeletal and connective tissue conditions NEC	205	739		2	72	223	133	516	
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1			
Musculoskeletal and connective tissue infections and inflammations NEC	3	7			1	1	2	6	
Musculoskeletal and connective tissue pain and discomfort	2,032	6,873	6	48	875	2504	1157	4369	
Myopathies		5						5	
Osteoarthropathies	6	18			1	3	5	15	
Psoriatic arthropathies	5	12					5	12	
Rheumatoid arthropathies	27	61		1			27	61	
Soft tissue disorders NEC	60	156			15	52	45	104	
Spine and neck deformities	1	1					1	1	
Spondyloarthropathies	5	21					5	21	
Synovial disorders	2	11				1	2	10	
Tendon disorders	11	28			2	5	9	23	
Trunk deformities		1				1			
	5,271	17,925	20	110	2101	5920	3170	12005	

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
B-cell lymphomas NEC		1				1
Bone neoplasms unspecified malignancy	1	2	1	1		1
Breast and nipple neoplasms malignant	8	12			8	12
Cardiovascular neoplasms benign		1		1		
Colorectal neoplasms malignant	1	1			1	1
Follicle centre lymphomas, follicular grade I, II, III		1				1
Gastric neoplasms malignant		1				1
Gastrointestinal neoplasms malignant NEC	1	1			1	1
Leukaemias acute NEC		1				1
Leukaemias chronic lymphocytic	1	1			1	1
Leukaemias NEC		1				1
Lymphomas unspecified NEC	2	11			2	11
Metastases to specified sites		7				7
Metastases to unknown and unspecified sites		1				1
Myelodysplastic syndromes		1				1
Myeloproliferative disorders (excl leukaemias)		1				1
Neoplasms malignant site unspecified NEC	3	6			3	6
Neoplasms unspecified malignancy and site unspecified NEC	3	4		1	3	3
Nervous system neoplasms unspecified malignancy NEC	2	3			2	3
Neuromas	1	2			1	2
Non-Hodgkin's lymphomas NEC	1	1			1	1
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	2	3			2	3
Plasma cell myelomas		1				1
Plasma cell neoplasms NEC		1				1
Renal neoplasms malignant	1	2			1	2
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	2	3			2	3
Skin neoplasms benign		2				2
Skin neoplasms malignant and unspecified (excl melanoma)	1	4			1	4

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Soft tissue neoplasms benign NEC	1	2	1	1		1
Soft tissue sarcomas histology unspecified		1				1
Urinary tract neoplasms unspecified malignancy NEC	1	1			1	1
	32	80	2	4	30	76

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes		9				2		7
Abnormal sleep-related events		3				2		1
Absence seizures	3	15					3	15
Acute polyneuropathies	12	28					12	28
Alzheimer's disease (incl subtypes)	1	1					1	1
Autonomic nervous system disorders	1	5					1	5
Central nervous system aneurysms and dissections	1	2					1	2
Central nervous system haemorrhages and cerebrovascular accidents	149	326					149	326
Central nervous system inflammatory disorders NEC		1						1
Central nervous system vascular disorders NEC	3	5					3	5
Cerebrovascular venous and sinus thrombosis	15	19					15	19
Cervical spinal cord and nerve root disorders	1	3					1	3
Choreiform movements		2						2
Coma states	3	6					3	6
Coordination and balance disturbances	107	314		1	20	63	87	251
Cortical dysfunction NEC	13	38			3	9	10	29
Cranial nerve disorders NEC	1	3					1	3
Dementia (excl Alzheimer's type)	3	16					3	16

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Nervous system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Demyelinating disorders NEC	6	7
Disturbances in consciousness NEC	566	2,153
Disturbances in sleep phase rhythm	1	1
Dyskinesias and movement disorders NEC	91	202
Dystonias	2	9
Encephalitis NEC		1
Encephalopathies NEC		3
Eye movement disorders	3	11
Facial cranial nerve disorders	118	421
Generalised tonic-clonic seizures	8	33
Headaches NEC	2,743	9,747
Hypoglossal nerve disorders		1
Increased intracranial pressure disorders	2	5
Lumbar spinal cord and nerve root disorders	4	21
Memory loss (excl dementia)	40	109
Mental impairment (excl dementia and memory loss)	75	239
Migraine headaches	298	936
Mixed cranial nerve disorders	1	1
Mononeuropathies	13	30
Multiple sclerosis acute and progressive	9	40
Muscle tone abnormal	1	10
Myelitis (incl infective)	3	18
Narcolepsy and hypersomnia	43	147
Nervous system cysts and polyps	1	1
Nervous system disorders NEC	6	16
Neurological signs and symptoms NEC	1,047	3,823
Neurologic visual problems NEC	8	20
Neuromuscular disorders NEC	2	14
Neuromuscular junction dysfunction	4	7
Olfactory nerve disorders	41	146
Optic nerve disorders NEC	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	7
1	8	165	464	401	1689
		1	1		
		21	43	70	159
				2	9
					1
					3
				3	11
	2	6	23	112	398
				8	33
5	44	1238	3406	1505	6341
					1
				2	5
		2	5	2	16
		8	24	32	85
	2	17	50	58	189
3	6	60	202	238	734
				1	1
		5	9	8	21
				9	40
			1	1	9
				3	18
		18	52	25	95
				1	1
		3	6	3	10
	16	435	1206	612	2617
			2	8	18
			3	2	11
				4	7
		13	52	28	94
				4	10

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Paraesthesias and dysaesthesias	652	2,097		7	283	758	369	1339
Paralysis and paresis (excl cranial nerve)	47	139		1		2	47	137
Parkinson's disease and parkinsonism	6	18			1	4	5	14
Partial complex seizures	1	4				1	1	3
Peripheral neuropathies NEC	15	52			2	3	13	49
Seizures and seizure disorders NEC	95	327			5	7	90	320
Sensory abnormalities NEC	286	908		2	129	386	157	522
Sleep disturbances NEC	27	101		1	12	37	15	64
Speech and language abnormalities	46	143		1	9	28	37	115
Spinal cord and nerve root disorders NEC	1	5				1	1	4
Structural brain disorders NEC	1	3					1	3
Transient cerebrovascular events	44	78					44	78
Tremor (excl congenital)	160	705		3	69	187	91	518
Trigeminal disorders	7	25			3	7	4	18
	6,841	23,583	9	94	2528	7046	4313	16537

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions not specified as induced or spontaneous		1				1
Abortions spontaneous	25	52			25	52
Amniotic fluid and cavity disorders of pregnancy NEC		1				1
Gestational age and weight conditions		3				3
Haemorrhagic complications of pregnancy	1	1			1	1
Labour onset and length abnormalities		1				1
Maternal complications of labour NEC		1				1
Maternal complications of pregnancy NEC		10				10

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Normal pregnancy, labour and delivery	1	3		2	1	1
Pregnancy complicated by maternal disorders	1	1			1	1
Stillbirth and foetal death	3	3			3	3
Unintended pregnancies	1	1			1	1
	32	78		2	32	76

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device malfunction events NEC	5	12	1	2	4	10
Device physical property and chemical issues		3		2		1
Product contamination and sterility issues	1	2	1	2		
Product distribution and storage issues	3	71	3	71		
Product packaging issues		4		4		
Product physical issues		3		3		
Product quality issues NEC	1	5		3	1	2
Product supply and availability issues		1		1		
	10	101	5	88	5	13

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour NEC	6	13				2	6	11
Abnormal food elimination	1	1					1	1
Adjustment disorders	2	2					2	2
Affect alterations NEC	4	10			2	3	2	7

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System Organ Class

**Psychiatric disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Amnesic symptoms	1	2
Anxiety symptoms	119	423
Attention deficit and disruptive behaviour disorders	2	2
Behaviour and socialisation disturbances	5	26
Bipolar disorders	1	3
Cognitive and attention disorders and disturbances NEC	15	63
Communications disorders	4	12
Confusion and disorientation	131	462
Decreased physical activity levels		1
Deliria	15	61
Delusional symptoms	3	5
Depressive disorders	26	79
Dissociative states	7	23
Disturbances in initiating and maintaining sleep	180	671
Dyssomnias	1	1
Eating disorders NEC	7	26
Emotional and mood disturbances NEC	39	121
Factitious disorders	1	1
Fear symptoms and phobic disorders (incl social phobia)	7	24
Fluctuating mood symptoms		10
Hallucinations (excl sleep-related)	28	109
Increased physical activity levels	29	74
Learning disorders		2
Mental disorders due to a general medical condition NEC		1
Mental disorders NEC	6	11
Mood alterations with depressive symptoms	39	133
Mood alterations with manic symptoms	1	5
Mood disorders NEC	7	27
Narcolepsy and associated conditions		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		45	129	74	294
				2	2
		1	6	4	20
				1	3
		4	12	11	51
		1	5	3	7
	1	26	84	105	378
					1
				15	61
		1	2	2	3
		3	4	23	75
		3	12	4	11
		55	226	125	445
		1	1		
			4	7	22
		17	41	22	80
				1	1
			8	7	16
			3		7
				28	109
		6	18	23	56
					2
			1		
		3	5	3	6
		9	28	30	105
				1	5
		2	5	5	22
					4

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Obsessive-compulsive disorders and symptoms		1							1
Orgasmic disorders and disturbances		1							1
Panic attacks and disorders	17	49			6	12	11		37
Parasomnias	38	123			20	56	18		67
Perception disturbances NEC	9	17			1	3	8		14
Psychiatric elimination disorders	2	6				2	2		4
Psychiatric symptoms NEC	1	4			1	1			3
Psychotic disorder NEC	1	11				1	1		10
Schizophrenia NEC	1	1					1		1
Sexual desire disorders	1	5				1	1		4
Sleep disorders NEC	77	242			35	107	42		135
Somatic symptom disorders	4	7			1	1	3		6
Speech and language usage disturbances		6				1			5
Speech articulation and rhythm disturbances	4	9			1	2	3		7
Stereotypies and automatisms	4	8			1	2	3		6
Stress disorders	1	2					1		2
Substance related and addictive disorders		1							1
Suicidal and self-injurious behaviour	12	24					12		24
Thinking disturbances	13	33			4	8	9		25
Tic disorders	1	1					1		1
	873	2,959		1	249	796	624		2163

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	48	170	12	31	36	139
Bladder disorders NEC	2	7			2	7
Bladder infections and inflammations	1	2			1	2
Genital and urinary tract disorders NEC		2				2

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glomerulonephritis and nephrotic syndrome	5	16			5	16
Myoneurogenic bladder disorders		7		3		4
Nephritis NEC		2				2
Renal disorders NEC	3	6			3	6
Renal failure and impairment	24	67			24	67
Renal lithiasis		1				1
Renal neoplasms	2	2			2	2
Renal structural abnormalities and trauma		1				1
Renal vascular and ischaemic conditions		1				1
Structural and obstructive urethral disorders (excl congenital)		1				1
Ureteric disorders NEC		1				1
Urinary abnormalities	20	55	7	22	13	33
Urinary tract signs and symptoms NEC	29	104	9	30	20	74
	134	445	28	86	106	359

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Benign and malignant breast neoplasms	1	2			1	1		1
Breast disorders NEC	13	26			2	5	11	21
Breast infections and inflammations	2	2					2	2
Breast signs and symptoms	98	212			20	54	78	158
Cervix disorders NEC	1	1					1	1
Erection and ejaculation conditions and disorders	6	17					6	17
Lactation disorders	3	8				1	3	7
Menopausal effects NEC	2	5				2	2	3
Menopausal effects on the genitourinary tract	5	7					5	7

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Menstruation and uterine bleeding NEC	46	90	2	2	13	33	33	57
Menstruation with decreased bleeding	26	68			6	21	20	47
Menstruation with increased bleeding	37	80	1	1	13	25	24	55
Ovarian and fallopian tube cysts and neoplasms	1	1			1	1		
Ovarian and fallopian tube disorders NEC		1						1
Pelvis and broad ligament disorders NEC		8						8
Penile disorders NEC (excl erection and ejaculation)		2						2
Prostate and seminal vesicles infections and inflammations	1	2					1	2
Prostatic signs, symptoms and disorders NEC	3	5			1	3	2	2
Reproductive tract disorders NEC (excl neoplasms)		2						2
Reproductive tract infections and inflammations NEC		1				1		
Reproductive tract signs and symptoms NEC	8	28			3	8	5	20
Scrotal disorders NEC	1	9			1	2		7
Sexual function and fertility disorders NEC		1						1
Spermatogenesis and semen disorders	2	2					2	2
Testicular and epididymal disorders NEC	7	16			5	7	2	9
Uterine disorders NEC	5	9			1	1	4	8
Uterine tone disorders		1				1		
Vulvovaginal cysts and neoplasms	1	2					1	2
Vulvovaginal disorders NEC	27	62			7	14	20	48
Vulvovaginal signs and symptoms	2	12				6	2	6
	298	682	3	3	74	186	224	496

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breathing abnormalities	402	1,562
Bronchial conditions NEC	3	7
Bronchospasm and obstruction	70	336
Conditions associated with abnormal gas exchange	5	23
Coughing and associated symptoms	234	885
Diaphragmatic disorders	1	1
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		2
Laryngeal spasm, oedema and obstruction	2	15
Lower respiratory tract inflammatory and immunologic conditions	4	24
Lower respiratory tract signs and symptoms	16	63
Nasal congestion and inflammations	29	99
Nasal disorders NEC	100	232
Neonatal hypoxic conditions		1
Paranasal sinus disorders (excl infections and neoplasms)	9	32
Parenchymal lung disorders NEC	7	11
Pharyngeal disorders (excl infections and neoplasms)	49	226
Pleural infections and inflammations	1	13
Pneumothorax and pleural effusions NEC	6	13
Pulmonary hypertensions		2
Pulmonary oedemas	7	22
Pulmonary thrombotic and embolic conditions	86	171
Respiratory failures (excl neonatal)		9
Respiratory signs and symptoms NEC	13	40
Respiratory tract disorders NEC	8	46
Thoracic musculoskeletal disorders		1
Tracheal disorders (excl infections and neoplasms)		2
Upper respiratory tract neoplasms	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	96	315	306	1247
		1	1	2	6
		19	68	51	268
				5	23
1	3	92	278	142	607
				1	1
					2
		1	1	1	14
			2	4	22
		4	12	12	51
	1	10	34	19	65
		36	76	64	156
					1
		2	7	7	25
		1	1	6	10
		30	65	19	161
				1	13
				6	13
					2
				7	22
	1			86	171
					9
	1	1	7	12	33
		1	10	7	36
					1
			2		
		1	1		

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Upper respiratory tract signs and symptoms	446	1,768	5	13	209	590	237	1178
Vascular pulmonary disorders NEC		1						1
	1,499	5,608	6	21	504	1470	995	4138

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acnes	9	14			3	4	6	10
Alopecias	17	33				4	17	29
Angioedemas	21	108				1	21	107
Apocrine and eccrine gland disorders	363	1,350		4	137	439	226	911
Bullous conditions	51	163			14	36	37	127
Connective tissue disorders		3						3
Dermal and epidermal conditions NEC	213	656		3	89	246	124	410
Dermatitis and eczema	67	204		1	20	60	47	144
Dermatitis ascribed to specific agent	2	9			1	3	1	6
Erythemas	239	752		1	145	369	94	383
Exfoliative conditions	16	45			7	11	9	34
Granulomatous and deep cutaneous inflammatory conditions	2	3			1	1	1	2
Hyperkeratoses	1	2					1	2
Hyperpigmentation disorders	2	2			1	1	1	1
Hypopigmentation disorders	1	3					1	3
Nail and nail bed conditions (excl infections and infestations)	5	10			2	3	3	7
Panniculitides	4	6			1	1	3	5
Papulosquamous conditions	8	15			4	7	4	8
Photosensitivity and photodermatitis conditions	6	28			1	6	5	22
Pigmentation changes NEC	3	4			1	2	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pilar disorders NEC	6	15
Pruritus NEC	370	1,220
Psoriatic conditions	16	34
Purpura and related conditions	21	53
Rashes, eruptions and exanthems NEC	717	2,236
Rosaceas	1	3
Scaly conditions	1	5
Sebaceous gland disorders	1	1
Skin and subcutaneous conditions NEC	1	12
Skin and subcutaneous tissue ulcerations	4	15
Skin cysts and polyps		1
Skin dystrophies	2	2
Skin haemorrhages	8	10
Skin hyperplasias and hypertrophies		1
Skin injuries and mechanical dermatoses	2	2
Skin vasculitides	3	9
Skin vasomotor conditions	3	16
Telangiectasia and related conditions	1	1
Urticarias	145	476
	2,332	7,522

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	4	12
		187	529	183	691
		2	9	14	25
		14	22	7	31
1	2	356	952	361	1284
			1	1	2
		1	3		2
				1	1
			3	1	9
		1	2	3	13
					1
		1	1	1	1
		2	2	6	8
			1		
				2	2
		1	2	2	7
		2	4	1	12
				1	1
		87	196	58	280
1	11	1083	2924	1249	4598

System Organ Class

**Social circumstances**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Age related issues	1	1
Disability issues	76	201
Non-occupational and unspecified environmental problems	1	1
Social issues NEC	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
22	59	54	142
		1	1
1	1	2	2

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tobacco use	1	1	1	1		
	82	207	24	61	58	146

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	4	22	4	22
	4	22	4	22

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial therapeutic procedures (excl aortic)	1	1			1	1
Breast therapeutic procedures NEC	1	1			1	1
Bronchial and pulmonary therapeutic procedures		1				1
Dental and gingival therapeutic procedures	1	1			1	1
Dietary and nutritional therapies	1	3			1	3
Gastrointestinal therapeutic procedures NEC	1	2			1	2
Immunisations	4	6		1	4	5
Limb therapeutic procedures	2	6		4	2	2
Nervous system therapeutic procedures NEC	2	2			2	2
Prophylactic procedures NEC	1	1			1	1
Respiratory tract therapeutic procedures NEC		1				1
Skin and subcutaneous tissue therapeutic procedures NEC	1	1	1	1		
Therapeutic procedures NEC	2	4	1	2	1	2

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	17	30	2	8	15	22

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	7	8					7	8
Aneurysms and dissections non-site specific	1	1					1	1
Aortic aneurysms and dissections		3						3
Aortic embolism and thrombosis	3	3					3	3
Aortic necrosis and vascular insufficiency		3						3
Arterial infections and inflammations	1	6					1	6
Blood pressure disorders NEC	3	12				2	3	10
Bruising, ecchymosis and purpura		1				1		
Circulatory collapse and shock	12	87					12	87
Haemorrhages NEC	42	88	1	2	1	5	41	83
Lymphangiopathies	1	1					1	1
Lymphoedemas	19	48		1	2	12	17	36
Non-site specific embolism and thrombosis	107	162		1			107	162
Non-site specific necrosis and vascular insufficiency NEC	7	12				1	7	11
Non-site specific vascular disorders NEC	10	27			4	8	6	19
Peripheral embolism and thrombosis	74	129		1	8	9	66	120
Peripheral vascular disorders NEC	166	569		1	90	226	76	343
Peripheral vasoconstriction, necrosis and vascular insufficiency	54	193		1	19	62	35	131
Phlebitis NEC	7	13			5	5	2	8
Site specific vascular disorders NEC	22	119			12	45	10	74
Varicose veins NEC	2	6				2	2	4
Vascular hypertensive disorders NEC	79	309		1	24	78	55	231

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vascular hypotensive disorders	45	185			16	46	29	139
Vasculitides NEC	15	32			5	6	10	26
Vena caval embolism and thrombosis		2						2
	677	2,019	1	8	186	508	491	1511

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED STATES**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia deficiencies	1	1			1	1		
Anaemias haemolytic immune	1	2					1	2
Anaemias haemolytic mechanical factor	1	1					1	1
Anaemias haemolytic NEC	3	7					3	7
Anaemias NEC	2	10			1	5	1	5
Bleeding tendencies		2				2		
Coagulopathies	9	15			2	3	7	12
Eosinophilic disorders		1				1		
Haematological disorders	3	7			3	5		2
Haemolyses NEC	1	1					1	1
Leukocytoses NEC		7				3		4
Leukopenias NEC		1						1
Lymphatic system disorders NEC	226	1,197	1	1	211	1120	15	77
Marrow depression and hypoplastic anaemias		4						4
Neutropenias	1	6					1	6
Platelet disorders NEC	2	4			1	2	1	2
Polycythaemia (excl rubra vera)		1				1		
Red blood cell abnormal findings NEC	1	1					1	1
Sickle cell trait and disorders	2	2					2	2
Spleen disorders	2	6				1	2	5
Thrombocytopenias	19	51					19	51
	274	1,327	1	1	219	1144	55	183

System Organ Class

**Cardiac disorders**

Interval Total #	Cumulative Total #	Non Interventional Study		Spontaneous	
		Serious		Nonserious	
		I	C	I	C

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Aortic valvular disorders		1							1
Cardiac conduction disorders	3	3					3	3	3
Cardiac disorders NEC	27	62			17	37	10	25	25
Cardiac hypertensive complications		1						1	1
Cardiac signs and symptoms NEC	86	447			63	345	23	102	102
Cardiac valve disorders NEC	2	5			1	2	1	3	3
Cardiomyopathies	1	6					1	6	6
Coronary artery disorders NEC	1	3			1	1		2	2
Heart failures NEC	3	19					3	19	19
Ischaemic coronary artery disorders	64	149			1	1	63	148	148
Mitral valvular disorders	1	3					1	3	3
Myocardial disorders NEC		3						3	3
Noninfectious myocarditis	9	19					9	19	19
Noninfectious pericarditis	5	22					5	22	22
Pericardial disorders NEC	2	12					2	12	12
Rate and rhythm disorders NEC	79	408	1	1	16	190	63	218	218
Right ventricular failures	1	1					1	1	1
Supraventricular arrhythmias	46	152			3	14	43	138	138
Tricuspid valvular disorders	1	1					1	1	1
Ventricular arrhythmias and cardiac arrest	23	76			3	12	20	64	64
	354	1,393	1	1	105	602	249	791	791

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Arterial disorders congenital		1				1	
Cerebral disorders congenital	3	3			3	3	
Coagulation disorders congenital	1	2			1	2	
Congenital disorders NEC		1				1	

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inborn errors of amino acid metabolism	1	1	1	1		
Inborn errors of lipid metabolism	1	2			1	2
Inborn errors of porphyrin metabolism		1				1
Neurological disorders congenital NEC	2	2	1	1	1	1
Retinal disorders congenital		1				1
Skin and subcutaneous tissue disorders congenital NEC		2		1		1
Tongue disorders congenital	1	2			1	2
Venous disorders congenital		1				1
	9	19	2	3	7	16

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	88	303	73	268	15	35
Eustachian tube disorders	1	3	1	2		1
External ear disorders NEC	6	12	5	11	1	1
Hearing losses	83	220	16	61	67	159
Hyperacusia	7	20	6	17	1	3
Inner ear disorders NEC	7	12	2	4	5	8
Inner ear signs and symptoms	220	580	151	447	69	133
Mastoid disorders	1	2	1	1		1
Middle ear disorders NEC		1		1		
	413	1,153	255	812	158	341

System Organ Class

**Endocrine disorders**

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	4	13	1	5	3	8
Adrenal cortical hypofunctions		4				4
Adrenal gland disorders NEC	1	3	1	2		1
Hyperparathyroid disorders		1		1		
Thyroid disorders NEC	10	20	7	16	3	4
Thyroid hyperfunction disorders	6	7			6	7
Thyroid hypofunction disorders	1	5		1	1	4
	22	53	9	25	13	28

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract conditions	4	8		1	4	7
Chambers (anterior and posterior) and lens infections and inflammations		1				1
Choroid and vitreous structural change, deposit and degeneration	5	14	1	5	4	9
Colour blindness (incl acquired)		1		1		
Conjunctival and corneal bleeding and vascular disorders	7	11			7	11
Conjunctival infections, irritations and inflammations		6		5		1
Corneal disorders NEC		2				2
Corneal infections, oedemas and inflammations		3		2		1
Corneal structural change, deposit and degeneration		2				2
Eyelid movement disorders	10	28	6	20	4	8
Glaucomas (excl congenital)	2	7			2	7
Iris and ciliary body structural change, deposit and degeneration	1	2		1	1	1

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iris and uveal tract infections, irritations and inflammations	3	9	1	2	2	7
Lacrimation disorders	17	89	15	81	2	8
Lid bleeding and vascular disorders	1	2	1	2		
Lid, lash and lacrimal infections, irritations and inflammations	16	64	11	55	5	9
Ocular bleeding and vascular disorders NEC	23	40	2	2	21	38
Ocular disorders NEC	117	450	98	377	19	73
Ocular infections, inflammations and associated manifestations	39	219	36	193	3	26
Ocular nerve and muscle disorders	11	24	4	9	7	15
Ocular sensation disorders	25	97	22	91	3	6
Optic nerve bleeding and vascular disorders	3	3			3	3
Orbital structural change, deposit and degeneration	1	2			1	2
Pupil disorders	8	13	6	11	2	2
Refractive and accommodative disorders	1	3	1	3		
Retinal bleeding and vascular disorders (excl retinopathy)	8	12	1	1	7	11
Retinal, choroid and vitreous infections and inflammations	1	2			1	2
Retinal structural change, deposit and degeneration	5	13			5	13
Retinopathies NEC		1				1
Scleral infections, irritations and inflammations	1	5		2	1	3
Scleral structural change, deposit and degeneration		1		1		
Structural change, deposit and degeneration of eye NEC	3	5			3	5
Visual colour distortions		4		4		
Visual disorders NEC	82	256	59	190	23	66
Visual impairment and blindness (excl colour blindness)	61	182	27	91	34	91
Visual pathway disorders	1	1			1	1
	456	1,582	291	1150	165	432

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	1	7			1	7		
Abdominal wall conditions NEC		2						2
Acute and chronic pancreatitis	5	18					5	18
Anal and rectal disorders NEC		1				1		
Anal and rectal pains		2				2		
Anal and rectal signs and symptoms	2	6			2	6		
Benign neoplasms gastrointestinal (excl oral cavity)		1				1		
Colitis (excl infective)	16	28			5	8	11	20
Dental and periodontal infections and inflammations	1	1			1	1		
Dental disorders NEC	4	11			4	10		1
Dental pain and sensation disorders	21	76			19	69	2	7
Dental surface disorders	1	1			1	1		
Diaphragmatic hernias		1				1		
Diarrhoea (excl infective)	262	1,093			224	984	38	109
Diverticula		1						1
Duodenal and small intestinal stenosis and obstruction	1	3					1	3
Dyspeptic signs and symptoms	28	92			24	87	4	5
Faecal abnormalities NEC	18	39			14	31	4	8
Flatulence, bloating and distension	29	100			28	94	1	6
Gastric and oesophageal haemorrhages	1	2					1	2
Gastric ulcers and perforation		2						2
Gastritis (excl infective)	2	6			2	5		1
Gastrointestinal and abdominal pains (excl oral and throat)	167	608			136	522	31	86
Gastrointestinal atonic and hypomotility disorders NEC	36	106			31	96	5	10
Gastrointestinal disorders NEC	30	85			27	76	3	9
Gastrointestinal dyskinetic disorders	7	20			7	20		
Gastrointestinal inflammatory disorders NEC	2	5			2	3		2

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System Organ Class

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gastrointestinal mucosal dystrophies and secretion disorders	2	3
Gastrointestinal signs and symptoms NEC	116	419
Gastrointestinal spastic and hypermotility disorders	13	29
Gastrointestinal stenosis and obstruction NEC		4
Gastrointestinal vascular malformations	1	1
Gastrointestinal vascular occlusion and infarction	1	2
Gingival disorders, signs and symptoms NEC	3	41
Gingival haemorrhages	2	9
Haemorrhoids and gastrointestinal varices (excl oesophageal)	4	10
Intestinal haemorrhages	9	21
Intestinal ulcers and perforation NEC	1	2
Large intestinal stenosis and obstruction		1
Nausea and vomiting symptoms	803	3,716
Non-site specific gastrointestinal haemorrhages	29	73
Oesophageal disorders NEC		2
Oesophageal stenosis and obstruction	1	1
Oesophageal ulcers and perforation		1
Oesophagitis (excl infective)	2	2
Oral dryness and saliva altered	37	139
Oral soft tissue disorders NEC	15	62
Oral soft tissue haemorrhages	3	9
Oral soft tissue infections		1
Oral soft tissue signs and symptoms	111	641
Oral soft tissue swelling and oedema	50	240
Pancreatic disorders NEC	2	3
Salivary gland disorders NEC	2	4
Salivary gland enlargements		2
Salivary gland stenosis and obstruction		1
Stomatitis and ulceration	13	54

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	2
1	1	98	347	18	72
		10	25	3	4
					4
				1	1
				1	2
		3	36		5
		1	7	1	2
		3	8	1	2
		1	2	8	19
				1	2
					1
3	3	661	3300	142	416
		1	1	28	72
			1		1
				1	1
					1
		2	2		
		27	118	10	21
		13	51	2	11
			4	3	5
			1		
		91	516	20	125
		38	171	12	69
		1	1	1	2
		1	3	1	1
			2		
					1
		12	49	1	5

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue disorders	7	45			6	39	1	6
Tongue signs and symptoms	76	290	1	1	46	197	30	93
Tooth missing		1						1
	1,937	8,146	5	5	1544	6907	393	1239

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site reactions NEC	1	5			1	5		
Adverse effect absent	31	80			31	80		
Application and instillation site reactions	2	4			2	3		1
Asthenic conditions	1,612	6,946	2	3	1461	6458	151	488
Body temperature altered	1	13				6	1	7
Complications associated with device NEC		2						2
Death and sudden death	44	125	1	1			44	125
Febrile disorders	781	3,917			696	3619	85	298
Feelings and sensations NEC	1,233	5,956			1115	5511	118	445
Gait disturbances	108	381			67	263	41	118
General signs and symptoms NEC	755	2,633	2	2	614	2221	141	412
Healing abnormal NEC	1	4			1	3		1
Hernias NEC		1						1
Inflamations	26	84			23	71	3	13
Injection site reactions	57	358			57	355		3
Interactions	9	38			6	30	3	8
Mass conditions NEC	20	60			15	52	5	8
Mucosal findings abnormal		10				8		2
Necrosis NEC	1	1					1	1
Oedema NEC	10	43			7	32	3	11
Pain and discomfort NEC	1,030	4,683	1	1	885	4191	145	492

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Therapeutic and nontherapeutic responses	569	1,759	2	4	35	84	534	1675
Ulcers NEC		7				5		2
Vaccination site reactions	767	4,706	2	2	744	4532	23	174
	7,058	31,816	10	13	5760	27529	1298	4287

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis	2	3			2	3
Cholestasis and jaundice	7	18	1	5	6	13
Gal bladder disorders NEC	3	11		5	3	6
Hepatic and hepatobiliary disorders NEC	2	8	1	5	1	3
Hepatic enzymes and function abnormalities	1	1			1	1
Hepatic failure and associated disorders		2				2
Hepatic fibrosis and cirrhosis		1				1
Hepatic vascular disorders	7	7			7	7
Hepatobiliary signs and symptoms	2	7	1	4	1	3
Hepatocellular damage and hepatitis NEC	4	12			4	12
Structural and other bile duct disorders	2	2	1	1	1	1
	30	72	4	20	26	52

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic sarcoidosis	2	2			2	2
Allergic conditions NEC	112	348	84	243	28	105

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergies to foods, food additives, drugs and other chemicals	28	141	20	109	8	32
Amyloidoses		1				1
Anaphylactic and anaphylactoid responses	124	348	1	2	123	346
Atopic disorders	6	14	6	14		
Autoimmune disorders NEC	9	22			9	22
Immune and associated conditions NEC	11	33	7	21	4	12
Immunodeficiency disorders NEC	2	8			2	8
Transplant rejections		1				1
	294	918	118	389	176	529

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	46	89			1	3	45	86
Bacterial infections NEC	28	76			5	10	23	66
Bone and joint infections		3						3
Bordetella infections		1						1
Borrelial infections	1	3					1	3
Breast infections	4	7			1	1	3	6
Candida infections	3	10			3	10		
Cardiac infections		3						3
Central nervous system and spinal infections	3	12					3	12
Clostridia infections	3	4					3	4
Coccidioides infections		2						2
Coronavirus infections	942	2,355	3	5	295	619	647	1736
Dental and oral soft tissue infections	10	23			8	17	2	6
Ear infections	11	26			10	19	1	7
Ectoparasitic infestations		3				1		2

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Epstein-Barr viral infections	3	5			2	3	1	2
Escherichia infections	3	4					3	4
Eye and eyelid infections	3	27			3	24		3
Female reproductive tract infections	1	4				2	1	2
Filovirus viral infections		1						1
Fungal infections NEC	7	17			6	15	1	2
Helicobacter infections		1						1
Hepatitis viral infections	1	1					1	1
Hepatobiliary and spleen infections	1	1					1	1
Herpes viral infections	98	329			79	283	19	46
Infections NEC	20	67			9	41	11	26
Influenza viral infections	32	104			29	97	3	7
Lower respiratory tract and lung infections	48	145			7	21	41	124
Male reproductive tract infections		4				1		3
Pneumocystis infections		1						1
Pseudomonal infections	1	1					1	1
Rhinoviral infections		2				2		
Rubeola viral infections	2	2					2	2
Sepsis, bacteraemia, viraemia and fungaemia NEC	8	24					8	24
Skin structures and soft tissue infections	7	24			4	17	3	7
Staphylococcal infections	4	10				2	4	8
Streptobacillus infections		1						1
Streptococcal infections	1	10				8	1	2
Tinea infections	2	3			2	3		
Treponema infections		1						1
Tuberculous infections		2						2
Upper respiratory tract infections	124	376			113	358	11	18
Urinary tract infections	43	118			26	70	17	48
Vascular infections		1						1
Viral infections NEC	13	42			7	20	6	22
	1,473	3,945	3	5	610	1647	863	2298

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal injuries NEC	11	17			11	15		2
Accidental exposures to product	5	41			5	41		
Bone and joint injuries NEC	7	15			6	13	1	2
Cardiovascular injuries	4	6					4	6
Cerebral injuries NEC	6	15			1	5	5	10
Chest and respiratory tract injuries NEC	4	9					4	9
Conditions caused by cold	3	9			3	8		1
Ear injuries NEC	1	1			1	1		
Exposures associated with pregnancy, delivery and lactation	50	277			40	255	10	22
Exposures to agents or circumstances NEC	42	99			40	85	2	14
Eye injuries NEC	3	13			2	12	1	1
Fractures and dislocations NEC	1	10			1	2		8
Gastrointestinal and hepatobiliary procedural complications		2				2		
Heat injuries (excl thermal burns)	1	1			1	1		
Intentional product misuses	1	3			1	3		
Intentional product use issues		2				2		
Limb fractures and dislocations	18	32			2	2	16	30
Medication errors, product use errors and issues NEC	97	893			96	884	1	9
Muscle, tendon and ligament injuries	9	36			7	29	2	7
Nerve injuries NEC	8	18			6	12	2	6
Non-site specific injuries NEC	109	269			64	161	45	108
Non-site specific procedural complications		9		1		2		7
Occupational exposures	5	14			5	13		1
Off label uses	106	634			103	625	3	9
Overdoses NEC	108	227			108	225		2
Pathways and sources of exposure	5	37			5	37		
Pelvic fractures and dislocations		1						1
Peripheral nerve injuries		2						2
Poisoning and toxicity	2	4					2	4

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\* AE=Adverse Event

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Product administration errors and issues	370	1,648			364	1629	6	19
Product confusion errors and issues		2				2		
Product dispensing errors and issues	1	1			1	1		
Product preparation errors and issues	120	321			120	316		5
Product prescribing errors and issues		3				3		
Product storage errors and issues in the product use system	19	31			19	31		
Product transcribing errors and communication issues		1				1		
Radiation injuries	1	7			1	6		1
Reproductive tract and breast procedural complications	1	1			1	1		
Site specific injuries NEC	29	93			21	67	8	26
Skin injuries NEC	51	170			43	144	8	26
Skull fractures, facial bone fractures and dislocations	3	4					3	4
Spinal fractures and dislocations	1	2					1	2
Stoma complications		3				2		1
Thermal burns	1	4			1	2		2
Thoracic cage fractures and dislocations	2	5				1	2	4
Transplantation complications		1						1
Underdoses NEC	31	210			31	209		1
Vaccination related complications	88	134	2	2	2	5	86	129
	1,324	5,337	2	3	1112	4855	212	482

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Adrenal medulla tests		1		1			
Autoimmunity analyses		1		1			

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System Organ Class

Investigations

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		2
1	7		2
7	42	12	45
1	1		
16	90	12	38
			1
	1	2	5
	2	1	2
			1
	3		1
6	13		
2	17	5	17
	2	1	1
4	11	4	9
	1		1
		1	2
	1		
1	1		
	5		5
1	1		
118	587	52	188
1	1		
	1		
	5		1
1	15		
7	14	5	5
	2		
11	33	8	18
	2		2
	1		

Bacteria identification and serology (excl mycobacteria)		4
Blood counts NEC	1	9
Blood gas and acid base analyses	19	87
Blood grouping and cross-matching analyses	1	1
Carbohydrate tolerance analyses (incl diabetes)	28	128
Cardiac auscultatory investigations		1
Cardiac function diagnostic procedures	2	6
Cell marker analyses	1	4
Cerebrospinal fluid tests (excl microbiology)		1
Chemistry analyses NEC		4
Cholesterol analyses	6	13
Coagulation and bleeding analyses	7	34
Digestive enzymes	1	3
ECG investigations	8	20
Endocrine analyses and imaging NEC		2
Foetal and neonatal diagnostic procedures	1	2
Gastrointestinal function diagnostic procedures		1
Gastrointestinal, pancreatic and APUD hormone analyses	1	1
Haematological analyses NEC		10
Haem metabolism analyses	1	1
Heart rate and pulse investigations	170	775
Histopathology procedures NEC	1	1
Imaging procedures NEC		1
Immunoglobulin analyses		6
Immunology analyses NEC	1	15
Investigations NEC	12	19
Lipoprotein and lipid tests NEC		2
Liver function analyses	19	51
Metabolism tests NEC		4
Microbiology and serology tests NEC		1

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mineral and electrolyte analyses	13	53	6	29	7	24
Musculoskeletal and soft tissue imaging procedures	1	1	1	1		
Mycobacteria identification and serology		1		1		
Neurologic diagnostic procedures	1	3	1	2		1
Ophthalmic function diagnostic procedures	2	8	2	6		2
Physical examination procedures and organ system status	113	394	89	340	24	54
Pituitary analyses anterior	2	7	1	4	1	3
Platelet analyses	19	60	8	26	11	34
Protein analyses NEC	2	23	1	17	1	6
Red blood cell analyses	6	38	2	21	4	17
Renal function analyses	6	23	3	17	3	6
Reproductive hormone analyses		1		1		
Reproductive organ and breast imaging procedures	1	1	1	1		
Respiratory and pulmonary function diagnostic procedures	1	2	1	2		
Respiratory tract and thoracic imaging procedures		1				1
Skeletal and cardiac muscle analyses	16	35	4	8	12	27
Thyroid analyses	2	6	2	6		
Toxicology laboratory analyses	2	2	1	1	1	1
Triglyceride analyses	2	5	2	3		2
Urinalysis NEC	16	44	14	38	2	6
Urinary tract function analyses NEC	4	7	4	7		
Vascular tests NEC (incl blood pressure)	102	432	58	261	44	171
Virus identification and serology	75	416	35	149	40	267
Vitamin analyses	7	12	5	9	2	3
Water and electrolyte analyses NEC	1	1			1	1
White blood cell analyses	17	86	13	53	4	33
	691	2,871	431	1866	260	1005

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	95	410	80	364	15	46
Calcium metabolism disorders		3				3
Diabetes mellitus (incl subtypes)	5	26			5	26
Diabetic complications NEC		1				1
Disorders of purine metabolism	4	17	3	15	1	2
Electrolyte imbalance NEC		2				2
Elevated cholesterol		1		1		
Fat soluble vitamin deficiencies and disorders	2	5	1	4	1	1
Fluid intake decreased	1	6	1	4		2
Fluid intake increased		2		2		
Food malabsorption and intolerance syndromes (excl sugar intolerance)	1	1	1	1		
General nutritional disorders NEC	21	67	17	57	4	10
Hyperglycaemic conditions NEC	3	7	1	3	2	4
Hyperlipidaemias NEC		1				1
Hypoglycaemic conditions NEC	1	13		7	1	6
Iron deficiencies	1	1	1	1		
Lipid metabolism and deposit disorders NEC		1		1		
Magnesium metabolism disorders		1				1
Metabolic acidoses (excl diabetic acidoses)		3		2		1
Mixed acid-base disorders	1	1			1	1
Potassium imbalance	2	6	1	1	1	5
Sodium imbalance	1	1	1	1		
Total fluid volume decreased	29	114	12	67	17	47
Total fluid volume increased	6	13	5	8	1	5
	173	703	124	539	49	164

System Organ Class

**Musculoskeletal and connective tissue disorders**

Interval Total #	Cumulative Total #	Non Interventional Study	Spontaneous	
		Serious	Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathies NEC	26	99
Bone disorders NEC	7	21
Bone related signs and symptoms	65	248
Bursal disorders	4	8
Cartilage disorders	1	7
Connective tissue disorders NEC	5	16
Extremity deformities	1	7
Intervertebral disc disorders NEC	2	6
Joint related disorders NEC	6	21
Joint related signs and symptoms	451	2,033
Ligament disorders		2
Lupus erythematosus (incl subtypes)	6	11
Metabolic bone disorders		2
Muscle infections and inflammations	1	6
Muscle pains	323	1,850
Muscle related signs and symptoms NEC	131	499
Muscle tone abnormalities	5	18
Muscle weakness conditions	69	270
Musculoskeletal and connective tissue conditions NEC	116	435
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	2
Musculoskeletal and connective tissue infections and inflammations NEC	1	5
Musculoskeletal and connective tissue pain and discomfort	1,166	4,595
Myopathies	2	3
Osteoarthropathies		8
Psoriatic arthropathies	2	5
Rheumatoid arthropathies	23	42
Soft tissue disorders NEC	14	55
Spine and neck deformities		2
Spondyloarthropathies	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		25	89	1	10
1	1	5	17	2	4
1	1	60	219	5	29
		2	5	2	3
			4	1	3
				5	16
		1	6		1
		1	4	1	2
		5	14	1	7
1	1	403	1888	48	145
			2		
		1	1	5	10
			2		
			1	1	5
1	1	294	1742	29	108
		102	421	29	78
		3	11	2	7
		45	197	24	73
		105	382	11	53
			1	1	1
		1	2		3
2	3	1041	4261	125	334
				2	3
			8		
				2	5
2	2		1	23	41
		13	48	1	7
			2		
				2	4

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Synovial disorders		2				2			
Tendon disorders	8	20			7	18	1	2	
	2,438	10,302	8	9	2114	9348	324	954	

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Aural neoplasms malignant and unspecified		1		1			
Bone neoplasms unspecified malignancy	1	2		1	1	1	
Breast and nipple neoplasms malignant		3				3	
Cardiovascular neoplasms benign		1				1	
Cardiovascular neoplasms malignant and unspecified		1				1	
Central nervous system neoplasms malignant NEC	1	1			1	1	
Colorectal neoplasms malignant		1				1	
Endocrine neoplasms benign NEC		1				1	
Leukaemias acute myeloid		4				4	
Leukaemias acute NEC		1				1	
Leukaemias chronic lymphocytic	2	2			2	2	
Leukaemias chronic myeloid		1				1	
Leukaemias NEC	2	7		1	2	6	
Lymphomas unspecified NEC	1	4			1	4	
Mediastinal neoplasms malignancy unspecified NEC		1				1	
Metastases to specified sites		1				1	
Neoplasms benign site unspecified NEC		1		1			
Neoplasms malignant site unspecified NEC	5	11			5	11	
Neoplasms unspecified malignancy and site unspecified NEC	7	10	5	7	2	3	

\* I=Interval, C=Cumulative  
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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-Hodgkin's lymphomas NEC		2				2
Ovarian neoplasms malignant (excl germ cell)		1				1
Plasma cell myelomas		1				1
Plasma cell neoplasms NEC	1	1	1	1		
Prostatic neoplasms malignant	3	5			3	5
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	1	4			1	4
Skin melanomas (excl ocular)	2	2			2	2
Skin neoplasms malignant and unspecified (excl melanoma)	1	4	1	3		1
Soft tissue neoplasms benign NEC	1	1			1	1
Thyroid neoplasms malignant	1	1			1	1
	29	76	7	15	22	61

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	1	4			1	2		2
Abnormal sleep-related events		2				2		
Acute polyneuropathies	7	27				1	7	26
Alzheimer's disease (incl subtypes)	1	2					1	2
Auditory nerve disorders		3				1		2
Autonomic nervous system disorders	2	6			2	5		1
Central nervous system aneurysms and dissections	2	4					2	4
Central nervous system haemorrhages and cerebrovascular accidents	104	248					104	248
Central nervous system vascular disorders NEC	1	1					1	1
Cerebrovascular venous and sinus thrombosis	5	5					5	5
Cervical spinal cord and nerve root disorders	1	2				1	1	1

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Choreiform movements		1
Chronic polyneuropathies	1	6
Coma states	1	5
Coordination and balance disturbances	82	252
Cortical dysfunction NEC	18	41
Cranial nerve disorders NEC		2
Dementia (excl Alzheimer's type)	4	19
Demyelinating disorders NEC	1	3
Disturbances in consciousness NEC	396	1,188
Disturbances in sleep phase rhythm	2	5
Dyskinesias and movement disorders NEC	59	200
Dystonias	6	9
Encephalitis NEC		5
Encephalopathies NEC	1	3
Encephalopathies toxic and metabolic		1
Eye movement disorders	2	10
Facial cranial nerve disorders	128	376
Generalised tonic-clonic seizures	4	9
Headaches NEC	1,104	5,369
Hypoglossal nerve disorders	3	4
Increased intracranial pressure disorders	5	9
Lumbar spinal cord and nerve root disorders	6	20
Memory loss (excl dementia)	44	109
Meningitis NEC		1
Mental impairment (excl dementia and memory loss)	30	150
Migraine headaches	81	317
Mononeuropathies	10	34
Multiple sclerosis acute and progressive	8	17
Muscle tone abnormal	1	6
Myelitis (incl infective)	6	12
Narcolepsy and hypersomnia	24	105

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	5
				1	5
		50	175	32	77
		7	20	11	21
					2
				4	19
				1	3
		116	508	280	680
		2	5		
		38	159	21	41
		1	2	5	7
					5
				1	3
					1
				2	10
		6	16	122	360
				4	9
		1005	5013	99	356
				3	4
				5	9
		6	14		6
		38	84	6	25
					1
		14	76	16	74
		64	275	17	42
		7	26	3	8
				8	17
		1	4		2
				6	12
		19	94	5	11

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Nervous system cysts and polyps		1							1
Nervous system disorders NEC	8	33			6	22	2		11
Neurological signs and symptoms NEC	624	2,657	1	1	491	2224	133		433
Neurologic visual problems NEC	10	29			3	9	7		20
Neuromuscular disorders NEC	4	14			4	9			5
Neuromuscular junction dysfunction	1	4					1		4
Olfactory nerve disorders	48	221			39	195	9		26
Optic nerve disorders NEC	3	8					3		8
Paraesthesias and dysaesthesias	434	1,894			339	1548	95		346
Paralysis and paresis (excl cranial nerve)	25	73			1	1	24		72
Parkinson's disease and parkinsonism	5	12			2	5	3		7
Partial complex seizures	1	1			1	1			
Peripheral neuropathies NEC	32	97			1	11	31		86
Seizures and seizure disorders NEC	72	146			1	1	71		145
Sensory abnormalities NEC	162	689			135	620	27		69
Sleep disturbances NEC	10	50			10	50			
Speech and language abnormalities	46	171			27	107	19		64
Spinal cord and nerve root disorders NEC		6							6
Structural brain disorders NEC	3	8					3		8
Transient cerebrovascular events	15	35					15		35
Tremor (excl congenital)	125	443		1	102	355	23		88
Trigeminal disorders	3	20			3	12			8
Vagus nerve disorders	1	2					1		2
	3,783	15,206	1	2	2542	11654	1241		3552

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions not specified as induced or spontaneous	1	2			1	2
Abortions spontaneous	8	30			8	30
Foetal complications NEC	2	2			2	2
Gestational age and weight conditions	5	7			5	7
Labour onset and length abnormalities	1	4			1	4
Maternal complications of pregnancy NEC	1	1			1	1
Normal pregnancy, labour and delivery		2		1		1
Stillbirth and foetal death	2	4			2	4
	20	52		1	20	51

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products		1		1		
Device issues NEC	1	1	1	1		
Device physical property and chemical issues	2	16	2	14		2
Product distribution and storage issues	53	188	53	188		
Product label issues		1		1		
Product packaging issues		6		6		
Product physical issues	3	30	3	30		
Product quality issues NEC	7	19	7	18		1
Product supply and availability issues	11	19	11	19		
	77	281	77	278		3

System Organ Class

**Psychiatric disorders**

Interval Total #	Cumulative Total #	Non Interventional Study	Spontaneous	
		Serious	Nonserious	Serious

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Psychiatric disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Abnormal behaviour NEC	6	16
Affect alterations NEC	3	3
Anxiety disorders NEC	2	4
Anxiety symptoms	116	434
Behaviour and socialisation disturbances	6	22
Bipolar disorders	1	1
Cognitive and attention disorders and disturbances NEC	3	7
Communications disorders	1	8
Confusion and disorientation	71	218
Decreased physical activity levels		1
Deliria	13	33
Delusional symptoms	2	4
Depressive disorders	10	30
Dissociative states	1	7
Disturbances in initiating and maintaining sleep	122	467
Dyssomnias	1	1
Eating disorders NEC	16	48
Emotional and mood disturbances NEC	29	85
Fear symptoms and phobic disorders (incl social phobia)	10	42
Fluctuating mood symptoms	1	4
Hallucinations (excl sleep-related)	21	67
Impulse control disorders		1
Increased physical activity levels	13	45
Learning disorders		1
Mental disorders NEC	8	24
Mood alterations with depressive symptoms	11	32
Mood alterations with manic symptoms	1	3
Mood disorders NEC	5	14
Narcolepsy and associated conditions	1	1
Obsessive-compulsive disorders and symptoms		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	8	3	8
		1	1	2	2
		2	3		1
		103	393	13	41
		3	16	3	6
				1	1
		3	7		
		1	4		4
		42	144	29	74
			1		
				13	33
			1	2	3
		7	21	3	9
		1	6		1
		107	426	15	41
		1	1		
		13	39	3	9
		28	75	1	10
		8	38	2	4
		1	2		2
				21	67
			1		
		11	39	2	6
					1
		7	19	1	5
	1	11	30		2
		1	2		1
		4	13	1	1
		1	1		
					1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Panic attacks and disorders	20	52			16	44	4	8
Parasomnias	18	77			16	70	2	7
Perception disturbances NEC	14	35			3	7	11	28
Pervasive developmental disorders NEC	1	1					1	1
Psychiatric symptoms NEC	1	4			1	4		
Psychotic disorder NEC	3	4			1	1	2	3
Schizophrenia NEC	1	1					1	1
Sleep disorders NEC	28	106			27	102	1	4
Somatic symptom disorders	2	4			2	4		
Speech and language usage disturbances	2	2					2	2
Speech articulation and rhythm disturbances	3	14			1	7	2	7
Stereotypies and automatisms		3				2		1
Stress disorders		2				2		
Substance related and addictive disorders		1						1
Suicidal and self-injurious behaviour	6	15			1	1	5	14
Thinking disturbances	11	50			10	45	1	5
Tic disorders		3				2		1
	584	1,998		1	437	1582	147	416

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	32	116	21	91	11	25
Bladder disorders NEC	2	5	2	5		
Genital and urinary tract disorders NEC		1		1		
Glomerulonephritis and nephrotic syndrome	2	2			2	2
Myoneurogenic bladder disorders		1		1		
Nephropathies and tubular disorders NEC	4	5		1	4	4
Renal disorders NEC	3	14	1	7	2	7

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\* AE=Adverse Event  
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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure and impairment	12	38		1	12	37
Renal lithiasis	10	22			10	22
Renal neoplasms		2		1		1
Renal obstructive disorders		1				1
Renal structural abnormalities and trauma	1	2			1	2
Renal vascular and ischaemic conditions	1	2			1	2
Ureteric disorders NEC		1				1
Urethral disorders NEC		2		1		1
Urinary abnormalities	6	32	6	25		7
Urinary tract signs and symptoms NEC	10	45	7	33	3	12
	83	291	37	167	46	124

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	6	12	5	11	1	1
Breast signs and symptoms	32	103	30	98	2	5
Erection and ejaculation conditions and disorders	4	11			4	11
Lactation disorders		2		2		
Menopausal effects NEC		1		1		
Menopausal effects on the genitourinary tract	6	8			6	8
Menstruation and uterine bleeding NEC	31	81	27	76	4	5
Menstruation with decreased bleeding	3	6	3	5		1
Menstruation with increased bleeding	23	35	21	31	2	4
Ovarian and fallopian tube cysts and neoplasms	1	1			1	1
Ovarian and fallopian tube disorders NEC	2	2	1	1	1	1
Pelvis and broad ligament disorders NEC		1		1		
Penile and scrotal infections and inflammations		1		1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Penile disorders NEC (excl erection and ejaculation)		1				1
Reproductive tract disorders NEC (excl neoplasms)		3		2		1
Reproductive tract signs and symptoms NEC	5	12	4	10	1	2
Scrotal disorders NEC	2	5	2	5		
Sexual function and fertility disorders NEC	1	2		1	1	1
Testicular and epididymal disorders NEC	2	7	1	5	1	2
Testicular and epididymal infections and inflammations		1		1		
Uterine disorders NEC	3	5		1	3	4
Uterine infections and inflammations (excl cervix)		1				1
Vulvovaginal disorders NEC	11	27	7	19	4	8
Vulvovaginal signs and symptoms	3	11	2	7	1	4
	135	339	103	278	32	61

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	375	1,268	2	2	217	762	158	506
Bronchial conditions NEC	1	1			1	1		
Bronchospasm and obstruction	80	239	1	1	48	155	32	84
Conditions associated with abnormal gas exchange	7	13					7	13
Coughing and associated symptoms	207	780	1	1	175	664	32	116
Diaphragmatic disorders	1	3			1	2		1
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1	3					1	3
Laryngeal spasm, oedema and obstruction	1	17			1	4		13

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions	4	9				1	4	8
Lower respiratory tract signs and symptoms	8	46			5	37	3	9
Nasal congestion and inflammations	78	319			73	296	5	23
Nasal disorders NEC	46	147			33	114	13	33
Newborn respiratory disorders NEC	1	1					1	1
Paranasal sinus disorders (excl infections and neoplasms)	23	95			21	89	2	6
Parenchymal lung disorders NEC	7	19			2	3	5	16
Pharyngeal disorders (excl infections and neoplasms)	66	278			38	170	28	108
Pleural infections and inflammations	1	5			1	2		3
Pneumothorax and pleural effusions NEC	7	14			1	2	6	12
Pulmonary hypertensions		1						1
Pulmonary oedemas	18	42					18	42
Pulmonary thrombotic and embolic conditions	76	117					76	117
Respiratory failures (excl neonatal)	1	11					1	11
Respiratory signs and symptoms NEC	5	26			2	17	3	9
Respiratory tract disorders NEC	33	100		1	20	70	13	30
Tracheal disorders (excl infections and neoplasms)		1						1
Upper respiratory tract signs and symptoms	451	1,851	1	1	375	1526	76	325
Vascular pulmonary disorders NEC	1	1					1	1
	1,499	5,407	5	6	1014	3915	485	1492

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	8	24	8	23		1
Alopecias	16	37	14	31	2	6

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Angioedemas	19	65
Apocrine and eccrine gland disorders	182	797
Bullous conditions	26	91
Connective tissue disorders	1	4
Dermal and epidermal conditions NEC	91	349
Dermatitis and eczema	18	64
Dermatitis ascribed to specific agent	1	3
Erythemas	125	546
Exfoliative conditions	9	25
Granulomatous and deep cutaneous inflammatory conditions		1
Hyperkeratoses		1
Hyperpigmentation disorders		2
Hypertrichoses		1
Hypopigmentation disorders	1	3
Nail and nail bed conditions (excl infections and infestations)	3	6
Panniculitides	1	2
Papulosquamous conditions	1	4
Photosensitivity and photodermatitis conditions	5	18
Pigmentation changes NEC		2
Pilar disorders NEC	3	10
Pruritus NEC	223	986
Psoriatic conditions	4	10
Purpura and related conditions	11	41
Rashes, eruptions and exanthems NEC	383	1,576
Rosaceas		3
Scaly conditions		1
Sebaceous gland disorders		1
Skin and subcutaneous conditions NEC	6	9
Skin and subcutaneous tissue ulcerations	1	6
Skin dystrophies	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	5	15	60
150	705	32	92
16	59	10	32
		1	4
77	304	14	45
15	57	3	7
	2	1	1
105	465	20	81
7	21	2	4
			1
			1
	1		1
	1		
1	3		
3	5		1
1	2		
1	4		
2	14	3	4
	1		1
3	9		1
191	858	32	128
2	8	2	2
7	26	4	15
322	1340	61	236
	3		
	1		
	1		
6	8		1
1	5		1
1	1		

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin haemorrhages	6	10	5	7	1	3
Skin vascular conditions NEC		1		1		
Skin vasculitides	4	9	1	3	3	6
Skin vasomotor conditions		6		3		3
Telangiectasia and related conditions	1	1	1	1		
Urticarias	125	621	91	491	34	130
	1,275	5,337	1035	4469	240	868

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Age related issues	1	1	1	1		
Disability issues	59	195	39	151	20	44
Employment issues	1	1	1	1		
Non-occupational and unspecified environmental problems		1		1		
Social issues NEC	1	7	1	6		1
	62	205	42	160	20	45

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	2	5	2	5
	2	5	2	5

System Organ Class

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Anaesthesia and allied procedures		1		1			
Cardiac device therapeutic procedures		1		1			
Contraceptive methods female	1	1	1	1			
Dental and gingival therapeutic procedures	2	2	2	2			
Hernia repairs	1	1	1	1			
Immunisations	1	4	1	4			
Induced abortions		1					1
Skin lesion excisions		1		1			
Spine and spinal cord therapeutic procedures		1					1
Therapeutic procedures NEC	3	5	3	5			
Thyroid therapeutic procedures	1	1	1	1			
Uterine therapeutic procedures	1	1			1	1	
	10	20	9	17	1	3	

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	1	10					1	10
Aneurysms and dissections non-site specific		2						2
Aortic infections and inflammations		1						1
Aortic necrosis and vascular insufficiency	1	1			1	1		
Blood pressure disorders NEC	7	31			6	23	1	8
Circulatory collapse and shock	5	26			1	1	4	25
Haemorrhages NEC	36	83			7	14	29	69
Lymphoedemas		15				15		
Non-site specific embolism and thrombosis	116	178	1	1	2	3	114	175
Non-site specific necrosis and vascular insufficiency NEC	6	9			3	4	3	5
Non-site specific vascular disorders NEC	11	25			6	20	5	5

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Non Interventional Study		Spontaneous			
		Nonserious		Serious	
I	C	I	C	I	C
		8	10	52	79
		61	395	14	87
		22	87	4	14
		3	5		
		8	44	6	19
		1	3	1	1
1	1	29	158	38	130
		9	42	15	48
		1	2		
2	2	168	827	287	678

Peripheral embolism and thrombosis 60 89  
 Peripheral vascular disorders NEC 75 482  
 Peripheral vasoconstriction, necrosis and vascular insufficiency 26 101  
 Phlebitis NEC 3 5  
 Site specific vascular disorders NEC 14 63  
 Varicose veins NEC 2 4  
 Vascular hypertensive disorders NEC 67 288  
 Vascular hypotensive disorders 24 90  
 Vasculitides NEC 1 2

455 1,505

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**UNITED STATES MINOR OUTLYING ISLANDS**

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Vaccination site reactions		1		1
		1		1

*System Organ Class*

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**URUGUAY**

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inflammatons	1	1	1	1
Pain and discomfort NEC	1	1	1	1
	2	2	2	2

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Synovial disorders	1	1	1	1
	1	1	1	1

\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

**Appendix 3 (Referred to in Section 9.2 Overview of Signals)**

**Tabular Summary of Safety Topics and Signals Evaluated During the Reporting Period**

**Product name: PF-07302048 (BNT162b2)**

**Reporting interval: 01 April 2021 – 29 April 2021**

Please note the following items that were included in SMSR #4 (01 Mar – 31 Mar 2021) and are therefore not included in the table below:

- On 06 April 2021, the safety topics Anosmia and Ageusia were determined not to be validated signals.
- On 06 April 2021, the safety signal Extensive swelling of vaccinated limb was reviewed and determined not to be a risk.

**Table 1. Tabular Summary of Safety Topics and Signals Evaluated During the Reporting Period**

Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
<b>Signals Determined to be Risks</b>							
On 27 Apr 2021, based on review of unblinded clinical study C4591001 safety data (data lock date 13 Mar 2021), and supported by post-authorization AE reports, the following AEs were determined to be causally associated adverse reactions for Pfizer/BNT COVID-19 Vaccine: Asthenia, lethargy, decreased appetite, hyperhidrosis, night sweats. These reactions will be added to the company core data sheet and subsequently to the local product label as per Pfizer and BNT regulatory submission processes.							
<b>Signals Determined not to be Risks</b>							
Herpes Zoster, including Ophthalmic herpes zoster	05 Oct 2020 as safety topic.  Reopened 21 Feb 2021  Re-opened 26 Apr 2021	Closed	14 April 2021  30 Apr 2021	Reports of herpes zoster in clinical studies and post-authorization AE reports on non-statistical line listing review	Initially opened as safety topic and closed as no risk following review of clinical study data (C4591001).  To determine if herpes zoster including ophthalmic herpes zoster is a risk	05 Oct 2020: Review of clinical study data.  21 Feb 2021: Review of post-authorization safety and O/E analyses  30 Apr 2021: Review of post-authorization, clinical study and O/E data	The available data do not support a causal association with the vaccine. The topic will continue to be monitored.  The re-evaluation of this signal in April 2021 confirmed the above assessment

**Table 1. Tabular Summary of Safety Topics and Signals Evaluated During the Reporting Period**

Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Seizure	01 Mar 2021	Closed	06 May 2021	Routine review of post-authorization neurological events  Request from a health authority (Saudi Arabia)	To determine if seizure is a risk	Clinical study and post-authorization safety database review	The available data do not support a causal association with the vaccine. The topic will continue to be monitored.
Myocarditis and Pericarditis	15 Feb 2021  Re-opened 19 April 2021	Closed	05 May 2021	Ongoing discussions with a health authority (Israel MoH)  Request from a health authority (MHRA)	To determine if myocarditis or pericarditis is a risk	Clinical study and post-authorization safety database review	The available data do not support a causal association with the vaccine. The topic will continue to be closely monitored.
<b>Safety Topics Determined not to be Validated Signals</b>							
Nephrotic syndrome	29 Apr 2021	Closed	05 May 2021	Literature case report	To determine if this topic is a validated signal	Post-authorization safety database review	Based on the available data, this safety topic was determined not to be a validated signal
Trigeminal Neuralgia	29 Apr 21	Closed	05 May 2021	Communication from Uppsala Monitoring Centre	To determine if this topic is a validated signal	Clinical study and post-authorization safety database review	Based on the available data, this safety topic was determined not to be a validated signal
Hemolytic Anemia	16 April 2021	Closed	23 April 2021	Spontaneous Reports	To determine if this topic is a validated signal	Clinical study and post-authorization safety database review	Review of the available data do not support this topic as a validated signal

**Table 1. Tabular Summary of Safety Topics and Signals Evaluated During the Reporting Period**

Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Optic Neuritis	13 April 2021	Closed	23 Apr 2021	Request from a health authority (Singapore)	To determine if this safety topic is a validated signal	Clinical study and post-authorization safety database review	Review of the available data do not support this topic as a validated signal
Cranial nerve palsy	13 April 2021	Closed	23 Apr 2021	Request from a health authority (Singapore)	To determine if this safety topic is a validated signal	Clinical study and post-authorization safety database review	Review of the available data do not support this topic as a validated signal
Hepatic events	01 Mar 2021	Closed	19 Apr 2021	Reports of post-authorization serious hepatic events	To determine if serious hepatic events are a validated signal	Clinical study and post-authorization safety database review	Based on the available data, this safety topic was determined not to be a validated signal
<b>Ongoing Signals/Safety Topics</b>							
NA							



**Appendix 3.1 (Referred to in Section 9.2 Overview of Signals)**

**Summary of Safety Topic and Signal Evaluations**

Table 1 presents summaries of safety topics and signals for PF-07302048 (BNT162b2) during the current reporting period.

Please note the following items that were included in SMSR #4 (01 Mar – 31 Mar 2021) and are therefore not included in the table below:

- On 06 April 2021, the safety topics Anosmia and Ageusia were determined not to be validated signals.
- On 06 April 2021, the safety signal Extensive swelling of vaccinated limb was reviewed and determined not to be a risk.

**Table 1. Summary of Safety Topic & Signal Evaluations During the Reporting Period**

Signal/Topic	Summary of Evaluation
<b>Signals determined to be risks</b>	
Asthenia, Lethargy, Decreased appetite, Hyperhidrosis, Night sweats	On 27 Apr 2021, based on review of unblinded clinical study C4591001 safety data (data lock date 13 Mar 2021), and supported by post-authorization AE reports, the following AEs were determined to be causally associated adverse reactions for Pfizer/BNT COVID-19 Vaccine: Asthenia, lethargy, decreased appetite, hyperhidrosis, night sweats. These reactions will be added to the company core data sheet and subsequently to the local product label as per Pfizer and BNT regulatory submission processes.
<b>Signals determined not to be risks</b>	
Herpes Zoster, including Ophthalmic herpes zoster	Reports of herpes zoster have been followed closes in Study C4591001 and the post-authorization period. In April, a request was received by the Swiss health authority (SwissMedic) to review cases of herpes zoster including ophthalmic herpes zoster. An evaluation of the available clinical study data and post-authorization data do not support a causal association of herpes zoster in any form with the use of Pfizer/BNT COVID-19 vaccine.
Seizure	Seizures occurring after vaccination are monitored as per routine pharmacovigilance for Pfizer/BNT COVID-19 vaccine. A request for information on the topic by a health authority (Saudi Arabia FDA) prompted a review of seizures/convulsions. An evaluation of the available information is included in the current SMSR; it concluded that the present data do not support a causal association with the Pfizer/BNT COVID-19 vaccine.
Myocarditis and Pericarditis	During regular meetings with a health authority (Israeli Ministry of Health), cases of myocarditis in young males (some in Army recruits) were discussed due to their temporality to vaccination with Pfizer/BNT COVID-19 vaccine. Subsequently, requests from other health authorities were received. An evaluation including all available information is included in the current SMSR; it concluded that the present data do not support a causal association with Pfizer/BNT COVID-19 vaccine and the topic will continue to be closely monitored.
<b>Safety topics determined not to be validated signals</b>	
Nephrotic syndrome	A review of this topic was undertaken following receipt of a literature cases report of minimal change disease and nephrotic syndrome after vaccination <sup>1</sup> . Following

**Table 1. Summary of Safety Topic & Signal Evaluations During the Reporting Period**

Signal/Topic	Summary of Evaluation
	review of the post-authorization safety database cases, this topic was determined not to be a validated signal.
Trigeminal neuralgia	A review of this topic was undertaken following receipt of a draft signal report in a communication from Uppsala Monitoring Centre. Following review of clinical study and post-authorization safety database cases, this topic was determined not to be a validated signal
Hemolytic anemia	A review of this topic was undertaken following routine review of spontaneous AE reports. Following review of clinical study and post-authorization safety database cases, this topic was determined not to be a validated signal
Optic neuritis	A review of this topic was undertaken following a request from a health authority (Singapore). Following review of clinical study and post-authorization safety database cases, this topic was determined not to be a validated signal
Cranial nerve palsy	A review of this topic was undertaken following a request from a health authority (Singapore). Following review of clinical study and post-authorization safety database cases, this topic was determined not to be a validated signal
Hepatic events	A review of this topic was undertaken following routine review of spontaneous AE reports. Following review of clinical study and post-authorization safety database cases, this topic was determined not to be a validated signal.
<b>Ongoing evaluations of safety topics or signals</b>	
Not applicable	

<sup>i</sup> Lebedev L, Sapojnikov M, Wechsler A, Varadi RL, Zamir D, Tobar A, Levin-Iaina N, Fytlovich S, Yagil Y, Minimal Change Disease Following the Pfizer-BioNTech COVID-19 Vaccine, *American Journal of Kidney Diseases* (2021), doi: <https://doi.org/10.1053/j.ajkd.2021.03.010>

## **APPENDIX 3.2 SAFETY EVALUATION OF POLYNEUROPATHY AND NEUROPATHY PERIPHERAL**

### **1. INTRODUCTION**

Because the ratio of observed to expected cases analyses for Polyneuropathy in the 4<sup>th</sup> March summary monthly safety report (SMSR) exceeded 1 over both risk windows ( 21 days and no risk window) for the interval period analysis (01 March 2021 through 31 March 2021), a full evaluation was performed. In the 3<sup>rd</sup> (February) SMSR, peripheral neuropathy was found to have a 95% CI very close to 1 for the interval 21-day risk window, and the topic was evaluated and determined not to be a validated signal. This report updates the review of peripheral neuropathy and includes a review of polyneuropathy.

### **2. METHODOLOGY**

The Pfizer safety database was searched for PT Polyneuropathy and PT Neuropathy peripheral reported cumulatively up to the 31<sup>st</sup> March 2021.

Phase 2/3 Study C4591001 placebo-controlled unblinded data (data cutoff date 13 March 2021) was also reviewed for the adverse events PT Polyneuropathy and PT Neuropathy peripheral.

The analysis of the 2 different PTs reported was performed separately.

### **3. NEUROPATHY PERIPHERAL**

#### **3.1. RESULTS OF SPONTANEOUS CASES OF NEUROPATHY PERIPHERAL**

Based on the search strategy provided above, a total of 152 spontaneous cases were retrieved from Pfizer safety database.

There were 113 females, 32 males, and in 7 cases sex was not reported. All 152 cases were reported as serious. Cases originated mainly from the United States (61), United Kingdom (37), Italy (12), and Japan (10).

Age distribution was as follows: 18-30 years (12); 31-50 years (56); 51-64 years (29); 65-74 years (27); Greater than or equal to 75 years (10), and age was unknown in 18 cases (mean = 52 years; n = 133).

Upon review of reported medical history, 51 cases reported the following pre-existing conditions (some cases reported more than one condition): Autoimmune thyroiditis, Bursitis, Cerebral infarction, Cerebrovascular accident, Diabetes mellitus, Fibromyalgia, Guillain-Barre syndrome, Hereditary spastic paraplegia, Immunodeficiency, Intervertebral disc protrusion, Lumbar vertebral fracture, Meniscus operation, Multiple sclerosis, Muscular weakness, Myelitis, Nerve injury, Neuropathy peripheral, Pain in extremity, Polyneuropathy,

Posterior tibial nerve injury, Raynaud's phenomenon, Sjogren's syndrome, Small fiber neuropathy, Spinal operation, Systemic lupus erythematosus, Upper limb fracture, and Wrist surgery.

Out of these 51 cases reporting pre-existing condition(s), 8 cases reported worsening or exacerbation of peripheral neuropathy.

Out of the overall dataset of 152 cases, 35 cases reported peripheral neuropathy as the only PT.

The most commonly co-reported events reported were: Paraesthesia (32), Arthralgia, Fatigue (27 each), Headache (25), Pain in extremity (21), Pyrexia (19), Pain (18), Myalgia (17), Chills (15), Hypoesthesia, Nausea (14 each), Vaccination site pain (11), Burning sensation, Dyspnoea, Malaise (10 each). Twenty-one (21) cases reported pre-existing asthma and/or allergies.

The majority of 152 patients reported the event post Dose 1. Out of 152 cases, one case reported electromyography result (a 55-year-old female patient who experienced Neuropathy peripheral, Paraesthesia, Feeling cold, Peripheral coldness, Bone pain, Arthralgia, Burning sensation, and Pain in extremity after second dose; had multiple tests done including electromyogram with negative results).

The latency was reported for all 152 Neuropathy peripheral events. Table 1 below presents latency in days.

**Table 1. Latency in Days per Neuropathy peripheral Event**

Latency in Days	Number of Events
0 days	33
1 day	39
2 days	9
3 days	13
4 days	5
5 days	4
6 days and 7 days	6 (3 each)
11 days and 12 days	4 (2 each)
8, 9, 10, 14, 20, 24, 29 days	7 (1 each)

When reported (for 15 out of 152 events), the duration of peripheral neuropathy was 2 hours (for 1 event), within 1 day (for 4 events), 2 days (for 5 events); 3 days, 6 days (for 2 events each); and 8 days (for 1 event).

The outcomes were reported as follows: not resolved for 58 events, resolved/resolving for 61 events, resolved with sequelae for 5 events, and unknown for 28 events.

### 3.2. CLINICAL TRIAL DATA

In the Phase 2/3 Study C4591001, the event peripheral neuropathy (PT Neuropathy peripheral) was reported in 1 (0.0%) participant out of 21,926 in the BNT vaccine group and 3 (0.0%) participants out of 21,921 in the placebo group from dose 1 to 1 month after dose 2 in subjects  $\geq 16$  years of age.

### 3.3. SUMMARY

The majority of spontaneous cases of peripheral neuropathy were reported in females from the age of 31 years through 64 years. Most events occurred 1-day post vaccination date (post dose 1), with the most common outcome per the event of resolved/resolving.

## 4. POLYNEUROPATHY

### 4.1. RESULTS OF SPONTANEOUS CASES OF POLYNEUROPATHY

A total of 13 spontaneous cases were retrieved using the search criteria described above.

There were 10 females and 3 males. Age ranged between 38 and 84 years (mean: 59; N: 11). Seven cases were reported by adults ( $\geq 18$  to  $< 65$  years), 4 by elderly ( $\geq 65$ ) and for 2 subjects age was not reported. Case outcome was reported as not recovered at time of reporting in 6, recovered/recovering in 5 and unknown in 2. Most cases were reported from France (3), followed by Germany and US (2 cases each). All cases were assessed as serious.

Medical history was reported for 7 patients, and among them 3 cases reported a pre-existing polyneuropathy, 2 cases reported arthritis (one of them was co-reported with Extranodal marginal zone B-cell lymphoma and another one was co-reported with Aortic valve incompetence/ Hypothyroidism / Neurodermatitis conditions). The remaining 2 cases reported previous COVID 19 and back pain/injury respectively.

Time to onset was reported for 12 of the cases and ranged from immediately after vaccination to 12 days after vaccination (mean: 2.8 days; median: 0.5 day; N: 12).

The 3 patients ( (b) (6) , (b) (6) and (b) (6) ) reporting a polyneuropathy in the medical history reported that this event was a worsening/flare of polyneuropathy.

Details of the 10 cases that did not report underlying polyneuropathy will be described below:

One case ( (b) (6) ) reported symptoms on the day of vaccination; she was diagnosed with myelitis and mild polyradiculoneuritis. The time to onset was a short time (less than a day) after vaccination therefore biologic plausibility is questionable.

One case ( (b) (6) ) reported tetraparesis with a normal MRI on the same day as vaccination. Similarly, to the case described above, the short time to onset does not support biological plausibility of the event to be correlated with the vaccine.

Another case reported ( (b) (6) ) 8 hours after dose 2 symptoms of myalgia with ataxic gait, motor deficit, sensory disorder. EMG and other examination were normal, and the physician reported that "It is possible that she had a reaction to the vaccination, but I think the sensory motor manifestations are functional".

One patient ( (b) (6) ) with a medical history of extranodal marginal zone B-cell lymphoma and rheumatoid arthritis reported polyneuropathy 1 day post vaccination and specified that she had similar symptomatology when she received the flu vaccination (date not reported).

Three cases ( (b) (6) , (b) (6) , (b) (6) ) reported only sensory symptoms starting 3 days post vaccination (for all 3 cases). Two had an outcome of recovered/recovering (duration of 7 days) and 1 of not recovered.

One case ( (b) (6) ) reported left ulnar nerve polyneuritis 12 days post vaccination. Ulnar nerve neuritis is often reported due to trapping of the nerve on the elbow usually after trauma, deformities (eg, rheumatoid arthritis), metabolic derangements (eg, diabetes), transient occlusion of the brachial artery during surgery and is not generally associated with deltoid vaccination.

The remaining 2 cases did not report any medical history; one reported autoimmune-mediated arm plexus neuritis/brachial plexus neuritis, polyneuropathy and left arm paresis ( (b) (6) ) with a time to onset on the day of vaccination and the last case ( (b) (6) ) reported 12 days after vaccination polyneuropathy with EMG confirming the diagnosis (EMG: sensory and motor polyradiculoneuritis in the lower limbs).

## 4.2. CLINICAL TRIAL DATA

In the Phase 2/3 Study C4591001 safety population, Polyneuropathy was not reported in participants in either the BNT vaccine or placebo groups from dose 1 to 1 month after dose 2 (data cut off: 13 Mar 2021).

## 4.3. SUMMARY

In summary most cases report a time to onset of the same vaccination day (7) or one day after (1) which is not likely to be sufficient time to develop an immune response able to trigger the symptoms. Most cases (except 1) do not report any diagnostic examination to support the polyneuropathy diagnosis. Overall, there is a paucity of cases with sufficient detail.

## 5. CONCLUSIONS

The totality of the available information, including the lack of reports with objective evidence and for polyneuropathy and peripheral neuropathy, do not support them being validated signals for the vaccine. No updates to the product information label are warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

## APPENDIX 3.3 SAFETY EVALUATION OF HERPES ZOSTER

### 1. INTRODUCTION

Herpes zoster (shingles) results from reactivation of latent varicella zoster virus (VZV). The lifetime risk of zoster is estimated to be 10–30% and incidence increases markedly with age, affecting up to 50% of people who live to 85 years. It is characterized by a painful vesicular dermatomal rash and can result in chronic pain (post-herpetic neuralgia), particularly in older individuals. The virus is thought to be maintained in its latent form by VZV-specific cell-mediated immunity. Therefore, people with cell-mediated immunosuppression are at increased risk of zoster. However, these individuals only constitute a minority of zoster cases in population-based studies, and the precise determinants of VZV reactivation in people without underlying immunosuppression are unknown. Case reports and case series have suggested that mechanical trauma precipitates zoster in the affected dermatome, perhaps because stimulation of the nerve triggers reactivation of virus in the dorsal root ganglion. A recent study investigated genetic susceptibility to zoster, studying polymorphisms at the promoter region of the gene for interleukin 10 (a cytokine that can downregulate cell-mediated immunity). A significantly higher proportion (53%) of 60 immunocompetent patients with zoster carried the ATA haplotype at this region of the gene compared with 152 (38%) of 400 blood donors. It is unclear whether the risk of zoster is increased in females. Women might be more likely to seek medical advice for their zoster compared with men or may have increased prevalence of risk factors for zoster, or there may be some biological mechanism by which women are more susceptible to VZV reactivation. An increased incidence of zoster in women is unexpected given the findings from a range of studies that strongly suggested that varicella contacts protect against zoster, because women might be expected to have more social contacts with children (and therefore with varicella) compared with men. However, the lower zoster incidence in women aged 35–44 years in the Rochester study (in the pre-HIV era) and the lower risk in the same age group in the MSGP4 analysis could indicate increased contacts with school-age children (and therefore with varicella), offsetting any increased risk in women due to other factors. Psychological stress was identified as a potential risk factor for zoster that might operate by suppressing cell mediated immunity.

Additional risks factor for herpes Zoster reactivation among adults has been analyzed by Marin M et al., the article concluded that personal and family history of HZ, stress, sleep disturbance, depression, and recent weight loss were risk factors for HZ. Reactivation of dormant herpes zoster virus leading to HZD typically arises during immunocompromised or weakened immunity states, such as cancer, HIV, immune-senescence, and long-term corticosteroid use. Vaccination, including the influenza vaccine, can decrease the frequency and function of T-regulatory cells. Depletion of these cells may enable a state of immune *dysfunction*, rather than true immunocompromise, that allows for opportunistic infections.

## 2. METHODOLOGY

Pfizer's safety database contains cases of adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality. The Pfizer safety database Argus was searched for all BNT162b2 vaccine spontaneous and literature reports and serious clinical trial reports received through 31 March 2021 using the following MedDRA version 23.1 search criteria: PT: Herpes Zoster.

For completeness a separate analysis will be conducted using the following PTs: Herpes zoster infection neurological, Varicella zoster virus infection, Herpes zoster cutaneous disseminated, Herpes zoster oticus, Ophthalmic herpes zoster, Herpes zoster reactivation received through 31 March 2021 using the following MedDRA version 23.1.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

Phase 2/3 Study C4591001 placebo-controlled unblinded data (data cutoff date 13 March 2021) was also reviewed for the adverse events Herpes zoster.

## 3. RESULTS

A total of 823 cases were retrieved using the search criteria mentioned above. There were 530 (64.4%) female, 245 (29.8 %) male and for 48 (5.8%) gender was not reported.



Age was reported for 709 subjects and ranged from 19 to 103 years (mean: 59.6, median: 60; N:709). A total of 373 (45.3%) events have been assessed as serious and 450 (54.7%) as non-serious.

A total of 419 cases were reported in adults ( $\geq 18 < 65$ ), 195 were reported in elderly ( $\geq 65$ ) and for 109 cases age was not reported. Age stratification is shown in Table 1.

**Table 1. Age Stratification**

Age Range	Number of Cases	Percentage (%)
18 - 30 years	39	4.7 %
31 - 50 years	181	22.0 %
51 - 64 years	199	24.2 %
65 - 74 years	131	15.9 %
Greater than or equal to 75 years	164	19.9 %
Unknown	109	13.2 %

Most cases were reported from the UK (292, 35.5%) and from the US (210, 25.5%). A detail reporting from the top ten reporting countries is reported in Table 2.

**Table 2. Top 10 Reporting Countries**

Countries	Number of Cases	Percentage (%)
UNITED KINGDOM	292	35.5 %
UNITED STATES	210	25.5 %
FRANCE	73	8.9 %
GERMANY	45	5.5 %
ITALY	40	4.9 %
SPAIN	38	4.6 %
ISRAEL	20	2.4 %
GREECE	18	2.2 %
HUNGARY	11	1.3 %
AUSTRIA	9	1.1 %
SWEDEN	9	1.1 %

**Table 3. Number of Cases, Gender, Age and Seriousness by Country**

Country	Number of cases	Female	Male	Unknown gender	Serious cases	Non serious cases	Adult ( $\geq 18 < 65$ )	Elderly ( $\geq 65$ )	Unknown age
US	210	132	60	18	35	175	83	72	55
UK	292	200	80	12	198	94	150	122	20
EU	284	182	92	10	131	153	166	88	30

Rest of the world	37	16	13	8	9	28	21	7	9
<b>Tot</b>	<b>823</b>	<b>530</b>	<b>245</b>	<b>48</b>	<b>373</b>	<b>450</b>	<b>420</b>	<b>289</b>	<b>114</b>

Time to onset was reported from 621 cases and ranged from the same vaccination day to 81 days post vaccination (median 5 days; mean: 5.4 days). The vast majority (84%) reported time to onset within 2 weeks from vaccine administration with the majority being between the same vaccination day to 7 days after vaccination (63.7%) (Table 4).

**Table 4. Time to Onset of Herpes Zoster After Vaccine Administration**

Time to onset from vaccine administration	Number of cases
0-1 day	112 (18%)
2-4 days	181 (29.1%)
5-7	103 (16.6%)
8-14	126 (20.3)
15-30	85 (13.8%)
30-81	14 (2.2%)
Tot	621

A total of 95 subjects reported a medical history of Herpes Zoster, in addition 24 cases reported in the medical history neoplasm, 22 reported autoimmune disease and 18 Immunodeficiency.

Duration of Herpes Zoster was reported for 51 cases and ranged between 1 to 53 days (median 12 days; mean: 13.6). Outcome was reported as recovered/recovering/recovered with sequel in 354 (43%), 312 (37.9%) reported not recovered at the time of reporting and unknown for 157 (19.1) cases.

#### 4. BROADER ANALYSIS ON SPECIFIC HERPES ZOSTER REPORTING

An additional analysis on herpes Zoster including the followings PTs Herpes zoster infection neurological, Varicella zoster virus infection, Herpes zoster cutaneous disseminated, Herpes zoster oticus, Ophthalmic herpes zoster, Herpes zoster reactivation has been performed for completeness.

A total of 57 cases were retrieved using the search criteria mentioned above. The distribution by PTs is reported below in

**Table 5. Distribution by PTs**

PTs	Number of cases
Herpes zoster infection neurological	3
Varicella zoster virus infection	3

Herpes zoster cutaneous disseminated	3
Herpes zoster oticus	9 (5 associated with facial paresis/paralysis)
Ophthalmic herpes zoster	29
Herpes zoster reactivation	11
Tot*	58

\* 1 case reported 2 PTs

There were 39 females and 18 males. Age ranged between 35 to 93 years (mean: 66; N 54). There were 28 adults ( $\geq 18 < 65$ ), 26 were reported in elderly ( $\geq 65$ ) and for 3 cases age was not reported.

Outcome was reported as recovered/recovering/recovered with sequel in 29, not recovered at time of reporting for 25 and unknown in 3. Most cases were received from France (14), UK (14) Germany (9) and Spain (7). A total of 53 cases were assessed as serious and 4 as nonserious.

Medical history was reported for 34 cases and Herpes Zoster was reported in 13 cases and additional 8 subjects reported in the medical history Rheumatoid arthritis, chronic kidney disease, diabetes mellitus, Immune system disorder, ovarian cancer, hypothyroidism, previous COVID 19 , meningitis and Polymyalgia rheumatica.

Among them there were a total of 7 cases that reported associated the PT herpes zoster and were discussed already in the analysis above.

Time to onset was reported for 48 cases and ranged between the same vaccination day to 28 days post vaccination (mean: 6.8, median: 5 days). About 65% reported the time to onset between the same vaccination day and 7 days post vaccination.

A total of 39 subjects reported the vaccination dose and 28 cases reported the event after dose 1 and 11 after dose 2.

## 5. CLINICAL TRIAL DATA

In the Phase 2/3 safety population, Herpes zoster was reported in 12 participants (0.1%) of 21926 in the BNT162b2 group compared with 10 participants (0.0%) of 21921 in the placebo group in AEs reported from Dose 1 to 1 month post dose 2 during the blinded controlled follow up period.

In the Phase 2/3 safety population, Ophthalmic Herpes zoster was reported in 1 (0.0%), Herpes Zoster cutaneous disseminated in 0 (0.0%) and Herpes Zoster Oticus in 0 (0.0%) of 21926 participants in the BNT162b2 group, compared with Ophthalmic Herpes zoster reported in 1 (0.0%), Herpes Zoster cutaneous disseminated in 1(0.0%) and Herpes Zoster Oticus in 1 (0.0%) of 21921 participants in the placebo group in AEs reported from Dose 1 to 1 month post dose 2 during the blinded controlled follow up period.

## 6. EXPECTED VERSUS OBSERVED ANALYSIS

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 873 reported herpes zoster cases. The O/E ratio was below 1 for both the 21-day risk window and no risk window, indicating there was not an increased risk of herpes zoster among recipients of the BNT162b2 vaccine.

**Table 5. Observed versus Expected (O/E) Analysis of 873 Spontaneously Reported Herpes Zoster Cases through 31 March 2021**

	<b>21-Day Risk Window (6,654,996 PY)</b>	<b>No Risk Window (14,657,849 PY)</b>
O/E ratio (95% CI)	0.030 (0.028, 0.032)	0.014 (0.013, 0.015)
Expected cases <sup>a</sup>	27,551.68	60,683.49

a. Derived from 4.14/1,000 PY background rate from Pfizer Internal Study C4591004

Observed case counts were identified using the PT codes included in the herpes zoster definition (herpes zoster, ophthalmic herpes zoster, herpes zoster reactivation, herpes zoster infection neurological, herpes zoster oticus, herpes zoster cutaneous disseminated, varicella zoster virus infection). Expected case counts were derived using a background incidence rate of 4.14 per 1,000 person years<sup>1</sup>. Person years of exposure estimates were derived from publicly available information reported by countries where the BNT162b2 vaccine is authorized<sup>2</sup>. For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report.

Herpes zoster rates are known to vary by age, ranging from age-specific incidence in a US cohort ranged from 0.86 per 1000 person-years in individuals <19 years of age to 12.78 per 1000 person-years among those 80 years of age and older, with substantial increase after 50 years of age. While age-specific exposure COVID-19 vaccine exposure data are lacking to enable an age-stratified or age adjusted O/E calculation, if we conservatively applied the 0.86/1000 PY rate to the 6,654,996 PY for the 21-day risk window, we would expect 5723 cases, far fewer than the 873 that were observed.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all 873 cases were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population. To date, the majority of exposure derives from the US.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

<sup>1</sup> Pfizer Internal Study C4591004.

<sup>2</sup> <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates> (accessed 1 April 2021).

## 7. CONCLUSION

As of 31 March 2021, a total of 823 cases reported Herpes zoster, for most of them time to onset was 2 to 7 days post vaccination (50.4%) and duration, when reported, ranged between 1 to 18 days. Most cases were reported in females and 60% of cases were reported in subjects 50 years and older. Of note, some patients were on immunosuppressants or oncologic chemotherapy treatment and some others had medical histories of autoimmunity or immunodeficiency.

Additional 50 cases were reported with PTs Herpes zoster infection neurological, Varicella zoster virus infection, Herpes zoster cutaneous disseminated, Herpes zoster oticus, Ophthalmic herpes zoster, Herpes zoster reactivation. Characteristics were similar to the ones reported for the PT herpes zoster with the vast majority being reported in females (68.4%), mostly in subjects >50 years of age (78.9%) and in subjects with a previous history of Herpes zoster, on immunosuppressants, medical histories of autoimmunity, immunodeficiency or frailty conditions.

Data from clinical trials did not show a difference in the occurrence of Herpes Zoster or ophthalmic herpes zoster in study participants receiving the vaccine compared to placebo. The ratio of observed to expected cases does not exceed 1 over either risk window.

Overall, given the totality of the available information, this signal does not suggest that herpes zoster is a risk of vaccination with BNT162b2. Therefore, changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit

risk profile of the vaccine remains favorable. The topic will continue to be monitored through routine PV.

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**COVID-19 Vaccine (BNT162, PF-07302048)**

**Safety Statement: Seizure**

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## LIST OF ABBREVIATIONS

<b>Abbreviation</b>	<b>Definition</b>
COVID-19	Coronavirus Disease 2019
CSF	cerebrospinal fluid
MedDRA	Medical Dictionary for Regulatory Activities
MMRV	measles, mumps, rubella, and varicella
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Coronavirus-2; virus causing the disease COVID-19
SMQ	standardized MedDRA query
TIV	trivalent inactivated influenza vaccine
US	United States

## 1. INTRODUCTION

A convulsion, or seizure, is a transient occurrence of signs and symptoms due to abnormal excessive or synchronous neuronal activity in the brain. A seizure can be acute symptomatic for example close temporal association with a transient central nervous system or systemic insult or can be unprovoked for example occurring in the absence of precipitating factors and may be caused by a static or progressive injury. Seizures can be focal when originating within 1 part of a cerebral hemisphere or generalized when the initial activity is consistent with rapidly engaging networks distributing in bilateral cerebral hemispheres. Epilepsy is instead defined as a disorder of the brain characterized by an enduring predisposition to generate epileptic seizures. Approximately 8% to 10% of the population will experience a seizure during their lifetime and only about 2% to 3% go on to develop epilepsy.<sup>1</sup>

As per the report (version 1.2) by the ACCESS/VAC4EU initiative the estimated incidence rate of generalized convulsions/seizure (across various age categories and data sources for the population included in the health system catchment area<sup>1</sup>) is 29 per 100,000 person years.

The overall prevalence of active epilepsy is estimated to range between 5.4 and 6.9 per 1,000 subjects.<sup>2</sup> The estimated prevalence of epilepsy in children and adolescents ranges between 4.5 and 5.0 per 1,000 subjects; in ages 20–64 years the prevalence is 6 per 1000 subjects; in ages 65 years and older the prevalence is 7 per 1,000 subjects. Approximately 20–30% of the epilepsy population has more than one seizure per month. Based on the age-specific incidence rates in European studies, the estimated incidence amongst European children and adolescents is 70 per 100,000 subjects per year; in adults 20–64 years, the incidence rate is 30 per 100,000 subjects per year; in the elderly, 65 years and older the incidence is 100 per 100,000 per year.<sup>2</sup> Similarly to Europe, a US study reported the epilepsy prevalence within all US age groups was 6.8 per 1000.<sup>3</sup>

## 2. CONVULSION AND COVID-19

Neurological manifestations of COVID-19 have been described in up to 36% of patients [headache (13%), dizziness (17%), impaired consciousness (8%), acute cerebrovascular problems (3%), ataxia (0.5), and seizures (0.5%)] with COVID-19.<sup>4</sup> The neurological manifestations may be due to the direct presence of the virus in the cerebrospinal fluid (CSF) that may be an indirect consequence of hypoxia-, sepsis-, and inflammation-associated damage of biological barriers during the disease course. Nevertheless, there are several studies that report neurological dysfunction even in the absence of virus in the CSF, and rather argue against direct viral CNS penetration.<sup>5</sup> The hypothesis through which SARS-CoV-2 induces seizures in some patients is linked to a consequence of hypoxia, metabolic derangements, organ failure, or even cerebral damage.<sup>6</sup>

Case reports have been published describing meningitis/encephalitis associated with SARS-CoV-2.<sup>7</sup> Other cases<sup>8-11</sup> reported seizures in the context of SARS-CoV-2 infection without other neurological symptoms; a case was also reported where the primary presentation was

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<sup>1</sup> ACCESS, Vaccine COVID-19 virus monitoring readiness. D3-Draft-Final-Report Version 1.2, 30Apr2021

focal status epilepticus.<sup>12</sup> Nevertheless, the number of reports with new onset or acute seizures in patients with COVID-19 in relation to the overall number of Covid-19 patients suggests that a relevant lowering of seizure thresholds is a rare event. Seizures may occur in patients with a severe condition and terminal stage patients, in whom an increased seizure susceptibility can be a consequence of fever and can be secondary to blood-brain barrier damage due to hypoxia or sepsis. Although the literature does not provide relevant evidence for seizure worsening in persons with epilepsy during the course of a SARS-CoV-2 infection, there are theoretical risks, for example, seizures triggered by fever.<sup>13-15</sup>

### 3. CONVULSION AND VACCINATION

Different scientific papers studied, using the vaccine adverse event reporting system (VAERS) database, the reporting frequency of seizures after trivalent inactivated influenza vaccine (TIV) in children 6-23 months of age: McMahon et al<sup>16</sup> reported that 17% of all serious adverse event reports were seizures occurring within 2 days after vaccination. Another study<sup>17</sup> reported an average reporting frequency of 34%. In a passive surveillance study, Hambidge et al<sup>18</sup> reported that after trivalent inactivated influenza vaccine (TIV) in children 6-23 months of age, a signal for convulsions in the 3 days risk window was not detected. Similarly, Goodman et al<sup>19</sup> could not confirm in their study the high seizure reports found in previous studies since they did not detect any signal for seizures, febrile or otherwise, in the 3-day risk window after TIV.

In 2010 during the pediatric influenza vaccination program in Western Australia an increase of febrile convulsion in children was detected upon use of the Fluvax formulation. The estimate rate of febrile convulsions in children under 5 years related to receipt of the 2010 Fluvax TIV was 3.3 per 1,000 doses which is high when compared with the reported rate of 1.4 per 100,000 TIV doses in 2004-2005 administered in the US.<sup>20</sup>

The frequency of convulsion/convulsion grand mal in adults ( $\geq 18$  years old) after vaccination has been reported as a rate of 0.16 per million vaccinations.<sup>21</sup>

- A specific correlation has been found with measles, mumps, rubella, and varicella vaccine (MMRV) in children aged 10–24 months that was found to be associated with an elevated risk of seizure or febrile seizure.<sup>22</sup> Similarly, also in older children (up to 5 years) MMRV was also associated with elevated risk of seizure or febrile seizure during the first two weeks after vaccination.<sup>23</sup>

### 4. METHODOLOGY AND CASE DEFINITION

The Pfizer safety database was searched for all BNT162b2 vaccine cases (spontaneous and clinical cases) received through 18 March 2021 using the MedDRA version 23.1 using the search criteria: SMQ: Generalised convulsive seizures following immunisation (SMQ) (Narrow scope).

For further review, medically confirmed cases, without reported co-suspect drugs, and with a reported latency were considered for further evaluation. Cases reporting anaphylaxis, anaphylactic reaction or hypersensitivity type reactions were considered confounded and not included in further review. Identified cases were divided into 2 groups, those without

confounding medical history/or relevant underlying medical conditions and those with relevant underlying conditions considered to have the potential of lowering the seizure threshold (such as epilepsy, history of seizure, stroke, cerebrovascular events, dementia).

Cases with a latency from vaccination of up to 7 days were individually reviewed. In addition, all fatal cases were reviewed individually.

Phase 2/3 Study C4591001 placebo-controlled unblinded data (data cutoff date 13 March 2021) was also reviewed for relevant adverse events.

## 5. RESULTS

### Clinical Trial Results:

In the Phase 2/3 Study C4591001 (data cut-off 13 March 2021), the event Generalised tonic-clonic seizure was reported in no (0.0%) participants out of 21,926 in the BNT vaccine group and 1 (0.0%) participant out of 21,921 in the placebo group from dose 1 to 1 month after dose 2 in subjects  $\geq$  16 years of age. The event term Seizure was reported in 1 (0.0%) participant in the vaccine group and none in the placebo group.

### Pfizer Safety Database Results

A total of 576 cases were retrieved from the Pfizer safety database using the search criteria above. A total of 355 (61.6%) were females, 195 (~33.8%) were males, and for 26 (~4.7%) subjects the gender was not reported. Age ranged from less than or equal to 16 years to greater than or equal to 107 years (mean 52.2 years; n=533). Case outcome was reported as follows: fatal in 28 cases, recovered/resolving/recovered with sequelae in 365 cases, not recovered at time of reporting in 72 cases, and unknown in 111 cases. Most cases were reported from UK (177), Mexico (74), US (58) and Germany (49) (see Table 1). Most cases were assessed as serious (568) [life threatening (52), hospitalization (184) disabling (20)]; 8 cases were reported as non-serious. All but 1 of the cases were spontaneous from post-marketing, one case was reported from a clinical study.

**Table 1. Cases Countries**

Countries	Number of Cases	Percentage (%)
UNITED KINGDOM	177	30.7
MEXICO	74	12.8
UNITED STATES	58	10.1
GERMANY	49	8.5
FRANCE	31	5.4
POLAND	24	4.2
ITALY	24	4.2
NETHERLANDS	24	4.2
SPAIN	14	2.4
BELGIUM	13	2.3
ISRAEL	10	
OTHER (26 countries)	78	

The most frequent events (from the Nervous system disorders SOC) in the 576 cases are summarized in the table below:

AE	n (%) (N = 576)
Seizure	352 (61.1%)
Epilepsy	134 (23.3%)
Headache	117 (20.26%)
Dizziness	74 (12.8%)
Generalised tonic-clonic seizure	60 (10.4%)
Loss of consciousness	51 (8.9%)
Febrile convulsion	39 (6.8%)
Syncope	35 (6.1%)
Tremor	27 (4.7%)
Status epilepticus	23 (4.0%)
Confusional State	14 (2.4%)
Tonic convulsion	11 (1.9%)
Paresthesia	10 (1.7%)
Depressed level of consciousness	10 (1.7%)

The most frequently co-reported events are summarized in the table below:

AE	n (%) (N = 576)
Pyrexia	93 (16.15%)
Dizziness	74 (12.85%)
Chills	65 (11.28%)
Asthenia	59 (10.24%)
Myalgia	59 (10.24%)
Pain	58 (10.07%)
Nausea	57 (9.90%)
Arthralgia	50 (8.68%)
Fatigue	48 (8.33%)
Malaise	37 (6.42%)
Dyspnoea	35 (6.08%)
Vomiting	35 (6.08%)
Sensitive Skin	32 (5.56%)

Of the 576 cases, 422 were medically confirmed. Of these, 377 cases provided a latency for the event between 0 up to 30 days. Ten (10) cases reported co-suspect drugs, and another 20 cases co-reported anaphylaxis, anaphylactic reaction, anaphylactic shock or hypersensitivity (2) alongside the relevant events and were also excluded from further review.

Of the remaining 347 cases, there were 201 cases without a confounding medical history, and 146 cases with reports of a confounding medical history (epilepsy, seizure, stroke or other relevant neurological condition such as Dementia/Alzheimer, Down's syndrome, cerebrovascular disorder or accident, leukoencephalopathy).

### Cases without confounding medical history (n = 201)

Of the remaining 347 cases, there were 201 cases did not have a confounding medical history. Ten of these cases had a fatal outcome which are reviewed separately below.

Of the remaining 191 non-fatal cases, the majority (138) reported the relevant events on the same day or the day after vaccination; in 35 of these cases the relevant events were reported within 2 hours of vaccination. See further details on reported latency below:

- Day 0: 98 cases (35 cases within 2 hours)
- Day 1: 41 cases
- Day 2 -7: 37 cases
- >7 Days (8-21): 16 cases

Cases with a latency of up to 7 days were manually reviewed (n = 176).

Of the 176 cases (that were medically confirmed and with an event latency of 7 days or less and without confounding medical histories), 100 cases reported the dose number (1<sup>st</sup> versus 2<sup>nd</sup> dose): in 58 cases the relevant events occurred after the first dose, (in 1 of these cases it was reported that no similar reaction occurred after the 2<sup>nd</sup> dose). In 42 cases the relevant events occurred after the 2<sup>nd</sup> dose (in 7 of these cases it was stated that no relevant events had occurred after the 1<sup>st</sup> dose). In 1 case ( (b) (6) ) a relevant event was reported after both the 1<sup>st</sup> and 2<sup>nd</sup> vaccination dose. The case concerned an 81-year old male where an absence seizure was reported 36 hours after the 2<sup>nd</sup> dose; it was also reported that the patient had a tonic-clonic seizure 13 days after the 1<sup>st</sup> dose.

The most frequently reported relevant events (PTs) in these 176 cases were: Seizure (120), Febrile convulsion (30), Epilepsy (25), Syncope (22), Generalised tonic-clonic seizure / or clonic convulsion (22). Where provided (170 cases), age ranged from 16 to 107 years [16 years (3), 18-55 years (122), 56 – 75 (24), 76-107 (21)].

One hundred (100) of the 176 cases were considered to provide insufficient and/or inconclusive information (the majority of these cases did not report on medical history and/or concurrent medications) to permit a reasonable evaluation. In a further 48 cases, there were co-reported events and/or relevant ongoing medical history that were considered confounding and provided a more likely explanation for the onset of the relevant events (e.g. hyper- and hypoglycaemia, schizophrenia, reflux syncope, description of hypersensitivity type reaction, stress-related onset, previous stress-related convulsive event, hippocampal sclerosis, non-epileptic attack disorder, on anti-epileptic medication, subdural haemorrhage, COVID-19 infection, brain tumor, event unlikely to be seizure).

There were 27 cases remaining, with relevant events reported within a plausible latency window of 0 and 5 days (16 cases on the same day (10 within 2 hours of vaccination), 7 cases on day one, and 6 cases between 2 to 5 days after vaccination). Still, in some of these cases, medical history and/or concomitant medications were not reported.

Most frequent relevant PTs in these the 27 cases were Seizure (19), Headache (8), Febrile convulsion (5), Generalised tonic-clonic seizure, Epilepsy, Syncope, Dizziness (4 each), Hypotension (3), Circulatory collapse (2). If mentioned, most of the relevant events were of short duration (few seconds to minutes); one case described a febrile convulsion lasting 4 hours.

The cases with a more immediate onset (minutes up to 2 hours) tended to report vasovagal type of symptoms in association with the relevant events such as hypotension, fainting, loss of consciousness, circulatory collapse, and psychogenic seizure. A number of the cases with longer latency co-reported signs of vaccine reactivity such as fever, headache, chills, fatigue, muscle pain, arthralgia with the relevant events. Some cases reported about further diagnostic workup; except for 1 case no abnormal findings were identified. In a case (b) (6) of a patient with a symptomatic epileptic seizure 30 minutes after vaccination, an MRI of the brain and lumbar puncture showed encephalitis changes which were assessed by the reporter to be 'side effects of the vaccine'. However, based on the description of the clinical signs in the narrative ('rotational dizziness, difficulty reading texts, confused and then lowered into consciousness') it was unclear whether an actual seizure had occurred.

#### **Cases with confounding medical history (n = 146)**

There were 146 cases had underlying confounding medical conditions which could make seizures more likely to occur. Eighty-six (86) patients had a medical history of epilepsy or was on antiepileptic therapy (1), 23 patients had a history of seizure; another 37 patients reported other confounding medical history such as cerebrovascular accident, leukoencephalopathy, stroke, Trisomy/Down's syndrome, ischaemic attack, ischaemic stroke, dementia, vascular dementia, Huntington's disease, mixed anxiety and depressive disorder, bipolar disorder.

Twelve (12) of the 146 cases had a fatal outcome and were reviewed separately, see below.

The majority (106) of the remaining 134 cases reported the relevant events on the same day or the day after (in 31 of these cases the events occurred within 2 hours of vaccination). See further detail on reported latency below:

- Day 0: 68 cases (31 cases within 2 hours)
- Day 1: 38 cases
- Day 2 to 7: 21 cases
- >7 Days (8-21): 7 cases

Of the 134, 127 cases reported a latency within 7 days which were further manually reviewed.

Eighty-five (85) of the 127 cases reported the relevant the dose number (i.e. 1<sup>st</sup> versus 2<sup>nd</sup> dose); in 66 of these cases the relevant events occurred after the 1<sup>st</sup> dose (in 1 case it was reported that no similar reaction occurred after the 2<sup>nd</sup> dose). In 19 cases, relevant events

were reported after the 2<sup>nd</sup> dose (in 3 of these cases it was stated that no relevant events had occurred after the 1<sup>st</sup> dose). In 1 case ( (b) (6) ), the same events were reported both after the 1<sup>st</sup> and 2<sup>nd</sup> dose. A 43-year-old female patient (with ongoing epilepsy with 2-3 seizures per year) was reported with a generalized tonic-clonic seizure within 15 minutes of each vaccination, lasting 15 minutes.

The most frequently reported relevant PTs were: Seizure (76), Epilepsy (or status epilepticus) (63), Generalised tonic-clonic seizure (22), Tonic convulsion (3), Syncope (8). There was only 1 case reporting Febrile convulsion, though another 12 cases co-reported Pyrexia.

Where provided (123 cases), patient age ranged from 16 to 102 years [16 years (1), 18-55 years (61), 56-75 (33), 76-107 (28)].

Of the 127 cases, 47 cases provided insufficient information precluding further analysis and 32 were confounded/ provided a possible alternative explanation for the onset of the relevant events (discontinuation of anti-epilepsy medication, ongoing unbalanced epilepsy, brain abscess, drug-resistant intractable ongoing epilepsy, ongoing pneumonia, hypersensitivity reaction, stroke, hyperglycaemia, airway obstruction, hyponatraemia).

In 14 cases (of the 127) it was mentioned that ongoing epilepsy had been well controlled (no seizures in last 12 months, up to 15 years). In 7 of these cases, the onset of the relevant events occurred on the same day, in 5 of these cases within 2 hours of vaccination. In the remaining 6 cases, latency of the event was 1 day (4 cases), 2 days (2 cases) or 4 days.

In 15 cases (of the 127) it was described that the ongoing seizure was not well controlled and/or the patients had seizure events in the last 12 months. In all but 2 of these cases, the onset of the events occurred the same day, in 3 of them within 2 hours. Eight cases provided insufficient information or were considered to be further confounded (seizure the previous evening). Given that the ongoing epilepsy in these cases was not well controlled, a causal attributability of the events to the vaccine is uncertain. It is considered likely that anxiety and circumstances around the vaccination event, and in some cases fever, may represent relevant triggers for the onset of seizure events.

There were 48 cases remaining with the relevant events occurring in the selected risk window of 0 and 7 days of vaccination (26 cases of these on the same day and 14 within minutes up to 2 hours), 15 cases on day 1, and 7 cases within 2-7 days) and in the absence of other apparent additional confounding factors (other than their relevant medical history) having been reported.

The most frequently reported relevant PTs in these cases were Seizure (31), Epilepsy (16), Generalised tonic-clonic (12), Dizziness (6), Headache (4), Syncope (3).

The characteristics of the reported seizure events in the patients with medical history of epilepsy tended to be similar to those familiar for that patient, and where reported, these seizures tended to be of longer duration than those observed in the patients without confounded medical history.



### Fatal cases (n = 28 cases - 1 duplicate)

Overall, there were 27 fatal cases; 23 were reported by a medical health care professional and 4 were consumer reports. Age range of the fatal cases was 24 to 95 years (age was not reported in 1 case), and 22 patients were > 65 years of age. The reported latency was as follows: 0 days (5), 1 day (5), 2 days (3), 3 days (1), 4 days (2), 5 days (1) 9 to 27 days (9); in 1 case latency was unclear. Fifteen cases reported relevant confounding medical history (dementia (5), epilepsy, cerebral palsy and ischaemic stroke [2 each], seizure, metastases to central nervous system, vascular encephalopathy, cerebral haematoma, Huntington's disease, drug abuser, dementia/vascular dementia and (1 each).

Upon review, all but 3 cases provided a more likely alternative explanation as the potential cause of death (ongoing COVID-19 infection, ischaemic lesions due to respiratory arrest, heart failure, meningitis, cerebrovascular accident, 'ongoing intracranial process', acute renal failure, thyrotoxicosis, suspected hashish consumption), or were considered unlikely to be potentially attributable to the vaccine due to a latency of > 7 days, and/or provided insufficient information for analysis.

The remaining 3 fatal cases involved a 32-year-old and 2 elderly patients (82 and 90 years) and are summarized below. The relevant events occurred 2, 5 and 13 hours after vaccination respectively. One of the elderly patients had a history of stroke (4 years prior) and vascular encephalopathy.

**Case ID (b) (6)** : A 32-year-old male patient received the first dose of BNT162b2 on 12 Feb 2021. Medical history included thyroid hormone replacement therapy. The patient was found deceased in the bathroom by his wife 13 hours after vaccination. It was suspected that the patient may have had a seizure due to epilepsy or vomiting due to intoxication. Autopsy confirmed the cause of death was aspiration of stomach contents.

Company comment: Insufficient information regarding cause of aspiration.

**Case ID (b) (6)** (consumer report): On 08 Feb 2021 (14:30), an 82-year-old male received the 1st dose COVID-19 immunization. Medical history included heart valve replacement (2016) and he was on oxygen at night. The patient's concomitant medications were not reported. The patient had no other vaccines on the same day as the COVID vaccine. By 16:30, he had passed away. The patient waited 15 minutes after he got the shot and he felt OK. He went to eat shortly after. When he was leaving, he reached for seatbelt and was suddenly quiet. He looked as if he was electrocuted. He was nonresponsive, stiff and seizing. He threw up on the way to the hospital. The doctors performed CPR. He was intubated, vomited again, and then passed away. Awaiting autopsy outcome.

Company comment: Limited case information (limited medical history or concomitant medications, consumer report), oxygen requirement at night, elderly.

**Case ID (b) (6)** : A 90-year-old female patient received first dose of BNT162b2 intramuscular on 05 Jan 2021. Medical history included vascular encephalopathy from an

unknown date and unknown if ongoing, last stroke from Oct 2016. The patient's concomitant medications were not reported. Before vaccination the patient was 'inconspicuous', normal food ingestion. The patient experienced cerebral seizures on 05 Jan 2021. Five (5) hours after vaccination the patient developed seizure cerebral of unknown duration. The patient died on 05 Jan 2021. Death cause was reported as seizure cerebral. It was not reported if an autopsy was performed. The PEI (Paul Ehrlich Institute) assessed the causality between the event and the vaccine as unclassifiable.

Company comment: vascular encephalopathy ongoing, stroke, elderly patient, limited information.

### Observed to Expected Ratio

The Observed to Expected (O/E) Ratios for spontaneously reported convulsion, for a no-risk window (cumulative through 31 Mar 2021) was 0.045 (95% CI: 0.041, 0.049), and for a 21-day risk window (cumulative through 31 Mar 2021) was 0.1 (95% CI: 0.091, 0.108). The background rate per 100,000 person years for seizures/convulsions/seizure disorders (including febrile) was 82.90; cumulative observed cases were 549 (see Table 2 below).

**Table 2. Observed versus Expected Analyses for convulsion (through 31 Mar 2021)**

AESI	Background Rate per 100,000 Person Years (PY)	Observed Cases, Cumulative	Expected Cases, Cumulative, 21-Day Risk Window <sup>a</sup>	Expected Cases, Cumulative, No Risk Window <sup>b</sup>	Observed Cases, Interval	Expected Cases, Interval, 21-Day Risk Window <sup>c</sup>	Expected Cases, Interval, No Risk Window <sup>d</sup>
Seizures/convulsions/seizure disorders (including febrile)	82.90 <sup>#</sup>	549	5,517.0	12,151.4	291	1,928.0	2,147.9

a. 6,654,996 PY

b. 14,657,849 PY

c. 2,325,708 PY

d. 2,590,988 PY

<sup>#</sup> Pfizer Internal Data Healthcare, specific PFE\_SE\_PNG

EB05 (through 11 Apr 2021) for seizure was 1.08, for febrile convulsion was 1.079, and for generalised tonic-clonic seizure was 1.011.

## 6. SUMMARY AND DISCUSSION

There were 303 relevant cases identified which were in the considered 7-day risk window, 176 without confounding medical history, and 127 cases (~40%) with confounding medical history (epilepsy, seizure, stroke or other conditions known to lower the seizure threshold). In 80% (245) of these cases, the latency of the relevant events occurred either the same day or the day after (with 63 of the cases occurring within a 2-hour window of vaccination). Upon individual case review, there were 27 cases (of the cases without relevant medical history)

without obvious confounders, and 48 of the cases with relevant confounding medical history. No relevant cases were identified from the clinical trials.

It is known that patients with ongoing epilepsy or history of seizure, and other neurological conditions affecting the brain, have a lower seizure threshold, and therefore are more likely to develop spontaneous seizure, often in response to specific (but often unknown) triggers including stress, anxiety, unaccustomed circumstances, or fever or significant pain. Aside of fever, systemic inflammatory conditions have also been implicated to lower the seizure threshold in experimental studies- conditions which are likely to arise post vaccination, especially in patients with more severe post vaccination reactivity such as fever, chills, severe headaches, arthralgia, pain, malaise, fatigue. Such reactions can begin within hours of the vaccination and last for 1 or 2 days in most cases. This time window is corresponding to the latency window in which most of the cases in this review were reported and it would be conceivable for seizures to be triggered in the context of severe post vaccine reactivity, especially in patients with ongoing relevant history.

The cases with a more immediate onset of the relevant events (within 2 hours of vaccination) were mostly co-reported with anxiety and/or vasovagal type of reactions and upon review it is considered that these events are less likely to be of a direct consequence of the vaccine itself, and more likely to be a result of anxiety or other psychogenic precipitant. Indeed, in some cases (of those without confounding medical history) it was not clear whether a true seizure had actually occurred. It would be expected that seizure events are more likely to occur in patients with relevant pre-existing conditions such as epilepsy.

Many of the cases with a latency of 0, 1, or 2 days for the seizure events co-reported other significant post vaccination reactivity events such as fever, chills, severe headaches, arthralgia, pain, malaise, or fatigue. It would therefore be conceivable that intense inflammatory processes stimulated by the vaccine may play a role in triggering the onset of seizure events, especially in patients with a lowered seizure threshold.

Of 185 cases where a dose number was reported for the event (124 cases after the 1<sup>st</sup> versus 61 cases after the 2<sup>nd</sup> dose), only 2 cases reported a reoccurrence of relevant events after the 2<sup>nd</sup> dose. In one case (an 82-year old patient with no information on medical history or comedication), the type of events and latency were quite different (Dose 1: tonic-clonic seizure on day 13 versus Dose 2: absence seizure on day 1) which is therefore not considered indicative of a positive rechallenge. In the other case (a 43-year old patient with ongoing epilepsy with 2-3 seizures/year), the same event (generalized tonic-clonic seizure) occurred at the same latency (within 15-20 minutes).

The observed versus expected ratio for spontaneously reported convulsion was below 1, i.e. number of observed cases (576) was less than expected.

## 7. CONCLUSION

Overall, whilst a reasonable temporal relationship may have been identified between vaccination and seizure, based on the available data to date (and in consideration of the total number of relevant identified cases, the quality of the cases, the observed versus expected ratio  $< 1$ , and no signal observed in the clinical studies), there is insufficient evidence to establish a causal association between the COVID-19 vaccine and convulsion. Continued monitoring of the safety topic is recommended.

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## APPENDIX 3.5 SAFETY EVALUATION OF OPTIC NEURITIS

### 1. METHODOLOGY

Pfizer's safety database contains cases of adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality. The Pfizer safety database Argus was searched for all BNT162b2 vaccine spontaneous and literature reports and serious clinical trial reports received through 13 April 2021 using the following MedDRA version 23.1 search criteria: PT: Optic neuritis.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

### 2. RESULTS

A total of 27 cases were retrieved using the search criteria mentioned above. Gender was reported as female for 23 cases and males for 4 cases. Age ranged from 31 to 74 years of age (mean:45.7, median: 42, N: 26). Outcome: 13 recovering, 5 unknown, 8 not recovering, 1 fatal.

Time to onset varied from the same vaccination day to 27 days (mean: 7.6, median: 6 days, N: 23).

Medical history was reported for 18 cases, among the relevant medical history there are 4 cases reported multiple sclerosis and 1 optic neuritis, in addition 4 had autoimmune diseases (1 Ankylosing spondylitis and 3 Autoimmune thyroiditis) and 1 reported a basal cell carcinoma.

The following cases are indicating either a pre-existing cause or a different causality:

One case ( (b) (6) ) not reporting a medical history reported the symptoms as flared up optic neuritis.

One case ( (b) (6) ) reported right retrobulbar pain (neuritis retrobulbar) secondary to headache, another case ( (b) (6) ) reported pain on all eye movements of right eye as optic neuritis.

Two cases reported MRI consistent with multiple sclerosis ( (b) (6) ) and two additional subjects reported MRI positive for optic neuritis ( (b) (6) , (b) (6) ).

An additional case ( (b) (6) ) reported optic neuritis in the context of air embolism and respiratory distress event 7 days after Bilateral blepharoplasty.

One case ( (b) (6) ) with a medical history of Hashimoto's thyroiditis reported pain upon movement/bulb movement but MRI was normal.

Case (b) (6) reported optic neuritis after the first and the second dose (19 and 1 day after the 1<sup>st</sup> and 2<sup>nd</sup> dose respectively). MRI showed plaques suggestive of a multiple sclerosis.

An additional case ( (b) (6) ) reporting in the medical history blindness since 20 years in 1 eye, report optic neuritis 2 days after vaccination without additional information.

Overall 6 cases reported MRI results and among them 2 cases were suggestive of multiple sclerosis (one with optic neuritis in the medical history) indicating a time to onset pre vaccination, 2 cases reporting alteration compatible with optic neuritis (1 case reporting autoimmune thyroiditis and one reporting Ankylosing spondylitis) , 1 case reported a normal MRI and 1 case reported it as abnormal without any additional specification.

### 3. OBSERVED VERSUS EXPECTED ANALYSIS

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 27 reported optic neuritis cases. The O/E ratio was below 1 for both the 21-day risk window and no risk window, indicating there was not an increased risk of optic neuritis among recipients of the BNT162b2 vaccine.

**Table 1. Observed versus Expected (O/E) Analysis of 27 Spontaneously Reported Optic Neuritis Cases through 13 April 2021**

	21-Day Risk Window (8,166,481 PY <sup>a</sup> )	No Risk Window (19,355,521 PY)
O/E ratio (95% CI)	0.059 (0.039, 0.086)	0.025 (0.016, 0.036)
Expected cases <sup>b</sup>	457.32	1,083.91

a. Person year (PY) estimates through 11 April 2021

b. Derived from 5.6/100,000 PY background rate from Pfizer Internal Data Healthcare, specific PFE\_SE\_PNG.



Expected case counts were derived using a background incidence rate of 5.6 per 100,000 person years<sup>1</sup>. Person years of exposure estimates were derived from publicly available information reported by countries where the BNT162b2 vaccine is authorized<sup>2</sup>. For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all 27 cases were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population. To date, the majority of exposure derives from the US.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

<sup>1</sup> Pfizer Internal Data Healthcare, specific PFE\_SE\_PNG.

<sup>2</sup> <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates> (accessed 13 April 2021).

#### 4. SUMMARY AND CONCLUSION

Considering the overall data with subjects that reported already multiple sclerosis as comorbidity where an event of optic neuritis is part of the disease; cases having an autoimmune disease as comorbidity where a possibility of an autoimmune optic neuritis may be reported with a higher incidence compared to subjects without an autoimmune disease ; the new cases where a MRI suggest an underlying multiple sclerosis previously undiagnosed (but not new as multiple lesion usually develop during few months/years); cases reporting it exclusively as pain in the retrobulbar area and the cases where no information are reported a new signal is not evidenced. The Observed versus expected analysis does not show an increase risk.

An estimated more than 200 million doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 12 April 2021.

The ratio of observed to expected cases does not exceed 1 over either risk window.

Overall, given the totality of the available information, changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

#### APPENDIX 1

AER Number	Age	Sex	Medical History	Conmed	Events	Country	Time to onset	Outcome	Dose	Important Info
(b) (6)	31	FEMALE	Drug hypersensitivity		Optic neuritis, Vision blurred, Myelitis transverse, Multiple sclerosis	UNITED STATES	3	not recovered	1	MRI brain on 15Jan2021- White matter lesions (High, consistent with multiple sclerosis (MS)); lumbar puncture on 28Jan2021- Positive IgG bands (High, consistent with MS).
(b) (6)	33	FEMALE	Multiple sclerosis	CLADRIBINE	Multiple sclerosis, Paraesthesia, Optic neuritis, Hyperaesthesia, Vertigo, Pyrexia, Chills	UNITED KINGDOM	1	recovering	2	Multiple sclerosis as comorbidity
(b) (6)	54	FEMALE		CITALOPRAM	Optic neuritis, Blindness, Eye pain, Visual field defect, Photophobia	UNITED KINGDOM		unk	unk	
(b) (6)	31	FEMALE	Ankylosing	CERTOLIZUMAB	Optic neuritis,	ITALY	7	recovered	1	ankylosing spondylitis,

			spondylitis / Steroid therapy / Uveitis	AB PEGOL	Visual impairment					and previous right uveitis. MRI confirmed optic neuritis
(b) (6)	32	FEMALE			Optic neuritis	UNITED KINGDOM	7	not recovered	unk	
(b) (6)	68	FEMALE	Autoimmune thyroiditis / Colectomy	LEVOTHYROXINE SODIUM	Papilloedema, Optic neuritis	ITALY	4	recovering	unk	autoimmune thyroiditis. MRI of the brain with contrast confirms optic neuritis excludes degenerative or oncological pathologies
(b) (6)	46	FEMALE	Autoimmune thyroiditis / Viral myocarditis	Optic neuritis		ITALY	18	not recovered	1	Hashimoto's thyroiditis and viral myocarditis
(b) (6)	42	FEMALE			Headache, Optic neuritis, Eyelid myoclonus, Myoclonus, Pain in extremity, Vaccination site pain, Eye pain	ITALY	7	recovering	1	right retrobulbar pain (neuritis retrobulbar). PAIN secondary to headache
(b) (6)	31	FEMALE	Asthma / Clinical trial participant / Myopia / Scoliosis	LANSOPRAZOLE / SALBUTAMOL	Optic neuritis, Eye pain, Headache, Myalgia, Pain in extremity	UNITED KINGDOM	1	recovered within 3 days	1	right-sided eye pain; severe pain on all eye movements of right eye
(b) (6)	35	FEMALE			Optic neuritis	GERMANY	3	not recovered	2	
(b) (6)	65	MALE	Blindness		Optic neuritis	UNITED STATES	2	unk	1	lost vision in one eye on unspecified date, 20 years ago in the military
(b) (6)	68	FEMALE	Thyroiditis chronic	LEVOTHYROXINE SODIUM / SODIUM	Optic neuritis, Papilloedema	ITALY	4	recovered with sequelae	1	Thyroiditis chronic; OCT macula which showed right optic papilla edema with modest

				CHLORIDE						peripapillary congestion
(b) (6)	26	FEMALE			Diarrhoea, Eye pain, Optic neuritis	POLAND	6	unk	1	eye pain as symptom
(b) (6)	74	FEMALE	COVID-19 / Depression / Diabetes mellitus / Multiple sclerosis	Optic neuritis, Paralysis, Mastication disorder, Nervous system disorder, Dysarthria, Eye disorder, Exophthalmos, Eye movement disorder, Allergy to vaccine		UNITED STATES	unk	not recovered	2	underlying MS and symptoms reported as changes in her eyes
(b) (6)	44	MALE			Optic neuritis	UNITED KINGDOM	6	recovered (in 1 month)	1	reported as pain on eye movement plus very blurred grey vision mainly central
(b) (6)	45	FEMALE	Disease risk factor / Relapsing-remitting multiple sclerosis		Multiple sclerosis, Optic neuritis	NETHERLANDS	8	recovering	1	multiple sclerosis (MS) of relapsing-remitting
(b) (6)	35	FEMALE	Asthma / Autoimmune thyroiditis / Facial paralysis / Migraine / Myocarditis	Optic neuritis, Hallucination, Pain, Memory impairment, Disturbance in attention, Influenza like illness, Dizziness, Nausea, Vomiting,		GERMANY	1	not recovered	2	Hashimoto's thyroiditis. Symptoms reported as pain upon movement/bulb movement pain. MRI: normal

				Arthralgia, Vaccination site pain, Diarrhoea						
(b) (6)	61	FEMALE	Gastroesophageal reflux disease / Multiple sclerosis / Oesophagitis / Optic neuritis / Osteoarthritis	GLATIRAMER ACETATE / PANTOPRAZOLE	Optic neuritis, Multiple sclerosis relapse	UNITED KINGDOM	27	recovering	1	history included optic neuritis, oesophagitis, multiple sclerosis
(b) (6)	52	MALE	Drug hypersensitivity / Hypertension / Osteoarthritis	Optic neuritis, Malaise, Feeling cold, Pain in extremity		SPAIN	1	recovering	1	ophthalmology : suspected retrobulbar neuritis
(b) (6)	42	FEMALE			Blindness, Optic neuritis, Burning sensation, Paraesthesia, Muscular weakness	UNITED STATES	2	unk	2	
(b) (6)	68	FEMALE	Addison's disease / Hypertension / Myocardial infarction / Optic neuritis / Rheumatoid arthritis	AMLODIPINE / ESTRADIOL / FLUDRACORTISONE / HYDROCORTISONE / METOPROLOL / OLMESARTAN	Myocardial infarction, Multiple sclerosis, Optic neuritis, Pain in extremity, Fatigue, Hypersomnia, Chromatopsia, Visual impairment	UNITED STATES	19 days after the first dose and 1 day after the 2nd dose	recovering	2	MRI Head done 10Mar2021, showed plaques in parietal area suspicious for demyelinating disorder
(b) (6)	42	FEMALE	Suppressed lactation / Suspected COVID-19	Optic neuritis		UNITED KINGDOM	19	not recovered	1	
(b) (6)	57	FEMALE	Dairy intolerance / Food allergy / Multiple sclerosis	Optic neuritis, Headache, Tremor, Balance disorder		UNITED STATES	6	not recovered	1	Medical history included multiple sclerosis

(b) (6)	60	MALE	Anaphylactic reaction / Asthma / Basal cell carcinoma / Blepharoplasty / Hypersensitivity	BUDESONIDE, FORMOTEROL FUMARATE / CETIRIZINE	Air embolism, Respiratory distress, Optic neuritis	FRANCE	22	fatal	2	7 days after Bilateral blepharoplasty
(b) (6)	27	FEMALE		ESOMEPRAZOLE SODIUM / ETHINYLESTRADIOL, LEVONORGESTREL	Optic neuritis, Magnetic resonance imaging abnormal	UNITED KINGDOM	0	recovered with sequelae	unk	MRI: abnormal
(b) (6)		FEMALE			Multiple sclerosis relapse, Optic neuritis, Hypoaesthesia, Musculoskeletal discomfort, Head discomfort, Headache, Muscle disorder, Speech disorder, Dysphagia	UNITED STATES	unk	unk	unk	reported as flared up optic neuritis
(b) (6)	21	FEMALE	COVID-19 / Cardiac murmur	Optic neuritis, Blindness		UNITED STATES		recovering	2	

## APPENDIX 3.6 SAFETY EVALUATION OF CRANIAL NERVE PALSY

### 1. INTRODUCTION

Cranial nerve disorder refers to an impairment of one of the twelve cranial nerves. Cranial nerve palsy may affect a sensory nerve, causing pain or diminished sensation or the motor part of the nerve causing weakness or paralysis.

Some of the different types of cranial neuropathies include:

- **Bell's palsy:** when the facial nerve (seventh cranial nerve) is affected.
- **Microvascular cranial nerve palsy:** this condition affects the nerves in the eye. It is most common in people who have diabetes and in those who have high blood pressure.
- **Third nerve palsy:** when the third cranial nerve is affected (most common symptoms include diplopia, ptosis, enlarged pupil)
- **Fourth nerve palsy:** also called superior oblique palsy as affects the superior oblique muscle
- **Sixth nerve palsy:** also called abducens palsy.

The causes of cranial neuropathies are various and include poorly controlled diabetes or high blood pressure, head injuries, infections, strokes, and brain tumors, herpes zoster, neuro sarcoidosis, LES, vasculitis, thyroid disorders, aneurism, demyelinating diseases, collagen vascular diseases, intracranial hypertension, intracranial hypotension, subarachnoid hemorrhage, among others.

### 2. METHODOLOGY

Pfizer's safety database contains cases of adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality. The safety database was searched for: IIIrd nerve paralysis /paresis, IVth nerve paralysis /paresis, VIth nerve paralysis /paresis, IXth nerve paralysis /paresis, XI nerve paralysis /paresis, Cranial nerve disorder, Cranial nerve paralysis, Paresis cranial nerve cases reported up to the 20<sup>th</sup> April 2021.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

### 3. RESULTS

A total of 51 cases were retrieved using the search criteria mentioned above. There were 23 female and 26 males and gender was not reported for 2 cases.

Age ranged from 30 to 93 years (mean: 61.9, N: 47), there were 25 adults ( $\geq 18 < 65$ ) and 22 elderly ( $\geq 65$ ) and for 4 subjects age was not reported.

Outcome was reported as recovered/recovering for 16, not recovered at time of reporting for 27, unknown in 7 and fatal in 1 case. Most cases were reported from UK (11, 21.6%), US (11, 21.6%), and Italy (10, 19.9%).

A total of 48 cases were assessed as serious and 3 as non-serious. Time to onset ranged from 1 to 21 days (mean: 7.1, median: 6, N: 46). A total of 23 cases reported the event after the first dose with a time to onset ranging from 1 to 21 days (mean: 7.9, Median: 6 days, N: 21) and 12 after the second vaccine dose and reported a time to onset ranging from 1 to 21 days ( mean: 6.8, median: 3, N: 11).

Medical history was reported in 37 cases. relevant medical history is reported in detail in Table 1.

**Table 1: Relevant Medical History**

Medical history	Number of cases
Hypertension	13 (2 associated with diabetes)
diabetes	5
Multiple sclerosis	1
Polycitemia vera/coagulopathy	3
Neoplasm	2
VIth nerve paralysis	1
IIIrd nerve paralysis	1
Thyroid disorders	2
Transient ischemic attack, intracranial hemorrhage	3
Pulmonary embolism	2
total	33

\*: few cases may report more than 1 pathology as comorbidity

Most cases reported VIth nerve paralysis followed by IIIrd and IVth as shown in Table 2.



**Table 2: Number of cases by specific PTs**

PT reported	Number of cases
VIth nerve paralysis /paresis	20
IIIrd nerve paralysis /paresis	14
IVth nerve paralysis	6
Cranial nerve disorder/ Cranial nerve paralysis	9 (3 VII nerve paralysis)
Paresis cranial nerve	3
*Total	53

\*Total is higher of the number of cases because few cases reported more than one event

Cases that have an alternative plausible aetiology are discussed below:

One case ( (b) (6) ) reported the event in the context of vasculitis and pulmonary embolism.

One case ( (b) (6) ) report in the MRI lesion appearing inflammatory in nature found in the Pons at origin of Cranial Nerve 6 and was diagnosed as possible Multiple sclerosis.

One case ( (b) (6) ) reported the event as occipital and retro auricular neuralgia as flare of MS.

Three cases reported VII nerve palsy and will be analyzed with all bell's palsy cases ( (b) (6) , (b) (6) , (b) (6) ).

One case ( (b) (6) ) reported in the CT scan data suggestive of a semi-recent stroke.

One case ( (b) (6) ) reported idiopathic intracranial hypertension.

One case ( (b) (6) ) reported a possible transient ischemic attack.

One case ( (b) (6) ) 8 hours after vaccination developed Covid and the cranial nerve disorder developed in the context of Covid infection.

In addition, a total of 13 cases reported negative CT or MRI but 7 had a concomitant comorbidity that put the subject at increased risk to develop palsy (hypertension, neoplasm, thyroid issue, polycythemia vera).

Among 28 cases that did not report a diagnostic examination 13 had a concomitant comorbidity that represent a confounding factor as diabetes, hypertension, pre-existing VIth nerve paralysis, polycythemia vera, previous transient ischemic attack and thyroid issues. The other cases did not report sufficient information for a proper diagnosis.

One case ( (b) (6) ) reported a rechallenge, the summary of the case is reported below:  
 A 44-year-old female patient received BNT162B2, 1st dose on 24Jan2021 and 2nd dose via on 14Feb2021. Medical history included ongoing allergy and migraine. There were no concomitant medications. On 24Jan2021 vaccine was administered into the left arm and approximately 15

minutes later, a one-time 15-second-lasting tiny muscle twitching on the left side of her face near the nose occurred, which was reported as probably due to nervousness. Two days after, the patient experienced mild headache, vaccination site was red and painful and she felt sensation of mild stiffing, tingling of left half of the face till in the evening the patient noticed mild lips asymmetry. Three days later the subjects experience migraine and saw that tongue directed slightly to one side. Neurologist said that it was an incomplete left-sided paresis of facial nerve. Conclusion of the physician on 02Feb2021 was lesion of mild extinction for cranial nerve VII, XII a V (left side) as a follow-up to vaccination, which was slowly recovering and recommended vitamin therapy. Outcome of the events was recovering. The patient had the 2nd dose and the events recurred.

One case ( (b) (6) ) reported a fatal outcome, the summary of the case is reported below. A 49-year-old patient of an unspecified gender received bnt162b2 on 14Jan2021. The patient's medical history and concomitant medications were not reported. The patient experienced one day after vaccination left hemisoma hyposthenia and deviation of the oral rhyme. The diagnosis was right arteria carotide dissection and the subject was hospitalized in the Neurology Department. Angio CT (computerised tomogram) intracranial vessels and CT skull neck vessels were performed for thrombolysis. The patient presents worsening of the clinical picture. Interventional neuroradiology is contacted and after viewing the images he recommends centralization for possible thrombectomy. The outcome of events was reported as fatal on an unspecified date.

#### 4. CONCLUSION

A total of 53 cases reported a cranial nerve disorder. Three were referring to a VII nerve paresis/paralysis and will be discussed separately in another review. In the remaining 50 cases most had either an alternative diagnosis or underlying comorbidities that are confounding factors and the few remaining did not report sufficient information for a proper evaluation.

Overall, given the totality of the available information, and the context in which the event was presented, changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

## **Pfizer-BioNTech COVID-19 Vaccine**

### **Myocarditis and Pericarditis**

#### **Report Prepared by:**

#### **BioNTech-Pfizer**

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## 1. INTRODUCTION

Myocarditis is an inflammation of the heart muscle that may present with chest pain, palpitations, arrhythmias and/or heart failure. It may occur in children and adults and is more common in young men than young women. An estimated global prevalence of myocarditis is 22 cases per 100,000 patients. Diagnostic work-up may include serum cardiac biomarkers such as troponins and creatine kinase, electrocardiogram, echocardiography, cardiovascular magnetic resonance imaging and endomyocardial biopsy (diagnostic gold standard). Etiologies can include infection (most commonly viral), autoimmune (e.g. sarcoid and systemic lupus erythematosus) and drugs or toxins. In 50% of cases, acute myocarditis resolves quickly within 2-4 weeks, however 25% may develop persistent cardiac dysfunction and 25% may deteriorate to end-stage dilated cardiomyopathy. Treatment is dependent on presentation and may be directed at a specific etiology, if determined, heart failure and arrhythmias, if present.<sup>123</sup>

Pericarditis is an inflammation of the pericardial sac that contains the heart and fixes it to the mediastinum. Males between 20-50 appear to be at highest risk for pericarditis. The incidence has been reported to be about 28 cases per 100,000 in an urban Italian area. Diagnosis of acute pericarditis is made if 2 of 4 clinical criteria are met: 1. Pericardial chest pain, 2. Pericardial rub on auscultation, 3. ECG changes, 4. Pericardial effusion. Etiologies can remain unknown in 40-85% of patients with pericarditis but may be microbial (most commonly viral > bacterial) or autoimmune (e.g. systemic lupus erythematosus, rheumatoid arthritis) or neoplastic. It can be self-limiting or complicated by pericardial effusion and constriction (tamponade). Treatment is directed at inflammation with colchicine or other NSAIDs, aspirin, corticosteroids and anakinra (IL-1 receptor antagonist). Recurrences occur in about 30% of patients.<sup>4</sup>

Myocarditis is not a common feature of COVID-19 but has been reported in case reports and case series. Ho et. al reviewed the literature for cases of myocarditis and found 51 patients: 12 with confirmed (by cardiac magnetic resonance imaging or endomyocardial biopsy) and 39 with possible (cardiac biomarkers, ECG and/or echocardiograms) myocarditis. Patients had a median age of 55 and 69% were male. In general, they presented with the range of symptoms seen in myocarditis of other etiologies. Mortality was 27%.<sup>5</sup>

## 2. METHODOLOGY

Pfizer's safety database contains adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse

event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

The safety database was searched for spontaneous AE reports for Pfizer/BNT COVID-19 vaccine using the search criteria: PT Pericarditis, PT Myocarditis and PT Pericardial effusion, cumulative to 17 April 2021.

### **3. RESULTS**

#### **3.1. Unblinded clinical study data**

Unblinded clinical study data from C4591001 (data-lock 13 Mar 2021) was searched for cases of myocarditis and pericarditis. During the blinded placebo-controlled follow-up period, there was one report of myocarditis in the placebo group and one report of pericarditis in the BNT162b2 group, a 66 year old white male who had pericarditis 29 days after dose 2 of vaccine which was ongoing at the time of the data cut-off. It was assessed as not related to study intervention by the investigator.

#### **3.2. Post-authorization data**

The search identified 278 reports. Thirty-one (31) reports were coded with the PT Pericardial effusion (without Pericarditis or Myocarditis). One hundred four (104) reports were coded with the PT Pericarditis, one hundred twenty-seven (127) reports were coded with the PT Myocarditis and sixteen cases (16) contained both PTs Pericarditis and Myocarditis. At the time of this search the number of spontaneous AE reports in the safety database for BNT162b2 was 133,166.

##### **3.2.1. Pericardial effusion**

All but 2 of the 31 reports coded with the PT Pericardial effusion (without pericarditis or myocarditis) were reviewed and eliminated from further consideration because they did not contain enough clinical detail to understand the clinical scenario or they described a pericardial effusion most likely attributed to another disease process such as neoplasm, acute

myocardial infarction, stroke, pulmonary embolism, exacerbation of congestive heart failure, or multiple organ failure. There was one death among these 29 cases.

- (b) (6) : a 75 year old man in the US with a history of diabetes mellitus 2 on multiple medications including for diabetes, hypertension and hyperlipidemia received the vaccine on 03 Feb 2021 and 10 days later presented to the ED with fever, headache, and upset stomach. He had a negative COVID-19 nasal swab at that time and the doctor thought he may be having a delayed reaction to the vaccine. He improved and on 19 Feb had another fever. He returned to the ED on 21 Feb after vomiting and losing consciousness, had another negative nasal swab, and arrested and could not be resuscitated. Results of a CT scan that he was sent for prior to his arrest showed COVID-like pneumonia and pericardial effusion which was felt to be his cause of death. An autopsy was not performed.

### 3.2.2. Pericarditis

The remaining 2 cases ( (b) (6) and (b) (6) ) were considered with the cases of pericarditis as they noted pericardial effusions caused by a virus, therefore they are described with the pericarditis cases. A total of 106 reports described pericarditis, including these 2 cases. However, 13 of the reports have alternative explanations for potential pericarditis including current COVID-19, history of autoimmune condition, renal failure and histories of tuberculosis. One additional report contained no information describing pericarditis.

Of the remaining 92 reports, ages ranged from 17 to 88 (mean 51.6, median 49) and there were 49 males and 42 females. Country of origin were distributed as follows: US (22), France (19), Israel (14), UK (13), Spain (8), Italy (6), Norway (3), Netherlands (2) and 1 each from Sweden, Romania, Portugal, Japan and Canada. Forty-seven (47) of the cases occurred following dose 1 of the vaccine, 32 after dose 2 and 13 reports did not specify the dose of vaccine. Time from vaccination to pericarditis onset was specified in all but 8 reports:

- Same day as vaccination: 6
- Day after vaccination: 15
- 2 to 7 days after vaccination: 31
- 8 to 21 days after vaccination: 23
- 22 to 41 days after vaccination: 10

Outcomes of pericarditis for the remaining were as follows:

- Recovered/Recovered with sequelae: 12
- Recovering: 37
- Not recovered: 20

- Unknown: 22
- Death: 1
  - (b) (6) : 72-year-old woman in the UK with a medical history of high cholesterol, acute myeloid leukaemia, hypertension elevated body mass index, GERD with unreported concomitant medications except chemotherapy with ado-trastuzumab emtansine at an unspecified time. She had her first vaccination on 18 Feb 2021 and developed chest pain on 21 Feb. She was hospitalized and was COVID-19 negative and neutropenic. A CT of the chest showed bilateral atelectasis and pericardial effusion. On 25 Feb, she went into cardiac arrest twice and died on 26 Feb 2021 reportedly due to pericarditis. It was not reported if an autopsy was performed.

Fourteen of the 92 patients had a history of pericarditis prior to vaccination and 7 had a history of COVID-19; one reported having influenza in the previous month. Of the 92 cases of pericarditis, 24 reported having ECGs, 27 reported having echocardiograms and 15 reported having both. Fifteen reports described pericardial effusions or pericardiocentesis being performed. One case described pericarditis occurring after dose 1 and dose 2.

- (b) (6) : 42-year-old man in Israel with a medical history of hypertension, dyslipidemia, smoking and tooth extraction (received antibiotics) at an unspecified time. The patient was reported to have perimyocarditis at an unspecified time after dose 1 and pericarditis after dose 2. The outcome was unknown, and no further details were provided.

### 3.2.2.1. Pericarditis – cases reported from Israel

Of the 14/92 cases of pericarditis reported from Israel, the ages ranged from 17 to 70 years (mean 37.0, median 32) and there were 12 males and 2 females. Five cases occurred after dose 1 and 9 occurred after dose 2. Seven cases occurred from 1 to 7 days following vaccination. One patient had a history of pericarditis, one with prostate and bladder cancer and one with a history of aortic valve replacement.

### 3.2.3. Myocarditis

One hundred twenty-seven (127) cases reported myocarditis. Of these reports, 16 had alternative explanations for myocarditis including current COVID-19, autoimmune disease and acute coronary syndromes. Two reports contained insufficient information about the reported event of myocarditis and 1 case was reported for a 4-month-old in the UK and was suspicious for an inaccurate report

Of the remaining 108 reports, ages ranged from 16 to 81 (mean 30.8, median 27) and there were 82 males and 25 females. Reporting countries were Israel (54), US (11), UK (9), Germany (9), France (5), , Italy (5), Sweden (4) Spain (2), Japan (2) and 1 each from Portugal, Poland, Greece, Finland, Denmark, Czech Republic and Canada. Eighteen (18) of the cases occurred following dose 1 of the vaccine, 75 after dose 2 and 15 reports did not

specify the dose of vaccine. Time from vaccination to myocarditis onset was not specified in 30 reports; the remaining times to onset were:

- Same day as vaccination: 14
- Day after vaccination: 16
- 2 to 7 days after vaccination: 40
- 8 to 21 days after vaccination: 7
- 27 days after vaccination: 1

Outcomes for the remaining were as follows:

- Recovered/Recovered with sequelae: 12
- Recovering: 14
- Not recovered: 18
- Unknown: 62
- Death: 2
  - (b) (6) : 47-year-old man in Israel with a medical history of diabetes (with target organ damage), hypertension, high cholesterol and hypothyroidism received his first dose of vaccine on an unspecified date. He presented to the ED with fever for 3 days, cough and difficulty breathing when laying down. He was anesthetized and resuscitated due to his rapidly deteriorating condition. He was diagnosed with myocarditis and died due to the condition at an unspecified time. It was not reported if an autopsy was performed.
  - (b) (6) : 19-year-old man in Israel with no underlying medical conditions. At an unspecified time following his second dose of the vaccine, he had an accelerated heartbeat and shortness of breath along with sharp pain radiating down his left arm. Labs revealed cardiac inflammation and he was diagnosed with myocarditis. He died 5 days following the 2<sup>nd</sup> dose. It was not known if an autopsy was done.

Three of the 108 patients had a history of myocarditis or myopericarditis prior to vaccination and 8 had a history of COVID-19. Of the 108 cases, 61 did not describe the use of cardiac biomarkers or diagnostic imaging studies. The remaining 47 cases had varying combinations of inflammatory biomarkers (e.g. C-reactive protein), cardiac biomarkers (e.g. Troponin), imaging studies (e.g. ECGs, echocardiograms, angiograms, cardiac magnetic resonance imaging). None of the reports described the gold-standard for diagnosis: endomyocardial biopsy for histology.



### 3.2.3.1. Myocarditis - cases reported from Israel

Of the 54/108 cases of myocarditis reported from Israel, the ages ranged from 16 to 56 years (mean 25.3, median 22.5) and there were 50 males and 4 females. Seven cases occurred after dose 1 and 44 occurred after dose 2 (3 unspecified). Four cases occurred on the same day as vaccination, 21 occurred from 1 to 5 days following vaccination. One 21-year-old patient had a history of myocarditis at the age of 14, and a 37-year-old patient had a history of perimyocarditis in the past due to streptococcal infections and responds well to colchicine. His last episode was 7 years ago. The majority of the 54 cases did not provide lab or imaging study detail and most outcomes (51) were unknown.

### 3.2.4. Both Pericarditis and Myocarditis

There were 16 reports that coded both myocarditis and pericarditis. For these cases, ages ranged from 17 to 81 (mean 31.2, median 25) and there were 12 males and 4 females. Reporting countries were Israel (12), France (2) and Austria and Germany (1 each). Eight (8) of the cases occurred following dose 1 of the vaccine, 4 after dose 2 and 4 reports did not specify the dose of vaccine. Time from vaccination to myocarditis onset was not specified in 3 reports; the remaining times to onset were:

- Day after vaccination: 2
- 2 to 7 days after vaccination: 9
- 8 to 21 days after vaccination: 2

Outcomes for the cases were as follows:

- Recovered 4
- Recovering: 6
- Not recovered: 1
- Unknown: 4
- Death: 1
  - (b) (6): 81-year-old woman in Austria with a medical history of COVID-19 (Dec 2020), meningioma, stroke with residual hemiparesis, hypertension and diabetes; concomitant medications were not reported. Two days prior to vaccination she developed a cough and cold, but her lungs were clear to auscultation on the day of vaccination. Three days following vaccination she had septic shock and multiple organ failure as well as extensive myocarditis and pericarditis with lactate and inflammation labs increased. She died 2 days later despite hemofiltration. The reporter did not think the vaccine caused the patient's death "but may have intensified the course." An autopsy confirmed pericarditis and myocarditis.

One of the 16 patients had a history of 3 episodes of pericarditis, one caused by EBV. This patient and 2 others had histories of COVID-19. Of the 16 cases, 2 described elevated troponins and 2 described cardiac MRIs showing myocarditis and pericarditis; a third case described an echocardiogram that showed pericarditis and effusion.

#### **3.2.4.1. Both Pericarditis and Myocarditis – cases reported from Israel**

Of the 16 reports coding both myocarditis and pericarditis, 12 were reported from Israel. Ages ranged from 17 to 48 years (mean 27.4, median 25) and there were 11 males and 1 female. Six cases occurred after dose 1 and 3 occurred after dose 2 (3 unspecified). Eight cases occurred from 1 to 3 days following vaccination, 1 occurred at 10 days and 3 were unspecified. None of the 12 patients described a history of myocarditis or pericarditis and none provided cardiac biomarkers or cardiac imaging studies. Eight of the patients tested negative for acute COVID-19 and 6 were diagnosed with concomitant multisystem inflammatory syndrome – adult (MIS-A). Outcomes were recovered (4), recovering (4) and unknown (4).

#### **3.2.5. Applying a standard definition to cases of myocarditis**

A recent publication by Bonaca et al.<sup>6</sup> proposed a case definition for myocarditis. The publication focused on patients receiving oncologic therapies, however the information on myocarditis and approach to diagnosis is aligned with current myocarditis literature and guidance.

With the exclusion of all other diagnosis/explanations (e.g. acute coronary syndrome) for myocarditis, the group defined 3 levels of certainty to be used in clinical studies.

- **Definite myocarditis:**

1. Tissue pathology **OR**
2. Diagnostic cardiac magnetic resonance imaging (CMR) + clinical syndrome + elevated biomarker or ECG evidence, **OR**
3. New wall motion abnormality on echocardiogram + Clinical syndrome + elevated biomarker + ECG evidence + Negative angiography

- **Probable myocarditis:**

1. Diagnostic CMR without any of the following: clinical syndrome, elevated biomarker or ECG evidence **OR**
2. Suggestive CMR with at least one of the following: clinical syndrome, elevated biomarker or ECG evidence **OR**
3. New wall motion abnormality on echocardiogram and clinical syndrome and 1 of the following: elevated biomarker or ECG evidence **OR**

4. Possible myocarditis with PET scan evidence and no alternative diagnosis

• **Possible myocarditis:**

1. Suggestive CMR without any of the following: clinical syndrome, elevated biomarker or ECG evidence OR
2. New wall motion abnormality on echocardiogram and one of the following: clinical syndrome, ECG evidence OR
3. Elevated biomarker and one of the following: clinical syndrome, ECG evidence

The above definitions were applied to the spontaneous cases of myocarditis (108) and both myocarditis and pericarditis cases (16). Of these 124 cases, 21 cases met the definition of possible myocarditis, 10 met the definition of probable myocarditis and 8 met the definition of definite myocarditis.

Cases of definite myocarditis consisted of 5 males and 3 females ages 19 to 81 (mean 34.4, median 28.5). Most myocarditis (6 cases) occurred following dose 2 of vaccine. The most common time to onset interval was 1 to 7 days (6 cases).

Cases of probable myocarditis consisted of 4 males and 6 females ages 12 to 81 (mean 38.6, median 35). Most cases (5) occurred after dose 1 of vaccine and the most common time to onset interval was tied between the same day (4 cases) and 1 to 7 days (4 cases).

Cases of possible myocarditis consisted of 11 males, 9 females and 2 patients of unspecified sex. Ages ranged from 16 to 56 (mean 34.5, median 32) and most cases occurred after dose 2 (14). The most common time to onset interval was 1 to 7 days (15 cases).

**Table 1. Eight Cases of Definite Myocarditis (Bonaca Criteria)**

AER Country Age/Sex	Certainty Dose	Findings
(b) (6) France 19 year/Male	Definite 2	Chest pain, Elevated troponin, Cardiac MRI: subepicardial edema in lateral wall, Echo: effusion
(b) (6) Italy 26/Male	Definite 2	Chest pain, Elevated troponin, CMRI: edema and acute myocardial changes, Echo: lower IVS hypokinesia
(b) (6) Spain 29/Male	Definite Unspecified	Chest pain, Echo: inferior hypokinesia, CMRI: compatible with acute myocarditis; Angiogram: normal
(b) (6) Italy 24/Male	Definite 2	Chest pain, ECG: arrhythmia, CMRI: acute myocarditis, Angiogram: normal
(b) (6) Denmark 31/Male	Definite 2	Chest pressure, Elevated troponin, CMRI: perimyocarditis

**Table 1. Eight Cases of Definite Myocarditis (Bonaca Criteria)**

AER Country Age/Sex	Certainty Dose	Findings
(b) (6) UK 37/Female	Definite 2	Chest pain, Elevated troponin, ECG: T wave abnormalities; CMRI: edema, subepicardial abnormalities, Angiogram: normal
(b) (6) Austria 81/Female	Definite 2	Diagnosis on tissue pathology (autopsy)
(b) (6) France 28/Female	Definite 1	Chest pain, Positive troponin, CMRI: Edema of left ventricular myocardium

**Table 2. Ten Cases of Probable Myocarditis (Bonaca Criteria)**

AER Country Age/Sex	Certainty Dose	Findings
(b) (6) Sweden 47/Female	Probable Unspecified	Chest pain, CMRI: revealed myocarditis
(b) (6) UK 35/Female	Probable Unspecified	Elevated troponin, CMRI: diagnostic of myocarditis; Angiogram: normal
(b) (6) Italy 21/Male	Probable 2	Elevated troponin, CMRI: suggestive of myocarditis
(b) (6) US 43/Male	Probable 1	Arm pain, CMRI: resulted in diagnosis of myocarditis, Angiogram: resulted in diagnosis of myocarditis
(b) (6) France 81/Female	Probable 2	Chest pain, Elevated troponin, Echo: favored myocarditis, Angiogram: normal
(b) (6) Israel 21/Male	Probable 2	Chest pain, Elevated troponin, ECG changes, Echo: decreased ejection fraction
(b) (6) UK 35/Female	Probable 1	Dizziness, tachycardia; Telemetry (ECG): normal, Echo: normal; CMRI: myocarditis
(b) (6) France 53/Male	Probable 1	Chest pressure, Echo: consistent with myopericarditis, CMRI: consistent with myopericarditis
(b) (6) UK 25/Female	Probable 1	Congestive heart failure symptoms, Elevated troponin, Echo: effusion and decreased ejection fraction
(b) (6) France 25/Female	Probable 1	Chest pain, Elevated troponin, CMRI: Pericarditis with or without myocarditis, ECG: normal, Echo: normal

**Table 3. Twenty-one Cases of Possible Myocarditis (Bonaca Criteria)**

AER Country Age/Sex	Certainty Dose	Findings
(b) (6) Germany 27/Male	Possible 2	Chest tightness, Elevated CK and troponin, CMRI: normal
(b) (6) UK 32/Female	Possible 2	Chest pain, Elevated troponin, ECG: ST elevations
(b) (6) Israel 16/Male	Possible 2	Chest pain, ECG: "bad"
(b) (6) Sweden 32/Male	Possible Unspecified	Chest pain, Elevated troponin, Echo and Angiogram: unremarkable
(b) (6) Canada 35/Female	Possible 1	Palpitations, effort intolerance; Elevated troponin, ECG: Tachycardia, Echo and Angiogram: normal
(b) (6) US 46/Female	Possible 1	Congestive heart failure symptoms, Echo: decreased ejection fraction
(b) (6) Sweden 54/Female	Possible Unspecified	Chest pain, Elevated troponin, ECG: ST elevation, Echo: normal
(b) (6) US 30/Male	Possible 2	Chest pain and shortness of breath, Elevated troponin, ECG: J-point elevation; Angiogram: normal
(b) (6) UK 56/Female	Possible 2	Chest pain, Elevated troponin, ECG: abnormal, Angiogram: showed effusion
(b) (6) Japan 27/Male	Possible 2	Chest pain, Elevated cardiac biomarker, ECG: abnormal, CMRI: performed but results not provided
(b) (6) Italy 29/Male	Possible 2	Chest pain, Elevated troponin
(b) (6) US 35/Female	Possible 2	Chest pain, shortness of breath, Elevated troponin, ECG and Echo: results unknown
(b) (6) US 43/Male	Possible 2	Chest pain, Elevated troponin, Angiogram: results not provided
(b) (6) UK 50/Female	Possible 1	Shortness of breath on exertion, Elevated troponin, ECG and Echo: results not provided
(b) (6) Germany 34/Female	Possible 1	Chest pain, Elevated troponin
(b) (6) Israel 19/Male	Possible 2	Chest pain, Elevated troponin, ECG: Sinus tachycardia

**Table 3. Twenty-one Cases of Possible Myocarditis (Bonaca Criteria)**

AER Country Age/Sex	Certainty Dose	Findings
(b) (6) Israel 24/Male	Possible 2	Chest pain, Elevated troponin
(b) (6) Czech Republic 38/Male	Possible 2	Burning chest pain, shortness of breath with activity; Elevated troponin
(b) (6) US 44/Female	Possible Unspecified	Chest pain, Elevated troponin
(b) (6) Japan 25/Male	Possible 2	Chest pain, Elevated troponin, ECG: ST elevation
(b) (6) Poland 28/Unspecified	Possible 2	Dyspnea, Tachycardia; Elevated cardiac biomarker

**4. EPIDEMIOLOGY**

The MAH conducted age-stratified observed to expected ratio (O/E) analyses for myocarditis and pericarditis for the summary monthly safety report.

**Table 4. Age-Stratified Observed to Expected (O/E) Ratios of Myocarditis and Pericarditis**

Age group	21-Day Risk Window		No Risk Window	
	O/E Ratio	95% CI	O/E Ratio	95% CI
<b>Myocarditis</b>				
18-64 years	0.607	0.514, 0.712	0.226	0.191, 0.265
65+ years	0.024	0.009, 0.052	0.009	0.003, 0.020
<b>Pericarditis</b>				
18-64 years	0.098	0.080, 0.119	0.037	0.030, 0.044
65+ years	0.045	0.033, 0.060	0.017	0.012, 0.022

**Table 5. Age-Stratified Observed versus Expected Analyses of Myocarditis and Pericarditis Inputs**

Age group	Background Rate per 100,000 Person Years (PY) <sup>7</sup>	Observed Cases <sup>a</sup>	Expected Cases, 21-Day Risk Window <sup>b</sup>	Expected Cases, No Risk Window <sup>c</sup>
<b>Myocarditis</b>				
18-64 years	4.40	151	248.87	669.15
65+ years	4.40	6	248.87	669.15

**Table 5. Age-Stratified Observed versus Expected Analyses of Myocarditis and Pericarditis Inputs**

Age group	Background Rate per 100,000 Person Years (PY) <sup>7</sup>	Observed Cases <sup>a</sup>	Expected Cases, 21-Day Risk Window <sup>b</sup>	Expected Cases, No Risk Window <sup>c</sup>
<b>Pericarditis</b>				
18-64 years	18.00	100	1,018.10	2,737.42
65+ years	18.00	46	1,018.10	2,737.42

- a. Through 29 April 2021
- b. 5,656,092 PY for both 18-64 years and 65+ years age groups through 30 April 2021
- c. 15,207,879 PY for both 18-64 years and 65+ years age groups through 30 April 2021

Observed case counts were identified using the PT codes myocarditis and pericarditis. Cases with age <18 years (n=5) were included in the 18-64 years age group, and cases with unknown age (n=22) were proportionally allocated to the 18-65 years and 65+ years age groups. Expected case counts were derived using a background incidence rate of 4.40 per 100,000 person years for myocarditis and 18.00 per 100,000 person years for pericarditis<sup>7</sup>. The same background rate was used for the 18-64 years and 65+ years age groups as the age-specific rates were not markedly variable in adults, though rates were higher in children. Person years of exposure estimates were derived from publicly available information reported by countries where the BNT162b2 vaccine is authorized<sup>8</sup>. For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report. Person years of exposure were assumed to be equally divided between the 18-64 years and 65+ years age groups, based on limited publicly available information on age distribution.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all cases of myocarditis and pericarditis were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure may be underestimated. Our exposure estimate also assumes that 50% of vaccinees

were in the 18-64 years age group and 50% in the 65+ years age group, so the exposure may be under or overestimated in each age group.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate, and the same across age groups. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population and across age groups. To date, most of exposure derives from the US.

A further limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

## 5. SUMMARY AND CONCLUSION

Pericarditis and myocarditis have been reported following vaccination with Pfizer/BNT COVID-19 Vaccine. A mechanism of causality is not evident, however, a systemic inflammatory reaction due to an immune response to the vaccine could be postulated. Fewer cases of pericarditis than myocarditis have been reported. A large proportion of the myocarditis reports (54/108, 50%) and the myocarditis + pericarditis reports (12/16, 75%) are from Israel and of a similar patient profile (young and male); this influences the aggregate picture of the cases of myocarditis toward a younger and more male profile. Unfortunately, most cases from Israel do not provide diagnostic or outcome details; follow-up is ongoing.

Application of a case definition of myocarditis resulted in 39 of the 124 cases (31.5%) being categorized as having some degree of certainty in diagnosis (possible > probable > definite). Considering the totality of the available data, including post-authorization reports, clinical trial experience and the O/E epidemiology analyses, a causal association between the vaccine and myocarditis and pericarditis is not supported at this time. However, surveillance will continue and further details on the Israel cases, through spontaneous reporting or via any future publications will be thoroughly reviewed.

<sup>1</sup> Caforio ALP et al. Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the European Society of Cardiology Working Group on Myocardial and



- Pericardial Diseases. *European Heart Journal* (2013) 34, 2636-2648.  
DOI:10.1093/eurheartj/ehv210
- <sup>2</sup> Ammirati E et al. Update on acute myocarditis. *Trends in Cardiovascular Medicine* 2020 Elsevier <https://doi.org/10.1016/j.tcm.2020.05.008>
- <sup>3</sup> Kindermann, I et al. Update on myocarditis. *JACC* (2012) 59, 9, 779-792
- <sup>4</sup> Adler Y 2015 ESC guidelines for the diagnosis and management of pericardial diseases. *European Heart Journal* (2015) 36, 2921-2964. DOI: 10.1093/eurheartj/ehv318
- <sup>5</sup> Ho, JSY Coronavirus-induced myocarditis: A meta-summary of cases *Heart & Lung* 49 (2020) 681-685.
- <sup>6</sup> Bonaca MP et al. Myocarditis in the setting of cancer therapeutics: proposed case definitions for emerging clinical syndromes in cardio-oncology. *Circulation*. 2019; 140:80-91.
- <sup>7</sup> Elfström P, Hamsten A, Montgomery SM, et al. Cardiomyopathy, pericarditis and myocarditis in a population-based cohort of inpatients with coeliac disease. *J Intern Med*. 2007;262(5):545-54. DOI: 10.1111/j.1365-2796.2007.01843.x.
- <sup>8</sup> Our World in Data. Coronavirus (COVID-19) Vaccinations. Available from: <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates>. Accessed May 2021.

## APPENDIX 3.8 SUMMARY OF CASES OF THROMBOEMBOLISM WITH THROMBOCYTOPENIA

In an effort to be vigilant for any reported cases that may indicate the co-occurrence of thromboses and thrombocytopenia similar to what has been rarely described coincident with vaccination by adeno-vector COVID-19 vaccines, the Pfizer safety database was searched for all spontaneous reports of BNT162b2 cumulative to 22 April 2021 using MedDRA (v 23.1) for cases within the SMQ Embolic and thrombotic events where the thrombosis/embolic PT occurred from Day 3 to Day 28 (inclusive) following vaccination with BNT162b2. That dataset was then searched for PTs that are in either the HLT Thrombocytopenias or HLT Platelet analysis.

The final dataset is comprised of 33 AE reports in the safety database for BNT162b2 as of 22 April 2021.

All cases were individually reviewed and separated into 5 categories:

1. Cases not relevant to the topic concurrent thrombosis/embolism and thrombocytopenia (9)
  - These AE reports lacked description of either thrombocytopenia or a thrombotic event and therefore are not relevant to the topic of current interest.
2. Cases with alternative explanations for the events of interest (8)
  - These AE reports described patients with other conditions such as cancer, DIC and congenital abnormalities that are more likely explanations for their adverse events than a vaccination-induced process.
3. Cases containing insufficient information (2)  
and
4. Cases of Thrombotic thrombocytopenic purpura (2)
  - These 4 AE reports lacked detail supporting the presence of thrombocytopenia and/or thromboembolic events or report on the specific condition of TTP which is distinct from the topic of current interest.
5. Remaining cases (12)
  - These AE reports describe patients of varying genders, ages, and thromboembolic events (e.g. arterial, venous, common, and less common locations). Many of them have reported risk factors for thromboembolic

events (both venous and arterial). Not all reports provide labs or studies supporting the diagnosis of thrombocytopenia, and varying severity of thrombocytopenia is described. The heterogeneity of the cases does not suggest a common trend; however, surveillance will continue for cases of co-reported thrombocytopenia and thromboembolic events.

This review of cases of thrombosis with thrombocytopenia does not indicate the presence of a causal association with the Pfizer/BNT COVID-19 Vaccine.

**Table 1. Cases Not Relevant to the Topic Concurrent Thrombosis/Embolism and Thrombocytopenia**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
1	(b) (6) United States 56 years/Male 05 January 2021  Fatal case	Cerebral haemorrhage, Immune thrombocytopenia, Haemorrhage intracranial, Haemorrhagic stroke, Petechiae	1  3 days after D1	Pt with PMH of hypertension on no medications presented with petechiae and was admitted for thrombocytopenia (PC 0) which was refractory to multiple treatments. Pt died of intracerebral hemorrhage 16 days after D1. There was no report of thrombosis or embolism.
2	(b) (6) United States 39 years/Female 21 Jan 2021 Thrombocytopenia (Recovered) Cerebral hemorrhage (Not recovered)	Thrombocytopenia, Cerebrovascular accident, Cerebral haemorrhage, Brain injury, Memory impairment	1  12 days	Pt with unreported PMH presented with cerebral hemorrhage and thrombocytopenia (PC 36). Thrombocytopenia recovered following a platelet and blood transfusion. Rehab was started for the cerebral hemorrhage. There was no report of thrombosis or embolism.
3	(b) (6) United States 68 years/Female 28 February 2021  Not recovered	Pain, Back pain, Arthralgia, Gait disturbance, Musculoskeletal stiffness, Heparin-induced thrombocytopenia, Respiratory disorder, Chronic obstructive pulmonary disease, Fatigue, Headache, Nausea, White blood cell count increased, Red blood cell count abnormal, Neutrophil count abnormal, Monocyte count abnormal, Basophil count abnormal, Platelet	2  5 days after D2 back pain worsened	Upon review of the case details, it was determined the case was miscoded with PT Heparin-induced thrombocytopenia; the case is being corrected.

**Table 1. Cases Not Relevant to the Topic Concurrent Thrombosis/Embolism and Thrombocytopenia**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
		disorder, Musculoskeletal stiffness, Neck pain, Pain in jaw, Ear pain, Diarrhoea		
4	(b) (6) United States 46 years/Female 17 March 2021  Recovering	Pyrexia, Cough, Myalgia, Peripheral swelling, Cardiogenic shock, Myocarditis, Respiratory failure, Thrombosis, Blood pressure decreased, Thrombocytopenia, Haemorrhage	1  14 days	Pt with PMH of COVID-19 pneumonia (Jan 2021) presented with symptoms of myocarditis and heart failure. On echocardiogram, her cardiac ejection fraction was 35% and an intracardiac mural thrombus was visualized. She was hospitalized for 20 days and during that time had thrombocytopenia (PC not reported)
5	(b) (6) United Kingdom 82 years/Female 27 March 2021  CVST (Recovered with sequelae)	Headache, Cerebral haemorrhage, Thrombosis, Seizure, Muscular weakness, Generalised tonic-clonic seizure, Superior sagittal sinus thrombosis, Jugular vein thrombosis, Syncope, Pulmonary embolism, Thrombocytopenia	1  12 days after D1 had headache	Pt with PMH of thrombocytopenia, obesity, suspected COVID-19 and multiple bone fractures presented with headache. She was found to have a cerebral venous sinus thrombosis. Despite her PMH of thrombocytopenia, her PCs in the hospital were 271 and 305. She was not thrombocytopenic.
6	(b) (6) Netherlands 80 years/Male 01 April 2021  PE (Recovering) Platelet count decreased (Unknown)	Atrioventricular block complete, Pulmonary embolism (PE), Blood creatinine increased, Platelet count decreased, Renal disorder	1  3 days	Pt with PMH of PE and LBBB presented with dyspnea and dizziness and was found to have AV block. A cardiac pacemaker was placed. During his hospitalization he had a PE and a platelet count of 149.
7	(b) (6) Portugal 89 years/Female 12 April 2021  Recovering	Pulmonary embolism, Dyspnoea at rest, Platelet count increased, Fibrin D dimer increased	2  26 days	Pt with PMH of hypertension and asthma presented with dyspnea at rest. She was suspected of having a PE. Her D-dimer level was elevated, and her PC was 171. She did not have thrombocytopenia.
8	(b) (6) United Kingdom 58 years/Male 12 April 2021  Thrombosis (Not recovered)	Cerebral venous sinus thrombosis, Confusional state, Thrombosis, Loss of consciousness, Platelet count decreased	2  20 days	Pt with no PMH presented with confusion and collapse. A CT venogram showed cerebral venous sinus thrombosis. His D-dimer was >6000 and his PC was >150. He did not have thrombocytopenia
9	(b) (6) United States	Jaundice, Nausea, Vomiting, Diarrhoea,	1	Pt with PMH of metastatic breast cancer who received an oncologic

**Table 1. Cases Not Relevant to the Topic Concurrent Thrombosis/Embolism and Thrombocytopenia**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
	49 years/Female 14 April 2021  Fatal case	Microangiopathic haemolytic anaemia, Thrombocytopenia, Hyperbilirubinaemia, Cholestasis, Coagulopathy, Thrombotic microangiopathy	7 days	study drug (ARV-471) 7 days prior to D1 of vaccine presented 7 days after vaccination with 1 week of jaundice, nausea, vomiting and diarrhea. She was diagnosed with microangiopathic hemolytic anemia. A PC was not reported nor were details on any thrombi/emboli
PMH=past medical history, PC=platelet count, unit is PC x 10 <sup>9</sup> /L; D1=dose 1, D2=dose 2, CT=Computed tomography				

**Table 2. Cases with Alternative Explanations for the Events of Interest**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
1	(b) (6) United States 70 years/Female 21 March 2021  Fatal case	Red cell distribution width increased, Platelet count decreased, Neutrophil count decreased, Band neutrophil count increased, Monocyte count increased, Metamyelocyte count increased, Myelocyte count increased, Neutrophil count decreased, Blast cell count increased, Pain in extremity, Thrombosis, Leukaemia, Acute myeloid leukaemia, Haemorrhagic stroke, Ischaemic stroke, Cerebral haemorrhage, Disseminated intravascular coagulation	2  2 days	Pt with PMH of breast cancer had an abnormal CBC with metamyelocytes. She went on to have lower extremity venous thromboses and Disseminated intravascular coagulation. She was diagnosed with acute myeloid leukemia. A platelet count was not provided. The patient's hematologic cancer and, potentially, the breast cancer, are potential causes of the adverse events.
2	(b) (6) Austria 66 years/Male 26 March 2021	Pulmonary embolism, Syncope, Fibrin D dimer increased, Hypotension, Troponin T increased, Brain natriuretic peptide increased,	1  1 day	Patient with PMH of Parkinson's disease, breast cancer and obesity presented with syncope and was found to have abnormal blood tests. He also had B cell lymphoma as a potential alternative explanation for

**Table 2. Cases with Alternative Explanations for the Events of Interest**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
	Thrombocytopenia (Recovered) Pulmonary embolism (Recovering)	Thrombocytopenia, C-reactive protein increased, Blood creatine phosphokinase increased, Venous thrombosis limb		his PE and low platelet count (nadir 103). D-dimer was 33.
3	(b) (6) United Kingdom 55 years/Male 28 March 2021  Thrombosis and thrombocytopenia (Not recovered)	Respiratory failure, Thrombosis, Condition aggravated, Thrombocytopenia, Diarrhoea, Urinary tract infection, Dyspnoea, Haemodynamic instability, Pulmonary embolism, Neutrophilia, Sepsis	1  15 days	Patient with PMH of alcohol use, DVT, morbid obesity, respiratory failure, polyarthropathy, gout, psoriasis presented with severe shortness of breath. He was intubated and found to have a PE. His platelet nadir was 47, D-dimer elevated 25.4, Fibrinogen low 1.6 and anti-PF4 antibodies were negative. A hematologist familiar with vaccine-induced thrombocytopenia and thrombosis evaluated the patient and attributed the thrombosis to immobility and obesity and the thrombocytopenia to alcohol use and sepsis.
4	(b) (6) France 76 years/Female 29 March 2021  Pulmonary embolism (Recovering) Thrombocytopenia (Unknown)	Pulmonary embolism, Thrombocytopenia, Dyspnoea	2  19 days	Pt with PMH of lower extremity thromboses, obesity and breast cancer thought to be in remission as of Aug 2019 presented with shortness of breath. She was found to have a PE and platelet count of 135. D-dimer was >20,000. She was treated with low molecular weight heparin and improved. Improvement on heparin is not likely if a HIT-like processes is present.
5	(b) (6) France 54 years/Male 02 April 2021  Not recovered	Portal vein thrombosis, Condition aggravated, Thrombocytopenia	1  9 days	Pt with hepatocellular carcinoma due to hepatitis C and PMH of portal vein thrombosis since Oct 2020 was found on CT scan (04 Mar 2021) to have progression of the portal vein thrombosis. His platelet count was 116 then 84. The patient's adenocarcinoma is a potential cause of the events.
6	(b) (6) United Kingdom 55 years/Male 16 April 2021  Fatal case	Intestinal ischaemia, Mesenteric vein thrombosis, Hypotension, Abdominal pain, Tachycardia, Thrombocytopenia	1  27 days	Pt with a PMH of congenital malrotation of his gut and colon adenoma had worsening abdominal pain with eating. He had a hemicolectomy to remove the adenoma and post-operatively had worsened abdominal pain and hypotension. He had mesenteric vein thrombosis and intestinal ischemia. His PC was 35 post-op; it is unknown if D-dimer and anti-PF4 antibodies

**Table 2. Cases with Alternative Explanations for the Events of Interest**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
				were sent. He died and on autopsy was found to have thrombosis of an abnormal small bowel venous drainage system. The congenital abnormalities are a potential precipitant to thromboses as is the recent surgery.
7	(b) (6) France 72 year/Male 19 April 2021  Fatal case	Disseminated intravascular coagulation, Thrombosis, Thrombocytopenia	1  14 days	Pt with PMH of atrial fibrillation and hypertension was found down. He was found to have pancreatitis grade D and lab abnormalities including a PC of 34 and CPK>8000 and was thought to be in DIC. He had been anticoagulated with rivaroxaban but had intracardiac, aortic and arm and leg arterial thromboses.
8	(b) (6) Sweden 66 year/Male 21 April 2021  Not recovered	Pulmonary embolism, Thrombocytopenia	2  9 days	Pt with PMH of hypertension presented with back, abdominal and pleuritic chest pain. He was found to have enlarged lymph nodes in the right pulmonary hilus along with a PE. Anticoagulation with apixaban was started and 5 days later his PC was 36. HIT antibodies were reported to be negative and apixaban (thrombocytopenia is ADR in labeling) was stopped.
PMH=past medical history, CT=Computed tomography, PC=platelet count, unit is PC x 10 <sup>9</sup> /L; D1=dose 1, D2=dose 2, PF4=Platelet factor 4, CPK=Creatine phosphokinase, HIT=Heparin-induced thrombocytopenia, ADR=Adverse drug reaction				

**Table 3. Cases with Insufficient Information**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose  Time to onset</b>	<b>Additional information</b>
1	(b) (6) Spain 92 year/Female 22 March 2021  Fatal case	Thrombotic microangiopathy, Thrombotic thrombocytopenic purpura	1  13 days	Pt with PMH of hypertension, osteoarthritis and vertigo presented with unspecified symptoms and was diagnosed with a thrombotic microangiopathy of the TTP type. No labs were reported. No specific events of thromboembolism are described. She died 10 days after presentation, and it was not known if an autopsy was performed.

**Table 3. Cases with Insufficient Information**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose Time to onset</b>	<b>Additional information</b>
2	(b) (6) United Kingdom 58 years/Female 11 April 2021  Fatal case	Death, Sudden death, Embolism, Thrombocytopenia	2  8 days	Pt with a PMH of asthma, depression, dyspepsia on hormone replacement therapy died suddenly and the case was reported because it was potentially relevant to thrombosis and thrombocytopenia syndrome. No specifics in terms of thromboses or PC were provided.
PMH=past medical history, PC=platelet count, unit is PC x 10 <sup>9</sup> /L; D1=dose 1, D2=dose 2, TTP=Thrombotic thrombocytopenic purpura				

**Table 4. Cases of Thrombotic Thrombocytopenic Purpura**

	<b>AE Report number Country Age/Sex Initial receipt date Outcome</b>	<b>Preferred terms</b>	<b>Dose Time to onset</b>	<b>Additional information</b>
1	(b) (6) United Kingdom 34 years/Female 08 April 2021  TTP (Not recovered)	Platelet count decreased, Thrombotic thrombocytopenic purpura	1  28 days to TTP	Pt with PMH of multiple sclerosis and neuralgia was found to have low PC (not reported), hospitalized and diagnosed with TTP. She was COVID-19 negative. Sites of thromboses were not provided. The events occurred 28 days following vaccination.
2	(b) (6) United Kingdom 83 years/Female 12 April 2021  Recovering	Immune-mediated hepatic disorder, Haemorrhage, Activated partial thromboplastin time shortened, Thrombotic thrombocytopenic purpura, Neurological symptom	2  4 days	Pt with no reported PMH presented with 1 day of fluctuating neurological symptoms. She was found to have severe thrombocytopenia (PC nadir 9) and red blood cell fragmentation. ADAMTS protein level was <1% and she was diagnosed with TTP. No thrombotic events were described.
PMH=past medical history, PC=platelet count, unit is PC x 10 <sup>9</sup> /L; D1=dose 1, D2=dose 2, ADAMTS=A Disintegrin-like And Metalloproteinase with Thrombospondin				



**Table 5. Remaining Cases of Concurrent Thromboembolism and Thrombocytopenia**

	AE Report number Country Age/Sex Initial receipt date Outcome	Preferred terms	Dose Time to onset	Additional information
1	(b) (6) US 22/Female 12 Jan 2021 Thromboses: recovering Thrombocytopenia: recovering	Deep vein thrombosis, Pulmonary embolism, Thrombocytopenia, Thrombosis	2 3 days	The reporter was a nurse and the patient. She had a history of blood clots and food allergies presented with back pain and blue, swollen legs and was found to have bilateral DVTs and PE. At an unspecified time, she was diagnosed with thrombocytopenia. Platelet count was not reported. She was treated with IV heparin and then oral rivaroxaban at home. The lack of PC and treatment with heparin suggest this case is not consistent with the thrombotic thrombocytopenic syndrome of interest.
2	(b) (6) Italy 84/Male 24 Mar 2021 PE: Not recovered	Thrombocytopenia, Pleural effusion, Acute kidney injury, Transient ischaemic attack, Pulmonary embolism, Pericardial effusion, Mitral valve incompetence, Tricuspid valve incompetence, Pulmonary infarction, Left ventricular dysfunction, Aortic dilatation, Right ventricular dilatation	1 12 days	Pt with history of hypertension, carotid arteriosclerosis on aspirin and amlodipine presented with unspecified complaints and was found to have 2 TIAs, a PE, acute renal failure, thrombocytopenia, pericardial and pleural effusions. Platelet count was not reported. D-dimer was tested but results not provided. Unspecified anticoagulation therapy was given.  This patient has risk factors for an ischemic thromboembolic event such as stroke. A specific PC is not provided. Overall the events are not consistent with the thrombotic thrombocytopenic syndrome of interest.
3	(b) (6) UK 33/Male 04 Apr 2021 CVST: Recovered Immune thrombocytopenia: Not recovered	Platelet count decreased, Immune thrombocytopenia, Cerebral venous sinus thrombosis, Headache, Petechiae	Unspecified  Low platelets 1 day after vaccination; CVST 18 days after vaccination	The consumer was the reporter; he had no known medical history and was diagnosed with immune thrombocytopenia after presenting with low PC 1 day after vaccination (PC nadir: 19). At 18 days following vaccination, he presented with "possible CVST" and PC 22. No brain imaging study was provided, and the patient was not aware if PF4 antibodies were measured. The very close temporality between vaccination and low platelet count put biological plausibility in question.
4	(b) (6) Poland	Acute kidney injury, Acute myocardial	1	Pt with a history of coronary artery disease, hypertension and

**Table 5. Remaining Cases of Concurrent Thromboembolism and Thrombocytopenia**

	AE Report number Country Age/Sex Initial receipt date Outcome	Preferred terms	Dose Time to onset	Additional information
	73/Male 05 Apr 2021 Fatal report	infarction, Thrombocytopenia, Pancreatitis acute	9 days	degenerative joint disease taking ramipril and lercanidipine HCl presented with acute renal failure, a transmural MI, acute pancreatitis, and thrombocytopenia (PC nadir 131) and died the same day. It was noted that baseline COD was pancreatitis, secondary COD was acute renal failure and direct COD was MI. An autopsy was not performed. The course of events (multiorgan failure) described are more likely attributable to pancreatitis than a rarer syndrome of thrombotic thrombocytopenia.
5	(b) (6) UK 74/Male 08 Apr 2021 Platelet count decreased: Unknown CVA: Recovered	Head injury, Cerebrovascular accident, Platelet count decreased	1  CVA 4 days after vaccination; Platelet count decreased 6 days after vaccination	Pt with a history of ischemic stroke, diabetes and smoking and normal pre-vaccination PC (220) had a head injury on an unspecified date then a thalamic infarction seen on brain MRI and 2 days later, a platelet count of 130 (nadir). No hemorrhages occurred. No anti-PF4 antibodies were identified. The risk factors for ischemic stroke are the likely cause of the stroke and the mild thrombocytopenia is not consistent with the thrombotic thrombocytopenic syndrome of interest.
6	(b) (6) UK 85/Male 09 Apr 2021 Fatal report	Cerebrovascular accident, Platelet count decreased	1  7 days	Pt with a history of gastrointestinal bleed, atrial fibrillation taking digoxin, finasteride, furosemide, salbutamol, solifenacin and tamsulosin and rivaroxaban which was recently stopped due to a GI bleed. The patient presented with a middle cerebral artery stroke 7 days after vaccination and a platelet count less than 150 (not specified). The patient died due to the stroke 7 days after the stroke. The patient has known risk factors for ischemic stroke, and these are more likely its cause than a rarer syndrome of thrombotic thrombocytopenia. In addition, the PC is not provided so the severity of thrombocytopenia is not known
7	(b) (6) UK 47/Female	Haemorrhage, Thrombosis, Embolism, Arterial thrombosis,	1	Pt with a history of pulmonary embolism, thrombosis concomitant medications not reported. The patient

**Table 5. Remaining Cases of Concurrent Thromboembolism and Thrombocytopenia**

	AE Report number Country Age/Sex Initial receipt date Outcome	Preferred terms	Dose Time to onset	Additional information
	11 Apr 2021 Arterial and venous thromboses: Recovered Thrombocytopenia: Unknown	Venous thrombosis, Cerebral venous sinus thrombosis, Cerebral haemorrhage, Chest injury, Thrombocytopenia, Abdominal pain, Muscular weakness	Platelet count < 150, 9 days after vaccination; Thromboses, 12 days after vaccination	presented with abdominal pain and left-hand weakness. She was found to have arterial and venous thromboses (splanchnic, hepatic portal thromboses, PE and CVST). She experienced bleeding at the CVST location. Platelet count was 11 at presentation (nadir 10), Fibrinogen 4.4, D-dimer 20,000, Anti-PF4 antibodies were identified. A hematologist was reported to have reviewed the case and assessed as probable vaccine-associated thrombosis and thrombocytopenia
8	(b) (6) UK 91/Female 11 Apr 2021 Not recovered	Dyspnoea, Blood fibrinogen decreased, Pancytopenia, Deep vein thrombosis, Disseminated intravascular coagulation, Thrombocytopenia	2 9 days	Pt with a history of iron deficiency anemia, MGUS, Angioedema (C1 deficiency), probably sarcoidosis, Urinary tract infections taking iron, loperamide, nitrofurantoin, omeprazole, presented with dyspnea and weakness and was found to have pancytopenia (WBC 3.9, PC 71), bilateral lower extremity DVTs and DIC. She had low fibrinogen (0.6) and D-dimer elevated but <4000, COVID-19 test was negative and PF4 assay was pending at the time of the report. The elderly patient has baseline conditions predisposing to venous thromboses and although the platelet count is below normal the D-dimer makes the diagnosis of the syndrome of interest less likely.
9	(b) (6) Spain 84/Male 14 Apr 2021 Thrombocytopenia: Recovering Ischemic stroke: Recovered	Thrombocytopenia, Ischaemic stroke, Facial paralysis, Dysphagia	1 6 days	Pt with history of diabetes, hypertension, primary cognitive impairment, atrial fibrillation (on LMWH) presented 6 days after dose 1 of vaccine with dysphagia, left facial paralysis and ischemic stroke on MRI and MRI angiogram). He was found to be thrombocytopenic (PC nadir 56). No bleeding was described. It is not stated whether the LMWH was continued. The patient was discharged after 10 days in hospital. The use of LMWH to anticoagulate this patient with AF for an unspecified amount of time complicates assessment of its role and the potential role of vaccination in the presenting events.

**Table 5. Remaining Cases of Concurrent Thromboembolism and Thrombocytopenia**

	AE Report number Country Age/Sex Initial receipt date Outcome	Preferred terms	Dose Time to onset	Additional information
10	(b) (6) Norway 75/Male 15 Apr 2021 Fatal report	Pneumonia, Thrombocytopenia, Respiratory failure, Depressed level of consciousness, Hemiplegia, Cerebral thrombosis	2 20 days	PT with medical history of lung fibrosis, high cholesterol, prostate hyperplasia, and acid reflux taking atorvastatin, pirfenidone, finasteride, aspirin and esomeprazole presented with severe pneumonia 20 days after 2 <sup>nd</sup> vaccination. He was treated with antibiotics and 2 days later had a decrease in consciousness, hemiplegia and was found to have a platelet count that went from 120 to 60 in 2 days. COVID-19 test was negative. The patient was reported to have an intracerebral thrombosis although no imaging study was described. Intensive care was stopped on the day of the apparent stroke and the patient died. The presence of an infection such as severe pneumonia is an alternative explanation for the other adverse events reported in this vulnerable patient
11	(b) (6) Sweden 87/Female 15 Apr 2021 Not recovered	Thrombocytopenia, Pulmonary embolism	2 12 days	Pt with medical history of anemia, hypertension, diabetes, chronic kidney disease (medications not reported) presented with unspecified complaints and was found to have a PE and thrombocytopenia (PC initially 127 then 112). She was anticoagulated with argatroban and oxygen. This patient presents with a less severe thrombocytopenia and more common location of venous thrombosis than has been described in the cases of concern.
12	(b) (6) US 36/Male 15 Apr 2021 Not recovered	Mesenteric vein thrombosis, Sepsis, Thrombocytopenia, Escherichia bacteraemia, Eating disorder, Abdominal pain, Nausea, Vomiting, Myalgia, Chills, Pyrexia, Lethargy	1 5 days	Pt with medical history of diverticulitis, COVID-19 and on escitalopram presented with abdominal pain. A CT of the abdomen and pelvis was performed and the patient was treated for uncomplicated diverticulitis. Three days later he returned to the ED for worsening abdominal pain and was found to have an inferior mesenteric vein thrombus protruding into the superior mesenteric and portal veins. In retrospect, the thrombus (albeit smaller) was present at the time of the first CT scan. He was also reported to be bacteremic (E. coli)

**Table 5. Remaining Cases of Concurrent Thromboembolism and Thrombocytopenia**

	AE Report number Country Age/Sex Initial receipt date Outcome	Preferred terms	Dose  Time to onset	Additional information
				and thrombocytopenic (PC not reported). He was treated with IV heparin and reportedly improved however he was in the ICU at the time of the report. The reporter states that the diverticulosis could be an explanation for the clinical presentation. Further lab work and follow-up on the patient's assessment and course would be helpful.
PMH=past medical history, PE=pulmonary embolism, PC=platelet count, unit is $PC \times 10^9/L$ ; D1=dose 1, D2=dose 2; LMWH= low molecular weight heparin				

**APPENDIX 4. CUMULATIVE APPROVAL/AUTHORISATION STATUS**

Product Detail Set Name	Marketing Authorization Holder	Country	Approval Date	Authorization Type
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer/BioNTech	United Kingdom	1-Dec-20	Temporary authorization under regulation 174
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Bahrain	3-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Israel	6-Dec-20	Special import approval Clause 29
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Canada	9-Dec-20	Interim Order
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Qatar	10-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Saudi Arabia	10-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Mexico	11-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United States	11-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Kuwait	13-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Oman	13-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Lebanon	14-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Singapore	14-Dec-20	Pandemic Special Access Route
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Costa Rica	15-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Ecuador	15-Dec-20	Importation Authorization
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United Arab Emirates	15-Dec-20	EUA

Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Chile	16-Dec-20	Special import for emergency use article 99
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Panama	16-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Jordan	17-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Serbia	17-Dec-20	Import License
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Switzerland	19-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Austria	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Belgium	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Bulgaria	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Croatia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Cyprus	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Czech Republic	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Denmark	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Estonia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Finland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	France	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Germany	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Greece	21-Dec-20	Conditional marketing authorization approval

Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Hungary	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Iceland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Ireland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Italy	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Latvia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Liechtenstein	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Lithuania	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Luxembourg	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Malta	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Netherlands	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Norway	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Poland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Portugal	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Romania	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Slovakia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Slovenia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Spain	21-Dec-20	Conditional marketing authorization approval



Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Sweden	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Argentina	22-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Iraq	27-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Colombia	6-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Malaysia*	8-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Tunisia	11-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Uruguay	21-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Australia	24-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Hong Kong	25-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Philippines	29-Jan-21*	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Peru	1-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	New Zealand	3-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Dominican Republic	8-Feb-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Japan	14-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Ukraine	22-Feb-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Brazil	23-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Macau	23-Feb-21	Special import permit

Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Albania	24-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Rwanda	1-Mar-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	South Korea	5-Mar-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	South Africa	11-Mar-21	Special Import Permit - Section 21
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Palestine	25-Mar-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Algeria	12-Apr-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United Kingdom	22-Apr-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Georgia	29-Apr-21	EUA

\* Compared to previous SMSRs, Authorization type in Malaysia updated to Conditional marketing authorization approval and Approval date updated to 29 January 2021 in the Philippines as per respective local Pfizer Country Offices confirmation

## APPENDIX 5. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Anti-acetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothermia hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lamb's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphaea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic



neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

## APPENDIX 5.1 OBSERVED VERSUS EXPECTED ANALYSIS FOR ADVERSE EVENTS OF SPECIAL INTEREST

### 2.5. INTRODUCTION

As part of ongoing signal detection activities, MAH is conducting observed versus expected analyses to determine whether the reported counts of spontaneously reported AESI are higher than expected based on the “natural” background rates of the AESI in the absence of vaccine exposure, as outlined in the “Considerations on core requirements for RMP’s of COVID-19 vaccines: coreRMP19 guidance”<sup>1</sup> and by Mahaux et al.<sup>2</sup> Analyses are reported cumulatively for the period since the vaccine was first granted emergency use authorization (9 December 2020) as well as for the monthly reporting interval (1 April 2021 – 29 April 2021).

### 2.6. METHODS

#### 2.6.1. Variables

The AESI list included in this report is informed by recommendations from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (VAERS surveillance) and MHRA. For SMSR 5, the MAH has added Disseminated intravascular coagulation to the unadjusted observed to expected ratio analyses compared to SMSR 4.

#### 2.6.2. Data sources and analysis

##### 2.6.2.1. Observed cases

Spontaneously reported case counts are processed from the safety database via the pre-defined MedDRA preferred term search criteria provided in Table 3 (Section 2.7). Unless otherwise noted, events have not undergone adjudication, which is considered appropriate in a setting where the goal of observed versus expected analyses is signal detection.<sup>2</sup>

##### 2.6.2.2. Expected cases

Expected case counts were determined cumulatively and for the monthly interval by multiplying estimated background incidence rates by the duration of post-vaccination exposure time.<sup>3</sup> Duration of exposure time was estimated for the cumulative and interval period using a 21-day risk window and no risk window.<sup>3</sup>

- Background incidence rates: Sources of background incidence rate estimates are noted in Table 2.
  - In this monthly report, the MAH used the background rates of AESI provided by the ACCESS/VAC4EU initiative as the primary source for generating expected counts of events. The incidence rates (narrow case definitions) from 2017-2019 were averaged within each of the ten data sources where available. From these, a single average rate was selected based on the range of observed values, type of care typically sought for the AESI (e.g. hospital or general practitioner), and relevant characteristics of the databases, as described in the ACCESS User Guide<sup>4</sup>. One exception was for cutaneous vasculitis, which used the 2019 narrow rate from BIFAP. Compared to the previous report,

SMSR #5 uses updated rates for acute disseminated encephalomyelitis; acute kidney injury/renal failure; acute liver injury/liver injury; acute respiratory distress syndrome; ageusia/anosmia; arrhythmia; chillblains; coronary artery disease; deep vein thrombosis; disseminated intravascular coagulation; erythema multiforme; Guillain-Barré syndrome; haemorrhagic stroke; heart failure; idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia; multisystem inflammatory syndrome; pulmonary embolus; seizures/convulsions/seizure disorders (including febrile); transverse myelitis; type 1 diabetes; and vasculitis.

- For AESIs not available through the ACCESS project, incidence rates were identified in the literature and analyses conducted within electronic health records. If a plausible range of background rates was identified across multiple data sources, a single rate from the low end of the range was selected. This conservative approach is more likely to identify a signal than an approach using a higher background rate.<sup>5</sup>
- Post vaccination exposure time: Estimated exposure time was derived from publicly available information reported by countries where the Pfizer-BioNTech COVID-19 vaccine is authorized.<sup>6</sup> For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report. Exposure time was calculated using a 21-day risk window and no risk window for both the interval and cumulative period.
  - Of note, the 21-day risk window is not applied to the observed case count. All cases observed during the interval or cumulative period are included regardless of proximity of event to date of vaccination. This is a conservative approach for the purpose of signal detection.

## 2.7. RESULTS: OBSERVED VERSUS EXPECTED ANALYSES

**Table 1. Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI)**

AESI	21-Day Risk Window, Cumulative		No Risk Window, Cumulative		21-Day Risk Window, Interval		No Risk Window, Interval	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Acute disseminated encephalomyelitis (ADEM)	4.597	3.433, 6.028	1.710	1.277, 2.242	4.716	2.696, 7.658	4.149	2.372, 6.738
Acute kidney injury/renal failure	0.006	0.006, 0.007	0.002	0.002, 0.003	0.007	0.005, 0.009	0.006	0.005, 0.008
Acute liver injury/liver injury	0.004	0.002, 0.007	0.002	0.001, 0.003	0.005	0.002, 0.011	0.004	0.001, 0.010
Acute myocardial infarction/myocardial infarction	0.019	0.017, 0.021	0.007	0.006, 0.008	0.024	0.021, 0.028	0.021	0.018, 0.025
Acute respiratory distress syndrome (ARDS)	0.002	0.002, 0.003	0.001	0.001, 0.001	0.003	0.002, 0.005	0.003	0.001, 0.004
Ageusia/anosmia	3.028	2.794, 3.276	1.126	1.039, 1.218	2.654	2.262, 3.095	2.335	1.991, 2.723
Arrhythmia	0.003	0.003, 0.004	0.001	0.001, 0.001	0.004	0.003, 0.005	0.003	0.003, 0.004
Autoimmune thyroiditis	0.029	0.017, 0.044	0.011	0.006, 0.016	0.033	0.013, 0.069	0.029	0.012, 0.060
Behcet's syndrome	0.072	0.024, 0.169	0.027	0.009, 0.063	0.097	0.012, 0.349	0.085	0.010, 0.307
Bell's palsy	0.510	0.483, 0.538	0.190	0.180, 0.200	0.537	0.487, 0.590	0.472	0.429, 0.519
Chillblains	0.038	0.029, 0.050	0.014	0.011, 0.019	0.085	0.059, 0.118	0.075	0.052, 0.104
Chronic fatigue syndrome/ME/PVFS	0.044	0.034, 0.056	0.016	0.013, 0.021	0.069	0.047, 0.099	0.061	0.042, 0.087
Coronary artery disease	0.001	0.000, 0.001	0.000	0.000, 0.000	0.001	0.000, 0.002	0.001	0.000, 0.002
Cutaneous vasculitis	0.011	0.006, 0.017	0.004	0.002, 0.006	0.010	0.003, 0.024	0.009	0.003, 0.021
Death	0.025	0.024, 0.026	0.009	0.009, 0.010	0.025	0.024, 0.027	0.022	0.021, 0.024
Deep vein thrombosis	0.031	0.028, 0.034	0.011	0.010, 0.013	0.071	0.063, 0.080	0.063	0.055, 0.070
Disseminated intravascular coagulation	0.048	0.021, 0.094	0.018	0.008, 0.035	0.119	0.044, 0.260	0.105	0.039, 0.229
Erythema multiforme	0.049	0.035, 0.065	0.018	0.013, 0.024	0.043	0.022, 0.075	0.038	0.020, 0.066
Fibromyalgia	0.001	0.001, 0.001	0.000	0.000, 0.001	0.001	0.001, 0.002	0.001	0.001, 0.001
Giant cell arteritis	0.105	0.063, 0.164	0.039	0.024, 0.061	0.203	0.101, 0.363	0.178	0.089, 0.319
Guillain-Barré syndrome	0.513	0.421, 0.618	0.191	0.157, 0.230	0.800	0.595, 1.051	0.703	0.524, 0.925
Haemorrhage	0.078	0.068, 0.090	0.029	0.025, 0.033	0.131	0.106, 0.159	0.115	0.094, 0.140
Haemorrhagic stroke	0.037	0.032, 0.042	0.014	0.012, 0.016	0.062	0.051, 0.074	0.054	0.045, 0.066
Heart failure	0.006	0.006, 0.007	0.002	0.002, 0.003	0.008	0.006, 0.009	0.007	0.006, 0.008
Herpes zoster	0.023	0.022, 0.024	0.009	0.008, 0.009	0.020	0.018, 0.023	0.018	0.016, 0.020
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	0.401	0.357, 0.449	0.149	0.133, 0.167	0.744	0.635, 0.865	0.654	0.559, 0.761

**Table 1. Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI)**

AESI	21-Day Risk Window, Cumulative		No Risk Window, Cumulative		21-Day Risk Window, Interval		No Risk Window, Interval	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Ischemic stroke	0.053	0.050, 0.057	0.020	0.019, 0.021	0.086	0.078, 0.093	0.075	0.069, 0.082
Limb ischemia	0.001	0.000, 0.001	0.000	0.000, 0.000	0.002	0.001, 0.003	0.001	0.001, 0.002
Meningitis	0.021	0.014, 0.030	0.008	0.005, 0.011	0.026	0.014, 0.046	0.023	0.012, 0.040
Multiple sclerosis (MS)	0.088	0.072, 0.105	0.033	0.027, 0.039	0.097	0.068, 0.133	0.085	0.060, 0.117
Multisystem inflammatory syndrome	0.835	0.648, 1.058	0.311	0.241, 0.394	0.614	0.344, 1.013	0.540	0.302, 0.891
Myasthenia gravis	0.884	0.515, 1.415	0.329	0.192, 0.526	1.040	0.382, 2.264	0.915	0.336, 1.992
Myocarditis	0.315	0.268, 0.369	0.117	0.100, 0.137	0.556	0.443, 0.689	0.489	0.390, 0.606
Narcolepsy	0.115	0.063, 0.192	0.043	0.023, 0.072	0.191	0.077, 0.394	0.168	0.068, 0.346
Pericarditis	0.072	0.061, 0.084	0.027	0.023, 0.031	0.102	0.078, 0.130	0.089	0.068, 0.115
Polyneuropathy	0.803	0.702, 0.914	0.299	0.261, 0.340	1.132	0.917, 1.382	0.996	0.807, 1.216
Postural orthostatic tachycardia syndrome	0.016	0.009, 0.025	0.006	0.003, 0.009	0.015	0.005, 0.034	0.013	0.004, 0.030
Pulmonary embolus	0.109	0.101, 0.118	0.041	0.038, 0.044	0.232	0.211, 0.255	0.204	0.186, 0.224
Rheumatoid arthritis, polyarthritis	0.023	0.019, 0.026	0.008	0.007, 0.010	0.034	0.027, 0.043	0.030	0.024, 0.038
Seizures/convulsions/seizure disorders (including febrile)	0.251	0.234, 0.269	0.093	0.087, 0.100	0.281	0.249, 0.316	0.247	0.219, 0.278
Transverse myelitis	1.288	0.959, 1.694	0.479	0.357, 0.630	1.179	0.645, 1.978	1.037	0.567, 1.740
Type 1 diabetes	0.004	0.003, 0.007	0.002	0.001, 0.003	0.007	0.003, 0.014	0.006	0.003, 0.013
Vasculitis	0.065	0.053, 0.079	0.024	0.020, 0.029	0.109	0.082, 0.143	0.096	0.072, 0.126

**Table 2. Observed versus Expected Analyses of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs**

AESI	Background Rate per 100,000 Person Years (PY)	Observed Cases, Cumulative	Expected Cases, Cumulative, 21-Day Risk Window <sup>a</sup>	Expected Cases, Cumulative, No Risk Window <sup>b</sup>	Observed Cases, Interval	Expected Cases, Interval, 21-Day Risk Window <sup>c</sup>	Expected Cases, Interval, No Risk Window <sup>d</sup>
Acute disseminated encephalomyelitis (ADEM)	0.10 <sup>7</sup>	52	11.3	30.4	16	3.4	3.9

**Table 2. Observed versus Expected Analyses of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs**

AESI	Background Rate per 100,000 Person Years (PY)	Observed Cases, Cumulative	Expected Cases, Cumulative, 21-Day Risk Window <sup>a</sup>	Expected Cases, Cumulative, No Risk Window <sup>b</sup>	Observed Cases, Interval	Expected Cases, Interval, 21-Day Risk Window <sup>c</sup>	Expected Cases, Interval, No Risk Window <sup>d</sup>
Acute kidney injury/renal failure	293.38 <sup>7</sup>	214	33,187.7	89,233.7	68	9,953.8	11,313.2
Acute liver injury/liver injury	29.91 <sup>7</sup>	14	3,383.5	9,097.4	5	1,014.8	1,153.4
Acute myocardial infarction/myocardial infarction	201.80 <sup>8</sup>	438	22,828.0	61,379.0	167	6,846.7	7,781.7
Acute respiratory distress syndrome (ARDS)	131.82 <sup>9</sup>	36	14,911.7	40,094.1	13	4,472.4	5,083.2
Ageusia/anosmia	1.81 <sup>9</sup>	620	204.8	550.5	163	61.4	69.8
Arrhythmia	980.95 <sup>9</sup>	371	110,966.9	298,363.4	130	33,281.7	37,827.0
Autoimmune thyroiditis	6.20 <sup>8</sup>	20	701.4	1,885.8	7	210.4	239.1
Behcet's syndrome	0.61 <sup>10</sup>	5	69.0	185.5	2	20.7	23.5
Bell's palsy <sup>c</sup>	23.84 <sup>11</sup>	1,375	2,696.8	7,251.1	434	808.8	919.3
Chillblains	12.18 <sup>12</sup>	53	1,377.8	3,704.6	35	413.2	469.7
Chronic fatigue syndrome/ME/PVFS	13.16 <sup>13</sup>	65	1,488.7	4,002.7	31	446.5	507.5
Coronary artery disease	185.78 <sup>9</sup>	15	21,015.8	56,506.4	7	6,303.2	7,164.0
Cutaneous vasculitis	14.10 <sup>14</sup>	17	1,595.0	4,288.6	5	478.4	543.7
Death	1116.40 <sup>15</sup>	3,154	126,289.2	339,561.5	954	37,877.3	43,050.2
Deep vein thrombosis	116.17 <sup>9</sup>	406	13,141.4	35,334.0	280	3,941.4	4,479.7
Disseminated intravascular coagulation	1.48 <sup>7</sup>	8	167.4	450.2	6	50.2	57.1
Erythema multiforme	8.19 <sup>12</sup>	45	926.5	2,491.1	12	277.9	315.8
Fibromyalgia	430.00 <sup>16</sup>	52	48,642.4	130,787.8	15	14,589.1	16,581.5
Giant cell arteritis	1.60 <sup>8</sup>	19	181.0	486.7	11	54.3	61.7
Guillain-Barré syndrome	1.88 <sup>9</sup>	109	212.7	571.8	51	63.8	72.5
Haemorrhage	22.30 <sup>8</sup>	197	2,522.6	6,782.7	99	756.6	859.9
Haemorrhagic stroke	53.34 <sup>9</sup>	224	6,033.9	16,223.8	112	1,809.7	2,056.9
Heart failure	424.37 <sup>9</sup>	308	48,005.5	129,075.3	110	14,398.0	16,364.4
Herpes zoster	414.21 <sup>17</sup>	1,077	46,856.6	125,986.3	288	14,053.5	15,972.8



**Table 2. Observed versus Expected Analyses of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs**

AESI	Background Rate per 100,000 Person Years (PY)	Observed Cases, Cumulative	Expected Cases, Cumulative, 21-Day Risk Window <sup>a</sup>	Expected Cases, Cumulative, No Risk Window <sup>b</sup>	Observed Cases, Interval	Expected Cases, Interval, 21-Day Risk Window <sup>c</sup>	Expected Cases, Interval, No Risk Window <sup>d</sup>
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	6.62 <sup>12</sup>	300	748.9	2,013.5	167	224.6	255.3
Ischemic stroke	172.61 <sup>18</sup>	1,039	19,525.7	52,500.0	501	5,856.3	6,656.0
Limb ischemia	260.00 <sup>19</sup>	22	29,411.7	79,081.0	14	8,821.3	10,026.0
Meningitis	13.47 <sup>20</sup>	32	1,523.8	4,097.0	12	457.0	519.4
Multiple sclerosis (MS)	11.60 <sup>8</sup>	115	1,312.2	3,528.2	38	393.6	447.3
Multisystem inflammatory syndrome	0.72 <sup>7</sup>	68	81.4	219.0	15	24.4	27.8
Myasthenia gravis	0.17 <sup>21</sup>	17	19.2	51.7	6	5.8	6.6
Myocarditis	4.40 <sup>22</sup>	157	497.7	1,338.3	83	149.3	169.7
Narcolepsy	1.08 <sup>12</sup>	14	122.2	328.5	7	36.6	41.6
Pericarditis	18.00 <sup>22</sup>	146	2,036.2	5,474.8	62	610.7	694.1
Polyneuropathy	2.50 <sup>8</sup>	227	282.8	760.4	96	84.8	96.4
Postural orthostatic tachycardia syndrome	10.10 <sup>23</sup>	18	1,142.5	3,072.0	5	342.7	389.5
Pulmonary embolus	55.93 <sup>9</sup>	690	6,326.9	17,011.5	441	1,897.6	2,156.8
Rheumatoid arthritis, polyarthritis	64.70 <sup>8</sup>	166	7,319.0	19,679.0	75	2,195.1	2,494.9
Seizures/convulsions/seizure disorders (including febrile)	29.09 <sup>7</sup>	827	3,290.7	8,847.9	277	987.0	1,121.8
Transverse myelitis	0.35 <sup>9</sup>	51	39.6	106.5	14	11.9	13.5
Type 1 diabetes	32.30 <sup>12</sup>	16	3,653.8	9,824.3	8	1,095.9	1,245.5
Vasculitis	14.27 <sup>24</sup>	105	1,614.2	4,340.3	53	484.2	550.3

- a. 11,312,184 PY
- b. 30,415,757 PY
- c. 3,392,806 PY
- d. 3,856,163 PY
- e. Case counts through 29 April 2021

**Table 3. Preferred Terms (PT) Used to Identify Spontaneously Reported Adverse Events of Special Interest (AESI)**

AESI	PTs
Acute disseminated encephalomyelitis (ADEM)	Acute disseminated encephalomyelitis, encephalitis, encephalopathy, encephalomyelitis
Acute kidney injury/renal failure	Acute kidney injury, renal failure
Acute liver injury/liver injury	Liver injury
Acute myocardial infarction/myocardial infarction	Acute myocardial infarction, myocardial infarction
Acute respiratory distress syndrome (ARDS)	Acute respiratory distress syndrome
Ageusia/anosmia	Ageusia, anosmia
Arrhythmia	Arrhythmia
Autoimmune thyroiditis	Autoimmune thyroiditis
Behcet's syndrome	Behcet's syndrome
Bell's palsy	Facial paresis, facial paralysis, oculofacial paralysis
Chillblains	Chillblains
Chronic fatigue syndrome/ME/PVFS	Chronic fatigue syndrome, post viral fatigue syndrome
Coronary artery disease	Coronary artery disease
Cutaneous vasculitis	Cutaneous vasculitis, vasculitic rash, urticarial vasculitis
Death	Fatal clinical outcome
Deep vein thrombosis	Deep vein thrombosis
Disseminated intravascular coagulation	Disseminated intravascular coagulation, disseminated intravascular coagulation in newborn
Erythema multiforme	Erythema multiforme
Fibromyalgia	Fibromyalgia
Giant cell arteritis	Giant cell arteritis
Guillain-Barré syndrome	Guillain-Barre syndrome
Haemorrhage	Haemorrhage
Haemorrhagic stroke	Haemorrhagic stroke, cerebral haemorrhage, cerebral haematoma, subarachnoid haemorrhage, brain stem haemorrhage, haemorrhage intracranial, intracranial haematoma
Heart failure	Cardiac failure, cardiac failure acute
Herpes zoster	Herpes zoster, ophthalmic herpes zoster, herpes zoster reactivation, herpes zoster infection neurological, herpes zoster oticus, herpes zoster cutaneous disseminated, varicella zoster virus infection
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	Immune thrombocytopenia, thrombocytopenia, thrombotic thrombocytopenic purpura, thrombocytopenic purpura
Ischemic stroke	Ischaemic stroke, cerebrovascular accident, cerebral infarction, basal ganglia stroke, cerebral thrombosis, cerebral venous sinus thrombosis, thrombotic stroke, basal ganglia infarction, basilar artery thrombosis, brain stem stroke, lacunar infarction
Limb ischemia	Peripheral ischaemia
Meningitis	Meningitis, meningitis aseptic
Multiple sclerosis (MS)	Optic neuritis, multiple sclerosis relapse, multiple sclerosis
Multisystem inflammatory syndrome	Systemic inflammatory response syndrome, multiple organ dysfunction syndrome, multisystem inflammatory syndrome in children
Myasthenia gravis	Myasthenia gravis
Myocarditis	Myocarditis

**Table 3. Preferred Terms (PT) Used to Identify Spontaneously Reported Adverse Events of Special Interest (AESI)**

AESI	PTs
Narcolepsy	Cataplexy, narcolepsy
Pericarditis	Pericarditis
Polyneuropathy	Polyneuropathy, neuropathy peripheral
Postural orthostatic tachycardia syndrome	Postural orthostatic tachycardia syndrome
Pulmonary embolus	Pulmonary embolism
Rheumatoid arthritis, polyarthritis	Rheumatoid arthritis, polyarthritis
Seizures/convulsions/seizure disorders (including febrile)	Febrile convulsion, seizure, generalized tonic-clonic seizure, partial seizures
Transverse myelitis	Myelitis transverse, myelitis
Type 1 diabetes	Type 1 diabetes mellitus
Vasculitis	Vasculitis, polymyalgia rheumatica

For most cumulative and interval data, the upper limit of the 95% CI is substantially less than one. For most AESI, the ratio is higher in the interval period than in the cumulative even when restricted to the 21-day risk window. This could reflect changes in the accuracy of the person year estimate, an increased reporting rate over time, an increased reporting rate with second dose as the proportion of vaccinees receiving a second dose is increasing over time, higher rates of spontaneous event reporting in countries where the vaccine was recently authorized, or a combination of these.

For purposes of signal detection, the MAH considers events for which the upper level of the 95% CI exceeds one for at least one of the risk periods (cumulative, interval) or risk windows (21 weeks, no risk window). While typically the lower level of the 95% CI would be the criterion for evaluating a difference from expectation, in this setting, given the generally substantial gap between the lower limit and one, an upper limit in excess of one might suggest the possibility of an excess risk in vaccinees.

Acute disseminated encephalomyelitis (ADEM), ageusia/anosmia, Guillain-Barré syndrome, multisystem inflammatory syndrome, myasthenia gravis, polyneuropathy, and transverse myelitis are further discussed below.

## 2.8. DISCUSSION

### 2.8.1. Cardiogenic shock

Although requested by regulatory authorities, cardiogenic shock is not included in this analysis since relevant background rates have not been identified at this time.

### 2.8.2. Ageusia/anosmia and multisystem inflammatory syndrome

For ageusia/anosmia, the upper level of the confidence interval exceeds one for both the 21-day and no risk windows in the interval period (01-30 April 2021) and the cumulative period, suggesting that the observed rate is higher in vaccinees compared to the background rate, which was generated from the ACCESS project data. Ageusia/anosmia is notably a symptom of COVID-19 illness. Contemporaneous background rates of this endpoint are therefore likely to be increased due to COVID-19 compared to the 2017-2019 data used for the

background rate. The MAH's COVID-19 vaccine requires two doses spaced 21 days apart before achieving maximum effectiveness. It is possible that COVID-19 may occur within the 21-day window between doses. Additionally, general awareness of ageusia/anosmia is currently increased because of COVID-19 compared to 2017-2019.

For Multisystem inflammatory syndrome, the upper level of the 95% CI exceeds 1 for the cumulative and interval 21-day risk windows. Multisystem inflammatory syndrome is also a condition known to be associated with COVID-19. The MAH's COVID-19 vaccine requires two doses spaced 21 days apart before achieving maximum effectiveness. It is possible that COVID-19 may occur within the 21-day window between doses. Contemporaneous background rates of multisystem inflammatory syndrome are likely to be increased due to COVID-19 compared to the 2017-2019 data used for the background rate.

The MAH will continue to seek more contemporaneous rates of events associated with COVID-19.

### **2.8.3. Acute disseminated encephalomyelitis, Guillain-Barré syndrome, myasthenia gravis, polyneuropathy, and transverse myelitis**

For ADEM, Guillain-Barré syndrome, myasthenia gravis, polyneuropathy, and transverse myelitis, the upper level of the 95% CI exceeds one for at least one of the risk windows in at least one of the risk periods, suggesting the possibility that the true O/E ratio may exceed one.

The ADEM O/E signal is new this month, following the adoption of the ACCESS narrow background rate for ADEM, 0.10 per 100,000 person years<sup>7</sup>, which is less than the rate of 5.3 per 100,000 person years derived from the ADVANCE effort used on previous monthly reports<sup>11</sup>. Had the previously referenced rate of 5.3 per 100,000 person years been used, an estimated 180 cases would have been expected in the 21-day risk window for the interval compared to the 16 cases observed. The narrow ACCESS definition restricts to ADEM events exclusively, whereas the observed cases encompass all spontaneous reports of ADEM, encephalitis, encephalopathy, and encephalomyelitis. If the observed cases were restricted to only those reports of ADEM, there would be three and nine cases in the interval and cumulative periods, respectively (compared to 16 and 52). Using these observed case counts, the upper level of the 95% CI would still exceed one. For the next monthly report, the MAH will evaluate whether the 5.3 per 100,000 person years is a more appropriate benchmark for signal detection.

The O/E ratio for Guillain-Barre is modestly increased this month compared to last month, in part due to the adoption of a new background rate of 1.88 vs 2.0. MAH continues to regularly review this safety topic and will include a discussion in the SMSR as warranted.

Myasthenia gravis and transverse myelitis were previously found to have an upper limit of the 95% CI of O/E ratio greater than 1 and were reviewed in detail in the March 2021 SMSR; the signals were determined not to be validated. The O/E for myasthenia gravis is similar to or lower than the ratio reported previously. For transverse myelitis, the adoption of the ACCESS narrow background rate of 0.35 per 100,000 person years<sup>9</sup> this month, replacing the 0.97 per 100,000 person year<sup>11</sup> rate from the ADVANCE project used in the previous

monthly report, has resulted in a higher O/E ratio than in the previous SMSR. The O/E ratio for polyneuropathy this month is similar to the ratio reported in previous reports. An evaluation of polyneuropathy is found in [Appendix 3.2](#) of this current SMSR.

#### **2.8.4. Age and European Economic Area stratified analyses**

The MAH is aware of the EMA request for age-stratified observed versus expected analyses for European Economic Area (EEA) countries. The MAH acknowledges that it may be informative to look at the observed versus expected number within age stratum, as an excess risk might be specific to a particular stratum, and also recognizes the methodologic challenges associated with determining background rates and Comirnaty vaccine exposure within age strata (Mahaux, 2016)<sup>2</sup>.

ECDC is publicly reporting country-specific vaccination information; for some countries, this exposure information includes sufficient information to estimate person years of exposure by age strata, i.e., counts of Comirnaty vaccinated persons by age and by interval (e.g., weekly/daily). Additionally, the ACCESS project has generated age-specific rates for the events included in that protocol.

Beginning with the May 2021 SMSR #6, MAH will provide age-stratified O/E analyses for EEA countries, where feasible, based on availability of sufficient information to estimate age-stratified exposure. For O/E events included in Appendix 5.1 of the SMSR that demonstrate marked variability in the background rate by age group (as highlighted in the ACCESS draft interim report Table 3)<sup>25</sup>, the appropriate age-specific expected background rates will be multiplied by the age-specific exposure and used to generate the expected counts. For events that do not demonstrate marked variability by age, country-age-stratified expected counts will be generated using the overall rate. Where feasible, the MAH will determine O/E ratios pooling countries with similar age categories rather than provide country specific results.

##### **2.8.4.1. Age-stratified death analysis**

Vaccination administrations were assumed to be evenly split between the 18-64 year and 65+ years age groups.

**Table 4. Age-Stratified Observed to Expected (O/E) Ratios of Death**

Age group	21-Day Risk Window, Cumulative		No Risk Window, Cumulative		21-Day Risk Window, Interval		No Risk Window, Interval	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
18-64 years	0.015	0.013, 0.016	0.005	0.005, 0.006	0.017	0.014, 0.020	0.015	0.012, 0.018
65+ years	0.012	0.011, 0.012	0.004	0.004, 0.004	0.010	0.009, 0.011	0.009	0.008, 0.010

**Table 5. Age-Stratified Observed versus Expected Analyses of Death Inputs**

Age group	Background Rate per 100,000 Person Years (PY) <sup>26</sup>	Observed Cases, Cumulative <sup>a</sup>	Expected Cases, Cumulative, 21-Day Risk Window <sup>b</sup>	Expected Cases, Cumulative, No Risk Window <sup>c</sup>	Observed Cases, Interval <sup>a</sup>	Expected Cases, Interval, 21-Day Risk Window <sup>d</sup>	Expected Cases, Interval, No Risk Window <sup>e</sup>
18-64 years	3.50	289	19,773.7	53,166.7	99	5,930.6	6,740.6
65+ years	39.60	2,588	223,958.6	602,171.2	686	67,170.8	76,344.3

- a. Excludes 2 cases initially reported as age <18 believed to be invalid
- b. 5,656,092 PY
- c. 15,207,879 PY
- d. 1,696,403 PY
- e. 1,928,082 PY

The upper level of the 95% CI is substantially less than one for both the 18-64 year and 65+ years age groups across both risk windows and risk periods, thus there is no evidence of a signal for increased risk of death within either age category.

### **2.8.5. Limitations**

There are several limitations to observed to expected analyses for signal detection. The observed case counts are likely to be underestimated due to underreporting that occurs with spontaneous report surveillance. Additional reasons for underestimations include incomplete reporting and lags in reporting. Spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported even if they do not meet the clinical definition. Conversely, events that have not been previously associated with a vaccine are more likely to be underreported due to lack of recognition of a potential association.

With respect to the expected case counts, estimates of both exposure to vaccine and the background rate have limitations. The exposure estimate assumes that the number of reported vaccine administrations is complete and accurate when in fact not all countries administering vaccine have reported to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. The background rates used in this analysis are derived from one large US electronic health records database, one large US insurance claims database, EU health care systems, or regional studies published in the literature, and the majority of exposure data derive from the US. However, it is possible that the delivery of health care, population demographics, and underlying health status of the US populations used for the background rate estimates differ from those expected in the vaccinated population.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

## **2.9. OBSERVED VERSUS EXPECTED ANALYSES FOR ANAPHYLAXIS (IDENTIFIED RISK)**

Since anaphylaxis has already been identified as a risk, the goal of the observed versus expected analysis is risk estimation rather than signal identification. Risk of anaphylaxis is reported per dose administered and compared to rates of anaphylaxis observed for other vaccines rather than rates in an unexposed population.

The MAH has conducted unadjusted observed versus expected analyses after reviewing the 4,286 cumulative cases of anaphylaxis occurring outside of a clinical trial setting reported in the global safety database through 29 April 2021. Anaphylaxis cases were identified using

the MedDRA version 23.1 SMQ anaphylactic reaction broad algorithm and then limited to cases presenting any symptom on day 0 (vaccination day). Cases assessed as Brighton Collaboration Levels 1-2 (N=1,851) were included in the analysis. A background rate<sup>27</sup> of 1.31 anaphylaxis cases per million vaccine doses was assumed.

An estimated 332,738,172 doses of Pfizer-BioNTech COVID-19 vaccine have been administered through 29 April 2021. Approximately 80% of shipped doses of the Pfizer-BioNTech COVID-19 vaccine are administered in the European Union and the United States. This administration estimate was applied to the 415,922,715 doses shipped worldwide through 29 April 2021.

Expected counts were determined by multiplying the number of doses administered by the expected rates per dose.

An O/E ratio of 4.247 (95% CI 4.055, 4.444) was observed for BNT162b2 compared to the background rate for anaphylaxis cases observed in the US. This rate has declined from the 5.12 (95% CI 4.85, 5.41) reported in SMSR 4 (through 31 March 2021), the 7.76 (95% CI 7.22, 8.33) reported in SMSR 3 (through 28 February 2021) and the 9.47 (95% CI, 8.61, 10.40) reported in SMSR 2 (through 31 January 2021). The reason for the decline is unknown but could reflect decreased reporting, changes in the accuracy of the exposure estimate, or changes in population being vaccinated.

There are several limitations to consider when interpreting these analyses. The analyses did not adjust for differences in characteristics such as age and comorbidities between persons being administered the vaccine and populations from which the background rate was derived. The spontaneous report system likely underestimates the true number of observed events in vaccinated persons due to incomplete or a lag in reporting.

Conversely, spontaneous report systems are prone to reporting bias whereby events that have been previously identified as potentially related to a vaccine are more likely to be reported than other events, for example, due to increased media attention. With respect to the expected case counts, estimates of both exposure to vaccine and the background rate have limitations. The exposure estimate assumes that 80% of all shipped doses are administered in each country. The true number of vaccines administered may be higher or lower than this estimate.

Additionally, there are differences in health care delivery, demographics, and underlying health status in the populations used to calculate background rate estimates compared to those in the population administered the vaccine.

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<sup>1</sup> Consideration on core requirements for RMPs of COVID19 vaccines  
coreRMP19 guidance EMA/544966/2020

<sup>2</sup> Mahaux O, Bauchau V, Van Holle L. Pharmacoepidemiological  
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## **APPENDIX 6. LITERATURE REVIEW IN THE REPORTING PERIOD (METHODOLOGY)**

A web-based literature review service is used to review medical literature from clinical and non-clinical literature sources for significant safety information relevant to authorized Pfizer medicinal product including reviews and practice guidelines.

The following bibliographic databases are searched in this order:

1. MEDLINE®
2. Embase

Each search uses controlled vocabulary terms that are unique to each database. For each database, the search focuses on the following:

- AEs, effects and outcomes
- Generic name of the drug
- Prenatal and perinatal exposure and exposure through breast milk
- Drug interactions
- Clinical studies
- Epidemiology and meta-analyses
- Poisoning and toxicity
- Drug resistance and drug tolerance
- Toxicity tests

Searches are limited by date and by literature type. Editorials, and news reports (i.e., works consisting of an announcement or statement of recent or current events of new data and matters of interest in the field of medicine or science) are excluded because they are not peer-reviewed.

## APPENDIX 7. OVERVIEW OF INTERVAL CASES NOT INCLUDED IN THE APRIL 2021 SMSR

Among cases received or downloaded to the safety database during the Summary Monthly Safety Report (SMSR) reporting period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status at least once) are included in that month's SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final data. As per monthly routine process, Pfizer applies a Late condition process that retrieves from the global safety database cases received but not captured in the previous month's SMSR due to lack of completeness. This condition ensures that no relevant cases are excluded from the SMSRs over time.

For the reporting period 01 April 2021 to 29 April 2021, there was a total of 59,048 case reports retrievable from the global safety database based on the Initial Safety Receipt Date; 45,874 case reports out of the 59,048 retrieved did not meet the defined criteria for inclusion in the April's SMSR and therefore are not included in the current SMSR.<sup>i</sup>

The table below presents the most frequently reported events by SOC and by PT for events reported in (≥1%) of the cases not included in the current SMSR.

### Events Reported in ≥1% in Cases\* not Included in the 5<sup>th</sup> SMSR

MedDRA SOC MedDRA PT	01 April 2021 Through 29 April 2021 AEs (AERP%) N = 45,874
<b>Blood and lymphatic system disorders</b>	
Lymphadenopathy <sup>a</sup>	1851 (4.03%)
<b>Cardiac disorders</b>	
Palpitations	500 (1.09%)
<b>Ear and labyrinth disorders</b>	
Tinnitus <sup>c</sup>	487 (1.06%)
Vertigo	464 (1.01%)
<b>Gastrointestinal disorders</b>	
Nausea <sup>a</sup>	3811 (8.31%)
Diarrhoea <sup>a</sup>	1484 (3.23%)
Vomiting <sup>a</sup>	1211 (2.64%)
<b>General disorders and administration site conditions</b>	
Pyrexia <sup>a</sup>	10252 (22.35%)
Vaccination site pain <sup>a</sup>	6723 (14.66%)
Fatigue <sup>a</sup>	6456 (14.07%)
Chills <sup>a</sup>	5132 (11.19%)
Malaise <sup>a</sup>	4600 (10.03%)
Pain <sup>a</sup>	3072 (6.70%)
Injection site pain <sup>a</sup>	1927 (4.20%)
Asthenia <sup>d</sup>	1715 (3.74%)
Vaccination site swelling <sup>a</sup>	1473 (3.21%)
Influenza like illness	1134 (2.47%)
Feeling abnormal	896 (1.95%)
Swelling <sup>c</sup>	788 (1.72%)
Feeling hot <sup>c</sup>	524 (1.14%)
Feeling cold <sup>c</sup>	508 (1.11%)
Chest pain	458 (1.00%)

**Events Reported in ≥1% in Cases\* not Included in the 5<sup>th</sup> SMSR**

MedDRA SOC MedDRA PT	01 April 2021 Through 29 April 2021 AEs (AERP%) N = 45,874
<b>Infections and infestations</b>	
Herpes zoster <sup>c</sup>	568 (1.24%)
<b>Injury, poisoning and procedural complications</b>	
Circumstance or information capable of leading to medication error <sup>b</sup>	507 (1.11%)
<b>Musculoskeletal and connective tissue disorders</b>	
Myalgia <sup>a</sup>	6285 (13.70%)
Arthralgia <sup>a</sup>	4732 (10.32%)
Pain in extremity <sup>a</sup>	3387 (7.38%)
Back pain	630 (1.37%)
<b>Nervous system disorders</b>	
Headache <sup>a</sup>	9838 (21.45%)
Dizziness <sup>d</sup>	2284 (4.98%)
Paraesthesia <sup>d</sup>	945 (2.06%)
Hypoesthesia	862 (1.88%)
Somnolence	493 (1.07%)
<b>Psychiatric disorders</b>	
Insomnia <sup>e</sup>	498 (1.09%)
<b>Respiratory, thoracic and mediastinal disorders</b>	
Dyspnoea <sup>c</sup>	1091 (2.38%)
Cough <sup>c</sup>	714 (1.56%)
Oropharyngeal pain	552 (1.20%)
<b>Skin and subcutaneous tissue disorders</b>	
Pruritus <sup>a</sup>	1523 (3.32%)
Rash <sup>a</sup>	1457 (3.18%)
Erythema <sup>a</sup>	990 (2.16%)
Urticaria <sup>a</sup>	860 (1.87%)
Hyperhidrosis <sup>d</sup>	550 (1.20%)

- a. Listed or consistent with listed AEs in current RSI;
  - b. Listed per case processing convention;
  - c. Consistent with anaphylactic reactions listed in the current RSI;
  - d. Evaluated to be risks (not important) and will be added to the RSI;
  - e. Evaluated and determined not to be a risk;
- \* Reporting proportion (% of total cases) in the current reporting period.

Most of the frequently reported events are listed or consistent with listed events as per the current RSI or have undergone specific safety reviews.

<sup>i</sup> There was a total of 30,752 case reports included in the April's SMSR, of which 13,174 captured based on their Initial Safety Receipt Date and 17,578 case reports captured applying the Late condition.

## APPENDIX 8. Q&A SECTION – EMA PRAC REQUESTS FOR NEXT SMSR

### QUESTION 1

1. *In the exposure section of the MSSR the MAH is requested to provide:*
  - a. *the administrated doses of Comirnaty per region/country.*
  - b. *the total number of administered Comirnaty doses 1 and 2 in the EU/EEA, per country, by gender and by age group.*

#### Response:

Refer to [Section 5.1](#) Cumulative and Interval Exposure Data Worldwide and [Section 5.2](#) Cumulative and Interval Exposure Data in the EU.

Please note that the estimated administrated doses of Comirnaty per region/country were added in the relevant tables, and the total number of administered Comirnaty doses 1 and 2 in the EU/EEA, per country, and by age group was provided based on data available at <https://covid19-vaccine-report.ecdc.europa.eu/> (point 6).

Data by gender are not currently available, the MAH committes to provide them once a reliable source for them is available.

### QUESTION 2

*The MAH refers to quality issues with ACCESS data that are not further specified. The MAH is requested to clarify these quality issues.*

#### Response:

Through participation in an ACCESS scientific community call, MAH learned that ACCESS researchers were concerned that some rates reported in the 03 March 2021 results overestimated the background rates and that they should be used with caution for signal detection. The ACCESS study team has updated their rates using new algorithms for all endpoints as of 29 April 2021, in addition to other changes.<sup>1</sup> These background rates have been incorporated in the O/E analysis in this Monthly report.

### QUESTION 3

*MAHs' commitment to generate EEA geography specific O/E results based on age groups is noted. If possible the MAH should provide clear timelines, when this will be adequately addressed. It is reiterated that O/E analysis stratified by age should be provided for events with background incidences that vary according to age (e.g. GBS, thromboembolic events, myocarditis, Herpes zoster). Moreover, in case estimations are used, sensitivity analyses should be provided, considering uncertainties/factors such as underreporting.*

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<sup>1</sup> [http://www.encepp.eu/documents/ACCESS\\_Report\\_BGR\\_20210430\\_v.1.2.pdf](http://www.encepp.eu/documents/ACCESS_Report_BGR_20210430_v.1.2.pdf).



**Response:**

The MAH acknowledges that it may be informative to look at the observed versus expected number within age stratum, as an excess risk might be specific to a particular stratum, and also recognizes the methodologic challenges associated with determining background rates and Comirnaty vaccine exposure within age strata (Mahaux,<sup>2</sup> 2016).

ECDC is publicly reporting country-specific vaccination information; for some countries, this exposure information includes sufficient information to estimate person years of exposure by age strata, i.e., counts of Comirnaty vaccinated persons by age and by interval (e.g., weekly/daily). Additionally, the ACCESS project has generated age-specific rates for the events included in that protocol.

Beginning with the May 2021 SMSR, MAH will provide age-stratified O/E for EEA countries, where feasible, based on availability of sufficient information to estimate age-stratified exposure. For O/E events included in Appendix 5.1 of the SMSR that demonstrate marked variability in the background rate by age group (as highlighted in the ACCESS draft interim report Table 3<sup>1</sup>), the appropriate age-specific expected background rates will be multiplied by the age-specific exposure and used to generate the expected counts. For events that do not demonstrate marked variability by age, country-age-stratified expected counts will be generated using the overall rate. Where feasible, MAH will determine O/E pooling countries with similar age categories rather than provide country specific results.

**QUESTION 4**

*The MAH is requested to continue to indicate in future MSSRs what proportion of EV cases with availability data before DLP is not included in future MSSRs. While the MAH states that the processing of serious cases, including fatal and life-threatening reports and serious AESIs, is prioritised, it is unclear whether all SAE and AESI cases have been included in the current MSSR. This should be clarified in future MSSRs.*

**Response:**

As per data (as of 30 April 2021), of the 15,937 cases downloaded from EudraVigilance for the period covered by the fifth SMSR, 3,573 cases (22.4 % of the total downloaded cases) are included in the dataset reviewed in the SMSR.

Of the 3,573 cases included, 3,374 are serious.

For the 12,364 cases from EudraVigilance downloaded in April 2021 but not included in the report, there are 10,297 non-serious cases and 2,067 serious cases.

Of note, the serious cases not included are those downloaded in April 2021 not fully processed in time to be included in the April 2021 SMSR, however, these reports are being

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<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5063172>.

processed within required timelines and they will be included in the subsequent May 2021 SMSR.

### QUESTION 5

*The MAH is requested to retrieve the outcomes of reported medication error events as much as possible or provide a discussion to justify the low numbers of known medication error event outcomes.*

#### Response:

As per *Good practice guide medication error recording coding reporting assessment (27 November 2015 europa.eu)*, patient outcome is not applicable for the medication error itself as the patient cannot recover from the error, only from the clinical consequence(s). The outcome of medication errors is “Unknown” unless the Medication error event is associated with an AE, at which point the outcome of the associate AE is followed-up. Of note, the most severe outcome is selected if multiple associated AEs are reported.

### QUESTION 6

*The MAH is requested to discuss if the findings of the paper of Krammer et al. (<https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1.full-text>) identifies new safety information, or otherwise justify or confirm that the findings in this paper do not identify any new safety information.*

#### Response:

Refer to [Section 9.1 Literature Review](#).

### QUESTION 7

*The MAH should provide additional (follow-up) information of:*

- a. case (b) (6) (Female 39 years-of-age. PTs: Thrombocytopenia, Cerebrovascular accident, Cerebral haemorrhage) lack of documented medical history, possible risk factors or concomitant medication precludes full causality assessment.
- b. case (b) (6) (56-year-old male. PTs: Cerebral haemorrhage, Immune thrombocytopenia, Haemorrhage intracranial, Haemorrhagic stroke) causality cannot be excluded and is possible due to the absence of risk factors.

#### Response:

Follow-up attempts for case (b) (6) were completed on 18 Mar 2021 and no past medical history was able to be obtained. Follow-up attempts for case (b) (6) were completed on 06 May 2021. Most of the information in the case appears to be from social media platforms. Per one reporter: “The medical examiner's report said there wasn't enough evidence to show whether the vaccine contributed to patient death. Given the history, autopsy, toxicology, and laboratory findings, the cause of death is complications of immune

thrombocytopenia following receipt of SARS-COV-2 vaccine," the report said. "Based on the circumstances as currently known, the manner of death is natural."

### QUESTION 8

*In EudraVigilance (EV gateway date 26 Jan 2021 until 06 April 2021) 16 additional CVST cases have been reported. In one case (b) (6) CVST was coreported with Contusion, Immune thrombocytopenia, Platelet count decreased, Rectal haemorrhage. In 15 out of 16 cases CVST was not reported in combination with thrombocytopenia. Consequently, these additional cases do not alter the current assessment conclusions. In addition, EMA conducted an EV query on TTS with cut-off 13 Apr 2021, which is included in ANNEX 6. The MAH is requested to discuss these cases, focusing on cases suggestive of thrombosis in combination with thrombocytopenia, if applicable.*

#### Response:

Refer to [Appendix 3.8](#) Summary of Cases of Thromboembolism with Thrombocytopenia.

### QUESTION 9

*The MAH is requested to report the results of the review of Polyneuropathy cases as this was considered a non-validated safety signal.*

#### Response:

Refer to [Appendix 3.2](#) for evaluation of Polyneuropathy.

### QUESTION 10

*The MAH is requested to report the results of their ongoing reviews of:*

- a. Hepatic events;*
- b. Seizure;*
- c. Herpes zoster (age-stratified O/E analyses should be presented by the MAH as part of the evaluation of this topic).*

*If results are not available yet, clear timelines should be provided.*

#### Response:

Refer to:

- [Appendix 3.1](#) for evaluation summary of Hepatic events;
- [Appendix 3.4](#) for evaluation of Seizure;
- [Appendix 3.3](#) for evaluation of Herpes zoster.

## QUESTION 11

*The MAH is requested to evaluate the safety topic of myocarditis and pericarditis and provide a cumulative review of myocarditis and pericarditis, from all available sources. In the cumulative review, the MAH should provide at least but not limited to the following:*

- *A tabulated overview of all cases, stratified by*
  - 1) *Age;*
  - 2) *Gender;*
  - 3) *Time-to onset;*
- *A summary overview of the serious cases*
  - 1) *for which the causality (as per WHO-UMC causality assessment system) is considered at least possible or probable; and*
  - 2) *for which the role of the vaccine cannot be excluded.*

*The summary overview should include the following details for each case:*

- Patient's age and gender;*
- EVDAS/EudraVigilance case ID;*
- Associated clinical signs/co-reported PTs;*
- Any underlying condition(s) (including COVID-19) or other confounders;*
- Time to onset, and whether following the 1st or 2nd dose;*
- Outcome;*
- Assessment of the causal relationship with the vaccine.*
- *Based on their review of the cases, the MAH should discuss any plausible mechanisms and whether any risk factors could be identified. In conclusion, the MAH should discuss the need to update the product information, including relevant risk minimisation measures.*

*Also, in the next MSSR, the MAH is requested to present more in-depth O/E analyses of AESIs Myocarditis and Pericarditis, including O/E analyses stratified by age and gender. The MAH should ensure that the most relevant background incidence rates are selected and used for comparison, e.g. based on the origin of the cases. A justification for the selected IR should be provided.*

### Response:

Refer to [Appendix 3.7](#) for evaluation of Myocarditis and Pericarditis.

## QUESTION 12

*A signal on Appendicitis has been identified by UMC based on data in the VigiBase: Mitchell J et al Appendicitis and the Covid-19 Vaccines, April 2021. The authors have identified 43 cases – 30 for Comirnaty and 13 for the Covid-19 Vaccine Moderna. The MAH is requested to comment on this signal.*

### Response:

Reports of appendicitis in Study C4591001 were closely followed throughout the study and were not determined to be a risk of the vaccine. Appendicitis has not emerged as a signal in post-authorization signal detection activities, however, the topic will be reviewed and discussed in the next SMSR #6 (covering the month of May 2021).

## QUESTION 13

*The MAH should provide a cumulative review of cases indicative of delayed onset skin reactions, including a discussion of the publication by Blumenthal et al.*

### Response:

The Blumenthal publication on delayed skin reactions following vaccination with the Moderna COVID-19 vaccine prompted the MAH to perform a cumulative review of cases indicative of delayed onset skin reactions reported in association with Pfizer/BNT COVID-19 Vaccine. This review was provided as an appendix in SMSR #4 (01 Mar 2021 – 31 Mar 2021) and concluded that the available data did not support a causal association between the vaccine and delayed skin reactions.

## QUESTION 14

*Regarding exposure during pregnancy, cumulative data and data occurring during the reporting interval should be made available in the framework of the next assessment report. Moreover, they should be presented accordingly to annex 3 of the “Guideline on the exposure to medicinal products during pregnancy: need for post-authorisation data (EMA/CHMP/313666/2005)”.*

### Response:

The MAH committes to provide requested data in the framework of the next assessment report.